UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 000-22873

Oruka Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**36-3855489**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
855 Oak Grove Avenue Suite 100 Menlo Park, California	**94025**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 606-7910

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	ORKA	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of June 30, 2024, was approximately $39.7 million based on the closing price of the Registrant's shares of common stock on The Nasdaq Capital Market on such date.

The number of the Registrant's Common Stock shares outstanding as of February 28, 2025 was 37,440,510.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements reflect the current views of Oruka Therapeutics, Inc. ("Oruka", the "Company", "we", or "us") with respect to future events and are based on assumptions and subject to known and unknown risks and uncertainties and other factors that may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. Factors that might cause such a difference are disclosed in the section titled "Risk Factors" in this Annual Report. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. You should evaluate all forward-looking statements made in this Annual Report in the context of these risks and uncertainties. We caution you that the risks, uncertainties and other factors referred to in this Annual Report may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, we operate in a very competitive and rapidly changing environment, and new risks and uncertainties emerge from time to time.

All statements, other than statements of historical facts contained in this Annual Report, including, without limitation, statements regarding: our future results of operations and financial position, business strategy, the length of time that we believe our existing cash resources will fund our operations, our market size, our competition, our potential growth opportunities, our clinical development activities and timeline, the efficacy and safety profile of our product candidates, the potential therapeutic benefits and economic value of our product candidates, the timing and results of preclinical studies and clinical trials, the expected impact of macroeconomic conditions, including inflation, increasing interest rates and volatile market conditions, current or potential bank failures, as well as global events, including military conflicts and geopolitical tensions on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on information available to us as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions, including those described in Item 1A, "Risk Factors" and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. While we believe that such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities laws. You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Unless the context indicates otherwise, as used in this Annual Report, the terms "Oruka," "ARCA biopharma, Inc.," "the Company," "we," "us," and "our" refer to Oruka Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries taken as a whole. "Oruka" and all product candidate names are our common law trademarks. This Annual Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

All references to "our product candidates," "our programs" and "our pipeline" in this Annual Report refer to the research programs with respect to which we have exercised the option to acquire intellectual property license rights to or have the option to acquire intellectual property license rights to pursuant to those certain antibody discovery and option agreements by and among the Company, Paragon Therapeutics, Inc. ("Paragon") and Paruka Holding LLC ("Paruka").

PART I

Item 1. Business.

Acquisition of Pre-Merger Oruka

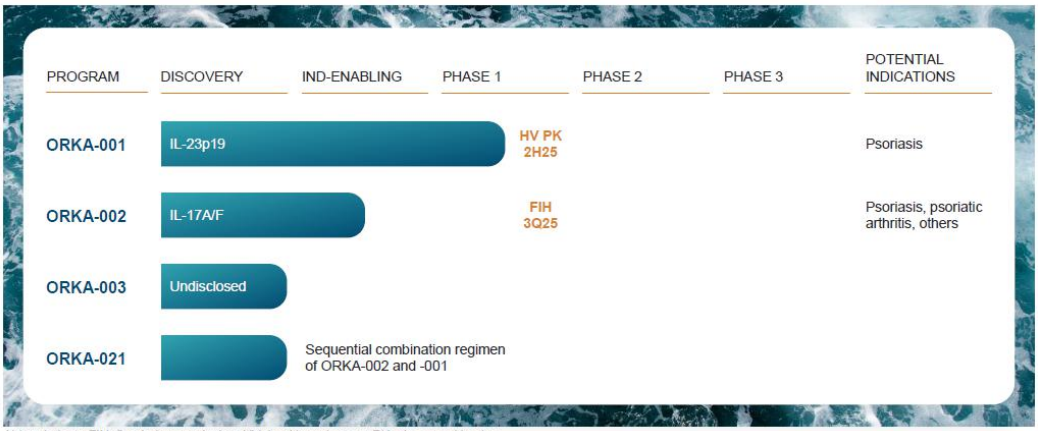
On August 29, 2024 (the "Merger Closing"), we completed our acquisition (the "Merger") of Oruka Therapeutics, Inc. ("Pre-Merger Oruka") pursuant to an Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024 (the "Merger Agreement"). Following the transactions contemplated by the Merger Agreement, Pre-Merger Oruka merged with and into Atlas Merger Sub Corp., a wholly owned subsidiary of ARCA biopharma, Inc. ("ARCA") and following that, Pre-Merger Oruka then merged with and into Atlas Merger Sub II, LLC ("Second Merger Sub"), with Second Merger Sub being the surviving entity. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC." Pre-Merger Oruka was a pre-clinical stage biotechnology company that was incorporated on February 6, 2024 under the direction of Peter Harwin, a Managing Member of Fairmount Funds Management LLC ("Fairmount"), for the purposes of holding rights to certain intellectual property being developed by Paragon Therapeutics, Inc. ("Paragon"). On August 29, 2024, we changed our name from "ARCA biopharma, Inc." ("ARCA") to "Oruka Therapeutics, Inc." and our Nasdaq ticker symbol from "ABIO" to "ORKA".

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing novel monoclonal antibody therapeutics for psoriasis ("PsO") and other inflammatory and immunology ("I&I") indications. Our name is derived from *or*, for "skin," and *arukah*, for "restoration," and reflects our mission to deliver therapies for chronic skin diseases that provide patients the most possible freedom from their condition. Our strategy is to apply antibody engineering and format innovations to validated modes of action, which we believe will enable us to improve meaningfully upon the efficacy and dosing regimens of standard-of-care medicines while significantly reducing technical and biological risk. Our programs aim to treat and potentially modify disease by targeting mechanisms with proven efficacy and safety involved in disease pathology and the activity of pathogenic tissue-resident memory T cells ("TRMs").

Our lead program, ORKA-001, is designed to target the p19 subunit of interleukin-23 ("IL-23p19") for the treatment of PsO. Our co-lead program, ORKA-002, is designed to target interleukin-17A and interleukin-17F ("IL-17A/F") for the treatment of PsO, psoriatic arthritis ("PsA"), and other conditions. These programs each bind their respective targets at high affinity and incorporate half-life extension technology with the aim to increase exposure and decrease dosing frequency. We believe that our focused strategy, differentiated portfolio, and deep expertise position us to set a new treatment standard in large I&I markets with continued unmet need.

Our Pipeline



Abbreviations: FIH, first-in-human dosing; HV, healthy volunteer; PK, pharmacokinetics

ORKA-001

ORKA-001 is a high affinity, extended half-life monoclonal antibody ("mAb") designed to target IL-23p19. IL-23 is a pro-inflammatory cytokine that plays a critical role in the proliferation and development of T helper 17 ("Th17") cells, which are the primary drivers of several autoimmune and inflammatory disorders, including PsO. IL-23 is composed of two subunits: a p40 subunit that is shared with IL-12 and a p19 subunit that is specific to IL-23. First-generation IL-23 antibodies bound p40 and inhibited both IL-12 and IL-23 signaling, while more recent IL-23 antibodies targeting the p19 subunit have shown improved efficacy and safety. Based on preclinical evidence, we believe that ORKA-001 could achieve higher response rates than established therapies in PsO while requiring less frequent dosing and maintaining the favorable safety profile of therapies targeting IL-23p19. ORKA-001 is engineered with YTE half-life extension technology, a specific three amino acid change in the fragment crystallizable ("Fc") domain to modify the pH-dependent binding to the neonatal Fc receptor ("FcRn"). As a result, it has a pharmacokinetic profile designed to support a subcutaneous ("SQ") injection as infrequently as once or twice a year. In addition, emerging evidence suggests that IL-23 blockade can modify the disease biology of PsO, possibly leading to durable remissions and preventing the development of PsA. We believe that the expected characteristics of ORKA-001 increase its potential to deliver these disease-modifying benefits.

We initiated dosing of healthy volunteers in a Phase 1 trial of ORKA-001 in the fourth quarter of 2024. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the second half of 2025 and initial efficacy on patients with PsO in the second half of 2026. Based on recent precedent for PsO, we anticipate that the entire development program from first-in-human to biologics license application ("BLA") filing could take as little as six to seven years based on the averages for recently approved medicines. However, we have no control over the length of time needed for United States Food and Drug Administration ("FDA") review, and this timeline could vary.

ORKA-002

ORKA-002 is a high affinity, extended half-life mAb designed to target IL-17A and IL-17F ("IL-17A/F"). IL-17 inhibition has become central to the treatment of psoriatic diseases, including PsO and PsA, and has also shown efficacy in other I&I indications, such as hidradenitis suppurativa ("HS") and axial spondyloarthritis ("axSpA"). More recently, the importance of inhibiting the IL-17F isoform along with IL-17A has become appreciated, and dual blockade with the recently approved therapy Bimzelx (bimekizumab) has led to higher response rates in patients than blockade of IL-17A alone. ORKA-002 is designed to bind IL-17A/F at similar epitopes, or binding sites, and affinity ranges as bimekizumab, but incorporates half-life extension technology that could enable more convenient dosing intervals. We plan to initiate dosing of healthy volunteers in a Phase 1 trial of ORKA-002 in the third quarter of 2025. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the first half of 2026.

We view ORKA-002 and ORKA-001 as highly complementary. Patients with moderate-to-severe PsO that have purely skin manifestations are most often treated with IL-23 inhibitors due to the high efficacy and tolerability of this mechanism. However, for patients who also have joint involvement or signs and symptoms of PsA, an IL-17 inhibitor is typically used due to its efficacy in addressing both skin and joint symptoms. In addition, IL-17 inhibitors are often used in patients with highly resistant skin symptoms that do not adequately resolve through treatment with an IL-23 inhibitor. Furthermore, we have the potential opportunity to administer ORKA-002 and ORKA-001 sequentially, called ORKA-021, to combine two attractive features of each program: the rapid response of an IL-17 inhibitor with the ideal maintenance profile of an IL-23 inhibitor. We believe that ORKA-001 and ORKA-002 provide the potential to offer a highly compelling product profile for most patients with PsO and/or PsA, as well as the opportunity to address additional I&I indications.

Additional Pipeline Program

We have a third mAb program, ORKA-003, designed to target an undisclosed pathway. Our strategy as a company is to remain highly focused on I&I diseases, and specifically on inflammatory dermatology conditions. Our third program provides the potential for indication expansion beyond PsO and may create combination opportunities with our more advanced programs.

Our Team, Investors, and Paragon Collaboration

We are led by a management team with significant experience in developing novel treatments for patients at biopharmaceutical companies such as CRISPR Therapeutics, Celgene, Novartis, CymaBay Therapeutics and Protagonist Therapeutics. Together, our team has a proven track record of building successful biotech organizations in high-growth environments.

Pre-Merger Oruka was founded in February 2024 by leading healthcare investor Fairmount. Fairmount founded Paragon in 2021 to conduct biologics discovery and optimization, including acting as the firm's discovery engine for biologics that potentially overcome limitations of existing therapies. We have entered into license agreements with Paragon pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 outside of the field of inflammatory bowel disease for ORKA-001 and for ORKA-002, certain antibodies and products targeting IL-17A/F.

Our Strategy

To achieve our goal of developing leading therapeutic antibodies for patients with inflammatory skin diseases, we are applying antibody engineering to validated modes of action. We believe this approach will enable us to improve meaningfully upon the efficacy and convenience of standard-of-care medicines while significantly reducing technical and biological risk. The key elements of our strategy include:

- ***Employ advanced antibody engineering to build biologics that could significantly improve upon existing therapies:*** We and our collaborators at Paragon have optimized a variety of parameters using a suite of antibody technologies to develop candidates with the potential to improve upon existing therapies. These parameters include extending half-life to increase exposure and reduce dosing frequency, enhancing affinity and specificity to maximize potency and safety, and optimizing developability to ensure consistency and enable convenient, high-dose formulations. Together, we believe these features have the potential to translate into more efficacious and convenient medicines for patients.

- ***Target validated mechanisms of action:*** Our initial targets, IL-23p19 and IL-17A/F, have established efficacy and safety for the treatment of PsO, PsA, and other indications. The FDA has approved four biologics in the IL-23 class, including three targeting IL-23p19, and four biologics in the IL-17 class, including one targeting IL-17A/F. While these therapies have advanced the standard of care in PsO and PsA, they have not addressed these diseases completely, and a significant fraction of patients do not achieve complete skin clearance. By applying our advanced antibody engineering to these validated targets, we believe we can maximize our chances of developing superior medicines for patients. In addition, the reduced technical and biological risk of these validated mechanisms may allow us to progress our programs more efficiently and rapidly.

- ***Leverage insights from earlier entrants to optimize our approach:*** We benefit from a large body of clinical evidence generated by prior therapies targeting IL-23 and IL-17. We continue to extract and apply learnings from this precedent to our programs, including in development candidate selection, clinical trial design, dosing regimens, formulations and presentations, regulatory pathway, and indication prioritization. For instance, based on correlations between affinity and efficacy, we have designed ORKA-001 and ORKA-002 to bind to similar epitopes and at similar or greater affinities as the leading antibodies in each class: risankizumab and bimekizumab, respectively, with the aim of maximizing efficacy. Also, by understanding the exposure-response relationships for efficacy and safety for other therapies, we plan to select dose levels and regimens that could maximize efficacy and maintenance of response while maintaining safety.

- ***Pursue opportunities with strong prospects of yielding meaningful new medicines as a "base case" and the potential to shift the treatment paradigm entirely as an "upside case":*** Our strategy seeks to maximize the potential for our programs to reach a base case product profile that could meaningfully advance the standard of care—for instance, for ORKA-001, SQ dosing one or twice a year with equal or greater efficacy compared to today's standard of care. At the same time, we aim to deliver an upside case that dramatically improves outcomes for patients—for instance, significantly increasing rates of complete skin clearance via higher antibody exposures or offering patients durable remissions free from therapy by introducing patient-specific dosing intervals.

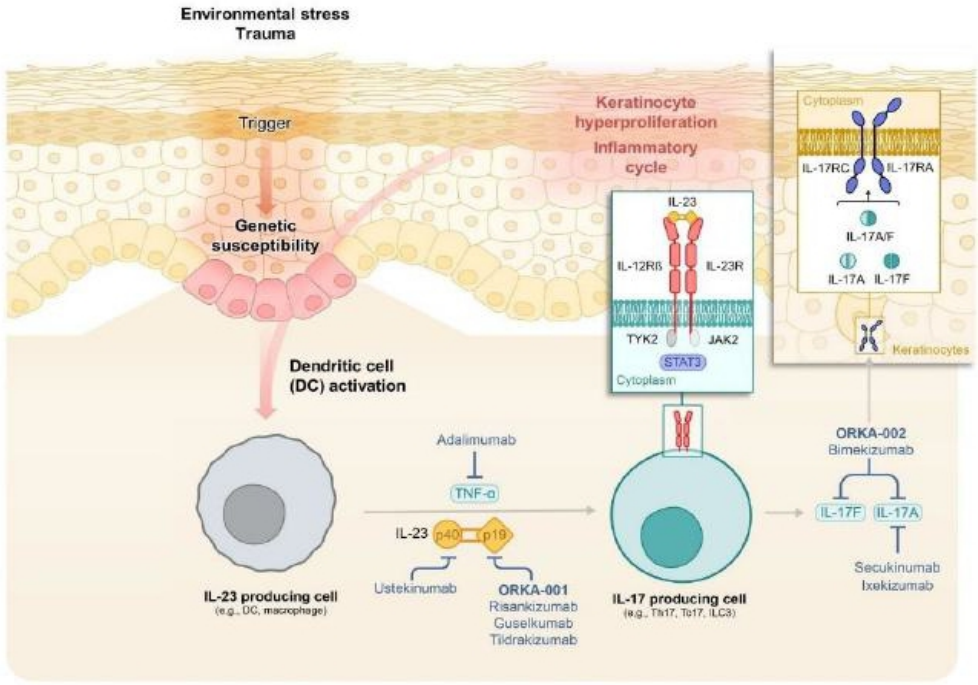
- ***Build a preeminent biotechnology company focused on chronic skin disease and other I&I indications:*** We are assembling a team of exceptional people and helping them reach their full potential and flourish so that together we can bring forward meaningful new medicines for patients.

We believe that pursuing the focused strategy outlined above will help us to succeed in our mission of offering patients living with PsO, PsA, and other dermatologic and inflammatory diseases the greatest possible freedom from their condition.

Targeting IL-23 and IL-17 to Treat Multiple I&I Indications

Our programs benefit from significant advances in the understanding of the biology of I&I diseases over the past four decades. ORKA-001 and ORKA-002 are designed to target two key cytokines that play a related role in multiple indications. IL-23 is an upstream regulator of Th17 cells, a pro-inflammatory subset of T helper cells characterized by their production of IL-17. IL-23 has a critical role in maintaining Th17 cells in the tissue as well as activating these cells to secrete IL-17, which acts downstream to trigger inflammation and other disease symptoms. Th17 cells are involved in PsO, PsA, HS, axSpA, and many other diseases. They play a particularly central role in PsO and PsA. The diagram below depicting the immunopathogenesis of PsO provides an example of how Th17 cells can mediate disease and how blocking IL-23 or IL-17 can break the inflammatory cycle that drives disease.

Immunopathogenesis of PsO and the role of IL-23 and IL-17



Adapted from 2022 Song (Immune Network) & 2014 Bartlett (Nature Reviews Drug Discovery)

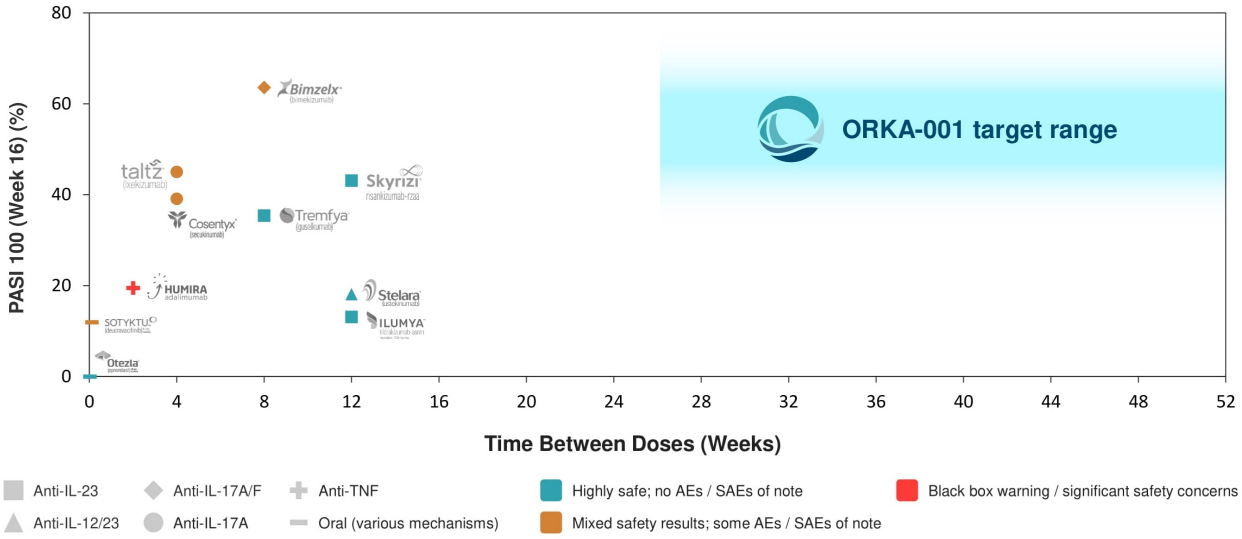
PsO develops when environmental triggers and a genetic predisposition combine to cause activation of an inflammatory cycle in the skin that leads to the formation of plaques and other disease manifestations. This process begins with the aberrant activation of the dendritic cells ("DCs"), specifically those producing IL-23 and other cytokines like IL-1β, IL-21, TNF-α, and IL-12. These cytokines induce the differentiation of Th17 cells, as well as other cell types, such as T helper type 1 ("Th1") cells that produce IFNγ and TNF-α and T helper type 22 ("Th22") cells that produce IL-22. IL-23 plays a key role in the differentiation and activation of Th17 cells to secrete IL-17, as well as Th22 cells to produce IL-22. IL-17 and these other cytokines induce keratinocyte hyperproliferation leading to plaque formation and a feedforward inflammatory response, with changes in gene expression in keratinocytes, the production of antimicrobial peptides, and neutrophil recruitment driving further inflammation. While many cytokines and cell types contribute to the pathogenesis of PsO, the IL-23/IL-17 axis plays an important role, as supported by the success of therapies targeting this axis.

While the successful treatment of PsO — for instance, with mAbs targeting IL-23 or IL-17 — can result in lesional skin returning to an apparently normal state, disease tends to recur at previously affected sites following cessation of therapy, suggesting a mechanism of "immunological memory" that predisposes individuals to recurrence in the same locations. Evidence suggests that pathogenic TRMs play a critical role in this memory. TRMs may arise from the Th17 cells and other cells that drove disease in the first place and remain in their resident tissue, in this case the epidermis and dermis, for long periods of time. Upon a disease trigger, these TRMs can actively produce proinflammatory cytokines, causing disease recurrence. IL-23 appears to play an important role in maintaining and potentiating TRMs, as indicated by the depletion of TRMs following treatment with an IL-23 inhibitor but not an IL-17 inhibitor, which may explain the longer remissions observed with IL-23 inhibitors following withdrawal of therapy. This type of data has raised the prospect that efficient IL-23 blockade could modify the disease biology of PsO, possibly leading to durable remissions.

The scientific discoveries that refined our understanding of the immunopathogenesis of PsO have led to waves of therapeutic advances, ultimately leading to today's standard of care. Before the 1980s, PsO was not even thought of as an immunologic disease, but rather a disease of keratinocyte dysfunction, leading to treatments such as phototherapy, methotrexate, and retinoids. The discovery in the 1980s that PsO results from immune dysfunction led to the use of broad immunosuppressants like cyclosporine. From 1990 to 2008, it was believed that Th1 cells were the predominant mediators of the disease, which led to the use of biologics targeting TNF-α such as Enbrel (etanercept) and Humira (adalimumab). Finally, the revelation that PsO is driven principally by Th17 cells resulted in the development of the primary therapies used today, which target IL-23 and IL-17. This increasingly refined understanding of the disease has narrowed the standard of care from broad immunosuppressive agents (such as cyclosporine) to more specific immunomodulators (TNF-α inhibitors) to precise biologic therapies targeting the key cytokines involved in disease pathology (IL-23 and IL-17 inhibitors), with each new therapeutic class raising the bar on both safety and efficacy.

Biologic therapies, especially mAbs, are now mainstays in the treatment of a wide variety of I&I diseases, including PsO and PsA. Therapies that have improved upon efficacy and/or reduced dosing frequency have achieved the most commercial success, even when launched many years after other biologics. Enbrel was first approved for PsO in 2004 with a weekly maintenance dosing schedule. Four years later, Humira was approved for PsO with an every-other-week (Q2W) dosing schedule. Stelara (ustekinumab) was approved a year later with similar Phase 3 data to Humira, but with a significantly improved dosing schedule of every twelve weeks (Q12W). Several drugs for PsO have been approved since 2009 that demonstrated higher efficacy in their pivotal studies compared to Stelara, but with more burdensome dosing schedules, including Tremfya (guselkumab), which has a dosing schedule of every eight weeks (Q8W), and Cosentyx (secukinumab) and Taltz (ixekizumab), which have dosing schedules of every four weeks (Q4W). While these therapies have all become generally successful products, the most commercially successful drug in the PsO market today is Skyrizi (risankizumab), which combines Stelara's Q12W dosing schedule with improvements in efficacy, as evidenced by a higher psoriasis area severity index (PASI) score of PASI 90 and PASI 100 rates (i.e., a 90% improvement in PASI score and a 100% improvement in PASI score (complete clearance), respectively) in clinical trials. In addition, Bimzelx (bimekizumab), approved by the FDA in 2023, has shown evidence of efficacy that exceeds even Skyrizi, though with a less convenient Q8W dosing schedule. Although many biologics have entered the PsO market over the past two decades, new entrants have had significant commercial success when they have improved upon efficacy and/or dosing frequency, and room remains to improve in both areas to set a new standard for the treatment of PsO.

Biologics have raised the bar on the standard of care in PsO, but leave room for improvement



The biology driving PsO and PsA is well understood today, and the standard of care has progressed dramatically. We believe that it is unlikely that a novel mechanism will emerge that is as safe and efficacious as targeting the IL-23/IL-17 axis. Therefore, we believe that innovation now should be focused on optimizing the product profile that can be offered to patients. While much effort is being directed toward daily oral formats to inhibit this axis, oral medicines have yet to match the efficacy of biologics. We believe that a better biologic with a longer dosing interval and the potential for improved efficacy will present a more attractive product profile for most patients.

Overview of Psoriasis (PsO)

PsO is a chronic autoimmune skin disorder that affects an estimated 125 million people worldwide with steadily increasing prevalence, estimated to be around 2 – 3% of the population currently, according to the World Psoriasis Day consortium. It is the largest pharmaceutical market within dermatology, with annual sales of approximately $25.0 billion in 2022, which is estimated to grow to $32 billion by 2028. The most common form of PsO is plaque psoriasis. Patients with chronic plaque psoriasis have well-demarcated, erythematous plaques with overlying, coarse, silvery-scaled patches. These plaques can occur anywhere on the body, though are typically found on the scalp, extensor areas of the knees and elbows, and gluteal cleft. Involvement of the palms, soles, or nails, and intertriginous areas, including the genitals, can also occur and can be particularly difficult to treat. Between one-quarter and one-half of PsO patients have moderate disease, defined as having 3% to 10% of the body surface area ("BSA") involved, or severe disease, defined as having more than 10% BSA involvement. The chronic inflammation in PsO is associated with multiple comorbidities, including PsA, obesity, metabolic syndrome, hypertension, diabetes, and atherosclerotic cardiovascular disease.

As discussed earlier, PsO is a complex immune-mediated disease driven primarily by Th17 cells and the cytokines IL-23 and IL-17. The interplay of environmental and behavioral risk factors and genetics is believed to trigger PsO. Multiple lines of evidence support a genetic component to the disease, including the observation that approximately 40% of patients with PsO and PsA have a family history of the disease and the identification of multiple susceptibility loci, many containing genes related to the regulation of the immune system, in genome-wide association studies.

Current PsO Treatments and Limitations

While patients with mild PsO typically rely on topical corticosteroids or oral therapies like Otezla (apremilast), these agents often do not provide an adequate response for patients with moderate-to-severe PsO. As a result, the American Academy of Dermatology-National Psoriasis Foundation recommends biologics as first-line therapy for moderate-to-severe PsO.

Several classes of biologic therapies have been approved for PsO over the past 20 years, resulting in progressively more complete symptom relief. Efficacy in PsO is typically measured via the PASI scoring system. The first biologics approved for PsO were tumor necrosis alpha ("TNF-α") inhibitors such as Enbrel (etanercept), Humira (adalimumab), and Remicade (infliximab), which achieved a PASI score of PASI 90 at 16 weeks in around 25 – 50% of patients and a PASI score of PASI 100 in around 5 – 20% of patients. Stelara (ustekinumab), which targets the p40 subunit of IL-23 that is shared with IL-12, was approved next and achieved efficacy on par with Humira. IL-17 inhibitors Cosentyx (secukinumab), Taltz (ixekizumab), and Siliq (brodalumab) followed and achieved responses of PASI 90 in around 70% of patients and PASI 100 in around 40% of patients with some risk of certain side effects such as oral candidiasis. Most recently, IL-23p19 inhibitors such as Ilumya (tildrakizumab), Tremfya (guselkumab), and Skyrizi (risankizumab) have achieved responses of PASI 90 in around 70 – 80% of patients and PASI 100 in around 30 – 50% of patients with highly tolerable profiles. Finally, IL-17A/F inhibitors such as Bimzelx (bimekizumab) have recently shown even higher response rates than IL-23 inhibitors, but with slightly less tolerable profiles.

Treatment expectations in PsO have evolved progressively with this continued innovation. A 75% improvement in PASI score was previously thought to be an adequate depth of response, and weekly SQ dosing was viewed as acceptable. With each subsequent generation of innovation, patient and caregiver expectations have advanced. Today, Skyrizi (risankizumab) is widely viewed as the leader in PsO biologic therapy. In Phase 3 clinical trials, 43% and 58% of patients achieved PASI 100 at 16 and 52 weeks, respectively, with SQ maintenance dosing every three months. Most recently, Bimzelx (bimekizumab) has shown evidence of efficacy that exceeds even Skyrizi, achieving a 64% PASI 100 rate at 16 weeks in Phase 3 trials. However, the increased efficacy comes with a less convenient Q8W dosing schedule and an increased risk of certain side effects, most notably oral candidiasis. While agents like Skyrizi and Bimzelx reflect the remarkable advancement in PsO treatment, there remains significant unmet need. Approximately half of moderate-to-severe PsO patients do not achieve full skin clarity, and while early signs are present, the promise of disease modifying therapy remains unrealized. In addition, a continued desire for more convenient dosing options has driven significant interest in orally delivered medicines targeting these same pathways. However, oral therapies have yet to match the efficacy and safety profile of biologics. We believe that ORKA-001 and ORKA-002 could represent the next step in biologic innovation in PsO, with the potential for higher rates of complete skin clearance, more durable remissions, and markedly more convenient dosing regimens.

Overview of Psoriatic Arthritis (PsA)

PsA is a chronic inflammatory condition that affects both the skin and joints, and often coexists with PsO. Around a quarter to a third of patients with moderate-to-severe PsO also have PsA. Most individuals develop PsO before being diagnosed with PsA, with a median gap of seven to eight years between the diagnosis of skin and joint disease, though in up to 30% of patients with PsA, joint symptoms appear before or simultaneously with skin manifestations. Patients with PsA present with joint pain, stiffness, and swelling affecting the peripheral joints, axial skeleton, or both. Enthesitis, dactylitis, nail lesions, fatigue, and ocular inflammation all occur commonly. PsA can lead to irreversible joint damage, including bony fusion across a joint (ankylosis). The pathogenesis of PsA is likely to be closely related to the mechanisms that underlie PsO. Like PsO, the exact cause of PsA remains unknown, but environmental triggers, including infection and trauma, and genetic factors play a role.

Current PsA Treatments and Limitations

Effective treatment of PsA requires a coordinated approach to address the unique combination of disease manifestations each patient has, which can include peripheral and axial arthritis, enthesitis, dactylitis, and skin and nail involvement. Many patients with milder disease symptoms will start with nonsteroidal anti-inflammatory drugs ("NSAIDs") and/or local treatments to address specific disease manifestations. However, those with more moderate or severe disease and/or multidomain involvement will typically receive a biologic therapy targeting TNF-α or IL-17, or less commonly an oral Janus kinase ("JAK") inhibitor. Comorbid conditions can also influence treatment selection. For example, an IL-17 inhibitor would be preferred for a patient with significant skin involvement, but not for patients with IBD or ocular symptoms, where a TNF-α inhibitor would be preferred. The most common endpoint used to measure the efficacy of TNF-α or IL-17 inhibitors in PsA is ACR response, or the proportion of patients achieving a specified percent improvement in American College of Rheumatology ("ACR") score, which measures peripheral joint disease. Approved TNF-α inhibitors, including Humira (adalimumab) and Cimzia (certolizumab), achieved a placebo-adjusted ACR50 response of around 30 – 35% at 24 weeks with Q2W dosing. Approved IL-17 inhibitors, including Cosentyx (secukinumab) and Taltz (ixekizumab), achieved a slightly lower placebo-adjusted ACR50 response of around 25 – 30% at 24 weeks, but with more convenient Q4W dosing. Bimzelx (bimekizumab), which was recently approved in the United States for PsA, achieved a placebo-adjusted ACR50 response of approximately 35% at 16 weeks with Q4W dosing. A significant fraction of patients with PsA still do not achieve a satisfactory response with available therapies, and even the most convenient regimens require monthly SQ dosing.

Overview of additional opportunities

In addition to PsO and PsA, inhibition of IL-23 or IL-17 has demonstrated efficacy in a number of additional I&I indications, including HS and axSpA.

HS is a chronic inflammatory skin disease characterized by lesions that include deep-seated nodules and abscesses, draining tracts, and fibrotic scars that occur most commonly in intertriginous areas, such as the armpits and groin. Due to the associated pain, sensitive locations, drainage, odor, and scarring, this condition can have a particularly negative psychosocial impact on affected individuals. HS is believed to be underdiagnosed and could have a prevalence well above 1% worldwide. Treatment varies depending on severity and can include topical and systemic antibiotics, hormone therapy, immune modulators, and surgery. Humira (adalimumab) was the only FDA-approved medication for the treatment of moderate-to-severe HS from its approval in 2015 until the approval of Cosentyx (secukinumab) in October 2023 and Bimzelx (bimekizumab) in November 2024. Now multiple other biologics are advancing through development and have demonstrated encouraging data in Phase 2 clinical trials, though a significant fraction of patients still do not achieve adequate responses.

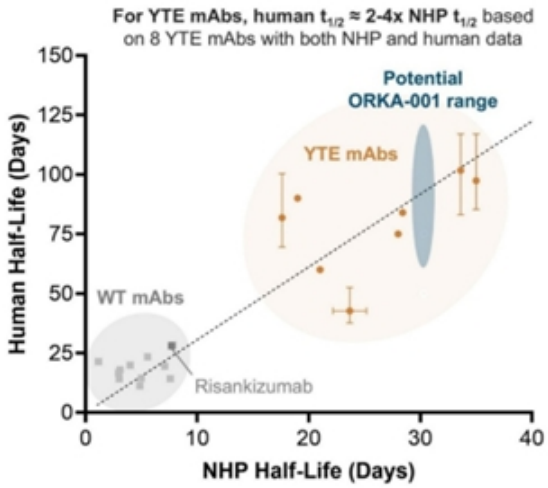
axSpA is a chronic inflammatory disease that primarily affects the spine and sacroiliac joints that comprise the axial skeleton. The disease causes severe pain, stiffness, and fatigue, and can have additional clinical manifestations like uveitis, enthesitis, peripheral arthritis, and PsO. Patients with axSpA may develop further structural damage in their spine, which can lead to the fusion of vertebra (spinal ankylosis), which has a massive negative impact on mobility, physical function, and quality of life. The overall prevalence of axSpA is estimated to be around 1% in the United States. Treatment of axSpA starts with physical therapy and NSAIDs. If patients do not have an adequate response to NSAIDs, a TNF-α inhibitor is typically used, followed by an IL-17 inhibitor, such as Cosentyx (secukinumab), Taltz (ixekizumab), or Bimzelx (bimekizumab), or less frequently a JAK inhibitor. Patients often need to cycle through therapies over time due to inadequate responses or loss of response.

Our Solution: Half-Life Extension and Antibody Engineering Technologies

Our antibody engineering campaigns are designed to optimize multiple attributes in parallel: binding affinity, potency in a variety of assays, developability, and consistently extended serum half-life in non-human primates ("NHPs"). Half-life extension is possible by modifying the pH-dependent binding affinity of the antibody Fc domain for FcRn. A primary mechanism of elimination of antibodies from the serum is through pinocytosis and degradation in the lysosomes of cells. Throughout this process, antibodies can be recycled back into the serum by binding to FcRn while they are in endosomes. The interior of the endosome is acidic, and therefore the efficiency of this recycling process depends on the ability of the antibody Fc domain to bind to FcRn at low pH. If this low pH binding is efficient enough, antibody recycling can be favored over degradation, potentially resulting in a much longer serum half-life.

Antibody engineers have discovered methods of modifying the Fc domain to optimize the efficiency of recycling via FcRn binding. Several engineering strategies have been identified over the past two decades, with the so-called "YTE" mutations (M252Y/S254T/T256E) and "LS" mutations (M428L/N434S) being the most frequently used. Importantly, while these strategies have been known for some time, it was only relatively recently that enough clinical precedent was established to provide confidence in how these mutations perform in humans. Two products incorporating YTE modification were approved in 2023 by the FDA, Beyfortus (nirsevimab) and Evusheld (tixagevimab and cilgavimab), and several more candidates are in clinical trials. Two products using LS mutations were approved in 2021 and 2022, Xevudy (sotrovima) and Ultomiris (ravulizumab), respectively, and several more candidates are in clinical trials. Based on clinical data in humans, antibodies with YTE mutations typically have a half-life that is two to four times longer than wildtype antibodies. In addition, preclinical data in NHPs can be used to predict the approximate half-life in humans, with the human half-life equaling around two to four times the NHP half-life.

Clinical experience with YTE-modified mAbs predicts significant half-life extension over wildtype mAbs



While this increasing body of clinical precedent serves to validate half-life extension, we do not yet have clinical data showing that the introduction of these amino acid substitutions in our programs leads to a longer serum half-life. However, we aim to establish this favorable pharmacokinetic profile early in the clinical development of our product candidates.

ORKA-001

Summary

ORKA-001 is a high affinity, extended half-life mAb designed to target the p19 subunit of IL-23. Based on preclinical data generated to date, we believe ORKA-001 has the potential to become the leading IL-23 inhibitor and achieve an optimal product profile in PsO consisting of the following:

- ***One to two maintenance doses per year.*** Standard-of-care therapies targeting IL-23 require maintenance dosing every eight to twelve weeks. We engineered the Fc portion of ORKA-001 to include YTE mutations to increase the half-life of ORKA-001 in circulation, which may enable dosing every six to twelve months — a dosing interval made feasible by half-life extension technology. In preclinical studies, serum levels from NHPs indicated an elimination half-life of over 30 days following SQ administration of ORKA-001. Based on published scientific literature on other antibodies incorporating YTE mutations and pharmacokinetic modeling, we anticipate this half-life in NHPs to translate to a half-life in humans that could allow subcutaneous dosing every six to twelve months while maintaining high antibody exposures.

- ***Higher PASI 100.*** ORKA-001 benefits from the robust validation of IL-23 inhibition in PsO by multiple approved therapies, such as Skyrizi (risankizumab) and Tremfya (guselkumab), while leveraging insights from these therapies to improve upon their clinical profile. ORKA-001 is designed to bind a similar epitope to the market-leading anti-IL-23 antibody, Skyrizi, with similar or greater affinity and could achieve much higher exposures in patients due to half-life extension and higher dosing. Skyrizi and Tremfya both have a robust exposure-response relationship, with higher drug exposures leading to higher response rates. Published data indicates that these therapies have not saturated this exposure-response relationship, and ORKA-001 could lead to higher response rates, including higher rates of complete skin clearance, or PASI 100, through increased exposure, even while having more convenient dosing with as few as one or two maintenance doses per year.

- ***Validated IL-23p19 safety profile.*** Existing commercially approved antibodies targeting IL-23 provide a robust precedent for the safety of IL-23 inhibition. Across thousands of patients dosed in dermatology and IBD indications, no correlations have been observed at the patient level between exposure and safety. While we are not pursuing IBD, the approved Skyrizi regimens for Crohn's disease and ulcerative colitis supports the safety of high peak exposures. Peak Skyrizi exposures during the IV induction phase in Crohn's disease and ulcerative colitis are multiple times higher than the anticipated peak ORKA-001 exposures at dose levels we currently plan to evaluate in PsO. In addition, an exposure-response analysis for Skyrizi in ulcerative colitis showed no relationship between exposures and evaluated safety endpoints in the 12-week induction or 52-week maintenance periods. In this assessment, the top quartile of average exposures were significantly higher than the highest anticipated exposures with ORKA-001 in the same periods.

- ***Potential to offer longer term remission to some patients.*** Emerging evidence suggests that IL-23 blockade can modify the disease biology of PsO, possibly leading to durable remissions and preventing the development of PsA. Dr. Andrew Blauvelt, chair of our Scientific Advisory Board, pioneered some of this work by using two- and four-times the approved dose levels of risankizumab to achieve best-in-indication response rates. This study, called KNOCKOUT, showed a robust depletion of TRMs following high dose IL-23 inhibition, which could lead to longer-lasting remissions in some patients. Additional evidence from a study of guselkumab, called GUIDE, showed that intervention early in the disease course can lead to longer treatment-free remissions. In addition, retrospective claims data suggests that treatment with an IL-23 inhibitor could help prevent progression to PsA, though this finding has yet to be confirmed by a prospective clinical trial. Given the high antibody exposures expected with ORKA-001, we believe that ORKA-001 could lead to durable remissions for some patients, especially those with short disease duration. We plan to pursue patient-specific dosing intervals to provide each patient the greatest possible freedom from their disease.

We believe that this target profile for ORKA-001 could offer improved freedom from disease to many patients affected by PsO and represent a step forward in the standard of care.

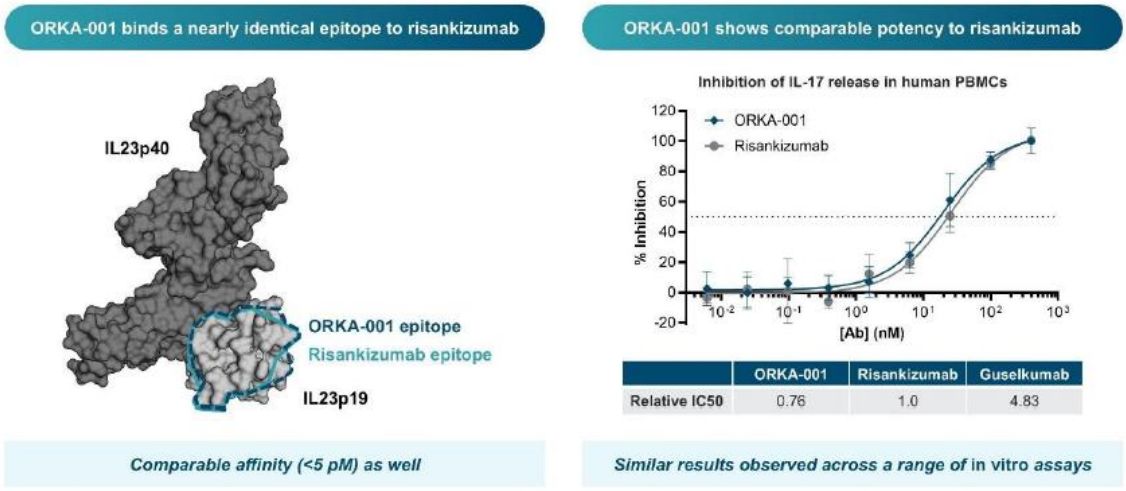
Preclinical Data

We evaluated ORKA-001 in numerous preclinical studies for several key features:

Potency that matches or exceeds Skyrizi (risankizumab) in vitro

We have tested the potency of ORKA-001 in vitro in multiple assays, including assays evaluating the inhibition of IL-17 release from human peripheral mononuclear blood cells, in comparison to risankizumab generated recombinantly based on amino acid sequences from patent filings. Based on the results of these experiments, we believe ORKA-001 binds a similar epitope as risankizumab with similar potency.

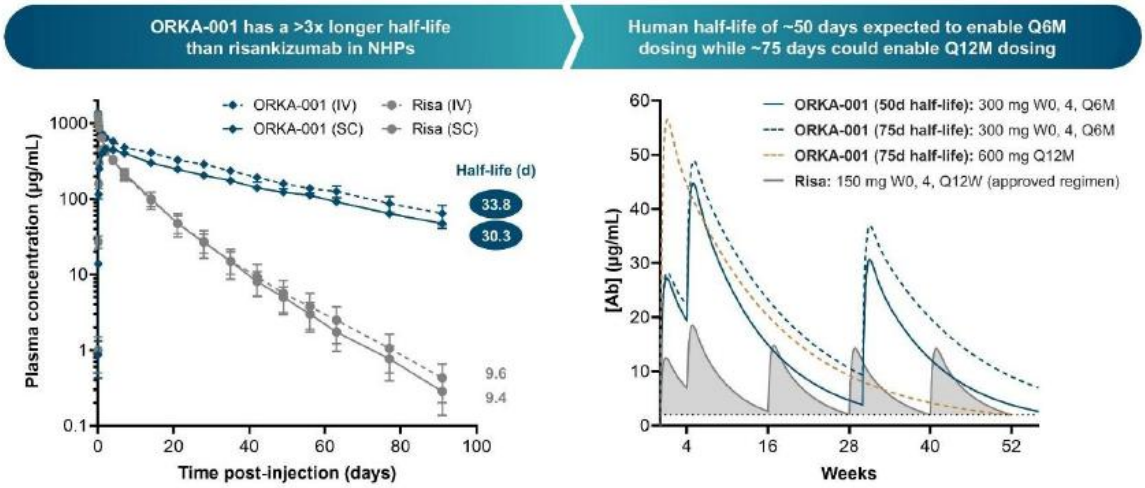
ORKA-001 binds to a similar epitope as risankizumab with similar potency



Significant half-life extension in NHPs that could enable a maintenance dosing interval of once or twice a year in humans

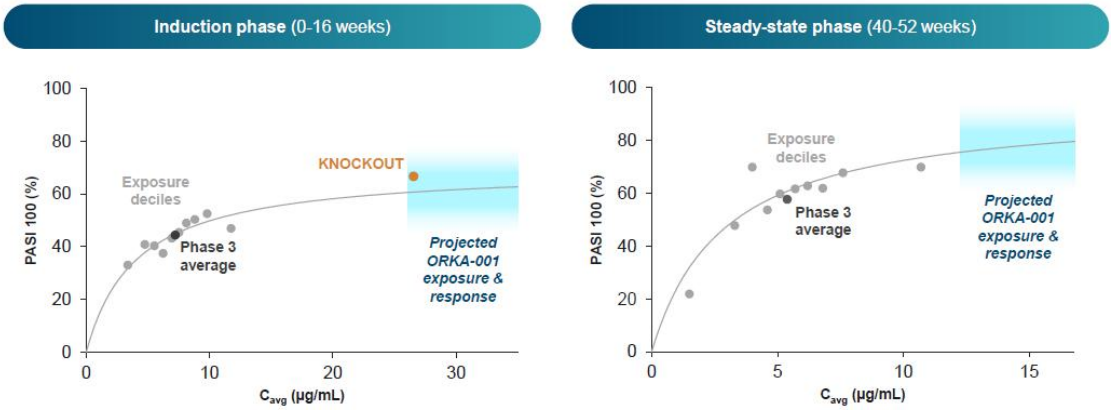
We assessed ORKA-001 in NHPs in comparison to risankizumab generated recombinantly based on amino acid sequences from patent filings. ORKA-001 had a significantly longer half-life, reaching over 30 days with SQ administration. Based on clinical experience with YTE-modified mAbs and pharmacokinetic modeling, we believe that this half-life extension could enable dosing once or twice per year, as shown in the figure below.

The incorporation of YTE mutations significantly extends half-life in NHPs, which could enable once or twice yearly dosing



In addition to enabling less frequent dosing, an extended half-life would increase the exposure of ORKA-001, which has the potential to increase efficacy. Based on published literature, Skyrizi (risankizumab) demonstrates a clear relationship between antibody exposure and efficacy, with higher average serum antibody concentration correlating with higher PASI 90 and PASI 100 rates short-term (at 16 weeks) and long-term (at 52 weeks), as shown for PASI 100 in the figure below. In addition, the KNOCKOUT study, which evaluated two- and four-times higher doses of Skyrizi than the approved regimen, yielded some of the highest PASI 100 rates observed to date, reaching 67% at 16 weeks. Based on our pharmacokinetic modeling, ORKA-001 could achieve four-fold higher average exposures than the approved Skyrizi regimen over the first 16 weeks and over two-fold higher average exposures at steady-state, exceeding even the exposures in KNOCKOUT. Based on the exposure-response relationship observed with other IL-23 inhibiting antibodies, we believe that these increased exposures could result in higher efficacy.

ORKA-001 is projected to extend the exposure-response relationship established by studies of Skyrizi



Notes & Sources: Adapted from 2019 Khatri (Clin Pharmacol Ther) and Skyrizi BLA Multi-disciplinary Review (Fig. 20); KNOCKOUT pooled PASI 100 from 2023 Blauvelt (WCD presentation); gray dots represent observed PASI 100 rates within each C_{avg} decile for Skyrizi; gray lines represent model-estimated probabilities for PASI 100 for Skyrizi derived from Khatri; for induction phase (0-16 weeks), model-estimated probabilities reflect all patients, and do not exclude Asian ethnicity

Safety in vitro and in vivo

We have evaluated ORKA-001 in several in vitro and in vivo preclinical studies to assess safety. In addition, we have a nonclinical program to characterize the toxicology, toxicokinetics, and anti-drug antibody profile of ORKA-001 in NHPs. Our nonclinical program supported the initiation of our Phase 1 clinical trial for ORKA-001 and our continuing clinical development.

Characteristics that support ease of manufacturing and potentially enable high-concentration formulations

Finally, we have assessed a variety of attributes essential for manufacturability and high-concentration formulation, including viscosity, solubility, and stability, among others. ORKA-001 shows evidence of desirable properties across these characteristics, which we believe will enhance our ability to manufacture ORKA-001 successfully and consistently and to deliver high doses of ORKA-001 subcutaneously using convenient, low-volume presentations.

Clinical Development

ORKA-001

We dosed the first participants in a Phase 1 clinical trial of ORKA-001 in healthy volunteers in the fourth quarter of 2024. This trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability, and pharmacokinetics of ORKA-001 in healthy volunteers. The trial is expected to enroll approximately 24 healthy volunteers across three subcutaneous dose cohorts. We expect to share interim data from this trial in the second half of 2025. We believe this data has the potential to provide key validation of initial safety and pharmacokinetics data, including half-life, to support extended dosing intervals.

We plan to initiate a Phase 2a proof-of-concept study of ORKA-001 in moderate-to-severe PsO in the second half of 2025. We believe that several aspects of PsO facilitate clinical development, including well-established, reproducible endpoints based on PASI scores, low placebo rates, particularly with PASI 90 and PASI 100, a rapid efficacy readout at 16 weeks, and potentially rapid enrollment due to the large patient population. Our Phase 2a clinical trial is anticipated to evaluate the safety and efficacy of a single dose level of ORKA-001 versus placebo in approximately 80 subjects, followed by randomization to one of two maintenance dosing arms. In one maintenance arm, subjects will receive ORKA-001 every six months. In the other, subjects will receive only induction dosing to assess the length of time patients maintain clear skin, which could support once-yearly dosing or even longer-term durability in some patients. The anticipated primary endpoint is PASI 100 at Week 16. After completing the trial, subjects may have the option to roll over to an open-label extension study. We expect to share initial data from the Phase 2a trial in the second half of 2026. We believe this data has the potential to inform efficacy at Week 16, as well as later timepoints, and provide us information on preliminary durability, including the potential for extended dosing intervals and longer-term remissions.

ORKA-002

Summary

ORKA-002 is a high affinity, extended half-life mAb designed to target IL-17A/F. Dual inhibition of both IL-17A and IL-17F has shown superior efficacy compared to IL-17A inhibition alone in PsO and other indications, as shown by the performance of Bimzelx (bimekizumab) compared to Cosentyx (secukinumab) and Taltz (ixekizumab) in Phase 3 trials. These therapies all utilize Q4W maintenance dosing in PsO and PsA, except Bimzelx, where Q8W maintenance dosing in PsO patients <120 kg is recommended. By binding IL-17A/F at similar epitopes and affinity ranges as Bimzelx while incorporating half-life extension technology to potentially enable dosing two to three times a year in PsO and PsA, we believe that ORKA-002 could become the leading therapy in the IL-17 class.

Preclinical Data

The preclinical program we are conducting for ORKA-002 mirrors that for ORKA-001 and spans potency, pharmacokinetics, safety, and manufacturing characteristics. Based on the results of these experiments, we believe ORKA-002 has the potential for comparable potency to bimekizumab, but with a significantly longer half-life, which we believe could support dosing two or three times per year based on extrapolation from clinical precedent and pharmacokinetic modeling.

Clinical Development Plans

We plan to initiate dosing of healthy volunteers in a Phase 1 trial of ORKA-002 in the third quarter of 2025. As with ORKA-001, initial data on ORKA-002 in healthy volunteers has the potential to provide key validation of both early safety and pharmacokinetics to support extended dosing intervals. Though clinical development of ORKA-002 will initially focus on one lead indication, we plan to evaluate ORKA-002 in a range of indications over time. We see ORKA-002 as highly complementary to ORKA-001, with the potential to provide an optimal therapy for the approximately one-quarter to one-third of moderate-to-severe PsO patients who have PsA, as well as for PsO patients with highly resistant skin symptoms that do not respond adequately to an IL-23 inhibitor. Furthermore, ORKA-002 could address indications beyond PsO, including PsA with limited skin involvement, HS, axSpA, and additional I&I diseases.

ORKA-021

The IL-17 and IL-23 classes each have distinct advantages. IL-17 inhibitors tend to have the fastest onset and highest peak response, while IL-23 inhibitors have less frequent dosing and better durability and safety. Combining the two mechanisms sequentially has the potential to provide two attractive features of each program: the rapid response of an IL-17 inhibitor with the ideal maintenance profile of an IL-23 inhibitor. As a result, following ORKA-002 and ORKA-001, we plan to explore a sequential combination regimen of ORKA-002 and ORKA-001, called "ORKA-021."

Additional Pipeline Program

We have a third mAb program, ORKA-003, that targets an undisclosed pathway. A core tenet of our strategy is to remain highly focused on I&I diseases, and specifically on inflammatory dermatology conditions. ORKA-003 provides the potential for indication expansion beyond PsO as well as combination opportunities with our more advanced programs. In the future, we may add additional programs to our portfolio beyond ORKA-001, ORKA-002, ORKA-021 and ORKA-003 that fit our strategic focus.

Intellectual Property

We strive to protect the proprietary programs and technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our programs, their methods of use and manufacture, related technologies, diagnostics, and other inventions.

Paragon has filed, on our behalf, provisional patent applications, and we have filed non-provisional patent applications, and may file additional patent applications directed to antibodies that target IL-23, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including ORKA-001. In addition, Paragon has filed, on our behalf, provisional patent applications, and we may file additional patent applications directed to antibodies that target IL-17, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including ORKA-002. We have exclusive rights to ORKA-001 and ORKA-002 and the corresponding IL-23 and IL-17 patent applications pursuant to license agreements with Paragon. If the patent applications mature into one or more issued patents covering ORKA-001 or ORKA-002, we would expect those patents to expire in 2045, absent any applicable patent term adjustments or extensions.

Commercial

Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs. Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We have exclusive worldwide rights to develop and commercialize ORKA-001 and ORKA-002 pursuant to license agreements with Paragon.

Manufacturing

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We have contracted and expect to continue to contract with third parties for the manufacture and distribution of our product candidates. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical, and quality experience. Our team has deep knowledge and understanding of the regulations that govern manufacturing, documentation, quality assurance, and quality control of drug supply that are required to support our regulatory filings.

Competition

The biotechnology and biopharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our programs, technology, development experience and scientific knowledge provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and therapies that may become available in the future. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient enrollment for clinical trials as well as in acquiring technologies complementary to, or necessary for, our programs.

Key competitive factors affecting the success of all our product candidates that we develop, if approved, are likely to be efficacy, safety, convenience, presentation, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or diseases as our two most advanced programs, ORKA-001 and ORKA-002, including major pharmaceutical companies. We do not yet have clinical data for any of our programs and there can be no assurance that our programs will have similar or comparable results.

There are several approved biologic therapies for the treatment of moderate-to-severe PsO. These include mAbs targeting IL-23, such as Skyrizi (risankizumab) from AbbVie, Tremfya (guselkumab) from Janssen, and Ilumya (tildrakizumab) from Sun Pharma, also marketed as Ilumetri by Almirall in Europe, which all target the p19 subunit, and Stelara (ustekinumab) from Janssen, which targets the p40 subunit; mAbs targeting IL-17, such as Bimzelx (bimekizumab) from UCB, which targets IL-17A/F, Cosentyx (secukinumab) from Novartis and Taltz (ixekizumab) from Eli Lilly, which both target IL-17A, and Siliq (brodalumab) from Ortho Dermatologics, also marketed as Kyntheum by LEO Pharma in Europe, which targets IL-17 receptor/A; and biologics targeting TNF-α, such as Humira (adalimumab) from AbbVie, Enbrel (etanercept) from Amgen, and Remicade (infliximab) from Janssen, and various biosimilar versions of each. In addition, there are several approved oral medicines in these indications, including the phosphodiesterase-4 (PDE4) inhibitor Otezla (apremilast) from Amgen and the tyrosine kinase 2 (TYK2) inhibitor Sotyktu (deucravacitinib) from Bristol-Myers Squibb. Many of these therapies also are approved or in development for PsA, HS, axSpA, and other I&I indications.

In addition, we are aware of several product candidates in clinical development for moderate-to-severe PsO, along with PsA, HS, axSpA, and other indications. These include the biologics picankibart from Innovent Biologics targeting IL-23p19 and sonelokimab from MoonLake Immunotherapeutics targeting IL-17A/F. Also, there are several oral agents in development, including JNJ-2113 from Janssen targeting the IL-23 receptor, DC-853 from Eli Lilly targeting IL-17A, and TAK-279 from Takeda and ESK-001 from Alumis, both targeting TYK2.

Significant Agreements

Paragon Therapeutics – Option Agreements

In March 2024, we entered into two antibody discovery and option agreements ("Option Agreements") with Paragon and Paruka Holding, LLC ("Paruka"). Paruka is an entity formed by Paragon as a vehicle to hold equity in our Company in order to share profits with certain employees of Paragon. Under the terms of each agreement, Paragon identifies, evaluates, and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. From time to time, we can choose to add additional targets to the collaboration upon agreement with Paragon and Paruka. Under the Option Agreements, we have the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title, and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture, and commercialize the antibodies and products directed to the selected target(s) (each, an "Option"). We have initiated certain research programs with Paragon that generally focus on discovering, generating, identifying and/or characterizing antibodies directed to a particular target (each, a "Research Program"), including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. Our exclusive option with respect to each Research Program is exercisable at our sole discretion at such time as specified in the Option Agreements (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the Option Agreements. For each of these agreements, once we enter into the corresponding license agreements, we will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones, up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale in each program.

We may terminate any Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that we must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate any Option Agreement or a Research Program immediately upon written notice to us if, as a result of any action or failure to act by us or our affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Option Agreements or any Research Program upon material breach that remains uncured or the other party's bankruptcy.

Additionally, as part of the Option Agreements, on December 31, 2024 and December 31, 2025, we granted and will grant, respectively, Paruka a warrant to purchase a number of shares equal to 1.00% of outstanding shares as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares on the grant date.

Paragon Therapeutics – License Agreements

In September 2024, we exercised the Option to acquire certain rights to ORKA-001, and in December 2024, we entered into the corresponding license agreement with Paragon (the "ORKA-001 License Agreement"), pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 in all fields other than the field of inflammatory bowel disease ("ORKA-001 Field"). In December 2024, we exercised the Option with respect to ORKA-002 for the IL-17A/F program, and in February 2025, we entered into the corresponding license agreement with Paragon (the "ORKA-002 License Agreement" and together with the ORKA-001 License Agreement, the "License Agreements"), pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-17A/F in all fields ("ORKA-002 Field" and together with the ORKA-001 Field, the "Fields").

The License Agreements provide us with exclusive licenses in the Fields to Paragon's patent applications covering the related antibodies, their method of use and their method of manufacture and Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies for the ORKA-001 Field or the ORKA-002 Field, respectively, for at least five years. Each of the ORKA-001 and ORKA-002 License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law.

Pursuant to the terms of each of the ORKA-001 and ORKA-002 License Agreements, we are obligated to pay Paragon non-refundable milestone payments of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones and up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, including a $1.5 million fee for nomination of a development candidate (or initiation of an investigational new drug ("IND") enabling toxicology study) and a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial for each of ORKA-001 and ORKA-002. In addition, we are obligated to pay Paragon a low single-digit percentage royalty for antibody products for each of ORKA-001 and ORKA-002. For each of the License Agreements, the royalty term ends on the later of (i) the last-to-expire licensed patent or our patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of a Company product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program.

Cell Line License Agreement

In March 2024, we entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the ORKA-001 and ORKA-002 programs.

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of $150,000. Additionally, to the extent that we manufacture our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, or a small molecule drug candidate's quality, safety and efficacy, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our company and our products or product candidates.

United States Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with current Good Clinical Practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the IND submission process, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment and such review may result in some delay before initiation of a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a risk evaluation and mitigation strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Combination Therapy

Combination therapy is a treatment modality that involves the use of two or more drugs to be used in combination to treat a disease or condition. If those drugs are combined in one dosage form, such as one pill, that is known as a fixed dose combination product and it is reviewed pursuant to the FDA's Combination Rule at 21 CFR 300.50. The rule provides that two or more drugs may be combined in a single dosage form when each component contributes to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug. But not all combination therapy falls under the category of a fixed dose combination. For example, the FDA recognizes that two drugs in separate dosage forms and in separate packaging, that otherwise might be administered as monotherapy for an indication, also may be used in combination for the same indication. In 2013, the FDA issued guidance to assist sponsors that were developing the range of combination therapies that fall outside the category of fixed dose combinations. That guidance provides recommendations and advice on such topics as: (1) assessment at the outset whether two or more therapies are appropriate for use in combination; (2) guiding principles for nonclinical and clinical development of the combination; (3) options for regulatory pathways to seek marketing approval of the combination; and (4) post-marketing safety monitoring and reporting obligations. Given the wide range of potential combination therapy variations, the FDA indicated it intends to assess each potential combination on a case-by case basis and encouraged sponsors to engage in early and regular consultation with the relevant review division at the agency throughout the development process for its proposed combination.

Regulation of Combination Products

Certain therapeutic products are comprised of multiple components, such as drug components, biologic components, and device components, that would normally be subject to different regulatory frameworks by the FDA and frequently regulated by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of drug/biologic-device combination product is attributable to the drug or biological product, the FDA center responsible for premarket review of the drug or biological product would have primary jurisdiction for the combination product. The FDA has also established the Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute. A combination product with a primary mode of action attributable to the drug or biologic component generally would be reviewed and approved pursuant to the drug or biologic approval processes set forth in the FDCA. In reviewing the new drug application or BLA for such a product, however, FDA reviewers would consult with their counterparts in the FDA's Center for Devices and Radiological Health to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulation applicable to medical devices.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;

- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or

- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. The FDA has issued guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Patent Term Extension

In the United States, after a BLA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of a BLA, plus the time between BLA submission date and the BLA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value.

The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that "caused" the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act.

We are also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH"), and their respective implementing regulations imposes data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information ("PHI") for or on behalf of such covered entities. These requirements imposed by HIPAA and the HITECH Act on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators. Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with the U.S. Department of Health and Human Services ("HHS") to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state Attorneys General, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CCPA"), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household - unless it is subject to HIPAA - and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, also exempt some data processed in the context of clinical trials; but others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely. Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence/machine learning, controlling for data bias, and antidiscrimination.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a list of 15 additional Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar's market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union ("EU") provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress.

In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for its drugs or put pressure on its drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("GDPR"), which came into force in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the European Economic Area ("EEA") that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on SCCs, data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework. With regard to the transfer of data from the EU to the United Kingdom ("UK"), personal data may freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions include a 'sunset clause' which entails that the decisions will automatically expire four years after their entry into force, unless renewed.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU Clinical Trials Regulation No. 536/2014 ("CTR"), European Medical Agency ("EMA") disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the "DPA 2018")), the DPA 2018, and related data protection laws in the UK). Separate from the fines that can be imposed by the GDPR, the UK regime has the ability to fine up to the greater of £17.5 million or 4% of global turnover.

Companies are subject to specific transfer rules under the UK regime, which broadly mirror the GDPR rules. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers (Addendum) and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime.

Regarding transfers from the UK to the EEA, personal data may flow freely since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization ("MA") for human medicines in the EU/EEA must have been carried out in accordance with EU regulations. This means that clinical trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EEA, including adhering to international good clinical practice and the Declaration of Helsinki. The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC, ("Clinical Trials Directive") and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the former regime, which will expire after a transition period of three years as outlined below in more detail, before a clinical trial can be initiated it must be approved in each EU member state where there is a site at which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority ("NCA") and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU member state before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU member state where they occur.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the Clinical Trials Information System or "CTIS"). One national regulatory authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application and consult and coordinate with the other concerned EU Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU Member States. However, a concerned EU member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database. The CTR foresees a three-year transition period. EU Member States will work in CTIS immediately after the system has gone live. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory and CTIS serves as the single entry point for submission of clinical trial-related information and data. By January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS. On July 19, 2023, the EC published guidance concerning the steps to be taken in this transition. This guidance provides, among other things, that (i) documentation which was previously assessed will not be reassessed, (ii) templates that were developed and endorsed by the EU Clinical Trials Expert Group to provide compliance with the CTR do not need to be updated and (iii) there is no need to retrospectively create a site suitability form, which are only necessary for new trial sites.

Under both the former regime and the new CTR, national laws, regulations, and the applicable GCP and GLP standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain a MA of a drug under EU regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

To be used or sold in the UK, a drug must have an effective MA obtained by a centralized application through EMA or a national application. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the Medicines and Healthcare products Regulatory Agency ("MHRA") Submissions Portal. The process from application to authorizations generally takes up to 210 days, excluding time taken to provide any additional information or data required by the MHRA.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Reliance Procedure ("IRP") for MAAs. The IRP applies since January 1, 2024 and replaces existing EU reliance procedures to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows medicinal products approved in other jurisdictions that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK.

Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the EMA that is valid for all EU Member States as well as in the three additional EEA Member States (Norway, Iceland and Liechtenstein). The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products ("ATMP") (gene therapy, somatic cell therapy or tissue engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

Under the centralized procedure, the CHMP established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure

Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization: (i) they can be authorized under the centralized procedure if they concern a significant therapeutic, scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state; or (iii) they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national MA (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned member states, are subsequently required to grant a MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA, subject only to limited redactions.

MA Validity Period

MAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA. Conversion refers to the procedure by which, as of January 1, 2021, MAs granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland but not in Great Britain, whereas, prior EU authorizations have all been automatically converted into UK MAs effective in Great Britain only.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on December 31, 2020 (the "Brexit Transition Period") will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining EU Member States, the three-year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including ATMPs are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to the Regulation (EC) No 1394/2007, the Committee for Advanced Therapies ("CAT") is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Exceptional Circumstances/Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU in exceptional circumstances. A conditional MA can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. Once a conditional MA has been granted, the MA holder must fulfil specific obligations within defined timelines. A conditional MA is valid for one year and must be renewed annually, but it can be converted into a standard MA once the MA holder fulfils the obligations imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. Innovative medicinal products, referred to as New Chemical Entities ("NCEs") approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product's first MA in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another non-cumulative one-year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of MA for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the EU's regulatory authorities to include an NCE. Even if a compound is considered to be an NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation. The current draft envisages e.g., a shortening of the periods of data exclusivity, however, there is currently neither a final version of this draft nor a date for its entry into force. While the European Parliament adopted its approving position on the reform on April 10, 2024, no further required legislative steps have been taken since.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted an MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval), or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has published guidance on the procedures for UK Paediatric Investigation Plans ("PIPs") which, where possible, mirror the submission format and requirements of the EU system. EU PIPs remain applicable for Northern Ireland and EU PIPs agreed by the EMA prior to January 1, 2021 have been adopted as UK PIPs.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and MAs. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of Periodic Safety Update Reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase 4 safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the MA granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals.

EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the Human Medicines Regulations 2012. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK-based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed.

The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials, and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 (the "MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Corporate Information

We were formed as a Delaware corporation in 1992 under the name "Nuvelo, Inc." and subsequently, in 2009, we completed a business combination with ARCA biopharma, Inc. On August 29, 2024, we completed the Merger with Pre-Merger Oruka and changed our name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." Our corporate headquarters are located at 855 Oak Grove Avenue, Suite 100, Menlo Park, California 94025. The telephone number at our corporate headquarters is (650) 606-7910. Our corporate website address is *www.orukatx.com*. We do not incorporate information contained on, or accessible through, our website into this Annual Report on Form 10-K, and you should not consider it part of this Annual Report.

Employees and Human Capital Resources

As of December 31, 2024 and as of February 28, 2025, we had 28 full-time employees and 36 full-time employees, respectively. We also engage temporary employees and consultants to augment our existing workforce. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that attracting, motivating, and retaining talent at all levels is vital to continuing our success. We invest in our employees through high-quality benefits, professional development opportunities, and various health and wellness initiatives and offer competitive compensation packages (base salary and incentive plans), ensuring fairness in internal compensation practices. The principal purposes of our incentive plans (bonus and equity) are to align with the long-term interests of our stakeholders and stockholders.

Item 1A. Risk Factors.

Risk Factors Summary

We are subject to a number of risks that could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Form 10-K and those we may make from time to time. The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any current or future collaborator. In addition, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future.

The following summary is not exhaustive and is qualified by reference to the full set of risk factors set forth in Item 1A "Risk Factors" of this Form 10-K. Please carefully consider all the information in this Form 10-K, including the full set of risks set forth in the "Risk Factors" section and in our other filings with the U.S. Securities and Exchange Commission ("SEC"), before making an investment decision regarding Oruka.

Risks Related to Drug Development and Regulatory Approval

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- We are substantially dependent on the success of our two most advanced programs, ORKA-001 and ORKA-002. Our projected development goals, including our clinical trials, may not be successful or we may fail to achieve our projected development goals in the time frames we announce and expect.
- We may not be able to meet requirements for the chemistry, manufacturing and control of our programs.
- The U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory approval processes are lengthy and time consuming and we may not be able to obtain or may be delayed in obtaining regulatory approvals for our product candidates. Moreover, even if we obtain regulatory approval, we will be subject to ongoing regulatory obligations.
- We face competition from entities that have developed or may develop programs for the diseases addressed by product candidates developed by us.

Risks Related to Our Financial Condition and Capital Requirements

- We are a clinical stage biopharmaceutical company with a limited operating history on which to assess our business; we have not completed any clinical trials, and have no products approved for commercial sale.
- We have historically incurred losses and we anticipate that we will continue to incur losses for the foreseeable future.
- We have never generated revenue from product sales and may never be profitable.
- We may not be able to raise the capital that we need to support our business plans.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Risks Related to Our Intellectual Property

- Our ability to obtain and protect our patents and other proprietary rights is uncertain and we may fail in obtaining or maintaining necessary rights to our programs.
- We may become subject to claims challenging the inventorship or ownership of our intellectual property and may be subject to patent infringement claims or may need to file such claims.

- Our patents and our ability to protect our products may be impaired by changes to patent laws, and our patent protection could be reduced or eliminated for non-compliance with legal requirements.

- We may fail to identify or interpret relevant third-party patents.

- Patent terms may be inadequate to protect our competitive position of our programs.

- Our technology licensed from third parties may be subject to retained rights.

Risks Related to Our Reliance on Third Parties

- We currently rely on agreements with third parties to develop our product candidates. If we are unable to maintain collaborations or licensing arrangements, or if our collaborations or licensing arrangements are not successful, our business could be negatively impacted.

- Third parties we rely on for the execution of nonclinical studies and clinical trials may fail to carry out their contractual duties.

- We may be unable to use third-party manufacturing sites, our third-party manufacturers may encounter difficulties in production or we may need to switch or create third-party manufacturer redundancies.

Other Risk Factors - Risks Related to Employee Matters, Managing Growth, Other Risks Related to Our Business, and Owning Our Common Stock

- Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

- Our business is dependent on key personnel, and we will be harmed if we cannot recruit and retain highly qualified personnel to successfully implement our business strategy.

- In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

- Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and consolidated financial performance.

- We may become exposed to costly and damaging liability claims and our insurance may not cover all damages from such claims.

- Our business could be adversely affected by macroeconomic or geopolitical conditions.

- We do not anticipate paying any dividends in the foreseeable future.

- Future sales of shares by existing stockholders could cause our stock price to decline.

- Future sales and issuances of equity and debt could result in additional dilution to our stockholders and could cause our stock price to decline.

Risk Factors

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical stage biopharmaceutical company with a limited operating history on which to assess our business; we have not completed any clinical trials, have no products approved for commercial sale, have historically incurred losses, and we anticipate that we will continue to incur significant losses for the foreseeable future. Moreover, we have never generated revenue from product sales and may never be profitable.

We are a clinical stage biopharmaceutical company with a limited operating history. We will need to raise substantial additional capital to continue to fund our operations in the future. We have based our estimates on assumptions that may prove to be wrong, and could exhaust our available financial resources sooner than we currently anticipate. We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, organizing and staffing our company, and providing general and administrative support for our operations.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect our losses to increase as our product candidates enter advanced clinical trials. It may be several years, if ever, before we complete pivotal clinical trials or have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our programs to determine the potential to advance product candidates to regulatory approval. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, coverage and adequate reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidates, including advancing our product candidates into larger, more expensive trials;
- continue efforts to discover and develop new product candidates, including initiating preclinical studies or clinical trials;
- progress our chemistry, manufacturing and control development, registration, and validation, including the manufacture of our product candidates by third parties, including increasing volumes manufactured by third parties;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- make milestone, royalty, or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with the development and potential regulatory approval of our product candidates such as safety issues, manufacturing delays, clinical trial delays, longer follow-up for planned studies or trials, additional major studies or trials, or supportive trials necessary to support marketing approval.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to curtail our product development activities and other activities commensurate with the magnitude of the shortfall and our product development activities may cease altogether, which could materially harm our business, financial condition, and results of operations. To the extent that the costs of our activities exceed our current estimates and we are unable to raise sufficient additional capital to cover such costs, we will need to reduce operating expenses, sell assets, enter into strategic transactions, or effect a combination of the above. No assurance can be given that we will be able to enter into any of such transactions on acceptable terms, if at all. Any of the following events could have a material adverse effect on our business, operating results, and prospects:

- a delay, scaling back, or discontinuation of the development or commercialization of our product candidates;
- seeking strategic partnerships, or amending existing partnerships, for research and development programs at an earlier stage than otherwise would be desirable or that we otherwise would have sought to develop independently, or on terms that are less favorable than might otherwise be available in the future;
- disposal of technology assets, or the relinquishing or licensing of assets on unfavorable terms, of our rights to technologies or any of our product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursuing the sale of the company to a third party at a price that may result in a loss on investment for our stockholders; or
- filing for bankruptcy or cease operations altogether.

Even if we are successful in raising new capital, we could be limited in the amount of capital we raise due to investor demand restrictions placed on the amount of capital we raise, or other reasons.

Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights.

To the extent that we raise additional capital through the sale of equity securities or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. For example, in September 2024, we entered into a Securities Purchase Agreement with certain new institutional and accredited investors, whereby the investors purchased an aggregate of 5,600,000 shares of common stock, 2,439 shares of Series A Preferred Stock and pre-funded warrants to purchase an aggregate of 680,000 shares of common stock for an aggregate purchase price of approximately $200.5 million. Each share of Series A Preferred Stock is convertible into 1,000 shares of common stock.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or product candidates or grant licenses on terms that may not be favorable to us. Debt financing, if available, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

We face competition from entities that have developed or may develop programs for the diseases addressed by our product candidates.

The development and commercialization of drugs is highly competitive. Product candidates developed by us, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of biopharmaceutical companies as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals, and marketing than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in establishing clinical trial sites, recruiting participants for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

Our competitors have developed, are developing or will develop programs and processes competitive with our programs and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if biosimilars enter the market and are able to gain market acceptance more quickly than we do or at wider scale.

Our product candidates may fail in development or suffer delays. We depend on the successful initiation and completion of clinical trials for our product candidates to advance our product development plans.

We have no products on the market, and all of our programs are in preclinical or clinical stages of development. As a result, we expect it will be many years before we can obtain regulatory approval for and commercialize any product candidate, if ever. Clinical testing is expensive, difficult to design and implement, and can take years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. It may be difficult for us to raise additional capital if we experience any issues that delay or prevent the regulatory approval or the ability to commercialize our product candidates.

We may experience a number of unforeseen events affecting our product development timeline, including the following:

- our clinical trials may fail to show safety or efficacy, produce negative or inconclusive results, or our product candidates may have undesirable side effects or unexpected characteristics, and we may decide, or regulators may require that we conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;

- the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- regulators or IRBs, the FDA, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at one or more prospective trial sites; or may require that we or our investigators materially modify, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;

- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data as well as data emerging from other therapies in the same class as our product candidates;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials; enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- trial conduct or data analysis errors may occur, including, but not limited to, failure by investigators or participants to adhere to the study protocol or data entry and/or labeling errors;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and/or contract research organizations ("CROs");

- our third-party contractors or clinical trial sites may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators and could potentially complicate the analysis of data;

- the cost of clinical trials of any of our programs may be greater than we anticipate;

- reports from clinical testing of other therapies may raise safety or efficacy concerns about our programs; and

- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements and our product development timeline may be adversely affected.

If our clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted. Moreover, the combined data from our trials may be inconclusive or may not be sufficient to ultimately gain marketing approval from the FDA or other regulatory authorities. There are equivalent processes and risks applicable to clinical trial applications in other countries outside of the United States.

In addition, because of the competitive landscape for immunology and inflammation (commonly referred to as "I&I") indications, we may also face competition for clinical trial enrollment. Clinical trial enrollment will depend on many factors, including if potential clinical trial participants choose to undergo treatment with approved products or enroll in competitors' ongoing clinical trials for programs that are under development for the same indications as our programs. An increase in the number of approved products for the indications we are targeting with our programs may further exacerbate this competition. Our inability to enroll a sufficient number of participants could, among other things, delay our development timeline, which may further harm our competitive position and have an adverse effect on our business and operations.

We are substantially dependent on the success of our two most advanced programs, ORKA-001 and ORKA-002, and our clinical trials of such programs may not be successful.

Our future success is substantially dependent on our ability to develop and timely obtain marketing approval for, and then successfully commercialize, our two most advanced programs, ORKA-001 and ORKA-002. We are investing a majority of our efforts and financial resources into the research and development of these programs. We have initiated a Phase 1 clinical trial of ORKA-001 in healthy volunteers and anticipate initiating a Phase 1 clinical trial of ORKA-002 in healthy volunteers in the second half of 2025, subject to the filing of an IND or foreign equivalent and regulatory approval. Currently, we believe that the success of our programs is dependent on observing a longer half-life of our product candidates in humans than monoclonal antibodies ("mAbs") currently marketed and in development as we believe this longer half-life has the potential to result in a more favorable dosing schedule for our product candidates, assuming they successfully complete clinical development and obtain marketing approval. This is based in part on the assumption that the longer half-life we have observed in NHPs will translate into an extended half-life of our product candidates in humans. To the extent we do not observe this extended half-life in humans, it would significantly and adversely affect the clinical and commercial potential of our product candidates.

If we do not achieve our projected development goals in the time frames we announce and expect, the development and potential commercialization of our product candidates may be delayed and our expenses may increase and, as a result, our business may be materially harmed and our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, such as the expected timing of our clinical trials in our target indications, anticipated data analysis and results from our clinical trials, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the development and potential commercialization of our product candidates may be delayed or never achieved and, as a result, our business may be materially harmed and our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Any drug delivery device that we may use to deliver our product candidates may have its own regulatory, development, supply and other risks.

We expect to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. If our product candidates are intended to be used with drug delivery devices, we expect to utilize drug delivery devices authorized for marketing under clearances of approvals held by third parties. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices that we choose to develop do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained for our products, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances, if required, for their drug delivery devices once they have been received. Failure of third-party companies to supply the devices on time and in accordance with the agreed-upon specifications, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching patients.

Our approach to the discovery and development of our programs is unproven, and we may not be successful in our efforts to build a pipeline of programs with commercial value.

Our approach to the discovery and development of the research programs with respect to which we have signed a license agreement, exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Option Agreements, leverages clinically validated mechanisms of action and incorporates advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies. Our programs are purposefully designed to improve upon existing product candidates and products while maintaining the same, well-established mechanisms of action. However, the scientific research that forms the basis of our efforts to develop programs using half-life extension technologies is ongoing and may not result in viable programs. There is limited clinical data available on product candidates utilizing half-life extension technologies, especially in I&I indications, demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of these technologies and the extended half-lives and exposure profiles of our programs compared to currently approved products are unknown.

We may ultimately discover that utilizing half-life extension technologies for our specific targets and indications and any programs resulting therefrom does not possess certain properties required for therapeutic effectiveness. In addition, programs using half-life extension technologies may demonstrate different chemical and pharmacological properties in human participants than they do in laboratory studies or preclinical studies. This technology and any programs resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways.

In addition, we may in the future seek to discover and develop programs that are based on novel targets and technologies that are unproven. If our discovery activities fail to identify novel targets or technologies for drug discovery, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from the research programs with respect to which we have signed license agreements with Paragon, exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Option Agreements prove to be ineffective, unsafe or commercially unviable, such programs would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process.

Furthermore, a failure of one or more clinical trials can occur at any stage of testing. Clinical data is often susceptible to varying interpretations and analyses, and in addition, we expect to rely on participants to provide feedback on measures such as measures of quality of life, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular participant, and from participant to participant and from site to site within a clinical trial.

We cannot be sure that the FDA, or comparable foreign regulatory authority, as applicable, will agree with our clinical development plan. We plan to use the data from our Phase 1 trials of our ORKA-001 and ORKA-002 programs in healthy volunteers to support Phase 2 trials in PsO and potentially other I&I indications. If the FDA and/or comparable foreign regulatory authority requires us to materially modify our proposed trial designs, conduct additional trials or enroll additional participants, our development timelines may be delayed. We cannot be sure that submission of an IND, Clinical Trial Application or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites; recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's current GCP requirements or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; delays or failure by our third party vendors or us in the manufacturing, packaging, labeling and proper delivery of clinical trial materials; and third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is required to be materially modified or suspended or terminated by us, the IRBs, by the Data Safety Monitoring Board, if any, or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend, put on clinical hold or terminate a clinical trial due to a number of factors, including not aligning with or supporting our clinical trial designs or our failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the programs, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may need to adjust or abandon our business plans and we may incur significant additional costs.

If we encounter difficulties enrolling participants in our current and future clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We depend on the successful completion of clinical trials for our product candidates.

We may experience difficulties in patient participant enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trial until conclusion. The enrollment of participants in future trials for any of our programs will depend on many factors, including if participants choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for programs that are under development for the same indications as our programs, and participants instead enroll in such clinical trials. Even if we are able to enroll a sufficient number of participants for our clinical trials, it may have difficulty maintaining participants in our clinical trials. Our inability to enroll or maintain a sufficient number of participants would result in significant delays in completing clinical trials and increased development costs or may require us to abandon one or more clinical trials altogether.

Preliminary, "topline" or interim data from our clinical trials may change as more participant data becomes available and are subject to audit and verification procedures, and should be viewed with caution until the final data are available.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our clinical trials may reveal significant adverse events, undesirable side effects or patient intolerance not seen in our preclinical studies or earlier clinical trials, and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of our product candidates.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or patient intolerance, adverse events or unexpected characteristics, and any of these occurrences could harm our business, financial condition, results of operations and prospects significantly. If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting participants to such trials, participants may drop out of the trials, or we may have to suspend, materially modify or abandon the trials or our development efforts of one or more programs altogether. We, the FDA or other applicable regulatory authorities, or an IRB, may suspend or require the material modification of any clinical trials of any program at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Moreover, negative or inconclusive results could cause the FDA or other regulatory agencies to require that we repeat or conduct additional clinical trials. If our clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

Even if side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to their tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also affect our clinical trials or inhibit market acceptance. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel.

In addition, even if we successfully advance our product candidates through clinical trials, such trials will only include a limited number of participants and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of participants are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of the research programs with respect to which we have signed a licensed agreement for or exercised the Option to acquire intellectual property license rights to or have the Option to acquire intellectual property license rights to pursuant to the Option Agreements prove to be unsafe, our pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue a particular program and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success.

We are initially focused on our most advanced programs, ORKA-001 and ORKA-002, and as a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may be in a position where we may have to relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which we would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Any approved products resulting from our programs may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, it may not gain market acceptance among physicians, patients, healthcare payors or the medical community. Market acceptance of our product candidates will depend on many factors, including factors that are not within our control. While there are several approved products and product candidates in later stages of development for the treatment of PsO, our programs incorporate advanced antibody engineering to optimize the half-life and formulation of antibodies, and to date, no such antibody has been approved by the FDA for the treatment of PsO. Market participants with influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates half-life extension for our targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or our existing or future collaborators. Moreover, an extended half-life may make it more difficult for patients to change treatments and there may be a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance.

Sales of medical products also depend on the willingness of healthcare providers to prescribe the treatment, and if any of our product candidates is approved but does not achieve an adequate level of acceptance, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing product candidates for the same indication, PsO, and may in the future develop our programs for other I&I indications. Each such program targets a different mechanism of action. However, developing multiple programs for a single indication may negatively impact our business if the programs compete with each other. For example, if multiple programs are conducting clinical trials at the same time, they could compete for the enrollment of participants. In addition, if multiple product candidates are approved for the same indication, they may compete for market share, which could limit our future revenue.

We may conduct clinical trials for programs at sites outside the United States, and the FDA may not accept data from trials conducted in such locations. Moreover, conducting clinical trials outside of the U.S. presents additional risks that may delay our clinical trials.

We may choose to conduct one or more of our future clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could impose additional conditions, such as requiring us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Further, conducting clinical trials outside of the U.S. presents additional risks that may delay completion of our clinical trials. These risks include the failure of investigators or enrolled participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, potential restrictions, such as local privacy restrictions, on data generated from the clinical trial, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we may not be able to commercialize, or may be delayed in commercializing, our product candidates, and our ability to generate revenue may be materially impaired.

The lengthy regulatory approval process as well as the unpredictability of clinical trial results may result in our failing to obtain or be delayed in obtaining approval to market our product candidates, which would significantly harm our business, results of operations and prospects. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials. Approval may never be obtained and the approval process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the failure to demonstrate that a product candidate's benefits outweigh safety risks; regulatory authorities may disagree with our interpretation of clinical data or the data collected may not be acceptable or sufficient to support submission; or the results may not meet the level of statistical significance required for approval by the relevant regulatory authorities or otherwise considered insufficient by the FDA or comparable foreign regulatory authorities. Regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product.

Moreover, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be materially impaired.

We may not be able to meet requirements for the chemistry, manufacturing and control of our programs.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our CMO partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation, manufacturing the drug product, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. As noted above, we may deliver our product candidates via a drug delivery device, which also requires us to meet certain chemistry, manufacturing and control requirements set forth by the FDA and other foreign regulatory authorities. Meeting these chemistry, manufacturing and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing and control requirements, we may not be successful in getting our products approved.

Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA"), includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as biologics under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review and may result in restrictions on the use of the product, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates. In addition, even if our product candidates receive approval, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current CGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with CGMPs.

If we or a regulatory authority discover previously unknown problems with a product or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements.

Disruptions at the FDA, the SEC and other government agencies and regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies or comparable foreign regulatory authorities, may also slow the time necessary for the review and approval of applications for clinical trial or marketing authorization, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Additionally, action by the new Trump Administration to limit federal agency budgets or personnel may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may face difficulties from legislative or regulatory reform measures.

We may be faced with additional or changing regulatory and governmental regulations that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The price of pharmaceuticals has been a topic of considerable public discussion that could lead to price controls or other price-limiting strategies by payors that have the effect of lowering payment and reimbursement rates for drugs or otherwise making the commercialization of pharmaceuticals less profitable. Many federal and state legislatures have considered, and adopted, healthcare policies intended to curb rising healthcare costs, such as the IRA. These cost-containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. Political, economic and regulatory developments may further complicate developments in healthcare systems and pharmaceutical drug pricing. These developments could, for example, impact our potential licensing agreements as commercial and collaborative partners may also consider the impact of these pressures on their licensing strategies.

Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our product candidates. The implementation of any price controls, caps on prescription drugs or price transparency requirements could adversely affect our business, operating results and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, including conflicts of interest rules, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us or may be affiliated with our other service providers, including CROs or site management organizations, and from time to time may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site or in the applicable trial may be questioned or jeopardized.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve costs and management attention. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to it, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Even if we are able to commercialize any product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such product candidates at competitive prices, which would seriously harm our business.

We intend to seek approval to market our product candidates in the United States and in selected foreign jurisdictions, and we will be subject to rules and regulations in those jurisdictions where we obtain approval. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. In some jurisdictions, government authorities and other third-party payors decide which medications they will pay for and establish reimbursement levels, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off-label uses of those product candidates, we may become subject to significant liability, which would materially adversely affect our business and financial condition.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the U.S. Physician Payments Sunshine Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly member states of the EU ("EU Member States"), the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. If the UK or EU Member States were to significantly alter their regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs.

Risks Related to Our Intellectual Property

Our ability to obtain and protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely upon a combination of patents, trademarks, trade secret protection, confidentiality agreements and the Option and License Agreements to protect the intellectual property related to our programs and technologies and to prevent third parties from competing unfairly with it. Our success depends in large part on our ability to obtain and maintain patent protection for our programs and our product candidates and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. Paragon has filed, on our behalf, provisional patent applications and we have filed non-provisional patent applications directed to antibodies that target IL-23, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including ORKA-001. In addition, Paragon has filed, on our behalf, provisional patent applications and we intend to file one or more additional provisional patent applications directed to antibodies that target IL-17, including applications covering composition of matter, pharmaceutical formulations, and methods of using such antibodies, including ORKA-002. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on programs worldwide is expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States; the reverse may also occur. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications.

Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our programs or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or programs. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our programs could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office (“USPTO”). Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we may own and license may not afford us any meaningful competitive advantage.

In addition to seeking patents for some of our technology and programs, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the personnel of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on agreements, such as confidentiality agreements, with our vendors, collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or state actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Lastly, if our trademarks and trade names are not registered or adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We may not be successful in obtaining or maintaining necessary rights to our programs through acquisitions and in-licenses.

Because our development programs currently do and may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our programs. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we do obtain, we may have to abandon development of the relevant program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we plan to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our programs, there may be times when the filing and prosecution activities for patents and patent applications relating to our programs are controlled by our current and future licensors or collaboration partners. If any of our current and future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and our counsel that took place prior to the date upon which we assumed control over patent prosecution. Moreover, if other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology.

Failure to obtain licenses at a reasonable cost or terms may require us to expend significant time and resources to redesign our technology, programs, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and the priority of invention of patented technology.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Because the intellectual property landscape in the biopharmaceutical industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third-party rights. Third party patent rights, if found to be valid and enforceable, could be alleged to render one or more of our product candidates infringing. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected product candidate and/or seek a license from the patent holder. Any intellectual property claims brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any litigation could have a material adverse effect on our business and operations, including our ability to raise funds.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming, and any such claims could provoke these parties to assert counterclaims against us. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if our programs are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our programs. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we, our employees or our consultants have inadvertently or otherwise used or disclosed alleged intellectual property, such as trade secrets, or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our programs, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States and foreign jurisdictions could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. In addition, geopolitical instability could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents.

The patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in Amgen, Inc. v. Sanofi (Amgen) stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in Amgen or other recent precedential court decisions.

In addition, a European Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for EU Member States. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated.

Although we do not currently own any European patents or applications, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our programs, our competitive position would be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent terms may be inadequate to protect the competitive position of our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our technology licensed from various third parties may be subject to retained rights.

Our future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, our future licensors may rely on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors would not be the sole and exclusive owners of any patents we in-license. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Risks Related to Our Reliance on Third Parties

We currently rely on licensing arrangements with Paragon through the License Agreements. If we are unable to maintain collaborations or licensing arrangements, or if our collaborations or licensing arrangements are not successful, our business could be negatively impacted.

We currently rely on our licensing arrangements with Paragon through the License Agreements for a substantial portion of our in-licenses.

Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our current or future collaborators or licensors experience delays in performance of, or fails to perform our obligations under their agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, the research programs with respect to which we have the option to acquire intellectual property license rights to pursuant to the Option Agreements, the licensing agreements we have pursuant to the License Agreements and our development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our programs and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or provide development or commercialization capabilities that complement ours. We may not realize the benefits of such collaborations, alliances or licensing arrangements. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

We may face significant competition in attracting appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs, CMOs and strategic partners, to supply, conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our programs in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications or refuse to approve our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our product candidates. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates.

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently own any facility that may be used as our clinical or commercial manufacturing and processing facility and must currently rely on CMOs to manufacture our product candidates. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have a sole source relationship for our supply of the ORKA-001 and ORKA-002 programs. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, it could have a negative effect on the clinical development of our programs and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs, delays, and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, proposed or actual legislative changes or requirements, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates.

Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE bill, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. We currently rely on foreign CROs and CMOs, including WuXi Biologics (Hong Kong) Limited and its affiliates ("WuXi Biologics") and will likely continue to rely on foreign CROs and CMOs in the future. WuXi Biologics is identified in the U.S. legislation known as the BIOSECURE Act, which was proposed in the 118th Congress, as a "biotechnology company of concern." The version of the BIOSECURE Act introduced in the U.S. House of Representatives during the 118th Congress would prohibit federal agencies from entering into procurement contracts with, as well as providing grants and loans to, an entity that uses biotechnology equipment or services from a biotechnology company of concern, and includes a grandfathering provision allowing biotechnology equipment and services provided or produced by named "biotechnology companies of concern" under a contract or agreement entered into before the effective date until January 1, 2032. The pathway and timing for the BIOSECURE Act or its provisions to become law are uncertain. Depending on whether the BIOSECURE Act becomes law, what the final language of the BIOSECURE Act includes, and how the law is interpreted by U.S. federal agencies, we could be potentially restricted from pursuing U.S. federal government business or grants in the future if we continue to use WuXi or other parties identified as "biotechnology companies of concern" beyond the grandfathering period.

Furthermore, our operations and financial condition may be negatively impacted as a result of any delays or increased costs arising from the trade restrictions and other foreign regulatory requirements affecting such collaborators. In addition, while we have established relationships with CROs and CMOs outside of China, moving to those suppliers in the event of geopolitical instability affecting our collaborators in China could introduce delays into the development program.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to pursue our growth strategy will be limited if we are unable to continue to attract and retain high quality personnel. We have been and will continue to be highly dependent on the research and development, clinical and business development expertise of our executive officers, as well as the other principal members of our management, scientific and clinical team. Any of our management team members may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Attracting and retaining qualified personnel will also be critical to our success, including with respect to any strategic transaction that we may pursue. The loss of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, facilitate regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel, as well as from universities and research institutions.

In addition, we rely on consultants and advisors to assist us in formulating our discovery and nonclinical and clinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. If we fail to comply with the regulatory requirements in foreign markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We have adopted a code of conduct and ethics, but it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Our internal information technology systems, or those of any of our third-party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, sensitive information). If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Further, cybersecurity breaches or other cybersecurity incidents may allow hackers access to our preclinical compounds, strategies, discoveries, trade secrets, and/or other confidential information. Additionally, sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, vendors' or partners' use of generative AI technologies. Our ability to monitor third parties' information security practices is limited, and these third parties may not have adequate security measures in place. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Moreover, while we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient or we may be unable to recover such award. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. The risk of a cybersecurity incident or other informational technology disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including clinical trial data) or applications, or for it to be believed or reported that any of these occurred, we could incur liability, including under laws and regulations governing the protection of protected health information and other personal data, and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, contractors (including sites performing our clinical trials), third-party service providers and supply chain companies, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions or from cyber-attacks by malicious third parties, or ransomware attacks, which, in each case, may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Our hybrid-remote workforce may create additional risks for our information technology systems and data because our employees work remotely and utilize network connections, computers, and devices working at home, while in transit and in public locations.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We and third parties who we work with are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, data transfer, and data security, the scope of which is changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which may have retroactive application) could adversely affect our stockholders or us. We continue to assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations or employees to determine the potential effect on our business and any assumptions we make about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States enacted the IRA, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.

We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

General Risk Factors

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. The use of a product candidate in clinical trials and the sale of any approved products in the future may expose us to liability claims. An individual or group of individuals may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect our business. While we carry product liability insurance for our clinical trials, it is possible that any liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations with collaborators and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, may continue to be necessary, which could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by economic downturns, inflation, fluctuation in interest rates, natural disasters, public health crises, political crises, geopolitical events or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced and may experience in the future extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, new or increased tariffs and other barriers to trade, trade and other international disputes, increases in inflation rates, fluctuation in interest rates, slower growth or recession, tighter credit, volatility in financial markets, high unemployment, labor availability constraints, public health crises, significant natural disasters, including as a result of climate change, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), particularly in the pharmaceutical and biotech areas, political and military conflict, and uncertainty about economic stability. Fluctuation in interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and in the Middle East and rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including materials, operational, labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Geopolitical events and global economic conditions may also affect the ability of the FDA and other regulatory authorities to perform routine functions. If such concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Owning Our Stock

The market price of our common stock has been, and may continue to be volatile.

The market price of our common stock has been and is likely to be highly volatile and is subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing and results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections that we may provide to the public;
- announcements of significant or potential equity or debt sales by us;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- failure to meet or exceed the financial and development projections of the investment community or if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- general market, macroeconomic or geopolitical conditions or market conditions in the pharmaceutical and biotechnology sectors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel, including scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with our products; and

- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

Furthermore, market volatility may lead to securities litigation or increased stockholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

Our certificate of incorporation and bylaws, as well as provisions under Delaware law, could make an acquisition of the company more difficult and may prevent attempts by our stockholders to replace or remove management.

Provisions in our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the company that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits stockholders owning more than 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Our governing documents provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our governing documents provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation or the bylaws, (iv) any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or bylaws, or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which for purposes of this risk factor refers to herein as the "Delaware Forum Provision." Our governing documents further provide that, unless we consent in writing to an alternative forum, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which for purposes of this risk factor refers to herein as the "Federal Forum Provision." Neither the Delaware Forum Provision nor the Federal Forum Provision will apply to any causes of action arising under the Exchange Act. In addition, any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on our stockholders in pursuing any such claims, particularly if such stockholders do not reside in or near the State of Delaware. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. In addition, shares of our common stock that are subject to our outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders beneficially own a significant percentage of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent our acquisition on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We collect, use, store, and transmit confidential, sensitive, proprietary, personal, and health-related information in the ordinary course of our business. As such, we leverage third-party information technology service providers who have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our information technology systems, including critical computer networks, third party hosted services, communications systems, hardware and software, and our data residing on these systems. Our Senior Vice President, Finance is responsible for overseeing these third-party service providers and processes.

Cybersecurity risks are identified by monitoring and evaluating our threat environment, and then assessed by various methods, for example, by manual and automated tools designed to identify and combat cybersecurity threats, analyzing reports of threats, conducting scans and assessments of the threat environment and to identify vulnerabilities, the use of detection and response services and conducting reviews of third-party service providers, among other things. Depending on the threat environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our information systems and data, including, for example, physical security and access controls, asset management, systems monitoring, incident detection and response, risk assessment, the implementation of security standards and certifications, encryption of data, network security controls, and a recovery/business continuity plan, among other mitigation tactics. Our recovery/business continuity plan is designed to mitigate and remediate identified cybersecurity incidents and escalate certain incidents as appropriate to management and the Audit Committee. We plan to conduct due diligence on and audits of key technology vendors, contract research organizations, and other third-party contractors and suppliers. Additionally, we conduct periodic employee training that covers cyber and information security, among other topics.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management process. Our Senior Vice President, Finance, who reports directly to the Chief Executive Officer, together with our senior management, is responsible for assessing and managing cybersecurity risks with support from our third-party information technology service providers that employ information technology consultants with over 20 years of experience managing cybersecurity programs. Our cybersecurity program aligns to the National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF) and is consistently updated as NIST recommendations change year over year. Our Senior Vice President, Finance, together with our senior management and other employees works closely with our information technology service providers to evaluate material cybersecurity threats against our overall business objectives as part of our cybersecurity incident response. The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage and mitigate those risks. The Audit Committee has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Senior Vice President, Finance. The Board also receives updates from management and the Audit Committee on cybersecurity risks on a regular basis.

In the last fiscal year, we have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks or threats that, if realized, are reasonably likely to materially affect us. For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our "Risk Factors" under Part 1 Item 1A. Risk Factors, in this Annual Report on Form 10-K.

Item 2. Properties.

Our corporate headquarters are in Menlo Park, California and we have an additional office in Waltham, Massachusetts. Our lease for our Menlo Park headquarters expires on September 30, 2027 and our lease for our Waltham office expires in 2029. We believe our current facilities are sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could reasonably be expected to have a material adverse effect on our results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Global Market under the symbol "ORKA."

Holders of Record

As of February 28, 2025, there were approximately 20 stockholders of record of our common stock based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Performance Graph

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, and pursuant to Instruction 6 to Item 201(e) of Regulation S-K, we are not required to provide the stock performance graph.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2024 (this "Annual Report"). This discussion contains forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions, hopes, beliefs, strategies or projections regarding the future of its pipeline and business and words such as "may," "will,", "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "potential," "seek," "target," "goal," "intend" and variations of such words and any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, and similar expressions are intended to identify forward-looking statements. You should not place undue reliance on these forward-looking statements. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report entitled "Risk Factors" and elsewhere in this Annual Report. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Annual Report. As used in this Annual Report, unless the context suggests otherwise, "we," "us," "our," "the Company," "Oruka Therapeutics, Inc.," "Oruka," "ARCA biopharma, Inc.," "ARCA," refers to Oruka Therapeutics, Inc. and its consolidated subsidiaries, including Oruka Therapeutics Operating Company LLC, taken as a whole.

Overview

We are a clinical-stage biotechnology company focused on developing novel monoclonal antibody therapeutics for psoriasis ("PsO") and other inflammatory and immunology ("I&I") indications. Our name is derived from *or*, for "skin," and *arukah*, for "restoration," and reflects our mission to deliver therapies for chronic skin diseases that provide patients the most possible freedom from their condition. Our strategy is to apply antibody engineering and format innovations to validated modes of action, which we believe will enable us to improve meaningfully upon the efficacy and dosing regimens of standard-of-care medicines while significantly reducing technical and biological risk. Our programs aim to treat and potentially modify disease by targeting mechanisms with proven efficacy and safety involved in disease pathology and the activity of pathogenic tissue-resident memory T cells ("TRMs").

Our lead program, ORKA-001, is designed to target the p19 subunit of interleukin-23 ("IL-23p19") for the treatment of PsO. Our co-lead program, ORKA-002, is designed to target interleukin-17A and interleukin-17F ("IL-17A/F") for the treatment of PsO, psoriatic arthritis ("PsA"), and other conditions. These programs each bind their respective targets at high affinity and incorporate half-life extension technology with the aim to increase exposure and decrease dosing frequency. We believe that our focused strategy, differentiated portfolio, and deep expertise position us to set a new treatment standard in large I&I markets with continued unmet need.

Since our inception in February 2024, we have devoted substantially all of our resources to raising capital, organizing and staffing the company, business and scientific planning, conducting discovery and research activities, establishing arrangements with third parties for the manufacture of our programs and component materials, and providing general and administrative support for these operations. We do not have any programs approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from the issuance of convertible preferred stock, common stock, a convertible note, pre-funded warrants, and the proceeds from the reverse recapitalization and merger with ARCA biopharma, Inc., our Pre-Closing Financing and subsequent PIPE Financing (as defined and further described in "Recent developments" below).

Since our inception, we have incurred significant losses and negative cash flows from our operations. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of any programs we may develop. We generated net losses of $83.7 million for the period from February 6, 2024 (inception) to December 31, 2024. For the period from February 6 (inception) to December 31, 2024, we have used net cash of $57.8 million for our operating activities.

We had cash, cash equivalents, and marketable securities of $393.7 million as of December 31, 2024. We expect that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating plans for at least twelve months from the date of filing of this Annual Report. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure.

ORKA-001

ORKA-001 is a high affinity, extended half-life monoclonal antibody ("mAb") designed to target IL-23p19. IL-23 is a pro-inflammatory cytokine that plays a critical role in the proliferation and development of T helper 17 ("Th17") cells, which are the primary drivers of several autoimmune and inflammatory disorders, including PsO. IL-23 is composed of two subunits: a p40 subunit that is shared with IL-12 and a p19 subunit that is specific to IL-23. First-generation IL-23 antibodies bound p40 and inhibited both IL-12 and IL-23 signaling, while more recent IL-23 antibodies targeting the p19 subunit have shown improved efficacy and safety. Based on preclinical evidence, we believe that ORKA-001 could achieve higher response rates than established therapies in PsO while requiring less frequent dosing and maintaining the favorable safety profile of therapies targeting IL-23p19.

ORKA-001 is engineered with YTE half-life extension technology, a specific three amino acid change in the fragment crystallizable ("Fc") domain to modify the pH-dependent binding to the neonatal Fc receptor. As a result, it has a pharmacokinetic profile designed to support a subcutaneous ("SQ") injection as infrequently as once or twice a year. In addition, emerging evidence suggests that IL-23 blockade can modify the disease biology of PsO, possibly leading to durable remissions and preventing the development of PsA. We believe that the expected characteristics of ORKA-001 increase its potential to deliver these disease-modifying benefits.

We initiated the dosing of healthy volunteers in a Phase 1 trial of ORKA-001 in the fourth quarter of 2024. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the second half of 2025 and initial efficacy data in PsO patients in the second half of 2026. Based on recent precedent for PsO, we anticipate that the entire development program from first-in-human to biologics license application ("BLA") filing could take as little as six to seven years based on the averages for recently approved medicines. However, we have no control over the length of time needed for United States Food and Drug Administration ("FDA") review, and this timeline could vary.

ORKA-002

ORKA-002 is a high affinity, extended half-life mAb designed to target IL-17A and IL-17F ("IL-17A/F"). IL-17 inhibition has become central to the treatment of psoriatic diseases, including PsO and PsA, and has also shown efficacy in other I&I indications, such as hidradenitis suppurativa and axial spondyloarthritis. More recently, the importance of inhibiting the IL-17F isoform along with IL-17A has become appreciated, and dual blockade with the recently approved therapy Bimzelx (bimekizumab) has led to higher response rates in patients than blockade of IL-17A alone. ORKA-002 is designed to bind IL-17A/F at similar epitopes, or binding sites, and affinity ranges as bimekizumab, but incorporates half-life extension technology that could enable more convenient dosing intervals. We plan to initiate the dosing of healthy volunteers in a Phase 1 trial of ORKA-002 in the third quarter of 2025. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the first half of 2026.

We view ORKA-002 and ORKA-001 as highly complementary. Patients with moderate-to-severe PsO that have purely skin manifestations are most often treated with IL-23 inhibitors due to the high efficacy and tolerability of this mechanism. However, for patients who also have joint involvement, or signs and symptoms of PsA, an IL-17 inhibitor is typically used due to its efficacy in addressing both skin and joint symptoms. In addition, IL-17 inhibitors are often used in patients with highly resistant skin symptoms that do not adequately resolve through treatment with an IL-23 inhibitor. Furthermore, we have the potential opportunity to administer ORKA-002 and ORKA-001 sequentially, called ORKA-021, to combine two features of each program: the rapid response of an IL-17 inhibitor with the ideal maintenance profile of an IL-23 inhibitor. We believe that ORKA-001 and ORKA-002 provide the potential to offer a highly compelling product profile for most patients with PsO and/or PsA, as well as the opportunity to address additional I&I indications.

Additional Pipeline Program

We have a third mAb program, ORKA-003, designed to target an undisclosed pathway. Our strategy as a company is to remain highly focused on I&I diseases, and specifically on inflammatory dermatology conditions. Our third program provides the potential for indication expansion beyond PsO and may create combination opportunities with our more advanced programs.

Recent Developments

Acquisition of Pre-Merger Oruka

On August 29, 2024 (the "Merger Closing"), we completed our acquisition (the "Merger") of Oruka Therapeutics, Inc. ("Pre-Merger Oruka") pursuant to an Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024 (the "Merger Agreement"). Following the transactions contemplated by the Merger Agreement, Pre-Merger Oruka merged with and into Atlas Merger Sub Corp., a wholly owned subsidiary of ARCA biopharma, Inc. ("ARCA") and following that, Pre-Merger Oruka then merged with and into Atlas Merger Sub II, LLC ("Second Merger Sub"), with Second Merger Sub being the surviving entity. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC." Pre-Merger Oruka was a pre-clinical stage biotechnology company that was incorporated on February 6, 2024 under the direction of Peter Harwin, a Managing Member of Fairmount Funds Management LLC ("Fairmount"), for the purposes of holding rights to certain intellectual property being developed by Paragon Therapeutics, Inc. ("Paragon"). On August 29, 2024, we changed our name from "ARCA biopharma, Inc." ("ARCA") to "Oruka Therapeutics, Inc." and our Nasdaq ticker symbol from "ABIO" to "ORKA".

Pre-Closing Financing

Immediately prior to the execution and delivery of the Merger Agreement on April 3, 2024, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (the "Subscription Agreement"), pursuant to which, and on the terms and subject to the conditions of which, immediately prior to the Closing, those investors purchased shares of common stock of Pre-Merger Oruka ("Pre-Merger Oruka Common Stock") and Pre-Merger Oruka pre-funded warrants for gross proceeds of approximately $275.0 million (which includes $25.0 million of proceeds previously received from the issuance of the Convertible Note (refer to Note 7 in our consolidated financial statements included in Part II – Item 8 of this Annual Report for additional details) and accrued interest on such note which converted to shares of Pre-Merger Oruka Common Stock) (the "Pre-Closing Financing"). We incurred transaction costs of $20.5 million, which was recorded as a reduction to additional paid-in capital in the consolidated financial statements. At the Closing, the shares of Pre-Merger Oruka Common Stock and Pre-Merger Oruka pre-funded warrants issued pursuant to the Subscription Agreement were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock in accordance with the Exchange Ratio (defined below).

In accordance with an Exchange Ratio determined by terms of the Merger Agreement and upon the effective time of the First Merger (the "First Effective Time"), (i) each then-issued and outstanding share of Pre-Merger Oruka Common Stock including outstanding and unvested Pre-Merger Oruka restricted stock and shares of Pre-Merger Oruka Common Stock issued in connection with the Subscription Agreement, were converted into the right to receive a number of shares of Company Common Stock, equal to the exchange ratio of 6.8569 shares of Company Common Stock (the "Exchange Ratio"), which were subject to the same vesting provisions as those immediately prior to the Merger, (ii) each share of Pre-Merger Oruka Series A convertible preferred stock, par value $0.0001 ("Pre-Merger Oruka Series A Preferred Stock"), outstanding immediately prior to the First Effective Time was converted into the right to receive a number of shares of ARCA Series B non-voting convertible preferred stock, par value $0.001 per share, which are convertible into shares of Company Common Stock at a conversion ratio of approximately 83.3332:1 after the reverse stock split discussed below, (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, (iv) each outstanding warrant to purchase shares of Pre-Merger Oruka Common Stock was converted into a warrant to purchase shares of Company Common Stock, and (v) each share of Company Common Stock issued and outstanding at the First Effective Time remain issued and outstanding in accordance with its terms and such shares. Subsequent to the close of the merger, the common stock shares were then, subject to a reverse stock split of 1-for-12 effected on September 3, 2024 ("Reverse Stock Split").

As part of the Pre-Closing Financing and the Closing, the investors in the Pre-Closing Financing received 22,784,139 shares of Company Common Stock in exchange for 39,873,706 shares of Pre-Merger Oruka Common Stock (which includes the issuance of 2,722,207 shares of Company Common Stock in exchange for 4,764,032 shares of Pre-Merger Oruka Common Stock on the conversion of Convertible Note along with the accrued interest through the conversion date) and 5,522,207 Company pre-funded warrants in exchange for 9,664,208 Pre-Merger pre-funded warrants.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Oruka was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (i) Pre-Merger Oruka stockholders own a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retain the largest interest in the combined company; (iii) Pre-Merger Oruka designated a majority of the initial members of the board of directors of the combined company; and (iv) Pre-Merger Oruka's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA; (ii) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka; and (iii) Pre-Merger Oruka was not a variable interest entity as it had sufficient equity at risk in order to fund its next development milestones at the time of the reverse recapitalization. Additional information regarding the Merger is included in Note 3 to the consolidated financial statements included in Part II – Item 8 of this Annual Report.

Reverse Stock Split

On September 3, 2024, we effected the Reverse Stock Split, a 1-for-12 reverse stock split of Company Common Stock. The par value per share and the number of authorized shares were not adjusted as a result of the Reverse Stock Split. The shares of Company Common Stock underlying outstanding stock options, common stock warrants and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

PIPE Financing

On September 11, 2024, we entered into a Securities Purchase Agreement for a private placement (the "PIPE Financing") with certain institutional and accredited investors. The closing of the PIPE Financing occurred on September 13, 2024.

Pursuant to the Securities Purchase Agreement, the investors purchased an aggregate of 5,600,000 shares of Company Common Stock at a purchase price of $23.00 per share, an aggregate of 2,439 shares of the Company's Series A non-voting convertible preferred stock, par value $0.001 per share ("Company Series A Preferred Stock"), at a purchase price of $23,000.00 per share (each Company Series A Preferred Stock is convertible into 1,000 shares of Company Common Stock), and pre-funded warrants to purchase an aggregate of 680,000 shares of Company Common Stock at a purchase price of $22.999 per pre-funded warrant, for aggregate net proceeds of approximately $188.7 million (net of issuance costs of $11.9 million).

Components of Results of Operations

Revenue

To date, we have not generated revenue from any sources, including product sales, and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales or payments from future collaboration or license agreements that we may enter into with third parties, or any combination thereof. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the development and research of our programs. These expenses include:

- costs of funding research performed by third parties, including Paragon, that conduct research and development activities on our behalf;
- costs incurred, and milestone payments under license and option agreements;
- expenses incurred in connection with continuing our current research programs and discovery-phase development of any programs we may identify, including under future agreements with third parties, such as consultants and contractors;
- expenses incurred under agreements with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and with clinical trial sites that conduct research and development activities on our behalf;
- the cost of development and validating our manufacturing process for use in our preclinical studies and current and future clinical trials;
- personnel-related expenses, including salaries, bonuses, employee benefits, travel, and stock-based compensation expense, including stock-based compensation related to the Paruka warrant; and
- allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered. Our primary focus since inception has been the identification and development of our pipeline programs. Our research and development expenses primarily consist of external costs, such as fees paid to Paragon under the Option Agreements. See "—Contractual Obligations and Commitments" below for further details on the Option Agreements.

We expect our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to the continued development of our programs, developing any future programs, including investments in manufacturing, as we advance any program we may identify and continue to conduct clinical trials. The success of programs we may identify and develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies;
- effective investigational new drug ("IND") or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any programs we may develop;
- successful enrollment and completion of clinical trials;
- positive results from our future clinical trials that support a finding of safety and effectiveness, acceptable pharmacokinetics profile, and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities; and
- maintenance of a continued acceptable safety, tolerability, and efficacy profile of any programs we may develop following approval.

Any changes in the outcome of any of these variables with respect to the development of programs that we may identify could mean a significant change in the costs and possible delays in timing associated with the development of such programs. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a program, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our programs.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, employee benefits, travel, and stock-based compensation, for our executive and other administrative personnel. Other significant general and administrative expenses include legal services, including intellectual property and corporate matters; professional fees for accounting, auditing, tax, insurance, and allocated human resource costs, information technology costs, and facility-related costs, including rent, utilities, maintenance, and depreciation for our leased office space.

We expect our general and administrative expenses will increase substantially for the foreseeable future as we anticipate an increase in our personnel headcount to support the expansion of research and development activities, as well as to support our operations generally. We also expect to continue to incur significant expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income, Net

Other income, net consists of interest earned on our cash, cash equivalents, and marketable securities; interest expense on the convertible note from a related party (see discussion herein); and foreign currency transactions gains and losses. Interest expense relates to a convertible note (the "Convertible Note") issued to Fairmount Healthcare Fund II, L.P. ("Fairmount"), a related party, in March 2024. At the effective time of the Merger, the Convertible Note, along with the accrued interest, was automatically converted into Company Common Stock.

Income Taxes

No provision for income taxes was recorded for the period from February 6, 2024 (inception) through December 31, 2024. Deferred tax assets generated from our net operating losses have been fully offset by the valuation allowance as we believe it is not more likely than not that the benefit will be realized due to our cumulative losses generated to date.

Results of Operations for the Period from February 6, 2024 (inception) to December 31, 2024

The following table summarizes our results of operations for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Operating expenses	
Research and development[(1)]	$ 75,060
General and administrative[(2)]	13,063
Total operating expenses	88,123
Loss from operations	(88,123)
Other income (expense)	
Interest income	5,863
Interest expense[(3)]	(1,468)
Other income, net	4
Total other income, net	4,399
Net loss	$ (83,724)

(1) Includes related party amount of $42,640 for the period from February 6, 2024 (inception) to December 31, 2024
(2) Includes related party amount of $1,364 for the period from February 6, 2024 (inception) to December 31, 2024
(3) Includes related party amount of $1,468 for the period from February 6, 2024 (inception) to December 31, 2024

Research and Development Expenses

The following table summarizes our research and development expenses for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
External research and development expenses[(1)]	$ 57,680
Other research and development expenses:	
Personnel-related (excluding stock-based compensation)	3,959
Stock-based compensation[(2)]	11,992
Other	1,429
Total research and development expenses	$ 75,060

(1) Includes related party amount of $32,283 for the period from February 6, 2024 (inception) to December 31, 2024
(2) Includes related party amount of $10,357 for the period from February 6, 2024 (inception) to December 31, 2024

Research and development expenses were $75.1 million for the period from February 6, 2024 (inception) to December 31, 2024 and consisted primarily of the following:

- $57.7 million of research and development expense primarily includes: $18.3 million related to Paragon services rendered under the Option Agreements for ORKA-001, including $4.8 million for milestones achieved under the Option and License Agreements upon exercise of the option to enter into a license agreement and achievement of development candidate for IL-23 and dosing of the first subject in a Phase 1 clinical trial; $13.3 million of research and development expense primarily related to Paragon services rendered under the Option Agreements for ORKA-002, including $2.3 million for milestones achieved under the Option and License Agreements upon exercise of the option to enter into a license agreement and achievement of development candidate for IL-17; $0.7 million of other research and development expense due to Paragon; $16.5 million of research and development expense on chemistry, manufacturing, and development costs; $5.7 million in toxicology testing with a third-party contract research organization; and $3.2 million of other external research and development costs;

- $4.0 million of personnel-related costs related to salaries, benefits, and other compensation-related costs;

- $12.0 million of stock-based compensation expense, including $10.4 million of stock-based compensation related to the Paruka warrant; and

- $1.4 million of other expense and allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Personnel-related (including stock-based compensation)[1]	$ 7,981
Professional and consulting fees[2]	4,606
Other[3]	476
Total general and administrative expenses	$ 13,063

(1) Includes related party amount of $609 for the period from February 6, 2024 (inception) to December 31, 2024
(2) Includes related party amount of $575 for the period from February 6, 2024 (inception) to December 31, 2024
(3) Includes related party amount of $180 for the period from February 6, 2024 (inception) to December 31, 2024

General and administrative expenses were $13.1 million for the period from February 6, 2024 (inception) to December 31, 2024 and consisted primarily of the following:

- $8.0 million of personnel-related costs related to salaries, benefits, other compensation-related costs, recruiting costs, including stock-based compensation of $2.9 million, and $0.6 million of personnel-related costs are recruiting costs reimbursed to Paragon for hiring of our executive team, legal, and finance and accounting functions;

- $4.6 million of professional and consulting fees associated with accounting, audit, and legal fees associated with becoming a public company, including $0.6 million of legal fees due to Paragon associated with patent-related activities; and

- $0.5 million of other business expenses and net of allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation for our leased office space to research and development expenses, including $0.2 million of other business expenses due to Paragon.

Total Other Income, Net

Interest income from cash equivalents and marketable securities was $5.9 million for the period from February 6, 2024 (inception) to December 31, 2024.

Interest expense was $1.5 million for the period from February 6, 2024 (inception) to December 31, 2024 relating to the Convertible Note from Fairmount.

Liquidity and Capital Resources

As of December 31, 2024, we had $393.7 million of cash, cash equivalents, and marketable securities.

Since our inception, we have incurred significant operating losses and negative cash flow from operations. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the pre-clinical and clinical development of our programs and our early-stage research activities. We have not yet commercialized any products, and we do not expect to generate revenue from sales of products for several years, if at all. Through December 31, 2024, we had funded our operations primarily with proceeds from issuances of convertible preferred stock, common stock, a convertible note, and pre-funded warrants. In March 2024, we received $2.9 million in net proceeds from the issuance of Pre-Merger Oruka Series A Preferred Stock and $25.0 million in gross proceeds from the issuance of the Convertible Note, both of which were related party transactions. In August 2024, we raised approximately $228.0 million in net proceeds from Pre-Closing Financing and received $4.9 million in cash from ARCA upon consummation of the Merger. In September 2024, we received approximately $188.7 million in net proceeds from the issuance of common stock, Company Series A Preferred Stock, and pre-funded warrants in connection with the PIPE Financing.

Our primary use of cash is to fund the development of our product candidates and advance our pipeline. This includes both the research and development costs and the general and administrative expenses required to support those operations. Since we are a clinical stage biotechnology company, we have incurred significant operating losses since our inception and we anticipate such losses, in absolute dollar terms, to increase as we continue to pursue clinical development of our product candidates, prepare for the potential commercialization of our product candidates, and expand our development efforts in our pipeline of nonclinical candidates. We expect that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating plans for at least twelve months from the date of filing of this Annual Report. We will need to secure additional financing in the future to fund additional research and development, and before a commercial drug can be produced, marketed, and sold. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity could have a material adverse effect on our company.

Cash Flows

The following table summarizes our cash flows for the period presented (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Net cash used in operating activities	$ (57,837)
Net cash used in investing activities	(330,127)
Net cash provided by financing activities	449,539
Net increase in cash and cash equivalents	$ 61,575

Operating Activities

From February 6, 2024 (inception) to December 31, 2024, net cash used in operating activities was $57.8 million, which was primarily attributable to a net loss of $83.7 million, offset by net non-cash charges of $14.3 million and net changes in operating activities of $11.6 million. Non-cash charges primarily consisted of $14.9 million in stock-based compensation expense (including $10.4 million related to the Paruka warrant) and $1.5 million of non-cash interest expense, partially offset by net accretion of premiums and discounts on marketable securities of $2.2 million. Net changes in our operating activities primarily consisted of a $3.5 million increase in accounts payable, a $3.3 million increase in accrued expenses and other current liabilities, a $6.0 million increase in related parties accounts payable and other current liabilities, partially offset by a $1.1 million increase in prepaid expenses and other current assets. The increase in amounts due to related parties, accounts payable, and accrued expenses and other current liabilities was primarily due to an increase in our business activity, as well as vendor invoicing and payments. The increase in prepaid expenses and other current assets was primarily due to prepaid research and development expenses with our contract research organization.

Investing Activities

From February 6, 2024 (inception) to December 31, 2024, net cash used in investing activities was $330.1 million, which was primarily attributable to purchases of marketable securities.

Financing Activities

From February 6, 2024 (inception) to December 31, 2024, net cash provided by financing activities was $449.5 million, consisting of $228.0 million of net proceeds from the Pre-Closing Financing, $188.7 million of net proceeds from the PIPE Financing, $25.0 million of net proceeds from the issuance of notes payable to related parties, $4.9 million of cash acquired in connection with the reverse recapitalization and $2.9 million of net proceeds from issuance of the Pre-Merger Oruka Series A Preferred Stock.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs, CMOs and with other vendors for preclinical research studies, clinical trials, manufacturing, and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is cancelled within a specified time, and therefore, are cancelable contracts. We do not expect any such contract terminations and did not have any non-cancellable obligations under these agreements as of December 31, 2024.

Paragon Therapeutics - Option Agreements

In March 2024, we entered into two antibody discovery and option agreements ("Option Agreements") with Paragon and Paruka Holding, LLC ("Paruka"). Under the terms of each agreement, Paragon identifies, evaluates, and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. From time to time, we can choose to add additional targets to the collaboration upon agreement with Paragon and Paruka. Under the Option Agreements, we have the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title, and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture, and commercialize the antibodies and products directed to the selected target(s) (each, an "Option"). We have initiated certain research programs with Paragon that generally focus on discovering, generating, identifying and/or characterizing antibodies directed to a particular target (each, a "Research Program"), including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. Our exclusive option with respect to each Research Program is exercisable at our sole discretion at such time as specified in the Option Agreements (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the Option Agreements. For each of these agreements, once we enter into the corresponding license agreements, we will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones, up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale in each program.

We may terminate any Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that we must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate any Option Agreement or a Research Program immediately upon written notice to us if, as a result of any action or failure to act by us or our affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Option Agreements or any Research Program upon material breach that remains uncured or the other party's bankruptcy.

Additionally, as part of the Option Agreements, on December 31, 2024 and December 31, 2025, we granted and will grant, respectively, Paruka a warrant to purchase a number of shares equal to 1.00% of outstanding shares as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares on the grant date.

The warrant is liability-classified and after the initial recognition, the liability is adjusted to fair value at the end of each reporting period, with changes in fair value recorded in the consolidated statement of operations and comprehensive loss as stock-based compensation expenses under research and development expenses. On issuance of the December 31, 2024 warrant to Paruka, the change in fair value of the warrant immediately prior to issuance was recorded in the consolidated statement of operations and comprehensive loss and the resultant carrying value of the liability was reclassified to equity on the consolidated balance sheet as of December 31, 2024.

Pursuant to the Option Agreements, on a research program-by-research program basis following the finalization of the research plan for each respective research program, we were required to pay Paragon a one-time, nonrefundable research initiation fee of $0.8 million related to the ORKA-001 program. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. In June 2024, pursuant to the Option Agreements with Paragon, we completed the selection process of our development candidate for IL-23 antibody for ORKA-001 program. We were responsible for 50% of the development costs incurred through the completion of the IL-23 selection process. We received the rights to at least one selected IL-23 antibody in June 2024. During the period from February 6, 2024 (inception) to December 31, 2024, we exercised our option for ORKA-001 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in our consolidated statement of operations and comprehensive loss. In addition, during the period from February 6, 2024 (inception) to December 31, 2024, we recorded a $2.5 million milestone payment related to the first dosing of a human subject in a Phase 1 trial of ORKA-001 in December 2024 as research and development expense in our consolidated statement of operations and comprehensive loss. Our share of development costs incurred for the period from February 6, 2024 (inception) to December 31, 2024 was $13.5 million, which was recorded as research and development expenses. An amount of $2.8 million related to ORKA-001 is included in related party accounts payable and other current liabilities as of December 31, 2024.

We were also required to reimburse Paragon $3.3 million for development costs related to ORKA-002 incurred by Paragon through December 31, 2023 and certain other development costs incurred by Paragon between January 1, 2024 and March 6, 2024 as stipulated by the Option Agreements. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. We are also responsible for the development costs incurred by Paragon from January 1, 2024 through the completion of the IL-17 selection process. We recognized an amount of $0.8 million payable to Paragon for the research initiation fee related to ORKA-002 following the finalization of the ORKA-002 research plan. This was recognized as research and development expenses in the period from February 6, 2024 (inception) to December 31, 2024. During the period from February 6, 2024 (inception) to December 31, 2024, we exercised our option for ORKA-002 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in our consolidated statement of operations and comprehensive loss. We accounted for development costs of $7.8 million for the period from February 6, 2024 (inception) to December 31, 2024 as research and development expenses. An amount of $2.7 million related to ORKA-002 is included in related party accounts payable and other current liabilities as of December 31, 2024.

We expense the service fees as the associated costs are incurred when the underlying services are rendered. Such amounts are classified within research and development expenses in the accompanying consolidated statement of operations and comprehensive loss.

We concluded that the rights obtained under the Option Agreements represent an asset acquisition whereby the underlying assets comprise in-process research and development assets with no alternative future use. The Option Agreements did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license options, which represent a group of similar identifiable assets. The research initiation fee represents a one-time cost on a research program-by-research program basis for accessing research services or resources with benefits that are expected to be consumed in the near term, therefore the amounts paid are expensed as part of research and development costs immediately. Amounts paid as reimbursements of on-going development cost, monthly development cost fee and additional development expenses incurred by Paragon due to work completed for selected targets prior to the effective date of the Option Agreements that is associated with services being rendered under the related Research Programs are recognized as research and development expense when incurred.

For the period from February 6, 2024 (inception) to December 31, 2024, we recognized $42.0 million of expenses in connection with services provided by Paragon and Paruka under the Option Agreements.

Paragon Therapeutics – License Agreements

In September 2024, we exercised the Option to acquire certain rights to ORKA-001, and in December 2024, we entered into the corresponding license agreement with Paragon (the "ORKA-001 License Agreement"), pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 in all fields other than the field of inflammatory bowel disease ("ORKA-001 Field"). In December 2024, we exercised the Option with respect to ORKA-002 for the IL-17A/F program, and in February 2025, we entered into the corresponding license agreement with Paragon (the "ORKA-002 License Agreement" and together with the ORKA-001 License Agreement, the "License Agreements"), pursuant to which Paragon granted us a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-17A/F in all fields ("ORKA-002 Field" and together with the ORKA-001 Field, the "Fields").

The License Agreements provide us with exclusive licenses in the Fields to Paragon's patent applications covering the related antibodies, their method of use and their method of manufacture and Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies for the ORKA-001 Field or the ORKA-002 Field, respectively, for at least five years. Each of the ORKA-001 and ORKA-002 License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law.

Pursuant to the terms of each of the ORKA-001 and ORKA-002 License Agreements, we are obligated to pay Paragon non-refundable milestone payments of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones and up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, including a $1.5 million fee for nomination of a development candidate (or initiation of an IND-enabling toxicology study) and a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial for each of ORKA-001 and ORKA-002. In addition, we are obligated to pay Paragon a low single-digit percentage royalty for antibody products for each of ORKA-001 and ORKA-002. For each of the License Agreements, the royalty term ends on the later of (i) the last-to-expire licensed patent or our patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of a Company product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program.

Cell Line License Agreement

In March 2024, we entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the ORKA-001 and ORKA-002 programs.

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of $150,000, which was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. Additionally, to the extent that we manufacture our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Note Payable with Related Party

In March 2024, we entered into a Series A Preferred Stock and Convertible Note Purchase Agreement (the "Purchase Agreement") with Fairmount, whereby we issued the Convertible Note, with an initial principal amount of $25.0 million that, at the time of issuance, could be converted into Pre-Merger Oruka Series A Preferred Stock (or a series of preferred shares that is identical in respect to the shares of preferred shares issued in its next equity financing) or shares of Pre-Merger Oruka Common Stock in exchange for aggregate proceeds of $25.0 million. The Convertible Note accrued interest at a rate of 12.0% per annum. At issuance, the Convertible Note required all unpaid interest and principal to mature on December 31, 2025 (the "Maturity Date") and prepayment was not permitted without prior written consent of Fairmount. At issuance, the principal payment along with the accrued interest on the Convertible Note was due in full on the Maturity Date. Pursuant to the Purchase Agreement, we had the right to sell and issue additional convertible notes up to an aggregate principal amount equal to $30.0 million, in addition to the $25.0 million initial principal amount of the Convertible Note.

Immediately prior to the completion of the Merger, the Convertible Note was converted into shares of Pre-Merger Oruka Common Stock based on the aggregate principal amount of $25.0 million, plus unpaid accrued interest of $1.5 million divided by the conversion price, which was determined based upon the Company's fully-diluted capitalization immediately prior to the Merger. At the effective time of the Merger, the Pre-Merger Oruka Common Stock issued upon the conversion of the Convertible Note (including accrued interest) automatically converted into shares of Company Common Stock. 2,722,207 shares of Company Common Stock were issued on conversion of the Convertible Note and accrued interest. As of December 31, 2024, there is no note payable to a related party.

Lease Agreement

Our contractual obligations include minimum lease payments under our operating lease obligation for our headquarters in Menlo Park, California. See Note 13 to the consolidated financial statements elsewhere in this report for additional information.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of its financial condition and results of operations is based on its financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues recognized and expenses incurred during the reporting periods. Our estimates are based on its historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, overhead costs, contract services and other related costs. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed, and progress in the period in cases when we have not received an invoice from the supplier. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense. When billing terms under these contracts do not coincide with the timing of when the work is performed, we are required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including our knowledge of the progress towards completion of the specific tasks to be performed, invoicing to date under the contracts, communication from the vendors of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by us.

Stock-Based Compensation

We measure stock options granted to employees and non-employees based on the estimated fair values of the awards as of the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions, including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield. For restricted stock awards and restricted stock units, the estimated fair value is the fair market value of the underlying stock on the grant date. We expense the fair value of our equity-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received. We account for award forfeitures as they occur. The expense for stock-based awards with performance conditions is recognized when it is probable that a performance condition is met during the vesting period.

Determination of Fair Value of Common Stock

A public trading market for Company Common Stock has been established in connection with the completion of the Merger. As such, it is no longer necessary for our board of directors to estimate the fair value of our stock-based awards in connection with its accounting for granted stock-based awards or other such awards we may grant, as the fair value of Company Common Stock and share-based awards is determined based on the quoted market price of Company Common Stock.

Prior to the merger, Pre-Merger Oruka's common stock valuations were prepared using a hybrid method, including an option pricing method ("OPM"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The hybrid method is a probability-weighted expected return method ("PWERM"), where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the Company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if Pre-Merger Oruka had used significantly different assumptions or estimates, the fair value of Pre-Merger Oruka's incentive shares and its stock-based compensation expense could have been materially different.

Recently Issued Accounting Pronouncements

See Note 2 to the consolidated financial statements included in Part II - Item 8 of this Annual Report for more information regarding recently issued accounting pronouncements.

Off-Balance Sheet Arrangements

As of December 31, 2024, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

ORUKA THERAPEUTICS, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Oruka Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oruka Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2024 and February 6, 2024, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity and of cash flows for the period from February 6, 2024 (inception) to December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and February 6, 2024, and the results of its operations and its cash flows for the period from February 6, 2024 (inception) to December 31, 2024 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

External Research and Development Costs

As described in Note 2 to the consolidated financial statements, research and development costs are expensed as incurred. Research and development costs include salaries and bonuses, stock-based compensation, employee benefits, and external costs of vendors and consultants engaged to conduct research and development activities, as well as allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation. As disclosed by management, the Company's research and development expense for the period from February 6, 2024 (inception) to December 31, 2024 was $75.1 million, $57.7 million of which relates to external research and development costs.

The principal consideration for our determination that performing procedures relating to external research and development costs is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's external research and development costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing external research and development costs, on a sample basis, by obtaining and agreeing the contractual terms of the agreement, amounts incurred to date, and estimates of work performed to date to the (i) underlying agreements with vendors engaged to conduct research and development; (ii) purchase orders; (iii) invoices received; (iv) underlying payments made for expenses incurred on the contracts; and (v) external confirmations or communications obtained by management from vendors.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 6, 2025

We have served as the Company's auditor since 2024.

ORUKA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2024	February 6, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 61,575	$ —
Marketable securities, current	314,073	—
Subscription receivable	—	1
Prepaid expenses and other current assets	1,221	—
Total current assets	376,869	1
Marketable securities, long-term	18,069	—
Property and equipment, net	162	—
Operating lease right-of-use assets	876	—
Other non-current assets	43	—
Total assets	$ 396,019	$ 1
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,462	$ —
Accrued expenses and other current liabilities	3,346	—
Operating lease liability, current	213	—
Related party accounts payable and other current liabilities	6,022	—
Total current liabilities	13,043	—
Operating lease liability, non-current	755	—
Total liabilities	13,798	—
Commitments and contingencies (Note 13)		
Series A convertible preferred stock, $0.0001 par value; no shares and 20,000,000 shares authorized as of December 31, 2024 and February 6, 2024, respectively; none issued and outstanding as of December 31, 2024 and February 6, 2024	—	—
Series A non-voting convertible preferred stock, $0.001 par value; none authorized as of December 31, 2024 and February 6, 2024; none issued and outstanding as of December 31, 2024 and February 6, 2024	—	—
Stockholders' equity:		
Series B non-voting convertible preferred stock, $0.001 par value; 251,504 and no shares authorized as of December 31, 2024 and February 6, 2024, respectively; 137,138 and no shares issued and outstanding as of December 31, 2024 and February 6, 2024, respectively	2,931	—
Common stock, $0.001 and $0.001 par value as of December 31, 2024 and February 6, 2024, respectively; 545,000,000 and 65,000,000 shares authorized, 37,440,510 and 3,197,975 shares issued and outstanding as of December 31, 2024 and February 6, 2024, respectively	37	—
Additional paid-in capital	463,018	1
Accumulated other comprehensive loss	(41)	—
Accumulated deficit	(83,724)	—
Total stockholders' equity	382,221	1
Total liabilities, convertible preferred stock and stockholders' equity	$ 396,019	$ 1

The accompanying notes are an integral part of these consolidated financial statements.

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Period from February 6, 2024 (Inception) to December 31, 2024
Operating expenses	
Research and development [1]	$ 75,060
General and administrative [2]	13,063
Total operating expenses	88,123
Loss from operations	(88,123)
Other income (expense)	
Interest income	5,863
Interest expense [3]	(1,468)
Other income, net	4
Total other income, net	4,399
Net loss	(83,724)
Unrealized loss on marketable securities	(41)
Comprehensive loss	$ (83,765)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.87)
Net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	$ (3,873.25)
Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	$ (322.81)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	16,789,362
Weighted-average shares used in computing net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	495
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	51,946

(1) Includes related party amount of $42,640 for the period from February 6, 2024 (inception) to December 31, 2024
(2) Includes related party amount of $1,364 for the period from February 6, 2024 (inception) to December 31, 2024
(3) Includes related party amount of $1,468 for the period from February 6, 2024 (inception) to December 31, 2024

The accompanying notes are an integral part of these consolidated financial statements.

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Series A Convertible Preferred Stock		Series A Non-Voting Convertible Preferred Stock		Series B Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of February 6, 2024 (inception)	—	$ —	—	$ —	—	$ —	3,197,975	$ 3	$ (2)	$ —	$ —	$ 1
Issuance of common stock	—	—	—	—	—	—	2,207,553	2	(2)	—	—	—
Issuance of Series A convertible preferred stock, net of issuance costs of $69	20,000,000	2,931	—	—	—	—	—	—	—	—	—	—
Exchange of Series A convertible preferred stock for Series B non-voting convertible preferred stock upon the closing of the reverse capitalization	(20,000,000)	(2,931)	—	—	137,138	2,931	—	—	—	—	—	2,931
Conversion of convertible notes (including accrued interest) into common stock upon the closing of the reverse recapitalization	—	—	—	—	—	—	2,722,207	3	26,445	—	—	26,448
Issuance of common stock and pre-funded warrants in the Pre-Closing Financing	—	—	—	—	—	—	20,061,932	20	248,437	—	—	248,457
Issuance costs of Pre-Closing Financing and reverse recapitalization	—	—	—	—	—	—	—	—	(20,504)	—	—	(20,504)
Issuance of common stock to former stockholders of ARCA biopharma, Inc. in connection with the closing of reverse recapitalization	—	—	—	—	—	—	1,208,883	1	4,999	—	—	5,000
Issuance of common stock, Series A non-voting convertible preferred stock, and pre-funded warrants in connection with the PIPE Financing	—	—	2,439	56,097	—	—	5,600,000	6	144,433	—	—	144,439
Issuance costs of PIPE Financing	—	—	—	(3,263)	—	—	—	—	(8,592)	—	—	(8,592)
Conversion of Series A non-voting convertible preferred stock to common stock	—	—	(2,439)	(52,834)	—	—	2,439,000	2	52,832	—	—	52,834
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	2,960	—	53	—	—	53
Reclassification of the Paruka warrant from liability to equity	—	—	—	—	—	—	—	—	10,357	—	—	10,357
Stock-based compensation expense	—	—	—	—	—	—	—	—	4,562	—	—	4,562
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	(41)	—	(41)
Net loss	—	—	—	—	—	—	—	—	—	—	(83,724)	(83,724)
Balances as of December 31, 2024	—	$ —	—	$ —	137,138	$ 2,931	37,440,510	$ 37	$ 463,018	$ (41)	$ (83,724)	$ 382,221

The accompanying notes are an integral part of these consolidated financial statements.

ORUKA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands)

	Period from February 6, 2024 (Inception) to December 31, 2024
Cash flows from operating activities:	
Net loss	$ (83,724)
Adjustments to reconcile net loss to net cash used in operating activities:	
Stock-based compensation expense	14,919
Net accretion of premiums and discounts on marketable securities	(2,245)
Non-cash interest expense	1,468
Non-cash lease expense	127
Depreciation expense	27
Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	(1,128)
Other non-current assets	(43)
Accounts payable	3,462
Accrued expenses and other current liabilities	3,292
Operating lease liability	(14)
Related party accounts payable and other current liabilities	6,022
Net cash used in operating activities	(57,837)
Cash flows from investing activities:	
Purchases of property and equipment	(189)
Purchases of marketable securities	(329,938)
Net cash used in investing activities	(330,127)
Cash flows from financing activities:	
Proceeds from issuance of Pre-Merger Oruka Series A Preferred Stock, net of issuance costs paid	2,931
Proceeds from issuance of notes payable to related party, net of issuance costs paid	24,980
Proceeds from the Pre-Closing Financing, net	227,953
Proceeds from the PIPE Financing, net	188,681
Cash acquired in connection with the reverse recapitalization	4,940
Proceeds from issuance of common stock	54
Net cash provided by financing activities	449,539
Net increase in cash and cash equivalents	61,575
Cash at beginning of period	—
Cash and cash equivalents at end of period	$ 61,575
Supplemental disclosures of non-cash operating and financing activities:	
Operating lease liability arising from obtaining operating right-of-use asset	$ 982
Assets acquired in connection with the reverse capitalization	$ 114
Other liabilities assumed in connection with the reverse recapitalization	$ (54)
Non-cash accrued interest on convertible note converted to common stock	$ 1,468
Non-cash exchange of Pre-Merger Oruka Series A preferred stock for Series B convertible preferred stock	$ 2,931
Conversion of Series A non-voting convertible preferred stock to common stock	$ 52,834
Reclassification of the Paruka warrant from liability to equity	$ 10,357

The accompanying notes are an integral part of these consolidated financial statements

1. Nature of the Business and Basis of Presentation

Background and Basis of Presentation

Oruka Therapeutics, Inc., together with its subsidiaries (collectively, the "Company"), formerly known as ARCA biopharma, Inc. ("ARCA"), is a clinical-stage biotechnology company that is the result of the reverse recapitalization discussed below. Prior to the reverse recapitalization, the private company Oruka Therapeutics, Inc. ("Pre-Merger Oruka") was established and incorporated under the laws of the state of Delaware on February 6, 2024 (referred to in the Notes as the inception of the Company). The Company is headquartered in Menlo Park, California. The Company is focused on developing novel monoclonal antibody therapeutics for psoriasis ("PsO") and other inflammatory and immunology ("I&I") indications.

The accompanying consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in conformity with United States ("U.S.") generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Reverse Recapitalization and Pre-Closing Financing

On August 29, 2024 (the "Merger Closing"), the Company completed the acquisition (the "Merger") of Pre-Merger Oruka pursuant to an Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024 (the "Merger Agreement"). Following the transactions contemplated by the Merger Agreement, Pre-Merger Oruka merged with and into Atlas Merger Sub Corp., a wholly owned subsidiary of ARCA and following that, Pre-Merger Oruka then merged with and into Atlas Merger Sub II, LLC ("Second Merger Sub"), with Second Merger Sub being the surviving entity. Second Merger Sub changed its corporate name to "Oruka Therapeutics Operating Company, LLC." On August 29, 2024, the Company changed its name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." and its Nasdaq ticker symbol from "ABIO" to "ORKA".

Following consummation of the Merger, the Company effected a 1-for-12 reverse stock split (the "Reverse Stock Split") of the common stock, par value $0.001 per share, of the Company ("Company Common Stock"), which became effective on September 3, 2024. The Company Common Stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the opening of trading on September 3, 2024. The Company is led by the Pre-Merger Oruka management team and remains focused on developing biologics to optimize the treatment of inflammatory skin diseases.

Immediately prior to the execution and delivery of the Merger Agreement on April 3, 2024, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (the "Subscription Agreement"), pursuant to which, and on the terms and subject to the conditions of which, immediately prior to the Closing, those investors purchased shares of common stock of Pre-Merger Oruka ("Pre-Merger Oruka Common Stock") and Pre-Merger Oruka pre-funded warrants for gross proceeds of approximately $275.0 million (which includes $25.0 million of proceeds previously received from the issuance of the Convertible Note (as defined in Note 7) and accrued interest on such note which converted to shares of Pre-Merger Oruka Common Stock) (the "Pre-Closing Financing"). The Company incurred transaction costs of $20.5 million which was recorded as a reduction to additional paid-in capital in the consolidated financial statements. At the Merger Closing, the shares of Pre-Merger Oruka Common Stock and Pre-Merger Oruka pre-funded warrants issued pursuant to the Subscription Agreement were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock in accordance with the Exchange Ratio (defined below).

In accordance with an Exchange Ratio determined by terms of the Merger Agreement and upon the effective time of the First Merger (the "First Effective Time"), (i) each then-issued and outstanding share of Pre-Merger Oruka Common Stock including outstanding and unvested Pre-Merger Oruka restricted stock and shares of Pre-Merger Oruka Common Stock issued in connection with the Subscription Agreement, were converted into the right to receive a number of shares of Company Common Stock, equal to the Exchange Ratio of 6.8569 shares of Company Common Stock, which were subject to the same vesting provisions as those immediately prior to the Merger, (ii) each share of Pre-Merger Oruka Series A convertible preferred stock, par value $0.0001 ("Pre-Merger Oruka Series A Preferred Stock"), outstanding immediately prior to the First Effective Time was converted into the right to receive a number of shares of ARCA Series B non-voting convertible preferred stock, par value $0.001 per share ("Company Series B Preferred Stock"), which are convertible into shares of Company Common Stock, at a conversion ratio of approximately 83:3332:1 (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, (iv) each outstanding warrant to purchase shares of Pre-Merger Oruka Common Stock was converted into a warrant to purchase shares of Company Common Stock, and (v) each share of Company Common Stock issued and outstanding at the First Effective Time remain issued and outstanding in accordance with its terms and such shares. Subsequent to the close of the merger, the common stock shares were then subject to the reverse stock split of 1-for-12 effected on September 3, 2024.

As part of the Pre-Closing Financing and the Merger Closing, investors in the Pre-Closing Financing received 22,784,139 shares of Company Common Stock in exchange for 39,873,706 shares of Pre-Merger Oruka Common Stock (which includes the issuance of 2,722,207 shares of Company Common Stock in exchange for 4,764,032 shares of Pre-Merger Oruka Common Stock on the conversion of Convertible Note along with the accrued interest through the conversion date) and 5,522,207 Company pre-funded warrants in exchange for 9,664,208 Pre-Merger pre-funded warrants.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Oruka was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (i) Pre-Merger Oruka stockholders own a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retain the largest interest in the combined company; (iii) Pre-Merger Oruka designated a majority of the initial members of the board of directors of the combined company; and (iv) Pre-Merger Oruka's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA, and (ii) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka. Additional information regarding the Merger is included in Note 3.

Reverse Stock Split

On September 3, 2024, the Company effected the Reverse Stock Split, a 1-for-12 reverse stock split of Company Common Stock. The par value per share and the number of authorized shares were not adjusted as a result of the Reverse Stock Split. The shares of Company Common Stock underlying outstanding stock options, common stock warrants and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

PIPE Financing

On September 11, 2024, the Company entered into a Securities Purchase Agreement for a private placement (the "PIPE Financing") with certain institutional and accredited investors. The closing of the PIPE Financing occurred on September 13, 2024.

Pursuant to the Securities Purchase Agreement, the investors purchased an aggregate of 5,600,000 shares of Company Common Stock at a purchase price of $23.00 per share, an aggregate of 2,439 shares of the Company's Series A non-voting convertible preferred stock, par value $0.001 per share ("Company Series A Preferred Stock"), at a purchase price of $23,000.00 per share (each Company Series A Preferred Stock is convertible into 1,000 shares of Company Common Stock), and pre-funded warrants to purchase an aggregate of 680,000 shares of Company Common Stock at a purchase price of $22.999 per pre-funded warrant, for aggregate net proceeds of approximately $188.7 million (net of issuance costs of $11.9 million).

Liquidity and Going Concern

Since its inception, the Company has devoted substantially all of its resources to advancing the development of its portfolio of programs, organizing and staffing the Company, business planning, raising capital, and providing general and administrative support for these operations. Current and future programs will require significant research and development efforts, including preclinical and clinical trials, and regulatory approvals to commercialization. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operating activities through a combination of equity offerings and debt financings.

The Company has not generated any revenue from product sales or other sources and has incurred significant operating losses and negative cash flows from operations since inception. For the period from February 6, 2024 (inception) to December 31, 2024, the Company has incurred a net loss of $83.7 million and used net cash of $57.8 million for its operating activities.

As of December 31, 2024, the Company had cash, cash equivalents, and marketable securities of $393.7 million. The Company's management expects that the existing cash, cash equivalents, and marketable securities will be sufficient to fund the Company's operating plans for at least twelve months from the date these consolidated financial statements were issued. The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting future pre-clinical activities and clinical trials and manufacturing for its existing product candidates and any future product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts needed, the Company may be required to significantly curtail, delay, or discontinue one or more of its research or development programs or the commercialization of any product candidate, or be unable to expand its operations or otherwise capitalize on the Company's business opportunities, as desired, which could materially harm the Company's business, financial condition and results of operations.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected within these consolidated financial statements include but are not limited to research and development expenses and related prepaid or accrued costs and the valuation of stock-based compensation awards and related expenses. The Company bases its estimates on known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts, and experience. Actual results could differ materially from those estimates or assumptions.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company's investment policy limits investments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies, highly rated banks, and corporate issuers, subject to certain concentration limits and restrictions on maturities. The Company's cash, cash equivalents and marketable securities are held by financial institutions that management believes are of high credit quality. The financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash deposits. Accounts at the Company's U.S. banking institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 per depositor. As of December 31, 2024, the balance at the Company's U.S. banking institution exceeded the FDIC limits. The Company has not experienced any losses on its deposits of cash and cash equivalents and its accounts are monitored by management to mitigate risk. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents, and bond issuers.

The Company is dependent on third-party organizations to research, develop, manufacture, and process its product candidates for its development programs, including its two most advanced programs, ORKA-001 and ORKA-002. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs could be adversely affected by a significant interruption in the supply of the necessary materials. A significant amount of the Company's research and development activities are performed under its agreements with Paragon Therapeutics, Inc. ("Paragon") (see Note 12).

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of initial purchase to be cash equivalents. The cash equivalents were comprised of investments in money market funds, U. S. treasury securities, U.S. government agency securities, and debt securities and are stated at fair value.

Marketable Securities

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies, commercial paper and corporate debt securities. The Company's marketable securities are classified as available-for-sale and reported at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive loss.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value and recognized in other income (expense) in the results of operations. For available-for-sale debt securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, an allowance is recorded for the difference between the present value of cash flows expected to be collected and the amortized cost basis of the security. Impairment losses attributable to credit loss factors are charged against the allowance when management believes an available-for-sale security is uncollectible or when either of the criteria regarding intent or requirement to sell is met.

Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit loss factors are recognized as a component of accumulated other comprehensive loss, net of unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in other income, net, in the results of operations.

Marketable securities with stated maturities of greater than three months from the date of purchase but less than one year from the consolidated balance sheet date are classified as current, while marketable securities with maturities in one year or beyond one year from the consolidated balance sheet date are classified as long-term. The cost of securities sold is determined using the specific-identification method. Interest earned and adjustments for the amortization of premiums and discounts on investments are included in interest income on the consolidated statements of operations and comprehensive loss.

Debt Issuance Costs

Debt issuance costs incurred in connection with the Convertible Note (see Note 7) are recorded as a reduction of the carrying value of the notes payable liability on the Company's balance sheet and are amortized to interest expense over the term of the loan using the effective interest method. At the effective time of the Merger the Converted Note was converted to common stock and is no longer on the balance sheet as of December 31, 2024.

Subscription Receivable

The Company accounts for any notes received in exchange for common stock as a subscription receivable, provided the note underlying the receivable is paid prior to the date the financial statement is available to be issued.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets that are identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to their relatively short maturity period.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Furniture and fixtures	3-5 years
Computer and office equipment	3-5 years

Classification of Convertible Preferred Stock

Prior to the reverse recapitalization, the Company had classified its Pre-Merger Oruka Series A Preferred Stock outside of stockholders' equity on the Company's consolidated balance sheet because the holders of such stock have certain liquidation rights in the event of a deemed liquidation event that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock.

Upon the closing of the Merger, the Company converted its Pre-Merger Oruka Series A Preferred Stock to Company Series B Preferred Stock and has classified the Company Series B Preferred Stock within stockholders' equity on its consolidated balance sheet because the Company Series B Preferred Stock is not redeemable or puttable to the Company by the holder under any circumstances.

In connection with the PIPE Financing (see Note 1) the Company issued Company Series A Preferred Stock, and has classified the Company Series A Preferred Stock outside of stockholders' equity on the Company's consolidated balance sheet because the holders of such stock have certain rights (see Note 8) that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. In November 2024, the Company Series A Preferred Stock shares were converted to common stock, and as of December 31, 2024, there were no shares of Company Series A Preferred Stock outstanding.

Note Payable to Related Party

The Company accounted for the Convertible Note (as defined in Note 7) at amortized cost. The Company considered if optional conversion features are required to be bifurcated and separately accounted for as a derivative. Costs related to the issuance of the Convertible Note were recorded as a debt discount, amortized over the term of the Convertible Note (see Note 7) and were accounted for as interest expense in other income (expenses) within the consolidated statement of operations and comprehensive loss using the effective interest method. At the effective time of the Merger, shares of Pre-Merger Oruka Common Stock issued pursuant to the conversion of the Convertible Note (including accrued interest) automatically converted into shares of Company Common Stock (see Note 1).

Research and Development Contract Costs Accruals

The Company records the costs associated with research studies and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's ongoing research and development activities conducted by third-party service providers, including contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), and the Company's related-party Paragon (see Note 12).

The Company accrues for expenses resulting from obligations under its two antibody discovery and option agreements (the "Option Agreements") (see Note 12), by and among Paragon, Paruka Holding LLC ("Paruka"), an entity formed by Paragon as a vehicle to hold equity in the Company, and the Company as well as agreements with CROs, CMOs, and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with Paragon, CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. If advance payments are made to Paragon, a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be expensed as the contracted services are performed. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. As of December 31, 2024, the Company has not experienced any material deviations between accrued and actual research and development expenses.

Leases

At the lease commencement date, when control of the underlying asset is transferred from the lessor to the Company, the Company classifies a lease as either an operating or finance lease and recognizes a right-of-use ("ROU") asset and a current and non-current lease liability, as applicable, in the balance sheet if the lease has a term greater than one year. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise its option.

At the lease commencement date, operating lease liabilities and their corresponding ROU assets are recorded at the present value of future minimum lease payments over the expected remaining lease term. The Company determines the present value of lease payments using the implicit rate, if it is readily determinable, or the risk-free discount rate for a period comparable with that of the lease term. For operating leases, lease expense for lease payments is recognized on a straight-line basis over the lease term. For finance leases, lease expense includes amortization expense of the ROU asset recognized on a straight-line basis over the lease term and interest expense recognized on the finance lease liability. In addition, certain adjustments to the ROU asset may be required for items such as lease prepayments, incentives received or initial direct costs. As of December 31, 2024, the Company has one operating lease and no finance leases.

The Company accounts for lease and non-lease components related to operating leases as a single lease component. The Company has elected that costs associated with leases having an initial term of 12 months or less are recognized in the consolidated statement of operations and comprehensive loss on a straight-line basis over the lease term and are not recorded on its consolidated balance sheets. Variable lease expense is recognized as incurred and consists primarily of real estate taxes, utilities, and other office space related expenses.

Segment Reporting

The Company operates as a single reportable and operating segment. Its Chief Executive Officer, serving as the Chief Operating Decision Maker ("CODM"), oversees operations on an aggregated basis to allocate resources effectively. In assessing the Company's financial performance, the CODM regularly reviews total operating expenses and consolidated net loss.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and bonuses, stock-based compensation, employee benefits, and external costs of vendors and consultants engaged to conduct research and development activities, as well as allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities, and depreciation.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses on the accompanying consolidated balance sheet. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered. If nonrefundable advance payments represent a one-time cost for obtaining goods or services, with anticipated benefits to be utilized within a year of period end, the payment is expensed immediately.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and bonuses, stock-based compensation, employee benefits, finance and administration costs, patent and intellectual property costs, professional fees, as well as allocated human resource costs, information technology costs, and facility-related costs, including rent, maintenance, utilities and depreciation.

Commitments and Contingencies

The Company is subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the balance sheet. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of December 31, 2024, no liabilities were recorded for loss contingencies (see Note 13).

Stock-Based Compensation

The Company estimates the fair value of its stock awards using the Black-Scholes option pricing model, which uses as inputs the fair value of the Company's common stock, and certain management estimates, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information is available. The Company selects companies with comparable characteristics with historical share price information that approximates the expected term of the equity-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period that approximates the calculated expected term of the stock options. The Company will continue to apply this method until a sufficient amount of historical information regarding the volatility of its stock price becomes available. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. For employee and non-employee awards (except the Paruka warrant) the Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data. For the Paruka warrant, the contractual term is used for the expected term. The expected dividend yield is assumed to be zero as the Company has no current plans to pay any dividends on common stock.

The Company measures restricted common stock awards ("RSAs") using the difference, if any, between the purchase price per share of the award and the fair value of the Company's common stock at the date of grant.

The Company grants stock options, restricted stock awards, and warrants that are subject to service or performance-based vesting conditions. Compensation expense for awards to employees and directors with service-based vesting conditions is recognized using the straight-line method over the requisite service period, which is generally the vesting period of the respective award. Compensation expense for awards to non-employees with service-based vesting conditions is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. Forfeitures are accounted for as they occur. As of each reporting date, the Company estimates the probability that specified performance criteria will be met and does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company has issued stock options, warrants, and RSAs with service-based and performance-based vesting conditions.

The Company recognizes the compensation expense for the option to purchase common stock under the Employee Stock Purchase Plan ("ESPP"), based on the fair value of the common stock estimated using the closing price of the Company's common stock as reported on the date of offering, less the purchase discount percentage provided for in the plan.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified, as applicable.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and events other than those with stockholders. The Company's unrealized gains and losses on marketable securities represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the consolidated statement of comprehensive loss.

Net Loss per Share Attributable to Stockholders

Basic and diluted net loss attributable to stockholders per share is presented in conformity with the two-class method required for participating securities (Pre-Merger Oruka Series A Preferred Stock). Basic earnings per share is computed by dividing net income available to each class of shares by the weighted-average number of shares of common stock and participating securities outstanding during the period. Pre-funded warrants were included as the exercise price is negligible and these warrants are fully vested and exercisable. Company Series A Preferred Stock and Company Series B Preferred Stock share the same characteristics as Common Stock and have no substantive preference attributed to them and, accordingly, have been considered as classes of Common Stock in the computation of net loss per share regardless of their legal form.

Net loss is allocated to common stock based on its proportional ownership on an as-converted basis. Net loss is not allocated to participating securities as they do not have an obligation to fund losses. The weighted-average number of shares outstanding of common stock reflects changes in ownership over the periods presented. See Note 8 — Convertible Preferred Stock and Stockholders' Equity.

Diluted net loss per share is computed by dividing the net loss attributable to stockholders adjusted for income (expenses), net of tax, related to any diluted securities, by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of this calculation, stock options to purchase common stock, employee warrants to purchase common stock, and unvested RSAs are considered potential dilutive common shares.

The Company generated a net loss for the periods presented. Accordingly, basic and diluted net loss per share is the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Other income, net

Other income, net, consists of interest earned on the Company's cash, cash equivalents, and marketable securities; interest expense on the convertible note from a related party and foreign currency transactions gains and losses.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement basis and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. The potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company had accrued no amounts for interest or penalties related to uncertain tax positions as of December 31, 2024.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which enhances the segment disclosure requirements for public entities on an annual and interim basis. Under this standard, public entities will be required to disclose significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss. Additionally, current annual disclosures about a reportable segment's profit or loss and assets will be required on an interim basis. Entities will also be required to disclose information about the CODM's title and position at the Company along with an explanation of how the CODM uses the reported measures of segment profit or loss in their assessment of segment performance and deciding how to allocate resources. Finally, ASU 2023-07 requires all segment disclosures for public entities that have only a single reportable segment. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted ASU 2023-07 in 2024 and additional required disclosures have been included in Note 10.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding taxes paid both in the U.S. and foreign jurisdictions. This update is effective beginning with the Company's 2025 fiscal year annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. This ASU requires more detailed disclosures, on an annual and interim basis, about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. This ASU may be applied either prospectively or retrospectively. The Company is currently evaluating the impact of the adoption of this ASU on its consolidated financial statements.

3. Reverse Recapitalization and Pre-Closing Financing

As described within the Reverse Recapitalization and Pre-Closing Financing section in Note 1, on August 29, 2024, the reverse recapitalization between Pre-Merger Oruka and ARCA was consummated. The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. At the effective time of the Merger, substantially all of the assets of ARCA consisted of cash and cash equivalents and other nominal non-operating assets and liabilities. No goodwill or intangible assets were recognized.

As part of the recapitalization, the Company acquired the assets and liabilities listed below (in thousands):

	August 29, 2024
Cash and cash equivalents	$ 4,940
Other current assets	114
Accrued liabilities	(54)
Net assets acquired	$ 5,000

4. Fair Value Measurements

The following tables present the Company's fair value hierarchy for financial assets measured as of December 31, 2024 (in thousands):

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 6,350	$ —	$ —	$ 6,350
U.S. treasury securities	—	19,660	—	19,660
U.S. government agency securities	—	3,988	—	3,988
Commercial papers	—	22,177	—	22,177
Total cash equivalents	6,350	45,825	—	52,175
Marketable securities				
Marketable securities, current				
U.S. treasury securities	—	190,792	—	190,792
U.S. government agency securities	—	12,966	—	12,966
Commercial papers	—	34,811	—	34,811
Corporate debt securities	—	75,504	—	75,504
Total marketable securities, current	—	314,073	—	314,073
Marketable securities, long-term				
U.S. treasury securities	—	13,607	—	13,607
U.S. government agency securities	—	4,462	—	4,462
Total marketable securities, long-term	—	18,069	—	18,069
Total cash equivalents and marketable securities	$ 6,350	$ 377,967	$ —	$ 384,317

There were no transfers in or out of Level 3 during the period from February 6, 2024 (inception) to December 31, 2024.

5. Cash equivalents and marketable Securities

Cash equivalents and marketable securities, which are classified as available-for-sale, consisted of the following as of December 31, 2024 (in thousands):

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents				
Money market funds	$ 6,350	$ —	$ —	$ 6,350
U.S. treasury securities	19,656	4	—	19,660
U.S. government agency securities	3,988	—	—	3,988
Commercial papers	22,180	—	(3)	22,177
Total cash equivalents	52,174	4	(3)	52,175
Marketable securities				
Marketable securities, current				
U.S. treasury securities	190,748	55	(11)	190,792
U.S. government agency securities	12,967	1	(2)	12,966
Commercial papers	34,808	3	—	34,811
Corporate debt securities	75,537	7	(40)	75,504
Total marketable securities, current	314,060	66	(53)	314,073
Marketable securities, long-term				
U.S. treasury securities	13,639	—	(32)	13,607
U.S. government agency securities	4,485	—	(23)	4,462
Total marketable securities, long-term	18,124	—	(55)	18,069
Total cash equivalents and marketable securities	$ 384,358	$ 70	$ (111)	$ 384,317

The following table summarizes the available-for-sale securities in an unrealized loss position, aggregated by major security type and length of time in a continuous unrealized loss position, for which an allowance for credit losses was not recorded as of December 31, 2024, (in thousands):

	December 31, 2024					
	Less than 12 months		12 months or longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Cash equivalents						
Commercial papers	$ 18,199	$ (3)	$ —	$ —	$ 18,199	$ (3)
Marketable securities						
Marketable securities, current						
U.S. treasury securities	49,904	(11)	—	—	49,904	(11)
U.S. government agency securities	4,713	(2)	—	—	4,713	(2)
Corporate debt securities	39,468	(40)	—	—	39,468	(40)
Marketable securities, long-term					—	—
U.S. treasury securities	13,607	(32)	—	—	13,607	(32)
U.S. government agency securities	4,462	(23)	—	—	4,462	(23)
Total	$ 130,353	$ (111)	$ —	$ —	$ 130,353	$ (111)

The Company evaluated its securities for credit losses and considered the decline in market value to be primarily attributable to current economic and market conditions and not to a credit loss or other factors. Additionally, the Company does not intend to sell the securities in an unrealized loss position and it is not more likely than not that the Company will be required to sell the securities before recovery of the unamortized cost basis, which may be at maturity. There were no material realized gains or realized losses on marketable securities for the period presented. Given the Company's intent and ability to hold such securities until recovery, and the lack of significant change in credit risk of these investments, the Company does not consider these marketable securities to be impaired as of December 31, 2024. As of December 31, 2024, the Company did not record an allowance for credit losses.

The following table summarizes the contractual maturities of the Company's marketable securities at estimated fair value (in thousands):

	December 31, 2024
Due in one year or less	$ 314,073
Due in 1-2 years	18,069
Total	$ 332,142

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2024
Accrued employee compensation and benefits	$ 2,041
Accrued professional and consulting	221
Accrued research and development	1,084
Total	$ 3,346

7. Note Payable with Related Party

In March 2024, Pre-Merger Oruka entered into a Series A Preferred Stock and Convertible Note Purchase Agreement (the "Purchase Agreement") with Fairmount Healthcare Fund II, L.P. ("Fairmount"), whereby Pre-Merger Oruka issued a convertible note (the "Convertible Note"), with an initial principal amount of $25.0 million that, at the time of issuance, could be converted into Pre-Merger Oruka Series A Preferred Stock (or a series of preferred shares that is identical in respect to the shares of preferred shares issued in its next equity financing) or shares of Pre-Merger Oruka Common Stock in exchange for aggregate proceeds of $25.0 million. The Convertible Note accrued interest at a rate of 12.0% per annum. At issuance, the Convertible Note required all unpaid interest and principal to mature on December 31, 2025 (the "Maturity Date") and prepayment was not permitted without prior written consent of Fairmount.

The Company assessed all terms and features of the Convertible Note in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the embedded features. The Company determined that the share settled redemption feature was clearly and closely related to the debt host and did not require separate accounting. The Company determined that the conversion options of the Convertible Note were not clearly and closely associated with a debt host. However, these features did not meet the definition of a derivative under ASC 815, Derivatives and Hedging, and as a result, did not require separate accounting as a derivative liability.

The Company paid debt issuance costs of less than $0.1 million in relation to the Convertible Note. The debt issuance costs were reflected as a reduction of the carrying value of Convertible Note on the consolidated balance sheet and were being amortized as interest expense over the term of the Convertible Note using the effective interest method. For the period from February 6, 2024 (inception) to December 31, 2024, the Company recognized interest expenses related to the Convertible Note of $1.5 million, which includes non-cash interest expense related to the amortization of debt issuance.

Immediately prior to the completion of the Merger (see Note 1), the Convertible Note was converted into shares of Pre-Merger Oruka Common Stock based on the aggregate principal amount of $25.0 million, plus unpaid accrued interest of $1.5 million divided by the conversion price which was determined based upon the Company's fully-diluted capitalization immediately prior to the Merger. At the effective time of the Merger, the Pre-Merger Oruka Common Stock issued upon the conversion of the Convertible Note (including accrued interest) automatically converted into 2,722,207 shares of Company Common Stock. As of December 31, 2024, the Convertible Note is not outstanding.

8. Convertible Preferred Stock and Stockholders' Equity

Pre-Funded Warrants

In August 2024, pursuant to the Subscription Agreement and immediately prior to the Closing, certain new and current investors purchased pre-funded warrants, which, at the effective time of the Merger, were exercisable for 5,522,207 shares of Company Common Stock at a purchase price of approximately $9.70 per warrant. After the Merger, there are 5,522,207 pre-funded warrants outstanding and are exercisable for 5,522,207 shares of the Company Common Stock at an exercise price of $0.01 per share.

In September 2024, in connection with the PIPE Financing, the Company issued and sold 680,000 pre-funded warrants, at a purchase price of $22.999 per warrant, exercisable for 680,000 shares of Company Common Stock at an exercise price of $0.001 per share.

The pre-funded warrants were recorded as a component of stockholders' equity within additional paid-in-capital and have no expiration date. As of December 31, 2024, none of the pre-funded warrants have been exercised and 6,202,207 pre-funded warrants remain outstanding.

Employee Warrants

In July 2024, Pre-Merger Oruka entered into a Subscription Agreement that provided for, among other things, the issuance of warrants to certain of Pre-Merger Oruka's employees and directors immediately prior to the closing of the Merger. During the period from February 6, 2024 (inception) to December 31, 2024, 3,054,358 employee warrants were issued at an exercise price of $7.80 per warrant. These warrants vest over a period of four years. Per the terms of the Employee Warrant Agreement, the holders of the Company's warrants shall not have any of the rights or privileges of a stockholder of the Company in respect of any shares purchasable upon the exercise of the warrant or any portion thereof unless and until a certificate or certificates representing such shares have been issued or a book entry representing such shares has been made and such shares have been deposited with the appropriate registered book-entry custodian. The Company recognizes compensation cost related to warrants on a straight-line basis over the requisite service period, which is the period in which the related services are received. As of December 31, 2024, none of the warrants have been exercised and 3,054,358 warrants remain outstanding.

Convertible Preferred Stock

In March 2024, Pre-Merger Oruka issued and sold an aggregate of 20,000,000 shares of Pre-Merger Oruka Series A Preferred Stock to Fairmount (see Note 15), at a purchase price of approximately $0.15 per share, for aggregate gross proceeds of $3.0 million. Pre-Merger Oruka incurred less than $0.1 million of issuance costs in connection with this transaction. Upon the issuance of the Pre-Merger Oruka Series A Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities as described below and determined that such features did not require the Company to separately account for these features.

In August 2024, upon the closing of the Merger, the Company converted the Pre-Merger Oruka Series A Preferred Stock to 137,138 shares of Company Series B Preferred Stock.

In September 2024, in connection with the PIPE Financing, the Company issued and sold an aggregate of 2,439 shares of the Company Series A Preferred Stock at a purchase price of $23,000.00 per share. In November 2024, the 2,439 shares of the Company Series A Preferred Stock were converted to 2,439,000 shares of Company Common Stock. As of December 31, 2024, there are no outstanding shares of Company Series A Preferred Stock.

As of December 31, 2024, convertible preferred stock consisted of the following (in thousands, except share data):

	December 31, 2024			
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Common Stock Issuable Upon Conversion
Series B convertible preferred stock	251,504	137,138	2,931	11,428,149

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock (the "Series A Certificate of Designation") filed in connection with the PIPE Financing, holders of Company Series A Preferred Stock were entitled to receive dividends on shares of Company Series A Preferred Stock equal to, on an as-if-converted-to-Company Common Stock basis, and in the same form as, dividends actually paid on shares of Company Common Stock. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Company Series A Preferred Stock did not have voting rights. The Company Series A Preferred Stock shall rank on parity with the Company Common Stock and Company Series B Preferred Stock upon any liquidation, dissolution or winding-up of the Company. Subject to the terms and limitations contained in the Series A Certificate of Designation, the Company Series A Preferred Stock issued in the PIPE Financing will not become convertible until the Company's stockholders approve the conversion of the Company Series A Preferred Stock into shares of Company Common Stock in accordance with the listing rules of the Nasdaq Stock Market (the "Stockholder Approval"), which, on issuance, resulted in the Company Series A Preferred Stock being classified outside of stockholders' equity on the Company's consolidated balance sheet. Following the Stockholder Approval in November 2024, each share of Company Series A Preferred Stock was automatically converted into 1,000 shares of Company Common Stock.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock (the "Series B Certificate of Designation") filed in connection with the Merger, holders of Company Series B Preferred Stock are entitled to receive dividends on shares of Company Series B Preferred Stock equal to, on an as-if-converted-to-Company Common Stock basis, and in the same form as, dividends actually paid on shares of Company Common Stock. Except as provided in the Series B Certificate of Designation or as otherwise required by law, the Company Series B Preferred Stock does not have voting rights. The Company Series B Preferred Stock shall rank on parity with the Company Common Stock as to the distribution of assets upon any liquidation, dissolution, or winding-up of the Company. Each share of Company Series B Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. As of December 31, 2024, each outstanding share of Company Series B Preferred Stock was convertible into common stock at a ratio of approximately 83.3332:1.

Paruka Warrant

On December 31, 2024, the Company settled its 2024 obligations under the Paruka Warrant Obligation (defined below) by issuing Paruka a warrant to purchase 596,930 shares of Company Common Stock at an exercise price of $19.39 per share. The warrant has a term of 10 years, is fully vested, and is exercisable in part or full at any time during the term of the warrant. As of December 31, 2024, the warrant issued under the Paruka Warrant Obligation is outstanding and unexercised. See Note 9 for additional information on the Paruka Warrant Obligation.

Common Stock

As of December 31, 2024, the Certificate of Incorporation provides for 545,000,000 authorized shares of Company Common Stock. As of December 31, 2024, 37,440,510 shares of Company Common Stock were issued and outstanding, including 2,207,553 shares of RSAs issued and outstanding.

As of December 31, 2024, the Company had common stock reserved for future issuance as follows:

	December 31, 2024
Shares issuable on conversion of Company Series B Preferred Stock	11,428,149
Shares issuable upon exercise of pre-funded warrants	6,202,207
Shares issuable upon exercise of warrant under the Paruka Warrant Obligation	596,930
Outstanding and issued stock options	1,567,760
Outstanding and issued employee warrants	3,054,358
Shares available for grant under 2024 Stock Incentive Plan	4,246,324
Shares available for grant under 2024 Employee Stock Purchase Plan	460,529
Total shares of common stock reserved	27,556,257

9. Stock-Based Compensation

2024 Equity Incentive Plan

The 2024 Equity Incentive Plan ("2024 Plan") was adopted by the board of directors of Pre-Merger Oruka on February 6, 2024. The 2024 Plan provided for Pre-Merger Oruka to grant stock options, restricted stock awards, restricted stock units, and other stock-based awards to employees, officers, directors, consultants, and advisors. Equity Incentive Stock options granted under the 2024 Plan generally vest over four years, subject to the participant's continued service, and expire after ten years, although two non-employee stock options were granted with vesting terms less than four years. As of December 31, 2024, there are no shares of common stock available for issuance.

2024 Stock Incentive Plan

On August 22, 2024, the 2024 Stock Incentive Plan ("2024 Stock Plan") was approved by the Company's stockholders and on August 29, 2024, the board of directors of the Company (the "Board") ratified the 2024 Stock Plan. The 2024 Stock Plan allows for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stockholder-based awards and incentive bonuses. The 2024 Stock Plan is administered by the Compensation Committee of the Board (the "Compensation Committee") or another committee designated by the Board to administer the Plan. The initial share pool under the 2024 Stock Plan is 4,634,891 shares of Company Common Stock. During the period from February 6, 2024 (inception) to December 31, 2024, 388,567 shares were subject to outstanding stock options, and as of December 31, 2024, there were 4,246,324 shares available in the pool. The shares that may be issued under the 2024 Stock Plan will be automatically increased on January 1 of each year beginning in 2025 and ending with a final increase on January 1, 2034 in an amount equal to 5% of the diluted stock (including Company Common Stock, preferred stock and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no, increase is determined by the Compensation Committee. Current or prospective employees, officers, non-employee directors, and other independent service providers of the Company and its subsidiaries are eligible to participate in the 2024 Stock Plan.

2024 Employee Stock Purchase Plan

The 2024 Employee Stock Purchase Plan (the "ESPP") became effective on August 29, 2024, at which time 463,489 shares of Company Common Stock were reserved for issuance. Eligible employees may purchase shares of Company Common Stock under the ESPP at 85% of the lower of the fair market value of the Company Common Stock as of the first or the last day of each offering period. Employees are limited to contributing 15% of the employee's eligible compensation and may not purchase more than $25,000 of stock during any calendar year. The ESPP will terminate ten years from the first purchase date under the plan, unless terminated earlier by the board of directors.

The shares that may be issued under the ESPP will be automatically increased on January 1 of each year beginning in 2025 and ending with a final increase on January 1, 2034 in an amount equal to 1% of the diluted stock (including Company Common Stock, preferred stock and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no increase is determined by the Compensation Committee. During the period from February 6, 2024 (inception) to December 31, 2024, 2,960 shares of Company Common Stock were issued out of the ESPP and as of December 31, 2024, there were 460,529 shares of Company Common Stock available in the pool.

For the period February 6, 2024 (inception) to December 31, 2024, stock-based compensation expense related to the ESPP was less than $0.1 million.

Stock Option Valuation

The following table summarizes the weighted-average assumptions used in calculating the fair value of the awards for the period from February 6, 2024 (inception) to December 31, 2024:

	Period from February 6, 2024 (Inception) to December 31, 2024
Expected term (in years)	6.1
Expected volatility	100.21%
Risk-free interest rate	4.26%
Expected dividend yield	—

Stock Options

The following table summarizes the stock option activities under the 2024 Plan and 2024 Stock Plan for the period of February 6, 2024 (inception) through December 31, 2024:

	Number of Stock Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Balance as of February 6, 2024 (inception)	—	$ —	—	$ —
Granted	1,567,760	$ 11.39		
Exercised	—	$ —		
Forfeited	—	$ —		
Balance as of December 31, 2024	1,567,760	$ 11.39	9.4	$ 15,470
Vested and expected to vest, December 31, 2024	1,567,760	$ 11.39	9.4	$ 15,470
Exercisable, December 31, 2024	—	$ —	—	$ —

The weighted average grant-date fair value per share of stock options granted during the period from February 6, 2024 (inception) to December 31, 2024 was $9.12 per share. Aggregate intrinsic value represents the difference between the estimated fair value of the underlying Company Common Stock and the exercise price of outstanding, in-the-money employee stock options.

Restricted Stock Awards

In February 2024 and March 2024, the Company issued 2,207,553 shares of RSAs to certain employees, directors, and consultants at a price of $0.0001 per share, the then par value of Pre-Merger Oruka Common Stock. Such RSAs have service-based vesting conditions only and vest over a four-year period, during which time all unvested shares are subject to forfeiture in the event the holder's service with the Company voluntarily or involuntarily terminates. As of December 31, 2024, none of the RSAs had vested. For the period February 6, 2024 (inception) to December 31, 2024, stock-based compensation expense related to RSAs was less than $0.1 million.

The following table summarizes the RSA activity for the period from February 6, 2024 (inception) through December 31, 2024:

	Number of RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of February 6, 2024 (inception)	—	$ —
Granted	2,207,553	$ —
Unvested balance as of December 31, 2024	2,207,553	$ —

Option Agreements and the Paruka Warrant Obligation

As part of the Option Agreements, on December 31, 2024 the Company granted and on December 31, 2025, will grant Paruka a warrant to purchase a number of shares equal to 1.00% of outstanding shares as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares on the grant date (the "Paruka Warrant Obligation").

The grant dates for the issuance of warrants were expected to be December 31, 2024 and December 31, 2025 as all terms of the award, including number of shares and exercise price, will be known by all parties. The Company determined that the 2024 and 2025 grants are two separate grants, as there would be no obligation for the 2025 grant had the Company exercised or terminated all of the options under the Option Agreements prior to December 31, 2024. The service inception period for the grant precedes the grant date, with the full award being vested as of the grant date with no post-grant date service requirement. Accordingly, the warrant expected to be granted to Paruka was accounted for as a liability on the balance sheet on the service inception date and, after the initial recognition, the liability is adjusted to fair value at the end of each reporting period, with changes in fair value recorded in the consolidated statement of operations and comprehensive loss as stock-based compensation expenses under research and development expenses. Accordingly, the Company measured the grant date fair value of the warrant granted on December 31, 2024 at $10.4 million. For the period from February 6, 2024 (inception) to December 31, 2024, $10.4 million was recognized as stock-based compensation expense related to the Paruka Warrant Obligation in the consolidated statement of operations and comprehensive loss. As of December 31, 2024, there was no unamortized expense related to the December 31, 2024 Paruka Warrant Obligation. On issuance of the warrant to Paruka, the fair value of the warrant was reclassified from liability to equity on the consolidated balance sheet as of December 31, 2024.

Employee Warrants

As stated above, on July 3, 2024, the Subscription Agreement was amended and restated, among other things, for employee warrants to be issued to certain Pre-Merger Oruka employees and directors immediately prior to the closing of the Merger. Pursuant to this amendment, during the period from February 6, 2024 (inception) to December 31, 2024, the Company issued 3,054,358 warrants at an exercise price of $7.80 per warrant, which are accounted as equity in the consolidated financial statements. The employee warrants were subject to performance and service based vesting requirements and upon completion of the Merger the performance-based requirements had been achieved.

The following table summarizes the warrant activity for the period from February 6, 2024 (inception) through December 31, 2024:

	Number of Employee Warrants Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in Thousands)
Balance as of February 6, 2024 (inception)	—	$ —	—	$ —
Granted	3,054,358	$ 7.80		
Exercised	—	$ —		
Forfeited	—	$ —		
Balance as of December 31, 2024	3,054,358	$ 7.80	9.5	$ 35,400
Vested and expected to vest, December 31, 2024	3,054,358	$ 7.80	9.5	$ 35,400
Exercisable, December 31, 2024	—	$ —	—	$ —

The weighted average grant-date fair value per share of warrants granted during the period from February 6, 2024 (inception) to December 31, 2024 was $6.27 per share. Aggregate intrinsic value represents the difference between the estimated fair value of the underlying Company Common Stock and the exercise price of outstanding, in-the-money warrants.

The following table summarizes the weighted-average assumptions used in calculating the fair value of the warrants for the period from February 6, 2024 (inception) to December 31, 2024:

	Period from February 6, 2024 (Inception) to December 31, 2024
Expected term (in years)	6.1
Expected volatility	99.02%
Risk-free interest rate	4.15%
Expected dividend yield	—

Stock-Based Compensation Expense

The following table summarizes the classification of the Company's stock-based compensation expense in the consolidated statement of operations and comprehensive loss (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Research and development	$ 11,992
General and administrative	2,927
Total	$ 14,919

As of December 31, 2024, total unrecognized compensation cost related to the unvested stock options was $12.7 million, which is expected to be recognized over a weighted average period of approximately 3.2 years. As of December 31, 2024, total unrecognized compensation cost related to the unvested RSAs was less than $0.1 million, which is expected to be recognized over a weighted average period of 3.1 years. As of December 31, 2024, the unrecognized compensation cost related to the employee warrants was $16.3 million, which is expected to be recognized over a weighted average period of 3.3 years.

The following table summarizes the award types of the Company's stock-based compensation expense in the consolidated statement of operations and comprehensive loss (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Paruka Warrant Obligation	$ 10,357
Employee warrants	2,899
Stock options	1,626
Employee stock purchase plan	37
Total	$ 14,919

10. Segment disclosures

The Company operates and manages its business activities on a consolidated basis and operates in one reportable segment.

The Company operates as a single reportable and operating segment. Its Chief Executive Officer, serving as the Chief Operating Decision Maker ("CODM"), oversees operations on an aggregated basis to allocate resources effectively. In assessing the Company's financial performance, the CODM regularly reviews total operating expenses and consolidated net loss.

The measure of segment assets is reported on the balance sheet as total consolidated assets. The Company's long-lived assets consist primarily of property and equipment, net. As of December 31, 2024 all of long-lived assets were in the U.S.

The table below is a summary of the segment loss from operations, including significant segment expenses (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Research and development personnel-related (excluding stock-based compensation)	$ 3,959
General and administrative personnel-related (excluding stock-based compensation)	5,054
Research and development stock-based compensation	11,992
General and administrative stock-based compensation	2,927
External research and development	57,680
Other research and development	1,429
General and administrative, excluding personnel-related and stock-based compensation	5,082
Total operating expenses	88,123
Loss from operations	$ (88,123)

11. Income Taxes

No provision for income taxes was recorded for the period from February 6, 2024 (inception) to December 31, 2024.

The following table summarizes the loss before income tax expense by jurisdiction for the periods indicated:

	Period from February 6, 2024 (Inception) to December 31, 2024
Domestic	$ (83,724)
Foreign	—
Loss before income tax expense	$ (83,724)

For the period from February 6, 2024 (inception) to December 31, 2024, the Company recognized no provision or benefit from income taxes. The difference between the Company's provision for income taxes and the amounts computed by applying the statutory federal income tax rate to income before income taxes is as follows:

	Period from February 6, 2024 (Inception) to December 31, 2024
Tax benefit derived by applying the federal statutory rate to income before income taxes	(21.00)%
Permanent differences	(0.18)
Research and development credits	(3.41)
Other	(0.87)
Change in the valuation allowance	25.46
Income tax (benefit) expense	0.00%

The components of the deferred tax assets and liabilities consist of the following (in thousands):

	December 31, 2024
Deferred tax assets	
Net operating loss carryforwards	$ 2,260
Research and development credits	3,080
Stock-based compensation	3,063
Accruals and other	424
Lease liability	203
Intangibles	1,477
Capitalized R&D expenses	10,994
Total deferred tax assets	21,501
Deferred tax liabilities	
Right- of- use asset	(184)
Total deferred tax liabilities	(184)
Less valuation allowance	(21,317)
Deferred tax assets, net	$ —

The Company has established a full federal and state valuation allowance equal to the net deferred tax assets due to uncertainties regarding the realization of the deferred tax asset based on the Company's lack of earnings history. The valuation allowance increased by $21.3 million primarily due to continuing loss from operations.

	December 31, 2024
Beginning balance as of February 6, 2024	$ —
Change in valuation allowance	21,317
Ending balance as of December 31, 2024	$ 21,317

As of December 31, 2024, the Company had U.S. net operating loss carryforwards ("NOL") of $10.8 million. The federal NOL carryforwards do not expire and can be utilized to offset up to 80% of the taxable income in any tax year. For the period from February 6, 2024 (inception) to December 31, 2024 the Company had federal tax credit carryforwards and state tax credit carryforwards of $3.8 million and $0.4 million, respectively. The federal credits will expire starting in 2044 if not utilized, and the state research credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss carryforwards in certain situations where changes occur in the stock ownership of a company. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed a Section 382 analysis through December 31, 2024. To the extent that an assessment is completed in the future, the Company's ability to utilize tax attributes could be restricted on a year-by-year basis and certain attributes could expire before they are utilized. The Company will examine the impact of any potential ownership changes in the future.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Beginning balance as of February 6, 2024	$ —
Changes related to tax positions taken in the current year	1,047
Ending balance as of December 31, 2024	$ 1,047

The Company includes penalties and interest expense related to income taxes as a component of income tax expense, as necessary. As of December 31, 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company will be filing initial year income tax returns in the United States federal jurisdiction and state jurisdictions. Due to net operating loss carryforwards, the statute of limitations will remain open for income tax examination.

12. Option Agreements and License Agreements

In March 2024, the Company entered into two antibody discovery and option agreements ("Option Agreements") with Paragon and Paruka. Under the terms of each agreement, Paragon identifies, evaluates, and develops antibodies directed against certain mutually agreed therapeutic targets of interest to the Company. From time to time, the Company can choose to add additional targets to the collaboration upon agreement with Paragon and Paruka. Under the Option Agreements, the Company has the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title, and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture, and commercialize the antibodies and products directed to the selected target(s) (each, an "Option"). The Company has initiated certain research programs with Paragon that generally focus on discovering, generating, identifying and/or characterizing antibodies directed to a particular target (each, a "Research Program"), including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. The exclusive option with respect to each Research Program is exercisable at the Company's sole discretion at such time as specified in the Option Agreements (the "Option Period"). There is no payment due upon exercise of an Option pursuant to the Option Agreements. For each of these agreements, once the Company enters into the corresponding license agreements, it will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones, up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale in each program.

The Company may terminate any Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that it must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate any Option Agreement or a Research Program immediately upon written notice to the Company if, as a result of any action or failure to act by the Company or its affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Option Agreements or any Research Program upon material breach that remains uncured or the other party's bankruptcy.

Paragon Therapeutics – License Agreements

In September 2024, the Company exercised the Option to acquire certain rights to ORKA-001, and in December 2024, it entered into the corresponding license agreement with Paragon (the "ORKA-001 License Agreement"), pursuant to which Paragon granted the Company a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-23 in all fields other than the field of inflammatory bowel disease ("ORKA-001 Field"). In December 2024, the Company exercised the Option with respect to ORKA-002 for the IL-17A/F program, and in February 2025, it entered into the corresponding license agreement with Paragon (the "ORKA-002 License Agreement" and together with the ORKA-001 License Agreement, the "License Agreements"), pursuant to which Paragon granted the Company a royalty-bearing, world-wide, exclusive license to develop, manufacture, commercialize or otherwise exploit certain antibodies and products targeting IL-17A/F in all fields ("ORKA-002 Field" and together with the ORKA-001 Field, the "Fields").

The License Agreements provide the Company with exclusive licenses in the Fields to Paragon's patent applications covering the related antibodies, their method of use and their method of manufacture and Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies for the ORKA-001 Field or the ORKA-002 Field, respectively, for at least five years. Each of the ORKA-001 and ORKA-002 License Agreements may be terminated on 60 days' notice to Paragon, on material breach without cure, and on a party's insolvency or bankruptcy to the extent permitted by law.

Pursuant to the terms of each of the ORKA-001 and ORKA-002 License Agreements, the Company is obligated to pay Paragon non-refundable milestone payments of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones and up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, including a $1.5 million fee for nomination of a development candidate (or initiation of an IND-enabling toxicology study) and a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial for each of ORKA-001 and ORKA-002. In addition, the Company is obligated to pay Paragon a low single-digit percentage royalty for antibody products for each of ORKA-001 and ORKA-002. For each of the License Agreements, the royalty term ends on the later of (i) the last-to-expire licensed patent or our patent directed to the manufacture, use or sale of a licensed antibody in the country at issue or (ii) 12 years from the date of first sale of a Company product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program.

Additionally, as part of the Option Agreements, on December 31, 2024 the Company granted and on December 31, 2025, will grant Paruka a warrant to purchase a number of shares equal to 1.00% of outstanding shares as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares on the grant date.

Pursuant to the Option Agreements, on a research program-by-research program basis following the finalization of the research plan for each respective research program, the Company was required to pay Paragon a one-time, nonrefundable research initiation fee of $0.8 million related to the ORKA-001 program. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. In June 2024, pursuant to the Option Agreements with Paragon, the Company completed the selection process of its development candidate for IL-23 antibody for ORKA-001 program. The Company was responsible for 50% of the development costs incurred through the completion of the IL-23 selection process. The Company received the rights to at least one selected IL-23 antibody in June 2024. During the period from February 6, 2024 (inception) to December 31, 2024, the Company exercised its option for ORKA-001 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in the Company's consolidated statement of operations and comprehensive loss. In addition, during the period from February 6, 2024 (inception) to December 31, 2024, the Company recorded a $2.5 million milestone payment related to the first dosing of a human subject in a Phase 1 trial of ORKA-001 in December 2024 as research and development expense in its consolidated statement of operations and comprehensive loss. The Company's share of development costs incurred for the period from February 6, 2024 (inception) to December 31, 2024 was $13.5 million (excluding research initiation fee and milestones), which were recorded as research and development expenses. An amount of $2.8 million related to ORKA-001 is included in related party accounts payable and other current liabilities as of December 31, 2024.

The Company was also required to reimburse Paragon $3.3 million for development costs related to ORKA-002 incurred by Paragon through December 31, 2023 and certain other development costs incurred by Paragon between January 1, 2024 and March 6, 2024 as stipulated by the Option Agreements. This amount was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. The Company is also responsible for the development costs incurred by Paragon from January 1, 2024 through the completion of the IL-17 selection process. The Company recognized an amount of $0.8 million payable to Paragon for the research initiation fee related to ORKA-002 following the finalization of the ORKA-002 research plan. This was recognized as research and development expenses in the period from February 6, 2024 (inception) to December 31, 2024. During the period from February 6, 2024 (inception) to December 31, 2024, the Company exercised its option for ORKA-002 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in its consolidated statement of operations and comprehensive loss. The Company accounted for development costs of $7.8 million (excluding research initiation fee, milestone, and reimbursements of development costs through December 31, 2023) for the period from February 6, 2024 (inception) to December 31, 2024 as research and development expenses. An amount of $2.7 million related to ORKA-002 is included in related party accounts payable and other current liabilities as of December 31, 2024.

The Company expenses the service fees as the associated costs are incurred when the underlying services are rendered. Such amounts are classified within research and development expenses in the accompanying consolidated statement of operations and comprehensive loss.

The Company concluded that the rights obtained under the Option Agreements represent an asset acquisition whereby the underlying assets comprise in-process research and development assets with no alternative future use. The Option Agreements did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in the exclusive license options, which represent a group of similar identifiable assets. The research initiation fee represents a one-time cost on a research program-by-research program basis for accessing research services or resources with benefits that are expected to be consumed in the near term, therefore the amounts paid are expensed as part of research and development costs immediately. Amounts paid as reimbursements of ongoing development cost, monthly development cost fee and additional development expenses incurred by Paragon due to work completed for selected targets prior to the effective date of the Option Agreements that is associated with services being rendered under the related Research Programs are recognized as research and development expense when incurred.

For the period from February 6, 2024 (inception) to December 31, 2024, the Company recognized $42.0 million of expenses in connection with services provided by Paragon and Paruka under the Option Agreements.

13. Commitment and Contingencies

Leases

In April 2024, the Company entered into an operating lease agreement for the Company's headquarters in Menlo Park, California, which commenced on June 15, 2024 with an initial term of 39.5 months. The Company leases office space under this noncancelable operating lease agreement. Lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate when measuring operating lease liabilities as discount rates were not implicit or readily determinable.

As of December 31, 2024, the Company had $0.9 million of operating lease right-of-use assets, operating lease liability, current of $0.2 million, and operating lease liability, noncurrent of $0.8 million on its consolidated balance sheet. As of December 31, 2024, the operating lease arrangement had a remaining lease term of 33 months and a discount rate of 17.95%. For the period from February 6, 2024 (inception) to December 31, 2024, the Company recorded operating and variable lease expense of $0.3 million in general and administrative expenses in its consolidated statement of operations and comprehensive loss.

The following table presents the Company's supplemental cash flow information related to leases (in thousands):

	Period from February 6, 2024 (Inception) to December 31, 2024
Cash paid for amounts included in the measurement of lease liabilities	$ 116

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of December 31, 2024 (in thousands):

Year ending December 31,	Amount
2025	$ 369
2026	494
2027	380
Total undiscounted lease payments	1,243
Less: imputed interest	(275)
Total discounted lease payments	968
Less: current portion of lease liability	(213)
Non-current portion of lease liability	$ 755

Cell Line License Agreement

In March 2024, the Company entered into the Cell Line License Agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"). Under the Cell Line License Agreement, the Company received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") and media and feeds to make, have made, use, sell and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the "WuXi Biologics Licensed Products"). Specifically, the WuXi Biologics Licensed Technology is used in certain manufacturing activities in support of the ORKA-001 and ORKA-002 programs.

In consideration for the license, the Company agreed to pay WuXi Biologics a non-refundable license fee of $150,000, which was recognized as a research and development expense during the period from February 6, 2024 (inception) to December 31, 2024. Additionally, to the extent that the Company manufactures its commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, the Company is required to make royalty payments to WuXi Biologics at a rate of less than one percent of net sales of WuXi Biologics Licensed Products manufactured by the third-party manufacturer. Pursuant to an amendment to the Cell Line License Agreement effective in November 2024, a provision was added that permits the royalties owed under the agreement to be bought out on a product-by-product basis for a lump-sum payment.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon six months' prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by the Company that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

14. Net Loss per Share

Basic and diluted net loss per share attributable to stockholders were calculated as follows (in thousands, except share and per share data):

	Period from February 6, 2024 (Inception) to December 31, 2024		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted
Common Stock	$ (65,037)	16,789,362	$ (3.87)
Company Series A Preferred Stock [1]	(1,918)	495	$ (3,873.25)
Company Series B Preferred Stock [2]	(16,769)	51,946	$ (322.81)
Net loss	$ (83,724)		

(1) The weighted-average number of shares of as-converted Company Series A Preferred Stock used in the loss allocation was 495,191 for the period from February 6, 2024 (inception) to December 31, 2024.

(2) The weighted-average number of shares of as-converted Company Series B Preferred Stock used in the loss allocation was 4,328,844 for the period from February 6, 2024 (inception) to December 31, 2024.

For the computation of basic net loss per share attributable to stockholders, the amount of weighted-average shares outstanding excludes all shares of unvested restricted common stock as such shares are not considered outstanding for accounting purposes until vested. The amount of weighted-average shares outstanding includes the pre-funded warrants as the exercise price is negligible and these warrants are fully vested and exercisable.

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to stockholders for the periods presented because including them would have had an anti-dilutive effect were as follows:

	December 31, 2024
Outstanding employee warrants to purchase common stock	3,054,358
Outstanding unvested restricted stock awards	2,207,553
Outstanding and issued common stock options	1,567,760
Outstanding and issued warrant to Paruka	596,930
Total	7,426,601

15. Related Party Transactions

Paragon and Paruka each beneficially own less than 5% of the Company's capital stock through their respective holdings of Company Common Stock.

Fairmount beneficially owns more than 5% of the Company's capital, currently has one representative appointed to the Board, and beneficially owns more than 5% of Paragon. Fairmount appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers of Paragon.

The following is a summary of related party accounts payable and other current liabilities (in thousands):

	December 31, 2024
Paragon reimbursable Option Agreements' fees	$ 1,482
Paragon milestone payments for Option Agreement	4,000
Paragon reimbursable other research expenses	515
Paragon reimbursable patent expenses	25
Total	$ 6,022

16. Subsequent Events

In February 2025, the Company entered into a lease agreement for an office space located in Waltham, Massachusetts. The lease is for an initial period of 54 months. The Company expects to pay approximately $1.6 million over the lease term.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and our Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. Based on the foregoing evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control – Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. For as long as we remain a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act and report less than $100 million of annual revenues in our most recent fiscal year, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the quarter ended December 31, 2024, no director or Section 16 officer (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth the names, ages as of March 6, 2025, and positions of the individuals who currently serve as executive officers and directors of the Company.

Name	Age	Position
Executive Officers and Employee Director		
Lawrence Klein, Ph.D.	42	President, Chief Executive Officer and Director
Arjun Agarwal	49	Senior Vice President, Finance and Treasurer
Joana Goncalves, MBChB	51	Chief Medical Officer
Paul Quinlan	62	General Counsel and Corporate Secretary
Non-Employee Directors		
Samarth Kulkarni, Ph.D.[(2)(3)]	46	Chair and Director
Kristine Ball[(1)(3)]	53	Director
Carl Dambkowski, M.D.[(1)]	40	Director
Peter Harwin[(2)(3)]	39	Director
Cameron Turtle, D.Phil.[(1)(2)]	35	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Governance Committee (the "Governance Committee").

Our business affairs are managed under the direction of our Board, which currently consists of six members. Our Board is divided into three classes, with members of each class holding office for staggered three-year terms. There are currently two Class I directors, who are up for election at the 2025 Annual Meeting of Stockholders for a term expiring at the 2028 Annual Meeting of Stockholders; two Class II directors, whose terms expire at the 2026 Annual Meeting of Stockholders; and two Class III directors, whose terms expire at the 2027 Annual Meeting of Stockholders. Each executive officer serves at the discretion of the of the Board and holds office until their successor is duly appointed and qualified or until their earlier resignation or removal.

Biographical and other information regarding our executive officers and directors is set forth below. There are no family relationships among any of our executive officers or directors.

Executive Officers and Employee Director

Lawrence Klein, Ph.D. Dr. Klein has served as Chief Executive Officer and as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Dr. Klein was a Partner at Versant Venture Management, LLC, a healthcare and biotechnology venture capital firm, from January 2023 to February 2024, where he invested in and helped to grow early-stage biotechnology companies. Prior to Versant, Dr. Klein served in various positions at CRISPR Therapeutics AG (Nasdaq: CRSP), a biopharmaceutical company, including Chief Operating Officer from January 2020 to October 2022, Chief Business Officer from January 2019 to January 2020, Senior Vice President, Business Development and Strategy from November 2017 to December 2018 and as Vice President, Strategy from February 2016 to November 2017, where he helped to initiate and execute on several transformative partnerships, establish the strategic direction of the company, oversee important pipeline programs and led several functions, including program and portfolio management. Before joining CRISPR, Dr. Klein was an Associate Partner at McKinsey & Company, a global management consulting firm, from October 2014 to February 2016. Dr. Klein served as a member of the board of directors of Dyne Therapeutics, Inc. (Nasdaq: DYN) from September 2019 to May 2023 and of Jasper Therapeutics, Inc. (Nasdaq: JSPR) from September 2021 to June 2023. Dr. Klein received his B.S. in biochemistry and physics from the University of Wisconsin-Madison and his Ph.D. in biophysics from Stanford University.

We believe Dr. Klein is qualified to serve as a member of the Board because of his business development, operational and senior management experience in the biotechnology industry and his academic expertise and accomplishments.

Joana Goncalves, MBChB. Dr. Goncalves has served as the Chief Medical Officer of the Company since the Merger Closing and of Pre-Merger Oruka from April 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Dr. Goncalves served as Chief Medical Officer of Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company, from October 2018 to April 2024, where she was responsible for representing Cara Therapeutics in interactions with regulatory agencies, the investor and scientific communities and the board of directors, building multifunctional terms and developing the clinical development strategy in dermatological conditions. Prior to Cara, Dr. Goncalves held various positions at Celgene Corporation, a pharmaceutical company, which was later acquired by Bristol-Myers Squibb Company, from April 2014 to October 2018, where she most recently served as Vice President, Medical Affairs for Dermatology and Neurology and was instrumental in planning and executing medical support activities for a number of programs, including OTEZLA® for psoriasis. Prior to Celgene, Dr. Goncalves served as Vice President, Medical Strategy and Scientific Affairs at LEO Pharma Inc., the U.S. subsidiary of LEO Pharma A/S, a global healthcare company specializing in dermatology and critical care, from February 2012 to April 2014. She began her pharmaceutical career at Novartis Pharmaceuticals, working on a range of products across various therapeutic areas from 2001 to 2012. Dr. Goncalves received her MBChB from the University of Cape Town, South Africa.

Paul Quinlan. Mr. Quinlan has served as General Counsel and Corporate Secretary of the Company since the Merger Closing and of Pre-Merger Oruka since April 2024 through the Merger Closing. Prior to joining Pre-Merger Oruka, Mr. Quinlan served as General Counsel, Chief Compliance Officer and Corporate Secretary of CymaBay Therapeutics, Inc., a biopharmaceutical company, from October 2020 to March 2024, where he was responsible for the general supervision of the company's legal affairs. From December 2017 to February 2020, he served as General Counsel and Corporate Secretary of CymaBay, where he was responsible for the general supervision of the company's legal affairs. Prior to CymaBay, Mr. Quinlan served as General Counsel and Secretary, from 2010 to January 2018, and Chief Legal Officer from 2016 to January 2018, of TerraVia Holdings, Inc., a biotechnology company, where he was responsible for the general supervision of the company's legal affairs. Prior to joining TerraVia, Mr. Quinlan served as General Counsel of Metabolex, Inc., a biopharmaceutical company, from 2005 to 2010. Prior to joining Metabolex, Mr. Quinlan held various positions at Maxygen, Inc., a biopharmaceutical company, from 2000 to 2005. Prior to Maxygen, Mr. Quinlan practiced law at Cooley LLP and Cravath, Swaine, & Moore LLP. Mr. Quinlan received a law degree from Columbia Law School and an M.Sc. in Medical Biophysics from the University of Toronto.

Arjun Agarwal. Mr. Agarwal has served as the Senior Vice President of Finance of the Company since the Merger Closing and of Pre-Merger Oruka from March 2024 through the Merger Closing, where he is responsible for overseeing the company's finance and accounting functions. Prior to joining Pre-Merger Oruka, Mr. Agarwal served as VP of Finance at Jasper Therapeutics, Inc. (Nasdaq: JSPR), a biotechnology company, from June 2021 to March 2024, including through multiple financings and the company's successful transition to become a publicly traded entity. Before joining Jasper, Mr. Agarwal served as Vice President, Corporate Controller at Protagonist Therapeutics, Inc. (Nasdaq: PTGX), a biotechnology company, from August 2019 to June 2021, where he was responsible for overseeing the company's finance and accounting functions. Prior to joining Protagonist, Mr. Agarwal served in various roles of increasing responsibility at McKesson Corporation (NYSE: MCK), an international healthcare services company, from 2009 to 2019. Prior to McKesson, Mr. Agarwal worked at PricewaterhouseCoopers LLP, where he managed a portfolio of audit clients. He is a graduate of Sydenham College of Commerce and Economics at Mumbai University, India. He is a Certified Public Accountant (CPA) and a Chartered Accountant accredited by the Institute of Chartered Accountants of India.

Non-Employee Directors

Samarth Kulkarni, Ph.D. Dr. Kulkarni has served as Chair and a member of the board of directors of the Company since the Merger Closing and as a member of the board of directors of Pre-Merger Oruka from February 2024 through the Merger Closing. Dr. Kulkarni has served as the Chief Executive Officer of CRISPR Therapeutics AG (Nasdaq: CRSP), a biopharmaceutical company, since December 2017, where he has also served as a member and chair of the board of directors since June 2018 and September 2023, respectively. Previously, Dr. Kulkarni served as CRISPR's President and Chief Business Officer from May 2017 to November 2017 and as Chief Business Officer from August 2015. Prior to joining CRISPR, Dr. Kulkarni was at McKinsey & Company, a global management consulting firm, from 2006 to 2015, with various titles, his most recent being Partner within the Pharmaceuticals and Biotechnology practice. Dr. Kulkarni has also served as a member of the boards of directors of Black Diamond Therapeutics, Inc. (Nasdaq: BDTX), Repare Therapeutics Inc. (Nasdaq: RPTX), and Centessa Pharmaceuticals plc (Nasdaq: CNTA). Dr. Kulkarni received a Ph.D. in Bioengineering and Nanotechnology from the University of Washington and a B. Tech. from the Indian Institute of Technology. Dr. Kulkarni has authored several publications in leading scientific and business journals.

We believe that Dr. Kulkarni is qualified to serve as a member of the Board because of his experience as a consultant and an executive in the biopharmaceutical industry and his academic expertise and accomplishments.

Kristine Ball. Ms. Ball has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka since May 2024 through the Merger Closing. Ms. Ball has served as President and Chief Executive Officer of Antiva Biosciences, Inc., a private biopharmaceutical company, since April 2023. Prior to Antiva, Ms. Ball served as Chief Executive Officer of Soteria Biotherapeutics, Inc., a private biotechnology company, from September 2020 to August 2022. Prior to joining Soteria, Ms. Ball served as Senior Vice President, Corporate Strategy and Chief Financial Officer of Menlo Therapeutics, Inc., a Nasdaq-listed biopharmaceutical company, which later became VYNE Therapeutics Inc. (Nasdaq: VYNE), from September 2017 to March 2020, where she was responsible for leading all non-R&D functions, including strategic planning, corporate development, commercial, human resources, legal, finance and information technology. Prior to joining Menlo, Ms. Ball served as Chief Financial Officer and Senior Vice President of Relypsa, Inc., a Nasdaq-listed pharmaceutical company, which was later acquired by Galenica Group, from November 2012 to October 2016. Prior to Relypsa, Ms. Ball held various other finance roles in the life sciences industry, including Senior Vice President of Finance & Administration and Chief Financial Officer of KAI Pharmaceuticals, Inc., a biopharmaceutical company, and Vice President of Finance at Exelixis, Inc. (Nasdaq: EXEL), a biotechnology company. Prior to that, Ms. Ball served as a senior manager in the life sciences audit practice of Ernst & Young LLP. Ms. Ball has previously served on the boards of directors of Atreca, Inc. (Nasdaq: BCEL), a biopharmaceutical company, from 2020 to 2024, Soteria from 2020 to 2022 and Forty Seven, Inc. (Nasdaq: FTSV), a Nasdaq-listed biotechnology company, which was acquired by Gilead Sciences, Inc., from 2018 to 2020. Ms. Ball received a B.S. from Babson College.

We believe Ms. Ball is qualified to serve as a member of the Board because of her experience as an executive officer and director of life sciences companies and her background in finance, corporate development and strategic planning.

Carl Dambkowski, M.D. Dr. Dambkowski has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Dr. Dambkowski has served as the Chief Medical Officer of Apogee Therapeutics, Inc. (Nasdaq: APGE), a biotechnology company, since September 2022. Prior to joining Apogee, Dr. Dambkowski served as a strategic and clinical leader for a variety of companies, including as Chief Medical Officer of QED Therapeutics, Inc., a private biotechnology company, from July 2021 to September 2022; Chief Strategy Officer and EVP of Operations of Origin Biosciences, Inc., a private bioecology company, from March 2018 to June 2021; and Chief Medical Officer of Navire Pharma, Inc., a private biotechnology company, from January 2020 to September 2022, where he served as the clinical lead starting prior to IND for BBP-398 through the out licensing of the compound to Bristol-Myers Squibb based on initial clinical data and for low-dose infigratinib in achondroplasia through initial proof-of-concept data. He was part of the core team that brought TRUSELTIQ® (infigratinib) and NULIBRY® (fosdenopterin) through regulatory review and FDA approval at QED Therapeutics and Origin Biosciences, respectively. From July 2016 to March 2018, Dr. Dambkowski was an associate at McKinsey & Company, a global management consulting firm, where he advised biotech and pharmaceutical companies across the world on a range of research and development activities. Dr. Dambkowski co-founded Novonate, Inc., a private medical device company focused on building life-saving devices for neonates, in January 2015. Dr. Dambkowski has coauthored numerous peer-reviewed publications and scientific abstracts and is a named inventor on multiple published and granted patents. Dr. Dambkowski was trained as a physician at Stanford University, where he also received his M.D. with a concentration in bioengineering. He also received a B.A. (with honors) from Stanford University and an M.A. from Columbia University.

We believe Dr. Dambkowski is qualified to serve as a member of the Board because of his significant experience and innovations in the biotechnology industry and his academic expertise and accomplishments.

Peter Harwin. Mr. Harwin has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Mr. Harwin is a Managing Member at Fairmount Funds Management, a healthcare investment firm he co-founded in April 2016. Prior to Fairmount Funds Management, Mr. Harwin was a member of the investment team at Boxer Capital, LLC, an investment fund that was part of the Tavistock Group, based in San Diego. Mr. Harwin also serves as chairman of the board of directors of Cogent Biosciences, Inc. (Nasdaq: COGT) and is a member of the board of directors of Apogee Therapeutics, Inc. (Nasdaq: APGE), Viridian Therapeutics, Inc. (Nasdaq: VRDN) and Spyre Therapeutics, Inc. (formerly Aeglea BioTherapeutics, Inc.) (Nasdaq: SYRE). Mr. Harwin received a B.B.A. from Emory University.

We believe Mr. Harwin is qualified to serve as a member of the Board because of his experience serving as a director of biotechnology companies and as a manager of funds specializing in the area of life sciences.

Cameron Turtle, D.Phil. Dr. Turtle has served as a member of the board of directors of the Company since the Merger Closing and of Pre-Merger Oruka from February 2024 through the Merger Closing. Dr. Turtle has served as Chief Executive Officer and a member of the board of directors of Spyre Therapeutics, Inc. (formerly Aeglea BioTherapeutics, Inc.) (Nasdaq: SYRE), a biotechnology company, since November 2023 and, before that, as Chief Operating Officer from June 2023 to November 2023. Prior to joining Spyre, Dr. Turtle was an advisor to Spyre Therapeutics, Inc., a private biotechnology company, from May 2023 to June 2023. Previously, he served as Venture Partner at Foresite Labs, a life sciences investment firm, from July 2022 to May 2023; Chief Strategy Officer of BridgeBio Pharma (Nasdaq: BBIO), a biotechnology company, from January 2021 to April 2022; and Chief Business Officer of Eidos Therapeutics (Nasdaq: EIDX), a biopharmaceutical company, from November 2018 to January 2021, where he led business development, investor relations, and multiple operational functions as the company advanced an investigational medicine for a form of heart failure. Prior to joining BridgeBio and Eidos, he was a consultant at McKinsey & Company, a global management consulting firm, where he worked with pharmaceutical and medical device companies on topics including M&A, growth strategy, clinical trial strategy, and sales force optimization. Dr. Turtle received his B.S. with honors in Bioengineering from the University of Washington and his D.Phil. in Cardiovascular Medicine from the University of Oxford, St. John's College. He is the recipient of several awards, including a Rhodes Scholarship, Goldwater Scholarship, Forbes 30 Under 30, San Francisco Business Times 40 Under 40, and the Biocom Life Sciences Catalyst Award.

We believe Dr. Turtle is qualified to serve as a member of the Board because of his experience as a leader in building, financing, and shaping biopharmaceutical organizations from preclinical development to late-stage clinical trials and commercialization.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that establishes the standards of ethical conduct applicable to all our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer, or persons performing similar functions. It addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets and how to report compliance concerns. A copy of the code is available on our website located at https://ir.oruka.com/corporate-governance under "Governance Documents." We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by applicable rules. The Audit Committee is responsible for applying and interpreting the code in situations where questions are presented to it. Information contained on, or that can be accessed through, the Company's website is not incorporated by reference into this report, and you should not consider information on the Company's website to be part of this report.

Insider Trading Policy

We have adopted insider trading policies and procedures governing the purchase, sale and other transactions in Company securities by our directors, officers and employees, and other covered persons, as well as the Company itself, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and Nasdaq Stock Market ("Nasdaq") listing rules, as applicable.

As part of these policies and procedures, we prohibit any employee, director or other covered person from engaging in short sales, transactions involving publicly traded options or other derivative securities based on the Company's securities, hedging transactions, margin accounts, pledges, or other inherently speculative transactions with respect to the Company's securities at any time.

Audit Committee and Audit Committee Financial Expert

We have a separately designated standing Audit Committee. The members of our Audit Committee are Ms. Ball, Dr. Dambkowski, and Dr. Turtle, each of whom qualifies as an "independent" director for audit committee purposes as defined under Nasdaq listing rules and the rules and regulations established by the SEC. Ms. Ball chairs the Audit Committee and qualifies as an "audit committee financial expert" as that term is defined under the rules and regulations established by the SEC, and all members of the Audit Committee are financially literate under Nasdaq listing rules.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, officers and persons who beneficially own more than 10% of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. To our knowledge, based solely on our review of Forms 3, 4 and 5 filed with the SEC or written representations that no Form 5 was required, during the year ended December 31, 2024, we believe that all of our directors, officers and persons who beneficially own more than 10% of a registered class of our equity securities timely filed all reports required under Section 16(a) of the Exchange Act.

Stockholder Proposals and Director Nominations for 2025 Annual Meeting of Stockholders

We will hold our 2025 Annual Meeting of Stockholders (the "Annual Meeting") on Monday, June 2, 2025.

Pursuant to Rule 14a-8 of the Exchange Act, stockholders who wish to submit proposals for inclusion in the proxy statement for the Annual Meeting must send such proposals to our Corporate Secretary at the address 855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025. Such proposals must be received by us a reasonable time before we begin to print and mail our proxy materials and must comply with Rule 14a-8 of the Exchange Act. The submission of a stockholder proposal does not guarantee that it will be included in the proxy statement.

On August 29, 2024, in connection with the Merger Closing, the Board adopted an amendment and restatement of our Bylaws, effective as of such date, as described in our Current Report on Form 8-K filed on September 5, 2024. As set forth in our Bylaws, if a stockholder intends to make a nomination for director election or present a proposal for other business (other than pursuant to Rule 14a-8 of the Exchange Act) at the Annual Meeting, the stockholder's notice must be received by our Corporate Secretary at the address 855 Oak Grove Avenue, Suite 100, Menlo Park, CA 94025 no earlier than the 120th day and no later than the close of business on the 90th day before the anniversary of the last annual meeting; provided, however, that if the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, the stockholder's notice must be delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the date on which the first public announcement of the date of such annual meeting is made by the Company. Therefore, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary no later than the close of business on March 16, 2025. Any such director nomination or stockholder proposal must be a proper matter for stockholder action and must comply with the terms and conditions set forth in our Bylaws (which includes the timing and information required under Rule 14a-19 of the Exchange Act). If a stockholder fails to meet these deadlines or fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

Item 11. Executive Compensation.

This section provides information regarding the compensation of our principal executive officer (Dr. Klein), and our two other highest paid executive officers who were serving as executive officers on December 31, 2024 (Dr. Goncalves and Mr. Quinlan). This section also includes compensation information for certain former executives of the Company (then known as ARCA). The individuals listed below are collectively referred to herein as the "NEOs" or "Named Executive Officers."

Name	Title
Lawrence Klein, Ph.D.	Chief Executive Officer(1)
Joana Goncalves, MBChB	Chief Medical Officer(1)
Paul Quinlan	General Counsel and Corporate Secretary(1)
Michael Bristow, M.D.	Former President and Chief Executive Officer(2)
Thomas A. Keuer	Former President and Chief Operating Officer(3)
C. Jeffrey Dekker	Former Chief Financial Officer(3)

(1) Drs. Klein and Goncalves and Mr. Quinlan were appointed to these positions in connection with the consummation of the Merger. Prior to the Merger, they each served in these positions at Pre-Merger Oruka.
(2) Dr. Bristow's employment with the Company terminated on April 3, 2024. Following his termination, Dr. Bristow provided transition services as a consultant.
(3) Mr. Keuer's and Mr. Dekker's employment with the Company terminated in connection with the Merger. Following the Merger, Mr. Dekker provided transition services as a consultant.

A Year of Transition

2024 was a year of transition for the Company as we completed the Merger, shifted our drug candidate pipeline to focus on novel biologics designed to set a new standard for the treatment of chronic skin diseases and transformed our management team. Our mission is to offer patients suffering from chronic skin diseases like plaque psoriasis the greatest possible freedom from their condition by achieving high rates of complete disease clearance with dosing as infrequently as once or twice per year. The compensation described below reflects both compensatory decisions necessary to engage a new leadership team that is critical to lead the advancement of the Company's pipeline of novel biologics and improve the standard of care for the treatment of chronic skin diseases and compensatory decisions made by ARCA prior to the consummation of the Merger with respect to the former executive officers.

2024 Summary Compensation Table

The following table shows information regarding the compensation earned by the NEOs during the fiscal years ending December 31, 2024 and 2023, by our named executive officers.

Name and Principal Position[1]	Year	Salary ($)[2]	Bonus ($)[3]	Option Awards ($)[4]	Non-Equity Incentive Plan Compensation ($)[5]	All Other Compensation ($)	Total ($)
Lawrence Klein, Ph.D. *Chief Executive Officer*	2024	203,288	—	—	317,623	—	520,911
Joana Goncalves, MBChB *Chief Medical Officer*	2024	155,854	—	—	162,132	—	317,986
Paul Quinlan *General Counsel*	2024	155,854	—	—	154,591	—	310,445
Michael Bristow, M.D. *Former President and Chief Executive Officer*	2024	96,865	—	39,676	—	373,875(6)	510,416
	2023	345,000	—	—	—	13,800	358,800
Thomas A. Keuer *Former President and Chief Operating Officer*	2024	235,385	165,000	22,484	—	430,651(7)	853,520
	2023	340,000	—	—	—	60,802	400,802
C. Jeffrey Dekker *Former Chief Financial Officer*	2024	206,923	165,000	24,947	—	359,734(8)	756,604
	2023	270,000	—	—	—	53,072	323,072

(1) The amounts reflected herein for Drs. Klein and Goncalves and Mr. Quinlan do not include any compensation they received from Pre-Merger Oruka prior to the Merger.

(2) Includes $157,595 of consulting fees for Dr. Bristow and $20,000 of consulting fees for Mr. Keuer, in each case, pursuant to their respective consulting agreements as described in more detail under "*Narrative Disclosure to Summary Compensation Table—ARCA Arrangements*" below.

(3) Amounts reported in this column represent retention bonuses, as described in more detail under "*Narrative Disclosure to Summary Compensation Table—ARCA Arrangements*" below.

(4) Amounts reported in this column represent the incremental fair value under Accounting Standards Codification Topic 718 ("ASC 718") resulting from the acceleration of the Named Executive Officer's stock options in the Merger, as described in more detail under "Narrative to Summary Compensation Table—ARCA Arrangements" below.

(5) Amounts reported in this column represent the annual bonuses earned under the 2024 annual bonus program, as described in more detail under "*Narrative to Summary Compensation Table—Elements of Compensation—Annual Bonus Program*" below.

(6) Includes $3,875 of Company contributions under the ARCA 401(k) plan and $370,000 of severance payments and benefits, as described in more detail under "*Narrative Disclosure to Summary Compensation Table—ARCA Arrangements*" below.

(7) Includes $16,800 of Company contributions under the ARCA 401(k) plan, $340,000 of severance payments and $69,715 in COBRA continuation premiums, as described in more detail under "*Narrative Disclosure to Summary Compensation Table—ARCA Arrangements*" below, and $4,136 for group term life insurance premiums.

(8) Includes $14,687 of Company contributions under the ARCA 401(k) plan, $270,000 of severance payments and $69,715 in COBRA continuation premiums, as described in more detail under "*Narrative Disclosure to Summary Compensation Table—ARCA Arrangements*" below, $2,692 for group term life insurance premiums and $2,640 for healthcare reimbursements.

Narrative Disclosure to Summary Compensation Table

In December 2024, our Compensation Committee adopted a compensation philosophy to frame future compensation decisions for the Company. Under this philosophy, compensation positioning is used to attract and retain key employees for the Company's continued success and growth. While market data is helpful to the Compensation Committee in setting compensation framework and guiding decisions, other factors such as Company strategy, stockholder feedback, tenure, performance and criticality are also considered. The compensation philosophy serves as the foundation to reinforce the Company's business strategy and desired culture, while balancing internal and external alignment.

Peer Group

In July 2024, Pre-Merger Oruka, in consultation with Alpine, the Compensation Committee's independent compensation consultant, established a peer group that focuses on U.S.-based, pre-clinical or early clinical biopharma companies (with priority placed on companies with a similar therapeutic focus) with a market capitalization ranging from $250 million to $2 billion and less than 100 employees. The peer group, which was used in making compensation decisions in connection with establishing post-Merger executive compensation for 2024, includes the following companies (the "Peer Group"):

Apogee Therapeutics	Astria Therapeutics	Cabaletta Bio
CARGO Therapeutics	Celldex Therapeutics	Contineum Therapeutics
Entrada Therapeutics	Janux Therapeutics	Kymera Therapeutics
Kyverna Therapeutics	Lexeo Therapeutics	Longboard Pharmaceuticals
Lyell Immunopharma	Pliant Therapeutics	Prime Medicine
Spyre Therapeutics	Structure Therapeutics	Third Harmonic Bio

Elements of Compensation

Base Salaries

Our Compensation Committee recognizes the importance of base salary as an element of compensation to provide our executive officers with steady cash flow during the year that is not contingent on short-term variations in our corporate performance. The setting of base salaries also includes an evaluation of each individual's job duties, responsibilities, performance and experience, as well as internal pay equity among the executive officer team. The Compensation Committee reviews base salaries at least annually and may recommend adjustment from time to time based on the results of that review. The Compensation Committee determines salary increases using a combination of relevant competitive market data, scope of responsibilities and assessment of individual performance.

For 2024, the annual base salaries of Drs. Klein and Goncalves and Mr. Quinlan were established in connection with the consummation of their employment with Pre-Merger Oruka as a result of negotiations in the context of a competitive recruitment process. The annual base salaries as of December 31, 2024 for each of our continuing NEOs were as follows: $600,000 for Dr. Klein and $460,000 for each of Dr. Goncalves and Mr. Quinlan.

Annual Bonus Program

We have an annual cash incentive plan under which cash incentives may be paid to each of our employees, including our executive officers, after the end of each calendar year. The Compensation Committee generally determines target bonuses based on Peer Group practices and each individual's job duties. For 2024, the target bonuses for each NEO (excluding the former ARCA executive officers), which were established by Pre-Merger Oruka in connection with the consummation of their employment with Pre-Merger Oruka, were as follows: 50% of base salary for Dr. Klein and 40% of base salary for each of Dr. Goncalves and Mr. Quinlan, in each case, pro-rated based on their respective start dates with Pre-Merger Oruka.

Pre-Merger Oruka established the corporate goals and targets for the 2024 bonus program, which were heavily weighted towards the preclinical development of ORKA-001 and ORKA-002, progress towards the commencement of their respective Phase 1 clinical studies and regulatory progress. In addition, the corporate goals included measures designed to ensure adequate funding for the Company.

The Board, upon the recommendation of the Compensation Committee, reviewed our achievement against our 2024 corporate goals and determined the achievement to have been 125% of target, based on the achievement of substantially all the goals, with overperformance on several of the goals.

Based on our corporate performance, the 2024 annual bonuses awarded to our continuing NEOs were as follows: $317,623 for Dr. Klein, $162,132 for Dr. Goncalves and $154,591 for Mr. Quinlan.

Long-Term Incentives

We intend our equity incentive program to reward longer-term performance and to align the interests of our executive officers with those of our stockholders. We also believe that our equity incentive program, which currently consists predominantly of time-based stock options (or, for certain grants by Pre-Merger Oruka, time-based compensatory warrants), is an important retention tool for our employees, including our NEOs. The Compensation Committee believes that stock options, which require increased stock price performance for value realization, create a key connection between the interests of the NEOs and stockholders. Each of the grants described below are presented after giving effect to the share conversion completed in the Merger and the subsequent 1-for-12 reverse stock split.

In connection with his appointment as Chief Executive Officer of Pre-Merger Oruka, Dr. Klein purchased 852,338 shares of restricted stock at fair market value, which vests as to 25% on February 26, 2025 and in equal monthly installments thereafter through February 26, 2028. In accordance with the anti-dilution provisions of his offer letter, as described in more detail below, on July 15, 2024, Dr. Klein received a compensatory warrant to purchase 1,628,513 shares of our common stock, which vests as to 25% on April 3, 2025 and in equal monthly installments thereafter through April 3, 2028.

In connection with her appointment as Chief Medical Officer of Pre-Merger Oruka, Dr. Goncalves was granted stock options to purchase 228,563 shares of our common stock, which vests as to 25% on April 18, 2025 and in equal monthly installments thereafter through April 18, 2028. On July 15, 2024, Dr. Goncalves was granted a compensatory warrant to purchase 199,992 shares of our common stock, which vests on the same schedule as her initial stock option grant.

In connection with his appointment as General Counsel of Pre-Merger Oruka, Mr. Quinlan was granted stock options to purchase 228,563 shares of our common stock, which vests as to 25% on April 30, 2025 and in equal monthly installments thereafter through April 30, 2028. On July 15, 2024, Mr. Quinlan was granted a compensatory warrant to purchase 99,996 shares of our common stock, which vests on the same schedule as his initial stock option grant.

None of the former ARCA executive officers received grants of equity incentive awards during 2024.

Offer Letters

In connection with their appointments, we entered into offer letters with each of Dr. Klein, Dr. Goncalves and Mr. Quinlan, each of which was amended and restated as of October 3, 2024 (for Dr. Klein) or October 1, 2024 (for Dr. Goncalves and Mr. Quinlan) following the Merger (collectively, the "Offer Letters"). The Offer Letters provided for each NEO's initial base salary, target annual bonus and initial equity incentive award. The Offer Letter with Dr. Klein also provided for periodic grants of stock options sufficient to maintain Dr. Klein's ownership at approximately 5% on a fully-diluted basis until Oruka raised an aggregate of $200 million in financing, which obligations were fully satisfied prior to the consummation of the Merger through the warrant issued on July 15, 2024. The Offer Letter with Dr. Goncalves also provided for a sign-on bonus of $100,000, which is subject to repayment in the event of a termination for cause or resignation without good reason prior to April 18, 2025.

Under the Offer Letters, the NEOs are eligible for certain payments or benefits upon certain terminations of employment, as described under "Additional Narrative Disclosure—Potential Payments Upon Termination or Change in Control" below. Each of Dr. Klein, Dr. Goncalves and Mr. Quinlan is also party to our standard employee invention assignment, confidentiality and non-competition agreement, which, among other things, provides standard protections regarding our ownership of intellectual property, the confidentiality of our proprietary information, non-competition and non-solicitation.

ARCA Arrangements

Michael Bristow, M.D. Dr. Bristow served as the Company's President and Chief Executive Officer through April 3, 2024. In connection with his separation, the Company (then known as ARCA) and Dr. Bristow entered into a separation agreement pursuant to which Dr. Bristow provided a release of claims in favor of the Company and the Company paid Dr. Bristow a lump sum severance payment of $370,000.

The Company and Dr. Bristow also entered into a consulting agreement, effective April 3, 2024, pursuant to which Dr. Bristow provided certain consulting services to the Company through the Merger. Under the consulting agreement, Dr. Bristow continued to vest in his outstanding equity awards during the consulting term.

Thomas A. Keuer and C. Jeffrey Dekker. Mr. Keuer served as the Company's President and Chief Operating Officer and Mr. Dekker served as the Company's Chief Financial Officer, in each case, through the consummation of the Merger. Pursuant to retention bonus letters approved by the ARCA Compensation Committee prior to the Merger, each of Messrs. Keuer and Dekker were paid a retention bonus upon consummation of the Merger of $165,000.

As a result of the Merger and the accompanying termination of their employment, the Company and each of Mr. Keuer and Mr. Dekker entered into a separation agreement, pursuant to which Mr. Keuer and Mr. Dekker each provided a release of claims in favor of the Company and the Company provided the following severance payments and benefits, in accordance with the terms of their employment agreement: (i) a lump sum cash severance payment equal to 12 months of their respective annual base salary ($340,000 and $270,000, respectively) and (ii) a lump sum cash payment of $69,715 in lieu of 12 months of group health plan continuation premiums.

Treatment of ARCA Equity Awards. In connection with the Merger, all outstanding ARCA stock options held by the NEOs were accelerated and cashed out for an amount equal to the difference between $3.9489 and the applicable per share exercise price; however, any ARCA stock options having an exercise price in excess of $3.9489 were cancelled for no consideration.

Outstanding Equity Awards at Fiscal Year End

The following table presents information regarding outstanding stock options, compensatory warrants and restricted stock held by each NEO as of December 31, 2024. The equity awards reflected below give effect to the share conversion completed in the Merger and the subsequent 1-for-12 reverse stock split. None of the former ARCA executive officers held any outstanding equity awards as of December 31, 2024.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[1]
Lawrence Klein, Ph.D.	—	1,628,513(2)	7.80	7/14/2034		
					852,338(3)	16,526,834
Joana Goncalves, MBChB	—	228,563(4)	6.84	10/30/2034		
	—	199,992(4)	7.80	7/14/2034		
Paul Quinlan	—	228,563(5)	6.84	10/30/2034		
	—	99,996(5)	7.80	7/14/2034		
Michael Bristow, M.D.	—	—	—	—	—	—
Thomas A. Keuer	—	—	—	—	—	—
C. Jeffrey Dekker	—	—	—	—	—	—

(1) The market value was determined by multiplying the numbers of shares by $19.39, the closing price of our common stock on December 31, 2024.
(2) These compensatory warrants vest as to 25% on April 3, 2025 and in equal monthly installments thereafter through April 3, 2028, subject to Dr. Klein's continued services to us.
(3) These restricted shares vest as to 25% on February 26, 2025 and in equal monthly installments thereafter through February 26, 2028, subject to Dr. Klein's continued services to us.
(4) These stock options and compensatory warrants vest as to 25% on April 18, 2025 and in equal monthly installments thereafter through April 18, 2028, subject to Dr. Goncalves' continued services to us.
(5) These stock options and compensatory warrants vest as to 25% on April 30, 2025 and in equal monthly installments thereafter through April 30, 2028, subject to Mr. Quinlan's continued services to us.

Additional Narrative Disclosures

Employee Benefits and Perquisites

Our NEOs are eligible to participate in our employee benefit plans, including our health and welfare plans, term life insurance, disability insurance and a 401(k) plan, in each case on the same basis as all our other employees. During 2024, following the Merger, we did not provide any Company contributions under the 401(k) plan; however, in 2025, the Company will make matching contributions of 100% of the first 3% of eligible compensation deferred by participants, subject to legal maximum contributions.

Following the Merger, we generally do not provide perquisites or personal benefits to our NEOs, except in limited circumstances.

Potential Payments Upon Termination or Change in Control

Pursuant to the terms of the Offer Letters, in the event each NEO that is a current executive officer is terminated by the Company without "cause" or as a result of a resignation for "good reason" (collectively, an "Involuntary Termination"), such NEO will, subject to the execution of a release in favor of the Company, receive: (i) severance payments equal to 12 months of base salary; (ii) Company-paid continuation coverage under the Company's group health plans for up to 12 months; and (iii) in the case of Dr. Klein, accelerated vesting of 30% of any outstanding time-based equity. However, if the Involuntary Termination is within three months before or 12 months after a change in control of the Company, the NEO will instead receive: (A) severance payments equal to 1.0 times (or, for Dr. Klein, 1.5x times) the sum of the NEO's base salary and target bonus; (B) Company-paid continuation coverage under the Company's group health plans for up to 12 months (or, for Dr. Klein, up to 18 months); and (C) full acceleration of all equity awards. In addition, upon severance due to the death or disability of the named executive officer, the officer's equity awards shall accelerate in full.

As used in the Offer Letters:

"Cause" generally means the NEO's (i) dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business that results in or is reasonably anticipated to result in material harm to the Company; (ii) conviction or plea of no contest to a felony or misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) failure to perform his or her duties or responsibilities, subject to a 30-day cure period; (iv) gross negligence, willful misconduct that results in or is reasonably anticipated to result in material harm to the Company; or (v) violation of any material provision of any agreement with the Company or any written Company policies.

"Good reason" generally means (i) a material diminution in the named executive officer's base salary or target bonus (excluding across-the-board reductions of less than 10%); (ii) a material geographic relocation or requirement to change the named executive officer's remote work location; (iii) a material reduction in the named executive officer's duties, authority or responsibilities; (iv) the failure of the Company to obtain the assumption of the Offer Letter by a successor; or (v) the material breach of any agreement between the NEO and the Company, in each case, subject to standard notice and cure periods.

Clawback Policy

We maintain a Compensation Recoupment (Clawback) Policy, which is intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive, including the NEOs, during the prior three fiscal years that exceeds the amount that the executive otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

Equity Grant Practices

Following the Merger, we generally grant annual equity awards, including stock options, in January of each year. We also grant stock options as new hire awards as of their date of employment commencement. Employees, including the NEOs, may enroll to purchase shares under the terms of our 2024 Employee Stock Purchase Plan, as amended (the "ESPP"), with purchase dates generally occurring during open trading windows in June and December of each year using payroll deductions accumulated during the prior six-month period. During 2024, the Compensation Committee did not take material nonpublic information into account when determining the timing and terms of stock options, and the Company did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Director Compensation

The following table provides information for the year ended December 31, 2024 regarding all compensation awarded to, earned by or paid to each person who served as a non-employee director for some portion of 2024. Employees who served on our Board during 2024 did not receive additional compensation for such service:

Name[(1)(2)]	Fees Earned or Paid in Cash ($)	Option Awards ($)[(3)]	Total ($)
Kristine Ball	20,548	-	20,548
Carl Dambkowski, M.D.	16,267	-	16,267
Peter Harwin	19,178	-	19,178
Samarth Kulkarni, Ph.D.	27,740	-	27,740
Cameron Turtle, D.Phil.[(4)]	20,377	-	20,377
Dan Mitchell	30,810	-	30,810
Raymond Woosley	27,500	-	27,500
Robert Conway	197,916	2,739	200,655
James Flynn	71,042	12,620	83,662
Linda Grais	168,124	2,739	170,863
Anders Hove	159,583	2,739	162,322
Jacob Ma-Weaver	119,167	8,215	127,382

(1) The amounts reflected herein for directors who served on the Pre-Merger Oruka board of directors do not include any compensation they received from Pre-Merger Oruka prior to the Merger.

(2) Messrs. Woosley and Mitchell resigned from our Board effective as of February 2, 2024. In connection with the Merger on August 29, 2024, Drs. Hove and Grais as well as Messrs. Conway, Ma-Weaver and Flynn resigned from our Board and Drs. Turtle, Dambkowski and Kulkarni as well as Ms. Ball and Mr. Harwin were appointed to our Board.

(3) In connection with the Merger, all outstanding ARCA stock options held by Drs. Hove and Grais and Messrs. Conway, Ma-Weaver and Flynn were accelerated and cashed out for an amount equal to the difference between $3.9489 and the applicable per share exercise price; however, any ARCA stock options having an exercise price in excess of $3.9489 were cancelled for no consideration. Amounts reported in this column represent the incremental fair value under ASC Topic 718 resulting from the acceleration of the stock options in the Merger. As of December 31, 2024, each of Drs. Turtle and Dambkowski and Ms. Ball held outstanding options or compensatory warrants to purchase 94,282 shares of our common stock (which were assumed by the Company in connection with the Merger), Dr. Kulkarni held outstanding options or compensatory warrants to purchase 199,992 shares of our common stock (which were assumed by the Company in connection with the Merger), and no other non-employee directors held any outstanding options or compensatory warrants.

(4) Prior to the Merger, Dr. Turtle purchased 85,233 shares (after giving effect to the share conversion completed in the Merger and the subsequent 1-for-12 reverse stock split) of restricted common stock that vest as to 25% on March 1, 2025 and in and in equal monthly installments thereafter through March 1, 2028. All of such restricted shares were outstanding as of December 31, 2024.

Non-Employee Director Compensation Program

Non-employee members of the Board are eligible to receive cash and equity compensation in accordance with our non-employee director compensation program. This program provides for the following annual cash retainers:

	Pre-Merger	Post-Merger
Annual Cash Retainer	$ 40,000	$ 40,000
Annual Board Chair Retainer	$ 30,000	$ 30,000
Audit Committee Retainers:		
Chair	$ 15,000	$ 15,000
Non-Chair Member	$ 7,500	$ 7,500
Compensation Committee Retainers:		
Chair	$ 10,000	$ 12,000
Non-Chair Member	$ 5,000	$ 6,000
Nominating and Corporate Governance Committee Retainers		
Chair	$ 10,000	$ 10,000
Non-Chair Member	$ 5,000	$ 5,000

In connection with the Company's annual meeting of stockholders, each member of the Board will receive an annual grant of stock options to purchase 17,500 shares of common stock, which will vest in equal monthly installments over 12 months so long as such director joined the Board prior to January 1 of the year in which such annual meeting occurs. Prior to the Merger, the annual grant of stock options was for 6,000 shares of common stock.

In addition, in connection with a non-employee director's initial appointment to the Board, they will receive an initial grant of stock options to purchase 35,000 shares of common stock, which will vest in equal monthly installments over 36 months. Prior to the Merger, the initial grant of stock options was for 12,000 shares of common stock.

All members of the Board are also reimbursed for reasonable and documented out-of-pocket travel and lodging expenses incurred in connection with attending meetings and activities of the Board and its committees.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our Common Stock as of February 15, 2025.

- each person or group of affiliated persons, who is known by us to be the beneficial owner of more than 5% of Common Stock;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

The column entitled "Percentage of Shares Outstanding Beneficially Owned" is based on a total of 37,440,510 shares of our Common Stock outstanding as of February 15, 2025.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to the Common Stock. Shares of Common Stock subject to options that are currently exercisable or exercisable within 60 days of the date of this table are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all the shares of Common Stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Oruka Therapeutics, Inc., 855 Oak Grove Ave., Suite 100, Menlo Park, CA 94025.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Outstanding Beneficially Owned
5% Stockholders:		
Entities affiliated with Fairmount Funds Management LLC[(1)]	8,511,824	19.99%
FMR LLC[(2)]	5,561,808	14.86%
Entities affiliated with Venrock Healthcare Capital Partners[(3)]	4,148,428	11.08%
Entities affiliated with RTW Investments, LP[(4)]	2,058,147	5.50%
Named Executive Officers and Directors:		
Lawrence Klein[(5)]	1,522,440	4.02%
Arjun Agarwal[(6)]	61,068	*
Joana Goncalves[(7)]	10,347	*
Paul Quinlan[(8)]	10,156	*
Michael R. Bristow[(9)]	399	*
Thomas A. Keuer[(10)]	3,394	*
C. Jeffrey Dekker[(11)]	3,333	*
Cameron Turtle[(12)]	110,579	*
Samarth Kulkarni[(13)]	35,713	*
Peter Harwin[(1)]	8,511,824	19.99%
Carl Dambkowski[(14)]	25,058	*
Kristine Ball	—	*
All current executive officers and directors as a group (9 persons)[(15)]	10,287,185	24.69%

* Less than 1%.

(1) Consists of (i) (A) 798,614 shares of common stock, (B) 409,326 shares of common stock issuable upon the exercise of pre-funded warrants and (C) 4,730,576 shares of common stock issuable upon conversion of 56,767 shares of Series B Preferred Stock held by Fairmount Healthcare Fund II L.P. ("Fairmount Fund II") and (ii) 2,573,308 shares of common stock held by Fairmount Healthcare Co-Invest III L.P. ("Fairmount Fund III"). Excludes (i) 4,888,338 shares of common stock issuable upon the exercise of the pre-funded warrants and (ii) 6,697,573 shares of common stock issuable upon the conversion of 80,371 shares of Series B Preferred Stock. The pre-funded warrants are subject to a beneficial ownership limitation of 9.99% and the shares of Series B Preferred Stock are subject to a beneficial ownership limitation of 19.99%, which such limitations restrict Fairmount Funds Management LLC ("Fairmount") and its affiliates from exercising that portion of the warrants and converting those shares of preferred stock that would result in Fairmount and its affiliates owning, after exercise or conversion, a number of shares of common stock in excess of the applicable ownership limitation. At such time as Fairmount and its affiliates beneficially own 9.0% or less of the shares of common stock, the beneficial ownership limitation applicable to the shares of Series B Preferred Stock will automatically reduce to 9.99%. Fairmount serves as investment manager for Fairmount Fund II and Fairmount Fund III. Fairmount Fund II and Fairmount Fund III have delegated to Fairmount the sole power to vote and the sole power to dispose of all securities held in Fairmount Fund II and Fairmount Fund III's portfolios. Because Fairmount Fund II and Fairmount Fund III have divested themselves of voting and investment power over the securities they hold and may not revoke that delegation on less than 61 days' notice, Fairmount Fund II and Fairmount Fund III disclaim beneficial ownership of the securities they hold. As managers of Fairmount, Peter Harwin and Tomas Kiselak may be deemed to have voting and investment power over the shares held by Fairmount Fund II and Fairmount Fund III. Fairmount, Peter Harwin and Tomas Kiselak disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the entities and individuals listed is 200 Barr Harbor Drive, Suite 400, West Conshohocken, PA 19428.

(2) All of the shares listed in the table above are owned by funds or accounts managed by direct or indirect subsidiaries of FMR LLC, all of which shares are beneficially owned, or may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.

(3) Consists of (i) 3,205,865 shares of common stock held by Venrock Healthcare Capital Partners EG, L.P. ("VHCPEG"), (ii) 856,747 shares of common stock held by Venrock Healthcare Capital Partners III, L.P. ("VHCP3"), and (iii) 85,816 shares of common stock held by VHCP Co-Investment Holdings III, LLC ("VHCPCo3"). Excludes 405,980, 107,788 and 10,775 shares of common stock issuable upon the exercise of the pre-funded warrants held by VHCPEG, VHCP3 and VHCPCo3, respectively. The pre-funded warrants are subject to a beneficial ownership limitation of 9.99%, which such limitations restrict Venrock Healthcare Capital Partners and its affiliates from exercising that portion of the warrants that would result in Venrock Healthcare Capital Partners and its affiliates owning, after exercise, a number of shares of common stock in excess of the applicable ownership limitation. VHCP Management III, LLC ("VHCPM3") is the sole general partner of VHCP3 and the sole manager of VHCPCo3. VHCP Management EG, LLC ("VHCPM EG") is the sole general partner of VHCPEG. As voting members of VHCPM3 and VHCPM EG, Dr. Bong Koh and Nimish Shah may be deemed beneficial owners of any securities beneficially owned by VHCPM3 and VHCPM EG. The principal business address of each of these persons and entities is 7 Bryant Park, 23rd Floor, New York, NY 10018.

(4) Consists of 2,058,147 shares of common stock held in the aggregate by RTW Master Fund, Ltd. ("RTW Master Fund"), RTW Innovation Master Fund, Ltd. ("RTW Innovation Master Fund"), and RTW Biotech Opportunities Operating Ltd. ("RTW Biotech" and together with RTW Master Fund and RTW Innovation Fund, the "RTW Funds"). RTW Investments, LP ("RTW"), in its capacity as the investment manager of the RTW Funds, has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such securities. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the securities held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The principal business address of RTW Investments, LP is 40 10th Avenue, Floor 7, New York, NY 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.

(5) Includes (i) 852,338 shares of common stock, (ii) 421,503 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table and (iii) 248,599 shares of common stock issuable upon the vesting of restricted stock awards that will vest within 60 days of the date of this table.

(6) Includes 61,068 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table.

(7) Includes (i) 191 shares of common stock and (ii) 10,156 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table

(8) Includes 10,156 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table

(9) Includes (i) 92 shares owned by Investocor Trust, of which Dr. Bristow is the sole trustee and (ii) 117 shares owned by NFS as Custodian for Michael Bristow's IRA. Dr. Bristow and ARCA mutually agreed to conclude Dr. Bristow's employment effective April 3, 2024.

(10) Mr. Keuer resigned as named executive officer at the Merger Closing and his last day of employment was September 1, 2024, which termination was considered to be without "cause" related to a change in control for purposes of his employment agreement with ARCA.

(11) Mr. Dekker resigned as named executive officer at the Merger Closing and his last day of employment was September 1, 2024, which termination was considered to be without "cause" related to a change in control for purposes of his employment agreement with ARCA.

(12) Includes (i) 85,233 shares of common stock held by the Turtle Family Trust, for which Mr. Turtle serves as Trustee, (ii) 2,262 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table and (iii) 23,084 shares of common stock issuable upon the vesting of restricted stock awards that will vest within 60 days of the date of this table.

(13) Includes 35,713 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table

(14) Includes 25,058 shares of common stock issuable upon the exercise of options that will vest within 60 days of the date of this table

(15) See notes (1), (5), (6), (7), (8), (12), (13) and (14) above.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information with respect to all our equity compensation plans in effect as of December 31, 2024.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options (a)	Weighted Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuances under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Security Holders:			
2024 Stock Incentive Plan	388,567	$ 26.91	4,246,324(1)
2024 Employee Stock Purchase Plan	—	—	460,529(2)
2024 Equity Incentive Plan(3)	1,179,193	$ 6.27	—
Equity Compensation Plans Not Approved by Security Holders:			
Non-Plan Compensatory Warrants(4)	3,054,358	$ 7.80	—
Total	**4,622,118**	**$ 9.02**	**4,706,853**

(1) The 2024 Stock Incentive Plan (the "2024 SIP") provides for an automatic increase in the number of shares reserved for issuance thereunder on January 1 of each year through and including January 1, 2034 equal to (a) 5% of number of issued and outstanding shares of common stock plus outstanding preferred stock and shares underlying unexercised pre-funded warrants on an as-converted basis) (collectively, "Shares Outstanding") on December 31 of the immediately preceding year, or (b) a lesser amount as approved by the Board each year. Pursuant to this provision, the number of shares available for issuance under the 2024 SIP increased by 2,753,543 shares on January 1, 2025.

(2) The ESPP provides for an automatic annual increase in the number of shares reserved for issuance thereunder on January 1 of each year through and including January 1, 2034 equal to (a) 1% of the number of Shares Outstanding on December 31 of the immediately preceding year, or (2) a lesser amount as approved by the Board each year. Pursuant to this provision, the number of shares available for issuance under the ESPP increased by 550,709 shares on January 1, 2025.

(3) Stock options granted by Pre-Merger Oruka under the 2024 Equity Incentive Plan were assumed by the Company in connection with the Merger. No further awards may be made under the 2024 Equity Incentive Plan.

(4) Non-plan compensatory warrants granted by Pre-Merger Oruka were assumed by the Company in connection with the Merger. No further non-plan compensatory warrants are expected to be granted following the Merger.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Transactions

Other than the compensation agreements and other arrangements disclosed above under "Executive Compensation," below we describe the transactions to which we or Pre-Merger Oruka were or are a party since January 1, 2023, in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our or Pre-Merger Oruka's total assets at year-end for the last two completed fiscal years and in which our or Pre-Merger Oruka directors, executive officers, holders of more than 5% of our common stock, or members of their immediate family had a direct or indirect material interest.

ARCA Transactions

Transactions With ARCA's Former President and Chief Executive Officer

ARCA previously entered into unrestricted research grants with its former President and Chief Executive Officer's academic research laboratory at the University of Colorado. Funding of any unrestricted research grants was contingent upon ARCA's financial condition, and could be deferred or terminated at ARCA's discretion. There was no expense under these arrangements for the year ended December 31, 2024. Total expense under these arrangements for the year ended December 31, 2023 was $(91,000). In December 2023, ARCA made a payment of $125,000 for the grant period July 2022 through December 2023 under these arrangements. In April 2024, the President and Chief Executive Officer resigned.

Pre-Merger Oruka Transactions

Private Placements of Securities

Pre-Merger Oruka Series A Preferred Stock and Convertible Note Financing

On March 6, 2024, Oruka entered into a Convertible Note Purchase Agreement with Fairmount Healthcare Fund II, L.P. ("Fairmount Fund II"), whereby Oruka issued and sold to Fairmount Fund II (i) an aggregate of 20,000,000 shares of Pre-Merger Oruka Series A Preferred Stock at a purchase price of $0.15 per share and (ii) a convertible note (the "Convertible Note") with an initial principal amount of $25.0 million at an interest rate of 12% per annum, for aggregate gross proceeds of $28 million. Fairmount Fund II contributed the aggregate principal amount of $25.0 million and all accrued interest under the Convertible Note (unpaid accrued interest of $1.5 million divided by the conversion price of $66.62 ($5.55 prior to the impact of the Reverse Stock Split) per share) in exchange for Pre-Merger Oruka Common Stock and Pre-Merger Oruka pre-funded warrants in connection with the Pre-Merger Closing Financing (as defined below), immediately prior to the completion of the Merger. Fairmount Funds Management ("Fairmount") is the investment manager of Fairmount Fund II. Peter Harwin, one of our directors, is a managing member of Fairmount.

Pre-Merger Oruka Pre-Merger Closing Financing

On April 3, 2024, in connection with the execution of the Merger Agreement, Pre-Merger Oruka entered into the Subscription Agreement to consummate the Pre-Merger Closing Financing. Pursuant to the Subscription Agreement, the Financing Investors purchased 39,873,706 shares of Pre-Merger Oruka common stock and 9,664,208 Pre-Merger Oruka pre-funded warrants for gross proceeds of approximately $275.0 million (which includes $25.0 million of proceeds previously received from the issuance of the Convertible Note and accrued interest on such note, which converted to 4,764,032 shares of Pre-Merger Oruka common stock), immediately prior to the Merger Closing and before the effect of the Reverse Stock Split. Three of the investors or their affiliates were beneficial holders of more than 5% of Pre-Merger Oruka's capital stock, and the table below sets forth the number of shares of Pre-Merger Oruka common stock and Pre-Merger Oruka pre-funded warrants purchased by such holders at the closing of the Pre-Merger Closing Financing.

Participant	Shares of Pre-Merger Oruka Common Stock	Pre-funded Warrants of Pre-Merger Oruka	Total Purchase Price
Entities affiliated with Fairmount	5,139,797	9,271,241	$ 79,907,282(1)
Entities affiliated with Venrock Healthcare Capital Partners	5,011,172	392,967	$ 29,996,067
Entities affiliated with FMR LLC	4,503,445	—	$ 24,999,974

(1) Includes $25.0 million of proceeds previously received by Pre-Merger Oruka from the issuance of the Convertible Note and accrued interest on such note, with the remainder of the purchase price paid in cash.

Company Transactions

September 2024 Private Placement

On September 11, 2024, the Company entered into a Securities Purchase Agreement (the "SPA") with certain selling stockholders to consummate a private placement (the "Private Placement"). Pursuant to the SPA, the selling stockholders purchased (i) an aggregate of 5,600,000 shares of Common Stock, at a price per share of $23.00, (ii) an aggregate of 2,439 shares of Series A Preferred Stock, at a price per share of $23,000.00, and (iii) pre-funded warrants to purchase an aggregate of 680,000 shares of Common Stock at a purchase price of $22.999 per pre-funded warrant, which represents the per share purchase price of the Private Placement Common Shares less the $0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately $200.5 million. Three of the selling stockholders or their affiliates were beneficial holders of more than 5% of the Company's capital stock, and the table below sets forth the number of shares of Common Stock, Series A Preferred Stock and pre-funded warrants purchased by such holders at the closing of the Private Placement.

Participant	Shares of Common Stock	Series A Preferred Stock	Pre-Funded Warrants	Total Purchase Price
Entities affiliated with FMR LLC	2,105,000	830	—	$ 67,505,000
Entities affiliated with Venrock Healthcare Capital Partners	150,000	200	300,000	$ 14,949,700
Entities affiliated with Fairmount	275,000	160	—	$ 10,005,000

Our Relationship with Paragon and Paruka

We are party to a number of agreements with Paragon and Paruka. Paragon and Paruka do not beneficially own more than 5% of our capital stock through their joint holdings of our Common Stock. Fairmount beneficially owns more than 5% of our capital, one of Fairmount's employees serves on our Board, and Fairmount beneficially owns more than 5% of Paragon. Fairmount appointed Paragon's board of directors and has the contractual right to approve the appointment of any executive officers of Paragon, but is not the beneficial owner of Paragon's securities. Paruka is an entity formed by Paragon as a vehicle to hold equity in our Company in order to share profits with certain employees of Paragon.

In March 2024, Pre-Merger Oruka entered into the Option Agreements with Paragon and Paruka. Under the terms of the Option Agreements, Paragon identifies, evaluates and develops antibodies directed against certain mutually agreed therapeutic targets of interest to us. The Option Agreements include two selected targets, IL-23 (ORKA-001) and IL-17A/F (ORKA-002). Under each of the Option Agreements, we have the exclusive option to, on a research program-by-research program basis, be granted an exclusive, worldwide license to all of Paragon's right, title and interest in and to the intellectual property resulting from the applicable research program to develop, manufacture, and commercialize the antibodies and potential products directed to the selected targets (each, an "Option"), with the exception of pursuing ORKA-001 for the treatment of inflammatory bowel disease. In September 2024, we exercised our Option to acquire the rights to ORKA-001 and executed the corresponding license agreement (the "IL-23 License Agreement") on December 17, 2024. In December 2024 we exercised our Option to acquire the rights to ORKA-002 and executed the corresponding license agreement (the IL-17A/F License Agreement) on February 4, 2025. Under each license agreement we are required to make non-refundable milestone payments to Paragon of up to $12.0 million under each respective agreement upon the achievement of certain clinical development milestones, up to $10.0 million under each respective agreement upon the achievement of certain regulatory milestones, as well as a low single-digit percentage royalty for antibody products beginning on the first commercial sale in each program. From time to time, we can choose to add additional targets to the collaboration by mutual agreement with Paragon. During 2024, we accrued two $1.5 million milestone payments related to the achievement of development candidates as research and development expense in our consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. As of December 31, 2024, this amount is included under related party accounts payable and other current liabilities on the consolidated balance sheet.

Pursuant to the terms of the Option Agreements, the parties initiated certain Research Programs. Each Research Program is aimed at discovering, generating, identifying and/or characterizing antibodies directed to the respective target. For each Research Program, the parties established a Research Plan (each, a "Research Plan") that sets forth the activities that will be conducted, and the associated research budget. We and Paragon agreed on initial Research Plans that outlined the services that were performed commencing at inception of the arrangement related to IL-17 and IL-23. Our exclusive option with respect to each Research Program was exercisable at our sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Plan activities. There is no payment due upon exercise of an Option pursuant to the Option Agreements.

Pursuant to the Option Agreements, on a research program-by-research program basis following the finalization of the Research Plan for each respective research program, the Company was required to pay Paragon a one-time nonrefundable research initiation fee of $0.8 million related to the ORKA-001 program. This amount was recognized as a research and development expense during the period from February 6 (inception) to December 31, 2024. In June 2024, pursuant to the Option Agreements with Paragon, the Company completed the selection process of its development candidate for IL-23 antibodies for the ORKA-001 program. The Company was responsible for 50% of the development costs incurred through the completion of the IL-23 selection process. The Company received the rights to at least one selected IL-23 antibody in June 2024. During 2024, the Company exercised its option for ORKA-001 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in the Company's consolidated statement of operations and comprehensive loss. In addition, during the period from February 6, 2024 (inception) to December 31, 2024, the Company recorded a $2.5 million milestone payment related to the first dosing of a human subject in a Phase 1 trial of ORKA-001 in December 2024 as research and development expense in its consolidated statement of operations and comprehensive loss. The Company's share of development costs incurred during the period from February 6, 2024 (inception) to December 31, 2024 was $13.5 million, which was recorded as research and development expenses. An amount of $2.8 million related to ORKA-001 is included in related party accounts payable and other current liabilities as of December 31, 2024.

The Company is also required to reimburse Paragon $3.3 million for development costs related to ORKA-002 incurred by Paragon through December 31, 2023 and certain other development costs incurred by Paragon between January 1, 2024 and March 6, 2024 as stipulated by the Option Agreements. This amount was recognized as a research and development expense during the period from February 6 (inception) to December 31, 2024. The Company is also responsible for development costs incurred by Paragon from January 1, 2024 through the completion of the IL-17 selection process. The Company recognized an amount of $0.8 million payable to Paragon for the research initiation fee related to ORKA-002 following the finalization of the ORKA-002 research plan. This was recognized as research and development expenses in the period from February 6 (inception) to December 31, 2024. During the period from February 6, 2024 (inception) to December 31, 2024, the Company exercised its option for ORKA-002 and recorded a $1.5 million milestone payment related to the achievement of development candidate as research and development expense in its consolidated statement of operations and comprehensive loss. The Company accounted for development costs of $7.8 million during the period from February 6, 2024 (inception) to December 31, 2024 as research and development expenses. An amount of $2.7 million related to ORKA-002 is included in related party accounts payable and other current liabilities as of December 31, 2024.

Furthermore, the Option Agreements provide for an annual equity grant of warrants to purchase a number of shares equal to 1.00% of the then outstanding shares of our stock, on a fully diluted basis, on each of December 31, 2024 and December 31, 2025, during the term of the Option Agreements, at the fair market value determined by our Board.

Indemnification Agreements and Insurance

We have entered into an indemnification agreement with each of our directors and senior officers and purchased directors' and officers' liability insurance. The indemnification agreements require us to indemnify our directors and officers to the fullest extent permitted under Delaware law.

Review, Approval or Ratification of Transactions with Related Parties

Prior to the Merger Closing, Pre-Merger Oruka did not have a formal policy regarding approval of transactions with related parties. All disclosable transactions with related parties that occurred prior to the Merger Closing were approved by the directors not interested in such transactions, pursuant to Section 144(a)(1) of the DGCL.

Our Board has adopted a written related person transactions policy. Under this policy, our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our Common Stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our Audit Committee, or a committee composed solely of independent directors in the event it is inappropriate for our Audit Committee to review such transaction due to a conflict of interest. The policy provides that, subject to limited exceptions, any transaction, arrangement or relationship or series of similar transactions, arrangements or relationships in which (1) the aggregate amount involved since the beginning of the Company's last completed fiscal year exceeds or is expected to exceed $120,000, (2) the Company or any of our subsidiaries is a participant, and (3) any related person has or will have a direct or indirect interest, will be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee will consider the material facts and other factors it deems appropriate, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Director Independence

Our Board has reviewed the independence of all directors in light of each director's (or any family member's, if applicable) affiliations with the Company and members of management, as well as significant holdings of our securities and all other facts and circumstances that the Board has deemed relevant in determining the independence of each director. The Board has determined that each of the directors other than Lawrence Klein, our current President and Chief Executive Officer, including Kristine Ball, Carl Dambkowski, Peter Harwin, Samarth Kulkarni and Cameron Turtle, qualify as "independent directors" as defined by the Nasdaq listing rules.

Nasdaq listing rules have objective tests and a subjective test for determining who is an "independent director." The subjective test states that an independent director must be a person who lacks a relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Board has not established categorical standards or guidelines to make these subjective determinations but considers all relevant facts and circumstances.

In addition, ARCA's board of directors determined that former directors Drs. Linda Grais, Anders Hove and Raymond Woosley, and Messrs. Robert Conway, Daniel Mitchell and James Flynn were independent during the period each served on the Board in 2024. ARCA's board of directors determined Dr. Michael R. Bristow, ARCA's former President and Chief Executive Officer, was not an independent director in 2024 by virtue of his employment relationship with ARCA.

Item 14. Principal Accountant Fees and Services.

Principal Accountant Fees and Services

The following is a summary of the audit fees billed and expected to be billed for the indicated fiscal year to Oruka by PricewaterhouseCoopers LLP ("PwC"), Pre-Merger Oruka's independent registered public accounting firm and Oruka's independent registered public accounting firm on and after August 30, 2024, and the fees billed by PwC for all other services rendered during the indicated fiscal year. All services associated with such fees on and after August 30, 2024 were pre-approved by our Audit Committee in accordance with the "Pre-Approval Policies and Procedures" described below.

	Fiscal Year ended December 31, 2024
Audit Fees[(1)]	$ 1,928,000
Audit-Related Fees	—
Tax Fees	—
All Other Fees[(2)]	2,000
Total	$ 1,930,000

(1) Audit Fees consisted of fees and expenses covering the audit of our consolidated financial statements, reviews of our interim quarterly reports, accounting and financial reporting consultations, and the issuance of consents and comfort letters in connection with registration statement filings with the Securities and Exchange Commission (the "SEC").
(2) All Other Fees consist of all other services and fees billed for an annual subscription to PwC's online resource library.

Pre-Approval Policies and Procedures

In connection with the Merger Closing, our Board and Audit Committee adopted a policy and procedures for the pre-approval of audit and non-audit services performed by our independent registered public accounting firm. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the Audit Committee for each engagement of our independent registered public accounting firm to perform other audit-related or non-audit services. The Audit Committee does not delegate its responsibility to pre-approve services performed by our independent registered public accounting firm to any member of management. The Audit Committee has delegated authority to the Audit Committee chair to pre-approve audit and non-audit services to be provided to us by our independent registered public accounting firm provided that the fees for such services do not exceed $100,000. Any pre-approval of services by the Audit Committee chair pursuant to this delegated authority must be reported to the Audit Committee at its next regularly scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) Financial Statements

See Index to Financial Statements included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(3) List of Exhibits required by Item 601 of Regulation S-K

Exhibit Number	Description	Incorporation By Reference		
		Form	Exhibit No.	Filing Date
2.1†	Agreement and Plan of Merger and Reorganization, dated as of April 3, 2024, by and among ARCA biopharma, Inc., Atlas Merger Sub Corp., Atlas Merger Sub II, LLC and Oruka Therapeutics, Inc.	8-K	2.1	4/3/2024
3.1	Second Amended and Restated Certificate of Incorporation	8-K	3.5	9/5/2024
3.2	Amended and Restated Bylaws	8-K	3.6	9/5/2024
3.3	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock	S-1/A	3.1(b)	5/24/2013
3.4	Certificate of Elimination of Series A Convertible Preferred Stock, dated August 29, 2024	8-K	3.8	9/5/2024
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock	8-K	3.9	9/5/2024
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock	8-K	3.1	9/13/2024
4.1	Description of Securities			Filed herewith
4.2	Investors' Rights Agreement by and among Oruka Therapeutics, Inc. and certain investors, dated March 6, 2024	S-4	4.3	5/14/2024
4.3	Form of Pre-Funded Warrant, dated August 29, 2024			Filed herewith
4.4	Form of Pre-Funded Warrant, dated September 13, 2024	8-K	4.1	9/13/2024
10.1#	Oruka Therapeutics, Inc. 2024 Stock Incentive Plan	8-K	10.10	9/5/2024
10.2#	Oruka Therapeutics, Inc. 2024 Employee Stock Purchase Plan	8-K	10.11	9/5/2024
10.3#	Amended and Restated 2024 Equity Incentive Plan	S-4	10.40	5/14/2024
10.4#	Second Amendment to the Oruka Therapeutics, Inc. Amended and Restated 2024 Equity Incentive Plan	8-K	10.13	9/5/2024
10.5#	Form of Employee Warrant Agreement	8-K	10.16	9/5/2024
10.6#	Form of Grant Notice for Nonqualified Stock Option and Standard Terms and Conditions for Stock Options (Directors)	S-8	99.2	11/14/2024
10.7#	Form of Grant Notice for Stock Option and Standard Terms and Conditions for Stock Options (Employees)	S-8	99.3	11/14/2024
10.8#	Form of Stock Option Agreement under the Oruka Therapeutics, Inc. Amended and Restated 2024 Equity Incentive Plan	S-4	10.42	5/14/2024
10.9#	Separation Agreement and Release by and between Michael Bristow and ARCA biopharma, Inc., dated April 3, 2024	8-K	10.1	4/4/2024
10.10#	Second Amendment to Retention Bonus Letter by and between ARCA biopharma, Inc. and Thomas A. Keuer, dated April 22, 2024	8-K	10.1	4/23/2024
10.11#	Second Amendment to Retention Bonus Letter by and between ARCA biopharma, Inc. and C. Jeffrey Dekker	8-K	10.2	4/23/2024
10.12†#	Consulting Agreement, effective as of August 30, 2024, by and between the Company and Jeff Dekker	8-K	10.25	9/5/2024

10.13#	Amended and Restated Director Offer Letter, dated March 22, 2024, by and between Oruka Therapeutics, Inc. and Samarth Kulkarni	S-4	10.43	5/14/2024
10.14#	Director Offer Letter, dated April 24, 2024, by and between Oruka Therapeutics, Inc. and Kristine Ball	S-4	10.44	5/14/2024
10.15#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Lawrence Klein, dated October 3, 2024	8-K	10.1	10/4/2024
10.16#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Arjun Agarwal, dated October 3, 2024	8-K	10.2	10/4/2024
10.17*#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Paul Quinlan, dated October 1, 2024			Filed herewith
10.18*#	Amended and Restated Employment Letter Agreement by and between Oruka Therapeutics, Inc. and Joana Goncalves, dated October 1, 2024			Filed herewith
10.19*#	Form of Indemnification Agreement			Filed herewith
10.20*	Non-Employee Directors Compensation Program			Filed herewith
10.21	Form of Lock-Up Agreement	8-K	10.4	4/3/2024
10.22	Form of Amendment to Subscription Agreement	8-K	10.1	7/9/2024
10.23	Form of Amended & Restated Subscription Agreement	8-K	10.2	7/9/2024
10.24	Form of Registration Rights Agreement, dated August 29, 2024	10-Q	10.4	11/13/2024
10.25†	Securities Purchase Agreement by and between Oruka Therapeutics, Inc. and each of the entities listed on Exhibit A thereto, dated September 11, 2024	8-K	10.1	9/13/2024
10.26	Form of Registration Rights Agreement, dated as of September 13, 2024	8-K	10.2	9/13/2024
10.27	Asset Purchase Agreement, dated August 14, 2024, by and between ARCA biopharma, Inc. and Genvara Biopharma, Inc.	8-K	10.1	8/15/2024
10.28†	Amended and Restated Antibody Discovery and Option Agreement (IL-17) by and among Paragon Therapeutics, Inc., Paruka Holding, LLC, and Oruka Therapeutics, Inc. dated March 28, 2024	S-4/A	10.50	6/18/2024
10.29*†	IL-17 License Agreement by and between Paragon Therapeutics, Inc. and Oruka Therapeutics, Inc., dated February 4, 2025			Filed herewith
10.30†	Amended and Restated Antibody Discovery and Option Agreement (IL-23) by and among Paragon Therapeutics, Inc., Paruka Holding, LLC, and Oruka Therapeutics, Inc. dated March 28, 2024	S-4/A	10.51	6/18/2024
10.31*†	IL-23 License Agreement by and between Paragon Therapeutics, Inc. and Oruka Therapeutics, Inc., dated December 17, 2024			Filed herewith
10.32*†	Cell Line License Agreement by and between WuXi Biologics Ireland Limited and Oruka Therapeutics, Inc., dated March 4, 2024			Filed herewith
10.33*†	Amendment No. 1 to the Cell Line License Agreement by and between WuXi Biologics Ireland Limited and Oruka Therapeutics, Inc., dated November 20, 2024			Filed herewith
14.1	Code of Business Conduct and Ethics	8-K	14.1	9/5/2024
16.1	Letter from KPMG LLP, dated September 5, 2024	8-K	16.1	9/5/2024
19.1*	Insider Trading Policy			Filed herewith
21.1*	List of subsidiaries of the Registrant			Filed herewith
23.1*	Consent of Independent Registered Public Accounting Firm			Filed herewith
24.1*	Power of Attorney (Incorporated by reference to the signature page of this Annual Report on Form 10-K)			Filed herewith

31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934	Filed herewith
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) promulgated under the Securities Exchange Act of 1934	Filed herewith
32.1**	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934	Furnished herewith
97.1*	Incentive Compensation Clawback Policy	Filed herewith
101.INS*	Inline XBRL Instance Document	Filed herewith
101.SCH*	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document	Filed herewith
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

* Filed herewith.

** Furnished herewith. The certifications on Exhibit 32.1 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

# Indicates management contract or compensatory plan.

† Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any exhibits or schedules so furnished. Certain portions of this exhibit (indicated by "[***]") have been omitted because they are both (i) not material and (ii) is the type of information that the registrant both customarily and actually treats as private and confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Oruka Therapeutics, Inc.

Date: March 6, 2025

By: /s/ Lawrence Klein
Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dr. Lawrence Klein and Mr. Arjun Agarwal, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K and to file same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lawrence Klein Lawrence Klein	Chief Executive Officer & Director (Principal Executive Officer)	March 6, 2025
/s/ Arjun Agarwal Arjun Agarwal	Senior Vice President, Finance and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 6, 2025
/s/ Samarth Kulkarni Samarth Kulkarni	Chairman of the Board	March 6, 2025
/s/ Kristine Ball Kristine Ball	Director	March 6, 2025
/s/ Carl Dambkowski Carl Dambkowski	Director	March 6, 2025
/s/ Peter Harwin Peter Harwin	Director	March 6, 2025
/s/ Cameron Turtle Cameron Turtle	Director	March 6, 2025

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes the material terms of the capital stock of Oruka Therapeutics, Inc. ("we," "us," "our" or the "Company"), as well as other material terms of certain provisions of the Delaware General Corporation Law (the "DGCL"), our second amended and restated certificate of incorporation ("Certificate of Incorporation") and amended and restated bylaws ("Bylaws"), both of which have been filed as exhibits to our Annual Report on Form 10-K of which this Exhibit 4.1 is a part, and are incorporated by reference herein. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Certificate of Incorporation and Bylaws. We encourage you to read our Certificate of Incorporation, our Bylaws, and the applicable provisions of the DGCL for more information.

Our authorized capital stock consists of 545,000,000 shares of Common Stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"), of which 251,504 shares have been designated as Series B Preferred Stock, $0.001 par value per share (the "Series B Preferred Stock").

As of December 31, 2024, there were 37,440,510 shares of our Common Stock and 137,138 shares of Series B Preferred Stock outstanding.

Common Stock

Our Certificate of Incorporation authorizes the issuance of up to 545,000,000 shares of Common Stock. All outstanding shares of Common Stock are validly issued, fully paid and nonassessable.

Dividend rights

Subject to preferences that may apply to any shares of Preferred Stock outstanding at the time, the holders of our Common Stock are entitled to receive dividends out of funds legally available if our board of directors (our "Board"), in its discretion, determines to issue dividends and then only at the times and in the amounts that our Board may determine.

Voting rights

Pursuant to our Bylaws, holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our Certificate of Incorporation. Accordingly, pursuant to our Certificate of Incorporation, holders of a majority of the shares of our Common Stock are able to elect all of our directors. Our Certificate of Incorporation establishes a classified Board, divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No preemptive or similar rights

Our Common Stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to receive liquidation distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our Common Stock and any participating Preferred Stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of Preferred Stock.

Preferred Stock

Under the terms of our Certificate of Incorporation, our Board is authorized, subject to limitations prescribed by Delaware law, to issue up to 5,000,000 shares of Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Subject to any certificates of designation, the Board can also increase or decrease the number of shares of any series of Preferred Stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our Board may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our Common Stock. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company and might adversely affect the market price of our Common Stock and the voting and other rights of the holders of our Common Stock.

Series B Preferred Stock

Certain holders of our Series B Preferred Stock are entitled to receive dividends on shares of Series B Preferred Stock equal to, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of our Common Stock. Except as provided in the Series B Certificate of Designation or as otherwise required by law, the Series B Preferred Stock does not have voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock: (a) (i) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (ii) alter or amend the Series B Certificate of Designation, or (iii) amend or repeal any provision of, or add any provision to, our Certificate of Incorporation or Bylaws in a manner that adversely affects any rights of the holders of the Series B Preferred Stock, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series B Preferred Stock, regardless of whether any of the foregoing actions will be by means of amendment to the Certificate of Incorporation or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (b) issue further shares of Series B Preferred Stock beyond those contemplated for issuance in the Merger Agreement or increase or decrease (other than by conversion) the number of authorized shares of Series B Preferred Stock, (c) at any time while at least 30% of the originally issued Series B Preferred Stock remains issued and outstanding, consummate either: (x) any Fundamental Transaction (as defined in the Series B Certificate of Designation) or (y) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of our capital stock immediately after such transaction, or (d) enter into any agreement with respect to any of the foregoing. The Series B Preferred Stock shall rank on parity with the Common Stock as to the distribution of assets upon any liquidation, dissolution, or winding-up of the Company. Each share of Series B Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. As of December 31, 2024, each outstanding share of Series B Preferred Stock was convertible into common stock at a ratio of approximately 83.3332:1.

Anti-Takeover Provisions

The provisions of Delaware law, our Certificate of Incorporation and our Bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our Company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our Board. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaw Provisions

Our Certificate of Incorporation and our Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our Company, including the following:

- ***Board of Directors vacancies***. Our Certificate of Incorporation and Bylaws require that the Board, and not stockholders, fill any directorships that become vacant or are created by an increase in the authorized number of directors by the affirmative vote of a majority of the remaining directors or by the sole remaining director. In addition, pursuant to our bylaws, the number of directors constituting our Board is permitted to be set only by a resolution adopted by a majority vote of the entire Board. These provisions prevent a stockholder from increasing the size of our Board and then gaining control of the Board by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of the Board but promotes continuity of management.

- ***Classified board***. Our Certificate of Incorporation provides that our Board is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

- ***Stockholder action; special meetings of stockholders***. Our Certificate of Incorporation and Bylaws provide that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our Bylaws or remove directors without holding a meeting of our stockholders called in accordance with our Bylaws. Further, our Bylaws provide that special meetings of stockholders may be called only by the Board, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- ***Advance notice requirements for stockholder proposals and director nominations***. Our Bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our Bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our Company.

- ***No cumulative voting***. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our Certificate of Incorporation and Bylaws do not provide for cumulative voting.

- ***Directors removed only for cause***. Our Bylaws provide that stockholders may remove directors only for cause, and only by the affirmative vote of the holders of at least 66 2/3% of the voting power of the stock outstanding and entitled to vote generally in the election of directors.

- ***Amendment of charter provisions***. Any amendment of the above provisions in our Certificate of Incorporation requires approval by holders of at least two-thirds of our outstanding Common Stock.

- ***Issuance of Preferred Stock***. Our Board has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of Preferred Stock with rights and preferences, including voting rights, designated from time to time by our Board. The existence of authorized but unissued shares of Preferred Stock enables our Board to render more difficult or to discourage an attempt to obtain control of us by merger, tender offer, proxy contest or other means.

- ***Choice of forum***. Our Certificate of Incorporation and Bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any complaint asserting any internal corporate claims. In addition, our Bylaws also provide that the federal district courts of the United States are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions do not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock and Series B Preferred Stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royall Street, Suite 101, Canton, MA 02021, and its telephone number is (800) 344-5128.

Listing

Our Common Stock is listed on The Nasdaq Global Market under the symbol "ORKA."

Exhibit 4.3

THE OFFER AND SALE OF THESE SECURITIES AND THE SECURITIES ISSUABLE UPON EXERCISE OF THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY APPLICABLE STATE SECURITIES LAWS. THE SECURITIES MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED, ASSIGNED OR OTHERWISE DISPOSED OF (I) IN THE ABSENCE OF (A) AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OR (B) AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN EACH CASE IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS OR BLUE SKY LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY AND ITS TRANSFER AGENT OR (II) UNLESS SOLD PURSUANT TO RULE 144 UNDER THE SECURITIES ACT. NOTWITHSTANDING THE FOREGOING, THE SECURITIES MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN OR FINANCING ARRANGEMENT SECURED BY THE SECURITIES; PROVIDED, THAT IN CONNECTION WITH ANY FORECLOSURE OR TRANSFER OF THE SECURITIES, THE TRANSFEROR SHALL COMPLY WITH THE PROVISIONS HEREIN AND IN THE SECURITIES PURCHASE AGREEMENT, AND UPON FORECLOSURE OR TRANSFER OF THE SECURITIES, SUCH FORECLOSING PERSON OR TRANSFEREE SHALL COMPLY WITH ALL PROVISIONS CONTAINED HEREIN AND IN THE SECURITIES PURCHASE AGREEMENT.

ORUKA THERAPEUTICS, INC.

PRE-FUNDED WARRANT TO PURCHASE COMMON STOCK

Warrant No. W-[001] Original Issue Date: August 29, 2024

Oruka Therapeutics, Inc., a Delaware corporation (the "*Company*"), hereby certifies that, for value received, [_____] or its permitted registered assigns (the "*Holder*"), is entitled to purchase from the Company up to a total of [_____] shares of common stock, $0.0001 par value per share (the "*Common Stock*"), of the Company (each such share, a "*Warrant Share*" and all such shares, the "*Warrant Shares*") at an exercise price per share equal to $0.01 per share (as adjusted from time to time as provided in Section 9 herein, the "*Exercise Price*"), at any time and from time to time on or after August 29, 2024(the "*Original Issue Date*") and until this Pre-Funded Warrant is exercised in full (the "*Expiration Date*"), and subject to the following terms and conditions:

This Pre-Funded Warrant (this "*Warrant*") is one of a series of similar warrants issued pursuant to that certain Subscription Agreement, dated April 3, 2024, by and among the Company and the Purchasers identified therein (the "*Purchase Agreement*"). All such Warrants are referred to herein, collectively, as the "*Warrants*."

1. Definitions. In addition to the terms defined elsewhere in this Warrant, capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Purchase Agreement.

2. Registration of Warrants. The Company shall register this Warrant, upon records to be maintained by or on behalf of the Company for that purpose (the "*Warrant Register*"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. Registration of Transfers. Subject to the restrictions on transfer set forth in Section 7.01 of the Purchase Agreement and compliance with all applicable securities laws, the Company shall register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, with the Form of Assignment attached as Schedule 2 hereto duly completed and signed, to the Company's transfer agent or to the Company at its address specified in the Purchase Agreement and (x) delivery, at the request of the Company, of an opinion of counsel reasonably satisfactory to the Company to the effect that the transfer of such portion of this Warrant may be made pursuant to an available exemption from the registration requirements of the Securities Act and all applicable state securities or blue sky laws and (y) delivery by the transferee of a written statement to the Company certifying that the transferee is an "accredited investor" as defined in Rule 501(a) under the Securities Act and making the representations and certifications set forth in Section 3 of the Purchase Agreement, to the Company at its address specified in the Purchase Agreement. Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a "*New Warrant*") evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall prepare, issue and deliver at its own expense any New Warrant under this Section 3.

4. Exercise and Duration of Warrants.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Original Issue Date and through and including 5:30 P.M., New York City time, on the Expiration Date, subject to the conditions and restrictions contained in this Warrant. At 5:30 P.M., New York City time, on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value and this Warrant shall be terminated and no longer outstanding.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the "*Exercise Notice*"), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice pursuant to Section 10 below). The date on which the Exercise Notice is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "*Exercise Date*." Within two (2) days following the delivery of the Exercise Notice (the "*Payment Deadline*"), the Holder shall make payment with respect to the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice); provided that the Company's obligations to deliver such Warrant Shares shall be delayed on a day-for-day basis each day after the Payment Deadline such payment of the Exercise Price is not paid. The delivery by (or on behalf of) the Holder of the Exercise Notice and the applicable Exercise Price as provided above shall constitute the Holder's certification to the Company that its representations contained in Sections 3.01 and 3.03 through 3.08 of the Purchase Agreement are true and correct as of the Exercise Date as if remade in their entirety (or, in the case of any transferee Holder that is not a party to the Purchase Agreement, such transferee Holder's certification to the Company that such representations are true and correct as to such transferee Holder as of the Exercise Date). The Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date the final Exercise Notice is delivered to the Company; provided that delivery of an electronic copy of the Warrant for surrender shall be sufficient and Holder shall not be required to surrender any physical copy of the Warrant, provide a medallion or other bank guarantee or take any similar action in connection therewith. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares, if any. For purposes hereof, "*Trading Day*" means (i) if the Warrant Shares are traded on a National Exchange, any day on which the Warrant Share is traded on a National Exchange or (ii) if the Warrant Shares are not traded on a National Exchange, a Business Day.

(c) The aggregate exercise price of this Warrant, except for a nominal exercise price of $0.01 per Warrant Share, was pre-funded to the Company on or prior to the Original Issue Date and, consequently, no additional consideration (other than the nominal Exercise Price) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever, including in the event this Warrant shall not have been exercised prior to the Expiration Date.

5. Delivery of Warrant Shares.

(a) Subject to Section 4(b), upon exercise of this Warrant, the Company shall promptly (but no later than two (2) Trading Days after the Exercise Date (or three (3) Trading Days after the Exercise Date if the last of the Exercise Notice, the Exercise Price (if applicable) and the opinion of counsel referred to below in this Section 5(a) (if applicable) is delivered after 5:00 P.M., New York City time, on the Exercise Date) or as soon as reasonably practicable in the event that a certificate is requested) issue or cause to be issued and cause to be delivered to or upon the written order of the Holder and in such name or names as the Holder may designate (provided that, if the Holder directs the Company to deliver a certificate for the Warrant Shares in a name other than that of the Holder or an Affiliate of the Holder, it shall deliver to the Company on the Exercise Date an opinion of counsel reasonably satisfactory to the Company to the effect that the issuance of such Warrant Shares in such other name may be made pursuant to an available exemption from the registration requirements of the Securities Act and all applicable state securities or blue sky laws), (i) an electronic delivery of the Warrant Shares to the Holder's account at the Depository Trust Company ("*DTC*") or a similar organization, or (ii), if requested by the Holder, a certificate for the Warrant Shares issuable upon such exercise, free of restrictive legends, unless in the case of clause (i) and (ii) a registration statement covering the resale of the Warrant Shares and naming the Holder as a selling stockholder thereunder is not then effective or the Warrant Shares are not freely transferable without volume and manner of sale restrictions pursuant to Rule 144 under the Securities Act, in which case such Holder shall receive a book-entry notation for the Warrant Shares issuable upon such exercise with appropriate restrictive legends. The Holder, or any Person permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date. If the Warrant Shares are to be issued free of all restrictive legends, the Company shall, upon the written request of the Holder, use its commercially reasonable efforts to deliver, or cause to be delivered, Warrant Shares hereunder electronically through DTC or another established clearing corporation performing similar functions, if available; provided, that, the Company may, but will not be required to, change its transfer agent if its current transfer agent cannot deliver Warrant Shares electronically through such a clearing corporation.

(b) To the extent permitted by law, the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 12 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same.

(c) In addition to any other rights available to the Holder, if the Company fails to cause its transfer agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 5(a) above pursuant to an exercise on or before the deadline set forth in this Section 5, and if, after such date, the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "*Buy-In*"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Warrant Shares upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of the Warrant Shares upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense in respect of the issuance of the Warrant Shares, all of which taxes and expenses shall be paid by the Company; *provided*, *however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liabilities that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are initially issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price (or upon a "cashless exercise" pursuant to Section 10) in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all commercially reasonable actions as may be necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

9. Certain Adjustments. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares, or (iii) combines its outstanding shares of Common Stock into a smaller number of shares, then in each such case, the Exercise Price shall be multiplied by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph) or (iii) rights or warrants to subscribe for or purchase any security, or (iv) any other asset (in each case, "*Distributed Property*"), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein. Notwithstanding anything herein to the contrary, the foregoing provisions in this Section 9(b) shall not apply to, or be triggered by, any rights issued by the Company (either separately or that attach to any securities of the Company) in connection with any stockholders rights agreement, poison pill or other similar anti-takeover provision under the Company's certificate of incorporation, bylaws or other documents.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding, the Company effects a "*Fundamental Transaction*" (defined as (i) any merger or consolidation of the Company with or into another Person, including, for avoidance of doubt, the Merger, (ii) any sale of all or substantially all of the Company's and its subsidiaries' assets, taken as a whole, in one or a series of related transactions, (iii) any reclassification of the Common Stock (other than a change to par value, or from par value to no par value or changes resulting from a combination or subdivision), (iv) any tender offer or exchange offer (whether by the Company or another Person) that is accepted by holders of capital stock representing more than 50% of the outstanding Common Stock of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (v) any business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital stock of the Company (except for any such transaction in which the stockholders of the Company immediately prior to such transaction maintain, in substantially the same proportions, the voting power of such Person immediately after the transaction) or (vi) any statutory exchange of the outstanding shares of Common Stock, as a result of which, the holders of the Common Stock would be entitled to receive, or their Common Stock would be converted into, or exchanged for, shares, stock, other securities, or other property or assets (including cash or any combination thereof)), then, to the extent then permitted under applicable laws, rules and regulations (including the rules of the Nasdaq Stock Market or any exchange on which the Common Stock is then listed), upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, the same kind and amount of securities, cash, assets or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "*Alternate Consideration*"). Except for the Merger pursuant to the Merger Agreement, the Company shall not effect any such Fundamental Transaction unless prior to or simultaneously with the consummation thereof, any successor to the Company or surviving entity shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this Section 9(c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to Section 9(a), the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the increased or decreased number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 9 shall be rounded down to the nearest whole cent or the nearest whole share, as applicable.

(f) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(g) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company, (ii) enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least three (3) Trading Days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its subsidiaries and the Company is subject to the reporting requirements of the Exchange Act, the Company shall use commercially reasonable efforts to promptly file the information contained in such notice with the Commission pursuant to a Current Report on Form 8-K.

10. Payment of Exercise Price. The Holder shall pay the Exercise Price in immediately available funds by wire transfer to an account designated by the Company; provided, however, that the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price at such time through a "cashless exercise", in which event the Company shall issue to the Holder the number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = the VWAP per share of Common Stock on the National Exchange on the Trading Day immediately preceding the Exercise Date (the "*Closing Sale Price*");

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

For purposes of this Warrant:

"*VWAP*" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a National Exchange, the daily volume weighted average price of a share of Common Stock for such date (or the nearest preceding date) on the National Exchange on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), or (b) if the Common Stock is not then listed on any National Exchange, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, and the holding period of the Warrant Shares being issued may be tacked on to the holding period of this Warrant, the Warrant Shares shall take on the characteristics of the Warrants being exercised. The Company agrees not to take any position to the contrary.

11. Company-Elected Conversion. The Company shall provide to the Holder prompt written notice if after the Original Issue Date the Company is unable to issue the Warrant Shares without restrictive legend, because the Commission has issued a stop order with respect to, or the Commission or Company has otherwise suspended or withdrawn, a registration statement covering the resale of the Warrant Shares, either temporarily or permanently, or otherwise (each a "*Restrictive Legend Event*"). To the extent that (A) a Restrictive Legend Event occurs, (B) at such time the Warrant Shares would be saleable under Rule 144 without compliance with the manner of sale or volume restrictions, (C) the Company has delivered the notice described in the immediately preceding sentence, and (D) the Holder attempts to exercise the Warrant after receipt of such notice by paying cash, the Company shall (i) if the Fair Market Value (as calculated above) of the Warrant Shares is greater than the Exercise Price, provide written notice to the Holder that the Company will deliver that number of Warrant Shares to the Holder as should be delivered in a cashless exercise in accordance with Section 10, and return to the Holder all consideration paid to the Company in connection with the Holder's attempted exercise of this Warrant (a "*Company-Elected Conversion*"), or (ii) at the election of the Holder to be given within five (5) days of receipt of notice of a Company-Elected Conversion, the Holder shall be entitled to rescind the previously submitted Exercise Notice and the Company shall return all consideration paid by Holder for such Warrant Shares upon such rescission.

12. Limitations on Exercise. Notwithstanding anything to the contrary contained herein, the number of Warrant Shares that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its Attribution Parties as determined in accordance with Section 13(d) of the Exchange Act, does not exceed 9.9999% (the "*Maximum Percentage*") of the total number of then issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise). For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by the Holder and its Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (i) exercise of the remaining, unexercised portion of this Warrant beneficially owned by such Person and its Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by the Holder and its Attribution Parties (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein; provided that in no event shall the aggregate number of shares beneficially owned by the Holder and its Affiliates, calculated in accordance with Section 13(d) of the Exchange Act, exceed the Maximum Percentage. Except as set forth in the preceding sentence (other than the proviso thereto), for purposes of this paragraph (including the proviso in the immediately preceding sentence), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act; it being acknowledged by the Holder that the Company is not representing to such Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the rules promulgated thereunder and such Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 12 applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of a Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder and its Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 12, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) if the Company is subject to the reporting requirements of the Exchange Act, the Company's most recent Form 10-Q or Form 10-K, as the case may be, (y) a more recent public announcement by the Company or (z) any other notice by the Company or its transfer agent setting forth the number of shares of Common Stock outstanding. Upon the written request of the Holder, the Company shall within three (3) Trading Days confirm in writing to such Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including the Warrants, by the Holder and its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. By written notice to the Company, the Holder may from time to time increase or decrease the Maximum Percentage to any other percentage not in excess of 9.9999% specified in such notice; provided, that (i) any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, and (ii) any such increase or decrease will apply only to the Holder and not to any other holder of Warrants. The provisions of this paragraph shall not apply to the Holder if the aggregate number of shares beneficially owned by the Holder and its Affiliates, calculated in accordance with Section 13(d) of the Exchange Act, exceed 9.9999% immediately prior to the Closing. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 12 to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. Any purported delivery of any number of shares of Common Stock or any other security upon exercise of this Warrant shall be void and have no effect to the extent, but only to the extent, that before or after such delivery, the exercising Holder, together with its Attribution Parties, would have beneficial ownership in excess of the Maximum Percentage. For purposes hereof, "*Attribution Parties*" means, collectively, the following Persons and entities: (i) any direct or indirect Affiliates of the Holder, (ii) any Person acting or who reasonably could be deemed to be acting as a group together with the Holder or any of the foregoing and (iii) any other Persons whose beneficial ownership of Common Stock reasonably could be aggregated with the Holder's and the other Attribution Parties for purposes of Section 13(d) or Section 16 of the Exchange Act (for clarity, the purpose of the foregoing is to subject collectively the Holder and all other Attribution Parties to the Maximum Percentage).

13. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based on the Closing Sale Price) for any such fractional shares.

14. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via email at the email address specified in the Purchase Agreement prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via email at the email address specified in the Purchase Agreement on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, and (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery. The address and email address of a Person for such notices or communications shall be as set forth in the Purchase Agreement unless changed by such Person by two (2) Trading Days' prior written notice to the other Persons in accordance with this Section 14.

15. Warrant Agent. The Company shall serve as warrant agent under this Warrant. Upon notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or stockholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

16. Miscellaneous.

(a) No Rights as a Stockholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (except upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) No Avoidance. Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate or articles of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

(c) Successors and Assigns. Subject to the restrictions on transfer set forth in this Warrant and in Section 7.01 of the Purchase Agreement, and compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and permitted assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(d) Authorized Shares. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the National Exchange upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

(e) Amendment and Waiver. Except as otherwise provided herein and subject to the restrictions set forth in Section 9.01 of the Purchase Agreement, the provisions of the Warrants may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holders of Warrants representing no less than a majority of the Warrant Shares obtainable upon exercise of the Warrants then outstanding.

(f) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(g) Governing Law; Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this warrant shall be governed by and construed and enforced in accordance with the laws of the state of New York, without regard to the principles of conflicts of law thereof. Each of the Company and the Holder hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City and County of New York for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the transaction documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such courts. Each of the Company and the Holder hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such person at the address in effect for notices to it under the purchase agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Each of the Company and the Holder hereby waives all rights to a trial by jury.

(h) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(i) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

ORUKA THERAPEUTICS, INC.

By: _____
Name: Lawrence Klein
Title: Chief Executive Officer

SCHEDULE 1

FORM OF EXERCISE NOTICE

[To be executed by the Holder to purchase shares of Common Stock under the Warrant]

Ladies and Gentlemen:

(1) The undersigned is the Holder of Warrant No. _____ (the "*Warrant*") issued by Oruka Therapeutics, Inc., a Delaware corporation (the "*Company*"). Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The undersigned hereby exercises its right to purchase _____ Warrant Shares pursuant to the Warrant.

(3) The Holder intends that payment of the Exercise Price shall be made as (check one):

☐ Cash Exercise

☐ "Cashless Exercise"

(4) If the Holder has elected a Cash Exercise, the Holder shall pay the sum of $_____ in immediately available funds to the Company in accordance with the terms of the Warrant.

(5) Pursuant to this Exercise Notice, the Company shall deliver to the Holder Warrant Shares determined in accordance with the terms of the Warrant.

(6) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934) permitted to be owned under Section 12 of the Warrant to which this notice relates.

(7) By its delivery of this Exercise Notice and pursuant to Section 4(b) of the Warrant, the undersigned certifies to the Company that its representations listed in Section 4(b) of the Warrant are true and correct as of the date hereof as if remade in their entirety (or, in the case of any transferee Holder that is not a party to the Purchase Agreement, such transferee Holder's certification to the Company that such representations are true and correct as to such transferee Holder as of the date hereof).

Dated:_____

Name of Holder: _____

By: _____
Name: _____
Title: _____

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)

SCHEDULE 2

FORM OF ASSIGNMENT

[To be completed and executed by the Holder only upon transfer of the Warrant]

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto (the "*Transferee*") the right represented by the within Warrant to purchase shares of Common Stock of Oruka Therapeutics, Inc. (the "*Company*") to which the within Warrant relates and appoints attorney to transfer said right on the books of the Company with full power of substitution in the premises. In connection therewith, the undersigned represents, warrants, covenants and agrees to and with the Company that:

(a) the offer and sale of the Warrant contemplated hereby is being made in compliance with Section 4(a)(2) of the United States Securities Act of 1933, as amended (the "*Securities Act*") or another valid exemption from the registration requirements of Section 5 of the Securities Act and in compliance with all applicable securities laws of the states of the United States;

(b) the undersigned has not offered to sell the Warrant by any form of general solicitation or general advertising, including, but not limited to, any advertisement, article, notice or other communication published in any newspaper, magazine or similar media or broadcast over television or radio, and any seminar or meeting whose attendees have been invited by any general solicitation or general advertising;

(c) the undersigned has read the Transferee's investment letter included herewith, and to its actual knowledge, the statements made therein are true and correct; and

(d) the undersigned understands that the Company may condition the transfer of the Warrant contemplated hereby upon the delivery to the Company by the undersigned or the Transferee, as the case may be, of a written opinion of counsel (which opinion shall be in form, substance and scope customary for opinions of counsel in comparable transactions) to the effect that such transfer may be made without registration under the Securities Act and under applicable securities laws of the states of the United States.

Dated: _____

_____

(Signature must conform in all respects to name of holder as specified on the face of the Warrant)

_____

Address of Transferee

_____

_____

In the presence of:

_____

October 1, 2024

Paul Quinlan
c/o Oruka Therapeutics, Inc.
855 Oak Grove Avenue, Suite 100
Menlo Park, CA 94025

Re: Amended and Restated Employment Letter Agreement

Dear Paul:

On behalf of Oruka Therapeutics, Inc. (the "Company"), I am pleased to offer you a continuing position as General Counsel (the "Role") pursuant to this letter agreement (the "Agreement"). Your Role commenced on April 30, 2024 pursuant to your letter agreement dated April 12, 2024. This Agreement will amend and restate that April 12, 2024 letter agreement, provided you accept this offer as indicated by your signature below, to be effective as of the date hereof.

1. Position. While serving in the Role, you will report to the Company's Chief Executive Officer. You will have such duties, authorities, and responsibilities as are customarily associated with the Role. This is a full-time employment position. It is understood and agreed that, while you are employed by the Company, you will not engage in any other employment, consulting or other business activities (whether full-time or part-time), except as expressly authorized in writing by the Company. Notwithstanding the foregoing, you may engage in religious, charitable and other community activities so long as such activities do not unreasonably interfere or conflict with your obligations to the Company.

2. Base Salary. Upon and following the date hereof, as cash compensation for your services, the Company will pay you an initial base salary of $460,000 per year, payable in accordance with the Company's standard payroll schedule and subject to applicable deductions and withholdings. Your base salary will be subject to periodic review and potential adjustment in the Company's discretion. Your base salary in effect at any given time is referred to herein as the "Base Salary."

3. Annual Bonus. You will continue to be eligible to receive an annual performance bonus targeted at 40% of your Base Salary. The target annual bonus in effect at any given time is referred to herein as "Target Bonus." Your 2024 annual bonus will be prorated based on your period of employment following April 30, 2024. The actual bonus amount is discretionary and may be subject to achievement of performance targets established by the Company for such year. To earn an annual bonus, you must be employed by the Company as of the payment date of such bonus. Any annual bonus will be paid no later than March 15th of the calendar year following the calendar year to which such bonus relates.

4. Benefits/Paid Time Off. You will continue to be eligible, subject to the terms of the applicable plans and programs, to participate in the employee benefits and insurance programs generally made available to the Company's full-time employees. Details of such benefits programs, including applicable employee contributions and waiting periods, if applicable, will be made available to you as such benefit(s) become available. You will be entitled to paid time off consistent with the terms of the Company's paid time off policy, as in effect from time to time. The Company reserves the right to modify, limit, amend or cancel any of its benefits plans or programs at any time.

5. Expense Reimbursement. The Company will reimburse you for all reasonable and necessary expenses incurred by you in connection with performing your duties as an employee of the Company and that are pre-approved by the Company, provided that you comply with any Company policy or practice on incurring, submitting, accounting for and documenting such expenses.

6. Location. Your primary work location will continue to be in Menlo Park, CA, provided that you may be required to engage in reasonable travel for business, consistent with the Company's business needs.

7. At-Will Employment; Resignation from Subsidiaries. At all times, your employment with the Company is "at will," meaning you or the Company may terminate it at any time for any or no reason, subject to the terms of this Agreement. Although your job duties, title, reporting structure, compensation and benefits, as well as the Company's benefit plans and personnel policies and procedures, may change from time to time (subject to the terms of this Agreement), the "at will" nature of your employment may only be changed in an express written agreement signed by you and an authorized executive officer of the Company. Your last day of employment for any reason is referred to herein as the "Date of Termination."

To the extent applicable, you shall be deemed to have resigned from all officer and board member positions that you hold with the Company or any of its respective subsidiaries and affiliates upon the termination of your employment for any reason. You shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

8. Accrued Obligations. In the event of the ending of your employment for any reason, the Company shall pay you (i) your Base Salary and, if applicable, any accrued but unused vacation, through the Date of Termination, and (ii) the amount of any documented expenses properly incurred by you on behalf of the Company prior to any such termination and not yet reimbursed. (the "Accrued Obligations").

9. Severance Pay and Benefits Outside of the Change in Control Period. If the Company terminates your employment without Cause (and not as a result of your death or Disability) or you resign with Good Reason, in each case, outside of the Change in Control Period (as such capitalized terms are defined in Appendix A), then, in addition to the Accrued Obligations, and subject to (i) your execution and non-revocation of a separation agreement and release in a form acceptable to the Company, which shall include a general release of claims against the Company and all related persons and entities and a reaffirmation of the Continuing Obligations (as defined below) and shall provide that if you breach the Continuing Obligations, all payments of the following severance pay and benefits shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven-day revocation period:

(a) The Company shall pay you an amount equal to 12 months of your Base Salary (the "Severance Amount"), payable in substantially equal installments over the 12-month period following the Date of Termination in accordance with the Company's regular payroll practices beginning on the Company's first regularly scheduled payroll date following the date that is 60 days after the Date of Termination; provided, however, that the first installment shall include any amounts that would have been paid following the Date of Termination had such installments commenced on the first regularly scheduled payroll date following the Date of Termination.

(b) Subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay to the group health plan provider(s), the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

Notwithstanding anything to the contrary in this Agreement, for the avoidance of doubt:

(i) if your employment ends as a result of a termination by the Company for Cause or a resignation by you without Good Reason, you will be entitled to the Accrued Obligations and will not be entitled to any further compensation from the Company; and

(ii) if your employment ends due to your death or Disability, (i) you will receive the Accrued Obligations and (ii) all outstanding equity-based awards subject to time-based vesting (the "Time-Based Equity Awards") as of the Termination Date shall immediately accelerate and become vested or nonforfeitable as of the Date of Termination, but you will not be eligible for any other severance pay or benefits, whether pursuant to Section 9, Section 10 or otherwise.

10. Severance Pay and Benefits Within the Change in Control Period. If the Company terminates your employment without Cause (and not as a result of your death or Disability) or you resign with Good Reason, in each case, within the Change in Control Period, then, in addition to you being entitled to the Accrued Obligations, and subject to your execution and non-revocation of the Separation Agreement and Release and it becoming fully effective, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven-day revocation period:

(a) The Company shall pay you an amount equal 1.0 times the sum of (i) your Base Salary and (ii) your Target Bonus for the year in which the termination occurs (in each case, calculated by reference to your Base Salary rate and Target Bonus as in effect immediately prior to your termination, but without giving effect to any prior reduction in Base Salary or Target Bonus by the Company that would give rise to your right to resign for Good Reason) (such salary and bonuses together, the "CIC Severance Amount"), payable in substantially equal installments over the 12-month period following the Date of Termination in accordance with the Company's regular payroll practices beginning on the Company's first regularly scheduled payroll date following the date that is 60 days after the Date of Termination; provided, however, that the first installment shall include any amounts that would have been paid following the Date of Termination had such installments commenced on the first regularly scheduled payroll date following the Date of Termination.

(b) Notwithstanding anything to the contrary in any applicable equity-based award agreement or plan, all of the unvested portion of your then outstanding Time-Based Equity Awards as of the Termination Date shall immediately accelerate and become vested or nonforfeitable as of the later of (i) the Date of Termination or (ii) the effective date of the Separation Agreement and Release (such later date being the "Accelerated Vesting Date"); and provided further that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between the Date of Termination and the Accelerated Vesting Date.

(c) All of your outstanding equity-based awards subject to performance-based vesting (the "Performance-Based Equity Awards") shall immediately accelerate and become vested or nonforfeitable as of the Accelerated Vesting Date with the performance criteria being deemed to have been met based on the greater of target or, if determinable, actual performance; provided, however, that the applicable award agreement for any Performance-Based Equity Award may provide for alternative treatment upon a termination covered by this Section 10.

(d) The Company shall pay to the group health plan provider(s), the COBRA provider or you a monthly payment equal to the monthly COBRA continuation premiums until the earliest of (A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

For the avoidance of doubt, Section 9 and Section 10 of this Agreement are mutually exclusive and in no event shall you be entitled to payments or benefits pursuant to both Section 9 and Section 10 of this Agreement.

11. Continuing Obligations.

(a) **Business Protection Agreement**. You have previously entered into an Invention Assignment, Non-Disclosure and Business Protection Agreement (the "Business Protection Agreement"). For purposes of this Agreement, the obligations in this Section 11 and those that arise in the Business Protection Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(b) **Third Party Agreements and Rights**. You hereby confirm that you are not bound by the terms of any agreement with any previous employer or other party that would prevent you from performing your obligations hereunder. You represent to the Company that your execution of this Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party. In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company or load or access on any electronic system of the Company, any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) **Litigation and Regulatory Cooperation**. You shall reasonably cooperate with the Company in (i) the defense or prosecution of any claims or actions now in existence or that may be brought in the future against or on behalf of the Company that relate to events or occurrences that transpired while you were engaged or employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information. Your full cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being reasonably available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your engagement and employment, you also shall reasonably cooperate with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. The Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 11(c).

(d) **Relief**. You agree that it would be difficult to measure any damages caused to the Company that might result from your breach of any of the Continuing Obligations, and that in any event money damages may be an inadequate remedy for any such breach. Accordingly, you agree that if you breach, or propose to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to seek an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company or posting any bond.

12. Golden Parachute Taxes.

(a) **Best After-Tax Result**. In the event that any payment or benefit received or to be received by you pursuant to this Agreement or otherwise ("Payments") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and (ii) but for this subsection (a), be subject to the excise tax imposed by Section 4999 of the Code, any successor provisions, or any comparable federal, state, local or foreign excise tax ("Excise Tax"), then, subject to the provisions of Section 14, such Payments shall be either (A) provided in full pursuant to the terms of this Agreement or any other applicable agreement, or (B) provided as to such lesser extent that would result in the Payments being $1.00 less than the amount at which any portion of the Payments would be subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state, local and foreign income, employment and other taxes and the Excise Tax (including, without limitation, any interest or penalties on such taxes), results in the receipt, on an after-tax basis, of the greatest amount of payments and benefits provided for hereunder or otherwise, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Unless the Company and you otherwise agree in writing, any determination required under this Section shall be made by independent tax counsel designated by the Company and reasonably acceptable to you ("Independent Tax Counsel"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required under this Section, Independent Tax Counsel may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code; provided that Independent Tax Counsel shall assume that you pay all taxes at the highest marginal rate. The Company and you shall furnish to Independent Tax Counsel such information and documents as Independent Tax Counsel may reasonably request in order to make a determination under this Section. The Company shall bear all costs that Independent Tax Counsel may reasonably incur in connection with any calculations contemplated by this Section. In the event that Section 13(a)(ii)(B) above applies, then based on the information provided to you and the Company by Independent Tax Counsel, the cutback described hereunder will apply as to compensation not subject to Section 409A of the Code prior to compensation subject to Section 409A of the Code and will otherwise apply on a reverse chronological basis from payments latest in time. If the Internal Revenue Service (the "IRS") determines that any Payment is subject to the Excise Tax, then Section 12(b) hereof shall apply, and the enforcement of Section 12(b) shall be the exclusive remedy to the Company.

(b) **Adjustments**. If, notwithstanding any reduction described in Section 12(a) hereof (or in the absence of any such reduction), the IRS determines that you are liable for the Excise Tax as a result of the receipt of one or more Payments, then you shall be obligated to surrender or pay back to the Company within one-hundred 120 days after a final IRS determination, an amount of such payments or benefits equal to the "Repayment Amount." The Repayment Amount with respect to such Payments shall be the smallest such amount, if any, as shall be required to be surrendered or paid to the Company so that your net proceeds with respect to such Payments (after taking into account the payment of the Excise Tax imposed on such Payments) shall be maximized. Notwithstanding the foregoing, the Repayment Amount with respect to such Payments shall be zero if a Repayment Amount of more than zero would not eliminate the Excise Tax imposed on such Payments or if a Repayment Amount of more than zero would not maximize the net amount received from the Payments. If the Excise Tax is not eliminated pursuant to this Section 12(b), you shall pay the Excise Tax.

13. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this Agreement or otherwise on account of your separation from service would be considered deferred compensation otherwise subject to the additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch- up payment covering amounts that would otherwise have been paid during the six- month period but for the application of this provision (without interest), and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in- kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non- qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the termination of your employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-l(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

14. Withholding; Tax Effect. All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or the Board related to tax liabilities arising from your compensation.

15. Recoupment. Amounts paid or payable under this Agreement shall be subject to the provisions of any applicable clawback or recoupment policies or procedures adopted by the Company, which clawback or recoupment policies may provide for forfeiture and/or recoupment of amounts paid or payable under this Agreement. No forfeiture or recoupment under such policies or procedures will give rise to a right to resign for Good Reason under this Agreement or under any other agreement between you and the Company.

16. Interpretation and Enforcement. This Agreement, together with Appendix A, the Business Protection Agreement and any award agreement between you and the Company constitute the complete agreement between you and the Company, contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. The terms of this Agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this Agreement or arising out of, related to, or in any way connected with this Agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by federal law to the extent applicable and otherwise by California law, excluding laws relating to conflicts or choice of law and excluding Disputes arising in connection with any equity incentive plan, which shall be governed by the terms of the applicable equity incentive plan. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the County of San Mateo and State of California in connection with any Dispute or any claim related to any Dispute, except for Disputes arising under any equity incentive plan, which shall be governed by the terms of the applicable equity incentive plan.

17. Assignment. Neither you nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; *provided, however*, that the Company may assign its rights and obligations under this Agreement without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further, that if you remain employed or become employed by the Company, the purchaser or any of their affiliates in connection with any such transaction, then you shall not be entitled to any payments, benefits or vesting pursuant to Section 9 or pursuant to Section 10 of this Agreement solely as a result of such transaction. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of your and its respective successors, executors, administrators, heirs and permitted assigns.

18. Waiver; Amendment. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized executive officer of the Company.

19. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

20. Conditions. You must submit satisfactory proof of your identity, successfully complete a criminal background check, which you hereby expressly authorize by your execution of this Agreement, and provide documentation of your legal authorization to work in the United States.

21. Employee Representations. It is the policy of the Company not to solicit or accept proprietary information and/or trade secrets of other companies or third parties. If you have or have had access to trade secrets or other confidential, proprietary information from your former employer or another third party, the use of such information in performing your duties at the Company is prohibited. This may include, but is not limited to, confidential or proprietary information in the form of documents, magnetic media, software, customer lists, and business plans or strategies. In making this employment offer, the Company has relied on your representation that: (a) you are not currently a party to any agreement that would restrict your ability to accept this offer or to perform services for the Company; (b) you are not subject to any noncompetition or non-solicitation agreement or other restrictive covenants that might restrict your employment by the Company as contemplated by this offer; (c) you have the full right, power and authority to execute and deliver the Agreement and to perform all of your obligations thereunder; and (d) you will not bring with you to the Company or use in the performance of your responsibilities at the Company any materials, documents or work product of a former employer or other third party that are not generally available to the public, unless you have obtained written authorization from such former employer or third party for their possession and use and have provided the Company with a copy of same.

22. Other Terms. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of your employment to the extent necessary to effectuate the terms contained herein. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement. This Agreement may be executed in separate counterparts. When both counterparts are signed, they shall be treated together as one and the same document. PDF copies of signed counterparts shall be equally effective as originals. This Agreement may also be executed electronically by any means that satisfies applicable electronic signature laws (e.g., DocuSign).

To indicate your acceptance of the Company's offer, please sign this Agreement in the space provided below and return it to me. If you have any questions regarding this letter agreement, feel free to contact me.

I look forward to working with you to make the Company a great success.

Sincerely,

/s/ Lawrence Klein
Lawrence Klein
Chief Executive Officer

Accepted and acknowledged:

/s/ Paul Quinlan
Paul Quinlan

Appendix A

1. "Cause" shall mean (i) your dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business that results in or is reasonably anticipated to result in material harm to the Company; (ii) your conviction or plea of no contest to: (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) your failure to perform in all material respects your lawful assigned duties and responsibilities to the reasonable satisfaction of the Board, which failure continues, in the reasonable judgment of the Board, for 30 days after written notice given to you describing such failure; (iv) your gross negligence, willful misconduct that results in or is reasonably anticipated to result in material harm to the Company; or (v) your violation of any material violation of any agreement(s) between you and the Company or any written Company policies including, without limitation, agreements relating to non-solicitation, non-disclosure and/or assignment of inventions or policies related to ethics or workplace conduct.

2. "Change in Control" shall have the meaning set forth in the Company's 2024 Stock Incentive Plan (or the meaning provided to any word of similar import under any successor plan).

3. "Change in Control Period" shall mean the period commencing three months prior to the first event constituting a Change in Control and ending 12 months following the first event constituting a Change in Control.

4. "Disability" shall mean a permanent and total disability as defined in Section 22(e) (3) of the Code.

5. "Good Reason" shall mean that you have complied with the Good Reason Process (hereinafter defined) following the occurrence, without your written consent, of any of the following events: (i) a material diminution in your base salary or Target Bonus except for across-the-board salary and target bonus reductions of no more than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (ii) a material change in the geographic location at which you are required to provide services to the Company or a requirement that you change your remote location from your then-current residence; (iii) a material reduction in your duties, authority or responsibilities; (iv) the failure of the Company to obtain the assumption of this Agreement by a successor; or (v) the material breach of this Agreement (or any other agreements with you) by the Company.

6. "Good Reason Process" shall mean that (i) you reasonably determine in good faith that a "Good Reason" condition has occurred; (ii) you notify the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) you cooperate in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) you terminate your employment within 30 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

October 1, 2024

Joana Goncalves
c/o Oruka Therapeutics, Inc.
855 Oak Grove Avenue, Suite 100
Menlo Park, CA 94025

Re: Amended and Restated Employment Letter Agreement

Dear Jo:

On behalf of Oruka Therapeutics, Inc. (the "Company"), I am pleased to offer you a continuing position as Chief Medical Officer (the "Role") pursuant to this letter agreement (the "Agreement"). Your Role commenced on April 18, 2024 pursuant to your letter agreement dated March 15, 2024. This Agreement will amend and restate that March 15, 2024 letter agreement, provided you accept this offer as indicated by your signature below, to be effective as of the date hereof.

1. Position. While serving in the Role, you will report to the Company's Chief Executive Officer. You will have such duties, authorities, and responsibilities as are customarily associated with the Role. This is a full-time employment position. It is understood and agreed that, while you are employed by the Company, you will not engage in any other employment, consulting or other business activities (whether full-time or part-time), except as expressly authorized in writing by the Company. Notwithstanding the foregoing, you may engage in religious, charitable and other community activities so long as such activities do not unreasonably interfere or conflict with your obligations to the Company.

2. Base Salary. Upon and following the date hereof, as cash compensation for your services, the Company will pay you an initial base salary of $460,000 per year, payable in accordance with the Company's standard payroll schedule and subject to applicable deductions and withholdings. Your base salary will be subject to periodic review and potential adjustment in the Company's discretion. Your base salary in effect at any given time is referred to herein as the "Base Salary."

3. Bonus Compensation.

(a) **Signing Bonus**. In connection with your commencement of employment with the Company on April 18, 2024, the Company advanced you a signing bonus of $100,000, less applicable deductions and withholdings, which was paid to you in the first payroll after your employment commencement. If you resign your employment with the Company for any reason or the Company terminates your employment for Cause, in either case prior to April 18, 2025, you agree to repay the Company, within 30 days following your separation date, a prorated portion of the signing bonus (based on the number of full months you worked for the Company).

(b) **Annual Bonus**. You will continue to be eligible to receive an annual performance bonus targeted at 40% of your Base Salary. The target annual bonus in effect at any given time is referred to herein as "Target Bonus." Your 2024 annual bonus will be prorated based on your period of employment following April 18, 2024. The actual bonus amount is discretionary and may be subject to achievement of performance targets established by the Company for such year. To earn an annual bonus, you must be employed by the Company as of the payment date of such bonus. Any annual bonus will be paid no later than March 15th of the calendar year following the calendar year to which such bonus relates.

4. Benefits/Paid Time Off. You will continue to be eligible, subject to the terms of the applicable plans and programs, to participate in the employee benefits and insurance programs generally made available to the Company's full-time employees. Details of such benefits programs, including applicable employee contributions and waiting periods, if applicable, will be made available to you as such benefit(s) become available. You will be entitled to paid time off consistent with the terms of the Company's paid time off policy, as in effect from time to time. The Company reserves the right to modify, limit, amend or cancel any of its benefits plans or programs at any time.

5. Expense Reimbursement. The Company will reimburse you for all reasonable and necessary expenses incurred by you in connection with performing your duties as an employee of the Company and that are pre-approved by the Company, provided that you comply with any Company policy or practice on incurring, submitting, accounting for and documenting such expenses.

6. Location. Your primary work location will continue to be remote in Connecticut, provided that you may be required to engage in reasonable travel for business, consistent with the Company's business needs. You may change your remote work location with prior written notice to and approval from the Company.

7. At-Will Employment; Resignation from Subsidiaries. At all times, your employment with the Company is "at will," meaning you or the Company may terminate it at any time for any or no reason, subject to the terms of this Agreement. Although your job duties, title, reporting structure, compensation and benefits, as well as the Company's benefit plans and personnel policies and procedures, may change from time to time (subject to the terms of this Agreement), the "at will" nature of your employment may only be changed in an express written agreement signed by you and an authorized executive officer of the Company. Your last day of employment for any reason is referred to herein as the "Date of Termination."

To the extent applicable, you shall be deemed to have resigned from all officer and board member positions that you hold with the Company or any of its respective subsidiaries and affiliates upon the termination of your employment for any reason. You shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

8. Accrued Obligations. In the event of the ending of your employment for any reason, the Company shall pay you (i) your Base Salary and, if applicable, any accrued but unused vacation, through the Date of Termination, and (ii) the amount of any documented expenses properly incurred by you on behalf of the Company prior to any such termination and not yet reimbursed. (the "Accrued Obligations").

9. Severance Pay and Benefits Outside of the Change in Control Period. If the Company terminates your employment without Cause (and not as a result of your death or Disability) or you resign with Good Reason, in each case, outside of the Change in Control Period (as such capitalized terms are defined in Appendix A), then, in addition to the Accrued Obligations, and subject to (i) your execution and non-revocation of a separation agreement and release in a form acceptable to the Company, which shall include a general release of claims against the Company and all related persons and entities and a reaffirmation of the Continuing Obligations (as defined below) and shall provide that if you breach the Continuing Obligations, all payments of the following severance pay and benefits shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven-day revocation period:

(a) The Company shall pay you an amount equal to 12 months of your Base Salary (the "Severance Amount"), payable in substantially equal installments over the 12-month period following the Date of Termination in accordance with the Company's regular payroll practices beginning on the Company's first regularly scheduled payroll date following the date that is 60 days after the Date of Termination; provided, however, that the first installment shall include any amounts that would have been paid following the Date of Termination had such installments commenced on the first regularly scheduled payroll date following the Date of Termination.

(b) Subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay to the group health plan provider(s), the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the 12-month anniversary of the Date of Termin(A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.ation; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

Notwithstanding anything to the contrary in this Agreement, for the avoidance of doubt:

(i) if your employment ends as a result of a termination by the Company for Cause or a resignation by you without Good Reason, you will be entitled to the Accrued Obligations and will not be entitled to any further compensation from the Company; and

(ii) if your employment ends due to your death or Disability, (i) you will receive the Accrued Obligations and (ii) all outstanding equity-based awards subject to time-based vesting (the "Time-Based Equity Awards") as of the Termination Date shall immediately accelerate and become vested or nonforfeitable as of the Date of Termination, but you will not be eligible for any other severance pay or benefits, whether pursuant to Section 9, Section 10 or otherwise.

10. Severance Pay and Benefits Within the Change in Control Period. If the Company terminates your employment without Cause (and not as a result of your death or Disability) or you resign with Good Reason, in each case, within the Change in Control Period, then, in addition to you being entitled to the Accrued Obligations, and subject to your execution and non-revocation of the Separation Agreement and Release and it becoming fully effective, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven-day revocation period:

(a) The Company shall pay you an amount equal 1.0 times the sum of (i) your Base Salary and (ii) your Target Bonus for the year in which the termination occurs (in each case, calculated by reference to your Base Salary rate and Target Bonus as in effect immediately prior to your termination, but without giving effect to any prior reduction in Base Salary or Target Bonus by the Company that would give rise to your right to resign for Good Reason) (such salary and bonuses together, the "CIC Severance Amount"), payable in substantially equal installments over the 12-month period following the Date of Termination in accordance with the Company's regular payroll practices beginning on the Company's first regularly scheduled payroll date following the date that is 60 days after the Date of Termination; provided, however, that the first installment shall include any amounts that would have been paid following the Date of Termination had such installments commenced on the first regularly scheduled payroll date following the Date of Termination.

(b) Notwithstanding anything to the contrary in any applicable equity-based award agreement or plan, all of the unvested portion of your then outstanding Time-Based Equity Awards as of the Termination Date shall immediately accelerate and become vested or nonforfeitable as of the later of (i) the Date of Termination or (ii) the effective date of the Separation Agreement and Release (such later date being the "Accelerated Vesting Date"); and provided further that any termination or forfeiture of the unvested portion of such Time- Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between the Date of Termination and the Accelerated Vesting Date.

(c) All of your outstanding equity-based awards subject to performance-based vesting (the "Performance-Based Equity Awards") shall immediately accelerate and become vested or nonforfeitable as of the Accelerated Vesting Date with the performance criteria being deemed to have been met based on the greater of target or, if determinable, actual performance; provided, however, that the applicable award agreement for any Performance-Based Equity Award may provide for alternative treatment upon a termination covered by this Section 10.

(d) The Company shall pay to the group health plan provider(s), the COBRA provider or you a monthly payment equal to the monthly COBRA continuation premiums until the earliest of (A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

For the avoidance of doubt, Section 9 and Section 10 of this Agreement are mutually exclusive and in no event shall you be entitled to payments or benefits pursuant to both Section 9 and Section 10 of this Agreement.

11. Continuing Obligations.

(a) **Business Protection Agreement**. You have previously entered into an Invention Assignment, Non-Disclosure and Business Protection Agreement (the "Business Protection Agreement"). For purposes of this Agreement, the obligations in this Section 11 and those that arise in the Business Protection Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(b) **Third Party Agreements and Rights**. You hereby confirm that you are not bound by the terms of any agreement with any previous employer or other party that would prevent you from performing your obligations hereunder. You represent to the Company that your execution of this Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party. In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company or load or access on any electronic system of the Company, any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) **Litigation and Regulatory Cooperation**. You shall reasonably cooperate with the Company in (i) the defense or prosecution of any claims or actions now in existence or that may be brought in the future against or on behalf of the Company that relate to events or occurrences that transpired while you were engaged or employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information. Your full cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being reasonably available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your engagement and employment, you also shall reasonably cooperate with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. The Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 11(c).

(d) **Relief**. You agree that it would be difficult to measure any damages caused to the Company that might result from your breach of any of the Continuing Obligations, and that in any event money damages may be an inadequate remedy for any such breach. Accordingly, you agree that if you breach, or propose to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to seek an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company or posting any bond.

12. Golden Parachute Taxes.

(a) **Best After-Tax Result**. In the event that any payment or benefit received or to be received by you pursuant to this Agreement or otherwise ("Payments") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and (ii) but for this subsection (a), be subject to the excise tax imposed by Section 4999 of the Code, any successor provisions, or any comparable federal, state, local or foreign excise tax ("Excise Tax"), then, subject to the provisions of Section 14, such Payments shall be either (A) provided in full pursuant to the terms of this Agreement or any other applicable agreement, or (B) provided as to such lesser extent that would result in the Payments being $1.00 less than the amount at which any portion of the Payments would be subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state, local and foreign income, employment and other taxes and the Excise Tax (including, without limitation, any interest or penalties on such taxes), results in the receipt, on an after-tax basis, of the greatest amount of payments and benefits provided for hereunder or otherwise, notwithstanding that all or some portion of such Payments may be subject to the Excise Tax. Unless the Company and you otherwise agree in writing, any determination required under this Section shall be made by independent tax counsel designated by the Company and reasonably acceptable to you ("Independent Tax Counsel"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required under this Section, Independent Tax Counsel may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code; provided that Independent Tax Counsel shall assume that you pay all taxes at the highest marginal rate. The Company and you shall furnish to Independent Tax Counsel such information and documents as Independent Tax Counsel may reasonably request in order to make a determination under this Section. The Company shall bear all costs that Independent Tax Counsel may reasonably incur in connection with any calculations contemplated by this Section. In the event that Section 13(a)(ii)(B) above applies, then based on the information provided to you and the Company by Independent Tax Counsel, the cutback described hereunder will apply as to compensation not subject to Section 409A of the Code prior to compensation subject to Section 409A of the Code and will otherwise apply on a reverse chronological basis from payments latest in time. If the Internal Revenue Service (the "IRS") determines that any Payment is subject to the Excise Tax, then Section 12(b) hereof shall apply, and the enforcement of Section 12(b) shall be the exclusive remedy to the Company.

(b) **Adjustments**. If, notwithstanding any reduction described in Section 12(a) hereof (or in the absence of any such reduction), the IRS determines that you are liable for the Excise Tax as a result of the receipt of one or more Payments, then you shall be obligated to surrender or pay back to the Company within one-hundred 120 days after a final IRS determination, an amount of such payments or benefits equal to the "Repayment Amount." The Repayment Amount with respect to such Payments shall be the smallest such amount, if any, as shall be required to be surrendered or paid to the Company so that your net proceeds with respect to such Payments (after taking into account the payment of the Excise Tax imposed on such Payments) shall be maximized. Notwithstanding the foregoing, the Repayment Amount with respect to such Payments shall be zero if a Repayment Amount of more than zero would not eliminate the Excise Tax imposed on such Payments or if a Repayment Amount of more than zero would not maximize the net amount received from the Payments. If the Excise Tax is not eliminated pursuant to this Section 12(b), you shall pay the Excise Tax.

13. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this Agreement or otherwise on account of your separation from service would be considered deferred compensation otherwise subject to the additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch- up payment covering amounts that would otherwise have been paid during the six- month period but for the application of this provision (without interest), and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non- qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the termination of your employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-l(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

14. Withholding; Tax Effect. All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or the Board related to tax liabilities arising from your compensation.

15. Recoupment. Amounts paid or payable under this Agreement shall be subject to the provisions of any applicable clawback or recoupment policies or procedures adopted by the Company, which clawback or recoupment policies may provide for forfeiture and/or recoupment of amounts paid or payable under this Agreement. No forfeiture or recoupment under such policies or procedures will give rise to a right to resign for Good Reason under this Agreement or under any other agreement between you and the Company.

16. Interpretation and Enforcement. This Agreement, together with Appendix A, the Business Protection Agreement and any award agreement between you and the Company constitute the complete agreement between you and the Company, contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. The terms of this Agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this Agreement or arising out of, related to, or in any way connected with this Agreement, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by federal law to the extent applicable and otherwise by California law, excluding laws relating to conflicts or choice of law and excluding Disputes arising in connection with any equity incentive plan, which shall be governed by the terms of the applicable equity incentive plan. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the County of San Mateo and State of California in connection with any Dispute or any claim related to any Dispute, except for Disputes arising under any equity incentive plan, which shall be governed by the terms of the applicable equity incentive plan.

17. Assignment. Neither you nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; *provided, however*, that the Company may assign its rights and obligations under this Agreement without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further, that if you remain employed or become employed by the Company, the purchaser or any of their affiliates in connection with any such transaction, then you shall not be entitled to any payments, benefits or vesting pursuant to Section 9 or pursuant to Section 10 of this Agreement solely as a result of such transaction. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of your and its respective successors, executors, administrators, heirs and permitted assigns.

18. Waiver; Amendment. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized executive officer of the Company.

19. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

20. Conditions. You must submit satisfactory proof of your identity, successfully complete a criminal background check, which you hereby expressly authorize by your execution of this Agreement, and provide documentation of your legal authorization to work in the United States.

21. Employee Representations. It is the policy of the Company not to solicit or accept proprietary information and/or trade secrets of other companies or third parties. If you have or have had access to trade secrets or other confidential, proprietary information from your former employer or another third party, the use of such information in performing your duties at the Company is prohibited. This may include, but is not limited to, confidential or proprietary information in the form of documents, magnetic media, software, customer lists, and business plans or strategies. In making this employment offer, the Company has relied on your representation that: (a) you are not currently a party to any agreement that would restrict your ability to accept this offer or to perform services for the Company; (b) you are not subject to any noncompetition or non-solicitation agreement or other restrictive covenants that might restrict your employment by the Company as contemplated by this offer; (c) you have the full right, power and authority to execute and deliver the Agreement and to perform all of your obligations thereunder; and (d) you will not bring with you to the Company or use in the performance of your responsibilities at the Company any materials, documents or work product of a former employer or other third party that are not generally available to the public, unless you have obtained written authorization from such former employer or third party for their possession and use and have provided the Company with a copy of same.

22. Other Terms. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of your employment to the extent necessary to effectuate the terms contained herein. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement. This Agreement may be executed in separate counterparts. When both counterparts are signed, they shall be treated together as one and the same document. PDF copies of signed counterparts shall be equally effective as originals. This Agreement may also be executed electronically by any means that satisfies applicable electronic signature laws (e.g., DocuSign).

To indicate your acceptance of the Company's offer, please sign this Agreement in the space provided below and return it to me. If you have any questions regarding this letter agreement, feel free to contact me.

I look forward to working with you to make the Company a great success.

Sincerely,

/s/ Lawrence Klein
Lawrence Klein
Chief Executive Officer

Accepted and acknowledged:

/s/ Joana Goncalves
Joana Goncalves

Appendix A

1. "Cause" shall mean (i) your dishonest statements or acts with respect to the Company or any affiliate of the Company, or any current or prospective customers, suppliers, vendors or other third parties with which such entity does business that results in or is reasonably anticipated to result in material harm to the Company; (ii) your conviction or plea of no contest to: (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) your failure to perform in all material respects your lawful assigned duties and responsibilities to the reasonable satisfaction of the Board, which failure continues, in the reasonable judgment of the Board, for 30 days after written notice given to you describing such failure; (iv) your gross negligence, willful misconduct that results in or is reasonably anticipated to result in material harm to the Company; or (v) your violation of any material violation of any agreement(s) between you and the Company or any written Company policies including, without limitation, agreements relating to non-solicitation, non-disclosure and/or assignment of inventions or policies related to ethics or workplace conduct.

2. "Change in Control" shall have the meaning set forth in the Company's 2024 Stock Incentive Plan (or the meaning provided to any word of similar import under any successor plan).

3. "Change in Control Period" shall mean the period commencing three months prior to the first event constituting a Change in Control and ending 12 months following the first event constituting a Change in Control.

4. "Disability" shall mean a permanent and total disability as defined in Section 22(e) (3) of the Code.

5. "Good Reason" shall mean that you have complied with the Good Reason Process (hereinafter defined) following the occurrence, without your written consent, of any of the following events: (i) a material diminution in your base salary or Target Bonus except for across-the-board salary and target bonus reductions of no more than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (ii) a material change in the geographic location at which you are required to provide services to the Company or a requirement that you change your remote location from your then-current residence; (iii) a material reduction in your duties, authority or responsibilities; (iv) the failure of the Company to obtain the assumption of this Agreement by a successor; or (v) the material breach of this Agreement (or any other agreements with you) by the Company.

6. "Good Reason Process" shall mean that (i) you reasonably determine in good faith that a "Good Reason" condition has occurred; (ii) you notify the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) you cooperate in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) you terminate your employment within 30 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

Exhibit 10.19

INDEMNIFICATION AGREEMENT

This Indemnification Agreement (this "Agreement") is entered into as of _____ by and between Oruka Therapeutics, Inc., a Delaware corporation (the "Company"), and _____ (the "Indemnitee") and shall be deemed effective upon the earliest date that the Indemnitee is duly elected or appointed as a director or officer of the Company.

RECITALS

WHEREAS, the Board of Directors of the Company (the "Board") has determined that the inability to attract and retain qualified persons as directors and officers is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there shall be adequate certainty of protection through insurance and indemnification against risks of claims and actions against them arising out of their service to and activities on behalf of the Company;

WHEREAS, the Company has adopted provisions in its Amended and Restated Bylaws (as may be amended or restated from time to time, the "Bylaws") providing for indemnification and advancement of expenses of its directors and officers to the fullest extent authorized by the General Corporation Law of the State of Delaware (the "DGCL"), and the Company wishes to clarify and enhance the rights and obligations of the Company and the Indemnitee with respect to indemnification and advancement of expenses;

WHEREAS, in order to induce and encourage highly experienced and capable persons such as the Indemnitee to serve and continue to serve as directors and officers of the Company and in any other capacity with respect to the Company as the Company may request, and to otherwise promote the desirable end that such persons shall resist what they consider unjustified lawsuits and claims made against them in connection with the good faith performance of their duties to the Company, with the knowledge that certain costs, judgments, penalties, fines, liabilities and expenses incurred by them in their defense of such litigation are to be borne by the Company and they shall receive appropriate protection against such risks and liabilities, the Board has determined that the following Agreement is reasonable and prudent to promote and ensure the best interests of the Company and its stockholders; and

WHEREAS, the Company desires to have the Indemnitee serve or continue to serve as a director or officer of the Company and in any other capacity with respect to the Company as the Company may request, as the case may be, free from undue concern for unpredictable, inappropriate, or unreasonable legal risks and personal liabilities by reason of the Indemnitee acting in good faith in the performance of the Indemnitee's duty to the Company; and the Indemnitee desires to continue so to serve the Company, provided, and on the express condition, that he or she is furnished with the protections set forth hereinafter.

AGREEMENT

NOW, THEREFORE, in consideration of the Indemnitee's service or continued service as a director or officer of the Company, the parties hereto agree as follows:

1. Definitions. For purposes of this Agreement:

(a) A "Change in Control" will be deemed to have occurred if, with respect to any particular 24-month period, the individuals who, at the beginning of such 24-month period, constituted the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the beginning of such 24-month period whose election, or nomination for election by the stockholders of the Company, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board.

(b) "Disinterested Director" means a director of the Company who is not or was not a party to the Proceeding in respect of which indemnification is being sought by the Indemnitee.

(c) "Expenses" includes, without limitation, expenses incurred in connection with the defense or settlement of any action, suit, arbitration, alternative dispute resolution mechanism, inquiry, judicial, administrative, or legislative hearing, investigation, or any other threatened, pending, or completed proceeding, whether brought by or in the right of the Company or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative, or other nature, attorneys' fees, witness fees and expenses, fees and expenses of accountants and other advisors, retainers and disbursements and advances thereon, the premium, security for, and other costs relating to any bond (including cost bonds, appraisal bonds, or their equivalents), and any expenses of establishing a right to indemnification or advancement under this Agreement, but shall not include the amount of judgments, fines, ERISA excise taxes, or penalties actually levied against the Indemnitee, or any amounts paid in settlement by or on behalf of the Indemnitee.

(d) "Independent Counsel" means a law firm or a member of a law firm that neither is presently nor in the past five years has been retained to represent (i) the Company or the Indemnitee in any matter material to either such party or (ii) any other party to the Proceeding giving rise to a request for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or the Indemnitee in an action to determine the Indemnitee's right to indemnification under this Agreement.

(e) "Proceeding" means any action, suit, arbitration, alternative dispute resolution mechanism, inquiry, judicial, administrative, or legislative hearing, investigation, or any other threatened, pending, or completed proceeding, whether brought by or in the right of the Company or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative, or other nature, to which the Indemnitee was or is a party or is threatened to be made a party or is otherwise involved in by reason of the fact that the Indemnitee is or was a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee of the Company is or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan (such status, the Indemnitee's "Corporate Status"), or by reason of anything done or not done by the Indemnitee in any such capacity, whether or not the Indemnitee is serving in such capacity at the time any expense, liability, or loss is incurred for which indemnification or advancement can be provided under this Agreement.

2. Service by the Indemnitee. The Indemnitee shall serve and/or continue to serve as a director or officer of the Company faithfully and to the best of the Indemnitee's ability so long as the Indemnitee is duly elected or appointed and until such time as the Indemnitee's successor is elected and qualified or the Indemnitee is removed as permitted by applicable law or tenders a resignation in writing.

3. Indemnification and Advancement of Expenses. The Company shall indemnify and hold harmless the Indemnitee, and shall pay to the Indemnitee in advance of the final disposition of any Proceeding all Expenses incurred by the Indemnitee in defending any such Proceeding, to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, all on the terms and conditions set forth in this Agreement. Without diminishing the scope of the rights provided by this Section, the rights of the Indemnitee to indemnification and advancement of Expenses provided hereunder shall include but shall not be limited to those rights hereinafter set forth, except that no indemnification or advancement of Expenses shall be paid to the Indemnitee:

(a) to the extent expressly prohibited by applicable law or the Amended and Restated Certificate of Incorporation of the Company (as may be amended or restated from time to time, the "Certificate of Incorporation") and the Bylaws;

(b) for and to the extent that payment is actually made to the Indemnitee under a valid and collectible insurance policy or under a valid and enforceable indemnity clause, provision of the certificate of incorporation or bylaws, or agreement of the Company or any other company or other enterprise (and the Indemnitee shall reimburse the Company for any amounts paid by the Company and subsequently so recovered by the Indemnitee); or

(c) in connection with an action, suit, or proceeding, or part thereof voluntarily initiated by the Indemnitee (including claims and counterclaims, whether such counterclaims are asserted by (i) the Indemnitee, or (ii) the Company in an action, suit, or proceeding initiated by the Indemnitee), except a judicial proceeding pursuant to Section 11 to enforce rights under this Agreement, unless (A) the action, suit, or proceeding, or part thereof, was authorized or ratified by the Board or the Board otherwise determines that indemnification or advancement of Expenses is appropriate or (B) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

4. Action or Proceedings Other than an Action by or in the Right of the Company. Except as limited by Section 3 above, the Indemnitee shall be entitled to the indemnification rights provided in this Section if the Indemnitee was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any Proceeding (other than an action by or in the right of the Company) by reason of the Indemnitee's Corporate Status, or by reason of anything done or not done by the Indemnitee in any such capacity. Pursuant to this Section, the Indemnitee shall be indemnified against all expense, liability, and loss (including judgments, fines, ERISA excise taxes or penalties, amounts paid in settlement by or on behalf of the Indemnitee, and Expenses) actually and reasonably incurred by the Indemnitee, or on behalf of the Indemnitee, in connection with such Proceeding, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe his or her conduct was unlawful.

5. Indemnity in Proceedings by or in the Right of the Company. Except as limited by Section 3 above, the Indemnitee shall be entitled to the indemnification rights provided in this Section if the Indemnitee was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any Proceeding brought by or in the right of the Company to procure a judgment in its favor by reason of the Indemnitee's Corporate Status, or by reason of anything done or not done by the Indemnitee in any such capacity. Pursuant to this Section, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee, or on behalf of the Indemnitee, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, that no such indemnification shall be made in respect of any claim, issue, or matter as to which the DGCL expressly prohibits such indemnification by reason of any adjudication of liability of the Indemnitee to the Company, unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the Indemnitee is entitled to indemnification for such expense, liability, and loss as such court shall deem proper.

6. Indemnification for Costs, Charges, and Expenses of Successful Party. Notwithstanding any limitations of Sections 3(c), 4, and 5 above, to the extent that the Indemnitee has been successful, on the merits or otherwise, in whole or in part, in defense of any Proceeding, or in defense of any claim, issue, or matter therein, including, without limitation, the dismissal of any action without prejudice, or if it is ultimately determined, by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal, that the Indemnitee is otherwise entitled to be indemnified against Expenses, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee in connection therewith.

7. Partial Indemnification. If the Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of the expense, liability, and loss (including judgments, fines, ERISA excise taxes or penalties, amounts paid in settlement by or on behalf of the Indemnitee, and Expenses) actually and reasonably incurred in connection with any Proceeding, or in connection with any judicial proceeding pursuant to Section 11 to enforce rights under this Agreement, but not, however, for all of the total amount thereof, the Company shall nevertheless indemnify the Indemnitee for the portion of such expense, liability, and loss actually and reasonably incurred to which the Indemnitee is entitled.

8. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the maximum extent permitted by the DGCL, the Indemnitee shall be entitled to indemnification against all Expenses actually and reasonably incurred by the Indemnitee or on the Indemnitee's behalf if the Indemnitee appears as a witness or otherwise incurs legal expenses as a result of or related to the Indemnitee's service as a director or officer of the Company, in any threatened, pending, or completed action, suit, arbitration, alternative dispute resolution mechanism, inquiry, judicial, administrative, or legislative hearing, investigation, or any other threatened, pending, or completed proceeding, whether of a civil, criminal, administrative, legislative, investigative, or other nature, to which the Indemnitee neither is, nor is threatened to be made, a party.

9. Determination of Entitlement to Indemnification. To receive indemnification under this Agreement, the Indemnitee shall submit a written request to the Secretary of the Company. Such request shall include documentation or information that is necessary for such determination and is reasonably available to the Indemnitee. Upon receipt by the Secretary of the Company of a written request by the Indemnitee for indemnification pursuant to this Agreement, the entitlement of the Indemnitee to indemnification, to the extent not provided pursuant to the terms of this Agreement, shall be determined by the following person or persons who shall be empowered to make such determination (as selected by the Board, except with respect to Section 9(e) below): (a) the Board by a majority vote of Disinterested Directors, whether or not such majority constitutes a quorum; (b) a committee of Disinterested Directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; (c) if there are no Disinterested Directors, or if the Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee; (d) the stockholders of the Company; or (e) in the event that a Change in Control has occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee. Such Independent Counsel shall be selected by the Board and approved by the Indemnitee, except that in the event that a Change in Control has occurred, Independent Counsel shall be selected by the Indemnitee. Upon failure of the Board so to select such Independent Counsel or upon failure of the Indemnitee so to approve (or so to select, in the event a Change in Control has occurred), such Independent Counsel shall be selected upon application to a court of competent jurisdiction. The determination of entitlement to indemnification shall be made and, unless a contrary determination is made, such indemnification shall be paid in full by the Company not later than 60 calendar days after receipt by the Secretary of the Company of a written request for indemnification. If the person making such determination shall determine that the Indemnitee is entitled to indemnification as to part (but not all) of the application for indemnification, such person shall reasonably prorate such partial indemnification among the claims, issues, or matters at issue at the time of the determination.

10. Presumptions and Effect of Certain Proceedings. The Secretary of the Company shall, promptly upon receipt of the Indemnitee's written request for indemnification, advise in writing the Board or such other person or persons empowered to make the determination as provided in Section 9 that the Indemnitee has made such request for indemnification. Upon making such request for indemnification, the Indemnitee shall be presumed to be entitled to indemnification hereunder and the Company shall have the burden of proof in making any determination contrary to such presumption. If the person or persons so empowered to make such determination shall have failed to make the requested determination with respect to indemnification within 60 calendar days after receipt by the Secretary of the Company of such request, a requisite determination of entitlement to indemnification shall be deemed to have been made and the Indemnitee shall be absolutely entitled to such indemnification, absent actual fraud in the request for indemnification. The termination of any Proceeding described in Sections 4 or 5 by judgment, order, settlement, or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself (a) create a presumption that the Indemnitee did not act in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, or with respect to any criminal Proceeding, had reasonable cause to believe his or her conduct was unlawful or (b) otherwise adversely affect the rights of the Indemnitee to indemnification except as may be provided herein.

11. Remedies of the Indemnitee in Cases of Determination Not to Indemnify or to Advance Expenses; Right to Bring Suit. In the event that a determination is made that the Indemnitee is not entitled to indemnification hereunder or if payment is not timely made following a determination of entitlement to indemnification pursuant to Sections 9 and 10, or if an advancement of Expenses is not timely made pursuant to Section 16, the Indemnitee may at any time thereafter bring suit against the Company seeking an adjudication of entitlement to such indemnification or advancement of Expenses, and any such suit shall be brought in the Court of Chancery of the State of Delaware unless, if the Indemnitee is an employee of the Company, otherwise required by the law of the state in which the Indemnitee primarily resides and works. The Company shall not oppose the Indemnitee's right to seek any such adjudication. In any suit brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the Indemnitee to enforce a right to an advancement of Expenses), it shall be a defense that the Indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL, including the standard described in Section 4 or 5, as applicable. Further, in any suit brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the Company shall be entitled to recover such Expenses upon a final judicial decision of a court of competent jurisdiction from which there is no further right to appeal that the Indemnitee has not met the standard of conduct described above. Neither the failure of the Company (including the Disinterested Directors, a committee of Disinterested Directors, Independent Counsel, or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the standard of conduct described above, nor an actual determination by the Company (including the Disinterested Directors, a committee of Disinterested Directors, Independent Counsel, or its stockholders) that the Indemnitee has not met the standard of conduct described above shall create a presumption that the Indemnitee has not met the standard of conduct described above, or, in the case of such a suit brought by the Indemnitee, be a defense to such suit. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of Expenses hereunder, or brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of Expenses, under this Section 11 or otherwise shall be on the Company. If a determination is made or deemed to have been made pursuant to the terms of Section 9 or 10 that the Indemnitee is entitled to indemnification, the Company shall be bound by such determination and is precluded from asserting that such determination has not been made or that the procedure by which such determination was made is not valid, binding, and enforceable. The Company further agrees to stipulate in any court pursuant to this Section 11 that the Company is bound by all the provisions of this Agreement and is precluded from making any assertions to the contrary. If the court shall determine that the Indemnitee is entitled to any indemnification or advancement of Expenses hereunder, the Company shall pay all Expenses actually and reasonably incurred by the Indemnitee in connection with such adjudication (including, but not limited to, any appellate proceedings) to the fullest extent permitted by law, and in any suit brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the Company shall pay all Expenses actually and reasonably incurred by the Indemnitee in connection with such suit to the extent the Indemnitee has been successful, on the merits or otherwise, in whole or in part, in defense of such suit, to the fullest extent permitted by law.

12. Non-Exclusivity of Rights; Survival of Rights; Insurance; Subrogation.

(a) The rights provided by this Agreement shall not be deemed exclusive of any other rights to which the Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, or Bylaws, any agreement, a vote of stockholders, a resolution of the Board, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision of this Agreement shall limit or restrict any right of the Indemnitee under this Agreement in respect of any action taken or omitted by the Indemnitee in his or her Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL, whether by statute or judicial decision, permits greater indemnification than would be afforded under the current Certificate of Incorporation or Bylaws and this Agreement, it is the intent of the parties hereto that the Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person serves at the request of the Company, the Company shall obtain coverage for the Indemnitee under such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any other director (if the Indemnitee is a director) or officer (if the Indemnitee is not a director but is an officer) of the Company under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms of this Agreement, the Company has director and officer liability insurance in effect, the Company shall give notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all commercially reasonable steps to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, [subject to the exceptions contained in Section 12(d) below,][1] the Company shall be subrogated to the extent of such payment to all of the rights of recovery of the Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company effectively to bring suit to enforce such rights.

1 **Note to Draft**: This clause will only apply to directors who are separately indemnified by an entity in connection with their appointment to the Board.

(d) [The Company hereby acknowledges that Indemnitee has certain rights to indemnification, advancement of expenses and/or insurance provided by _____ and/or [their/its] affiliates (collectively, the "Designee Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort vis-à-vis the Designee Indemnitors (i.e., its obligations to Indemnitee are primary and any obligation of the Designee Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all indemnity amounts to the extent required by the terms of this Agreement and the Bylaws, without regard to any rights Indemnitee may have against the Designee Indemnitors, and (iii) notwithstanding any other provision in this Agreement or the Bylaws, that it irrevocably waives, relinquishes and releases the Designee Indemnitors from any and all claims against the Designee Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Designee Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Designee Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Designee Indemnitors are express third-party beneficiaries of this Section 12(d).][2]

(e) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that the Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(f) The Company's obligation to indemnify or advance Expenses hereunder to the Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount the Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.

13. Expenses to Enforce Agreement. In the event that the Indemnitee is subject to or intervenes in any action, suit, or proceeding in which the validity or enforceability of this Agreement is at issue or seeks an adjudication to enforce the Indemnitee's rights under, or to recover damages for breach of, this Agreement, the Indemnitee, if the Indemnitee prevails in whole or in part in such action, suit, or proceeding, shall be entitled to recover from the Company and shall be indemnified by the Company against any Expenses actually and reasonably incurred by the Indemnitee in connection therewith.

14. Continuation of Indemnity. All agreements and obligations of the Company contained herein shall continue during the period the Indemnitee is a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee is serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan, and shall continue thereafter with respect to any possible claims based on the fact that the Indemnitee was a director, officer, employee, agent, or trustee of the Company or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan. This Agreement shall be binding upon all successors and assigns of the Company (including any transferee of all or substantially all of its assets and any successor by merger or operation of law) and shall inure to the benefit of the Indemnitee's heirs, executors, and administrators.

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2 **Note to Draft**: This clause will only apply to directors who are separately indemnified by an entity in connection with their appointment to the Board.

15. Notification and Defense of Proceeding. Promptly after receipt by the Indemnitee of notice of any Proceeding, the Indemnitee shall, if a request for indemnification or an advancement of Expenses in respect thereof is to be made against the Company under this Agreement, notify the Company in writing of the commencement thereof; but the omission so to notify the Company shall not relieve it from any liability that it may have to the Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company. Notwithstanding any other provision of this Agreement, with respect to any such Proceeding of which the Indemnitee notifies the Company:

(a) The Company shall be entitled to participate therein at its own expense;

(b) Except as otherwise provided in this Section 15(b), to the extent that it may wish, the Company, jointly with any other indemnifying party similarly notified, shall be entitled to assume the defense thereof, with counsel satisfactory to the Indemnitee. After notice from the Company to the Indemnitee of its election so to assume the defense thereof, the Company shall not be liable to the Indemnitee under this Agreement for any expenses of counsel subsequently incurred by the Indemnitee in connection with the defense thereof except as otherwise provided below. The Indemnitee shall have the right to employ the Indemnitee's own counsel in such Proceeding, but the fees and expenses of such counsel incurred after notice from the Company of its assumption of the defense thereof shall be at the expense of the Indemnitee unless (i) the employment of counsel by the Indemnitee has been authorized by the Company, (ii) the Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and the Indemnitee in the conduct of the defense of such Proceeding, or (iii) the Company shall not within 60 calendar days of receipt of notice from the Indemnitee in fact have employed counsel to assume the defense of the Proceeding, in each of which cases the fees and expenses of the Indemnitee's counsel shall be at the expense of the Company. The Company shall not be entitled to assume the defense of any Proceeding brought by or on behalf of the Company or as to which the Indemnitee shall have made the conclusion provided for in (ii) above; and

(c) Notwithstanding any other provision of this Agreement, the Company shall not be liable to indemnify the Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without the Company's written consent, or for any judicial or other award, if the Company was not given an opportunity, in accordance with this Section 15, to participate in the defense of such Proceeding. The Company shall not settle any Proceeding in any manner that would impose any penalty or limitation on or disclosure obligation with respect to the Indemnitee, or that would directly or indirectly constitute or impose any admission or acknowledgment of fault or culpability with respect to the Indemnitee, without the Indemnitee's written consent. Neither the Company nor the Indemnitee shall unreasonably withhold its consent to any proposed settlement.

16. Advancement of Expenses. All Expenses incurred by the Indemnitee in defending any Proceeding described in Sections 4 or 5 shall be paid by the Company in advance of the final disposition of such Proceeding at the request of the Indemnitee. Notwithstanding the foregoing, the Company shall not advance or continue to advance Expenses to the Indemnitee if a determination is reasonably made that the facts known at the time such determination is made demonstrate clearly and convincingly that the Indemnitee acted in bad faith or in a manner that the Indemnitee did not reasonably believe to be in or not opposed to the best interests of the Company, or, with respect to any criminal Proceeding, that the Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such determination shall be made: (i) by the Board by a majority vote of directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) by a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; or (iii) if there are no such directors, or if such directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee. To receive an advancement of Expenses under this Agreement, the Indemnitee shall submit a written request to the Secretary of the Company. Such request shall reasonably evidence the Expenses incurred by the Indemnitee and shall include or be accompanied by an undertaking, by or on behalf of the Indemnitee, to repay all amounts so advanced if it shall ultimately be determined, by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal, that the Indemnitee is not entitled to be indemnified for such Expenses by the Company as provided by this Agreement or otherwise. The Indemnitee's undertaking to repay any such amounts is not required to be secured. Each such advancement of Expenses shall be made within 20 calendar days after the receipt by the Secretary of the Company of such written request. The Indemnitee's entitlement to Expenses under this Agreement shall include those incurred in connection with any action, suit, or proceeding by the Indemnitee seeking an adjudication pursuant to Section 11 of this Agreement (including the enforcement of this provision) to the extent the court shall determine that the Indemnitee is entitled to an advancement of Expenses hereunder.

17. Severability; Prior Indemnification Agreements. If any provision or provisions of this Agreement shall be held to be invalid, illegal, or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law (a) the validity, legality, and enforceability of such provision in any other circumstance and of the remaining provisions of this Agreement (including, without limitation, all portions of any paragraphs of this Agreement containing any such provision held to be invalid, illegal, or unenforceable, that are not by themselves invalid, illegal, or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby, and (b) to the fullest extent possible, the provisions of this Agreement (including, without limitation, all portions of any paragraph of this Agreement containing any such provision held to be invalid, illegal, or unenforceable, that are not themselves invalid, illegal, or unenforceable) shall be construed so as to give effect to the intent of the parties that the Company provide protection to the Indemnitee to the fullest enforceable extent set forth in this Agreement. This Agreement shall supersede and replace any prior indemnification agreements entered into by and between the Company and the Indemnitee and any such prior agreements shall be terminated upon execution of this Agreement.

18. Headings; References; Pronouns. The headings of the sections of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof. References herein to section numbers are to sections of this Agreement. All pronouns and any variations thereof shall be deemed to refer to the singular or plural as appropriate.

19. Other Provisions.

(a) This Agreement and all disputes or controversies arising out of or related to this Agreement shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to the laws of any other jurisdiction that might be applied because of conflicts of laws principles of the State of Delaware, unless, if the Indemnitee is an employee of the Company, otherwise required by the law of the state in which the Indemnitee primarily resides and works.

(b) This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party.

(c) This Agreement shall not be deemed an employment contract between the Company and any Indemnitee who is an officer of the Company, and, if the Indemnitee is an officer of the Company, the Indemnitee specifically acknowledges that the Indemnitee may be discharged at any time for any reason, with or without cause, and with or without severance compensation, except as may be otherwise provided in a separate written contract between the Indemnitee and the Company.

(d) This Agreement may not be amended, modified, or supplemented in any manner, whether by course of conduct or otherwise, except by an instrument in writing specifically designated as an amendment hereto, signed on behalf of each party. No failure or delay of either party in exercising any right or remedy hereunder shall operate as a waiver thereof, and no single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such right or power, or any course of conduct, shall preclude any other or further exercise thereof or the exercise of any other right or power.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the Company and the Indemnitee have caused this Agreement to be executed as of the date first written above.

ORUKA THERAPEUTICS, INC.

By: _____
Name:
Title:

_____
Indemnitee:

[Signature Page to Indemnification Agreement]

Exhibit 10.20

Oruka Therapeutics, Inc.

Non-Employee Directors Compensation Program

Each of our non-employee directors receives compensation pursuant to the non-employee director cash and equity compensation program adopted by our Board. This program provides for the following annual cash retainers:

Annual Cash Retainer	$	40,000
Annual Board Chair Retainer	$	30,000
Audit Committee Retainers:		
Chair	$	15,000
Non-Chair Member	$	7,500
Compensation Committee Retainers:		
Chair	$	12,000
Non-Chair Member	$	6,000
Nominating and Corporate Governance Committee Retainers		
Chair	$	10,000
Non-Chair Member	$	5,000

In connection with the Company's annual meeting of stockholders, each member of the Board will receive an annual grant of stock options to purchase 17,500 shares of common stock, which will vest in equal monthly installments over 12 months so long as such director joined the Board prior to January 1 of the year in which such annual meeting occurs. In addition, in connection with a non-employee director's initial appointment to the Board, they will receive an initial grant of stock options to purchase 35,000 shares of common stock, which will vest in equal monthly installments over 36 months.

All members of the Board are also reimbursed for reasonable and documented out-of-pocket travel and lodging expenses incurred in connection with attending meetings and activities of the Board and its committees.

Exhibit 10.29

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

IL-17 LICENSE AGREEMENT

This License Agreement ("**Agreement**") is entered into and effective as of February 4, 2025 (the "**Effective Date**"), by and between Paragon Therapeutics, Inc., a Delaware corporation ("**Paragon**"), and Oruka Therapeutics, Inc., a Delaware corporation ("**Oruka**"). Paragon and Oruka are also referred to herein individually as a "**Party**", or collectively as the "**Parties**."

RECITALS

Whereas, Paragon has developed a proprietary platform technology for the discovery and development of antibodies against therapeutically relevant targets;

Whereas, pursuant to that certain Amended and Restated Antibody Discovery and Option Agreement by and among Paragon, Oruka and Paruka Holding, LLC, a Delaware limited liability company, dated as of March 28, 2024 (as such agreement may be further amended from time to time, the "**Option Agreement**"), Oruka has engaged Paragon to identify, evaluate and develop one or more antibody candidates directed to certain therapeutic targets and has been granted an exclusive option to enter into one or more separate license agreements to develop, manufacture and commercialize the resulting antibodies with respect to a given target;

Whereas, Oruka has exercised such option with respect to the Licensed Target (as defined below), and the Parties desire to memorialize the exclusive license from Paragon to Oruka with respect to such Licensed Target, all on the terms and subject to the conditions set forth in this Agreement.

Now Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE I

DEFINITIONS.

The following initially capitalized terms have the following meanings (and derivative forms of them shall be interpreted accordingly):

1.1 "**Achievement of Development Candidate**" means the first to occur of: (a) nomination by Oruka's Board of Directors of an Oruka Product as a "Development Candidate"; and (b) the initiation by or on behalf of Oruka or its Affiliate or Sublicensee of a toxicology study with respect to an Oruka Product that employs applicable then-current good laboratory practice standards, the results of which are intended to be submitted as part of an IND.

1.2 "**Acquired Program**" has the meaning set forth in Section 2.2(c).

1.3 "**Acquiring Entity**" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than (a) the applicable Party in the definition of Change of Control, and (b) such Party's Affiliates, determined immediately prior to the closing of such Change of Control ((a) and (b) collectively, the "**Pre-Existing Entities**").

1.4 "**Affiliate**" means any entity controlled by, controlling, or under common control with a Party hereto. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" or "under common control") means the direct or indirect ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) in the equity of, or the right to appoint more than fifty percent (50%) of the directors or management of, such corporation or other business entity. Notwithstanding the foregoing, (a) with respect to either Party, Affiliates of such Party do not include [***] or its Affiliates other than such Party and its subsidiaries, (b) Paragon and its Affiliates, on the one hand, and Oruka and its subsidiaries, on the other hand, shall not be deemed to be Affiliates of each other, and (c) Affiliates of Paragon do not include new entities formed by or on behalf of Paragon for the sole *bona fide* purpose of further developing, manufacturing, commercializing or otherwise exploiting Antibodies and Antibody products (excluding any Licensed Antibody Technology or Other Licensed Technology) using, among other sources, funds from Third Party investors.

1.5 "**Agreement**" has the meaning set forth in the preamble.

1.6 "**Annual Net Sales**" means total Net Sales by Oruka, its Affiliates and Sublicensees in the Territory of all of the Products in a particular Calendar Year, calculated in accordance with U.S. generally accepted accounting principles (GAAP) consistently applied.

1.7 "**Anti-Corruption Laws**" has the meaning set forth in Section 7.2(q)(i).

1.8 "**Antibody**" means any molecule, including [***].

1.9 "**Applicable Law**" means any national, supra-national, federal, state or local laws, rules, guidances, and regulations, in each case, as applicable to the subject matter and the Party at issue.

1.10 "**Bankruptcy Code**" has the meaning set forth in Section 8.4.

1.11 "**Bankruptcy Event**" has the meaning set forth in Section 8.4.

1.12 "**Business Day**" means any day other than Saturday, Sunday or a national holiday in the United States.

1.13 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.14 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.15 "**Change of Control**" means, with respect to any entity, any of the following: (a) the sale or disposition of all or substantially all of the assets of such entity or its direct or indirect controlling Affiliate to a Third Party; or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such entity or any of its Affiliates, of more than fifty percent (50%) of the then-outstanding shares of voting capital stock of such entity or its direct or indirect parent entity that holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then-outstanding shares of voting capital stock of such entity (a "**Parent Entity**"), or (ii) the acquisition, merger or consolidation of such entity or its Parent Entity with or into another entity, other than, in the case of clause (i) or (ii), an acquisition or a merger or consolidation of such entity or its Parent Entity in which the holders of shares of voting capital stock of such entity or its Parent Entity, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation, and in each case of (a) or (b), whether through a single transaction or a series of related transactions, but excluding any and all *bona fide* financing transactions or internal reorganizations for tax purposes (including the change of place of incorporation or domicile of such entity).

1.16 "**Claim**" has the meaning set forth in Section 9.3.

1.17 "**COC Program**" has the meaning set forth in Section 2.2(b).

1.18 "**Combination Product**" has the meaning set forth in Section 1.59.

1.19 "**Commercialize**" or "**Commercializing**" means any and all activity to market, promote, distribute, offer for sale, sell, have sold, seek reimbursement, import, have imported, export, have exported, or otherwise commercialize an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, Multispecific Product, as applicable, and including interacting with Regulatory Authorities following receipt of Regulatory Approval and seeking and maintaining any required Reimbursement Approval. When used as a noun, "**Commercialization**" means any and all activities involved in Commercializing.

1.20 "**Commercially Reasonable Efforts**" means those efforts and resources, including reasonably necessary and qualified personnel, equivalent to the efforts and resources that a reasonable international biopharmaceutical company or a pharmaceutical company, in each case, that is of comparable size and resources to the applicable Party would typically devote as part of an active and continuing program of development and commercialization of a pharmaceutical or biologic product of similar market potential, at a similar stage of its product life, taking into account the competitiveness of the marketplace and the proprietary position, regulatory status, and relative safety and efficacy of such product. Commercially Reasonable Efforts requires, with respect to an obligation, that the applicable Party (a) assign responsibility for such obligation to specific employees who are held accountable for progress and monitor such progress on an on-going basis, (b) set and seek to achieve reasonable objectives for carrying out such obligation, and (c) make and implement reasonable decisions and allocate resources designed to advance progress with respect to such objectives.

1.21 "**Confidential Information**" of a Party means Know-How and any and all non-public scientific, business, regulatory or technical information that is disclosed or made available by or on behalf of one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") in connection with this Agreement, regardless of whether such information is specifically marked or designated confidential, whether in writing, orally, visually, or otherwise. Notwithstanding any provision of this Agreement to the contrary, the Licensed Antibody Technology shall be the Confidential Information of Oruka.

1.22 "**Control**" (including any variations such as "**Controlled**" and "**Controlling**") means, with respect to any technology (including Know-How) or other Intellectual Property Rights, possession by a Party or one of its Affiliates of the ability (whether by ownership, license or otherwise (other than by a license, sublicense or other right granted pursuant to this Agreement)) to grant a license or a sublicense of or under such technology or Intellectual Property Rights without violating the terms of any agreement or other arrangement with any Third Party; *provided, that* if following the Effective Date (a) Paragon would Control any Patent that would be included in the Licensed Antibody Technology or Other Licensed Patents but for an obligation to pay royalties or other consideration for the Development, Manufacture or Commercialization of an Oruka Product in the Territory in connection with a grant to Oruka of a license under such Patent, and (b) Oruka, pursuant to Section 2.8, consents to being a sublicensee of such Patent and complies with the Reimbursement Obligation, then such Patent shall be deemed Controlled by Paragon. Notwithstanding the foregoing, a Party and its Affiliates shall not be deemed to "Control" any technology or Intellectual Property Rights that (i) prior to the consummation of a Change of Control of such Party is owned or in-licensed, or (ii) after the consummation of a Change of Control of such Party, becomes owned or in-licensed (to the extent such technology or Intellectual Property Rights are developed outside of the scope of the activities conducted hereunder and without use of or reference to any technology or Intellectual Property Rights Controlled by such Party or any Affiliate of such Party immediately before such Change of Control, or any Confidential Information of the other Party), in each case ((i) or (ii)), by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Change of Control or an assignee of such Party after the Effective Date as the result of an assignment of this Agreement in connection with a Change of Control unless prior to the consummation of such Change of Control or assignment, such Party or any of its Affiliates also Controlled such technology or Intellectual Property Rights.

1.23 "**Cover**" or "**Covering**" means, with respect to a particular product, any Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, importation, or exportation of such product would infringe a valid and unexpired claim of such Patent.

1.24 **"Derived Antibody"** means any Antibody that is created by or on behalf of Oruka (other than an Antibody created by Paragon under the Option Agreement), its Affiliates or its or their licensees and: (a) is derived from or constitutes a modification of a Licensed Antibody, including [***], (b) [***]and (c) [***]. For avoidance of doubt, any Antibody that [***] will be deemed a Derived Antibody, irrespective of origin. Notwithstanding the foregoing, a Derived Antibody shall not include (i) [***], or (ii) [***].

1.25 "**Designated Multispecific Antibody**" has the meaning set forth in Section 2.6(b).

1.26 "**Develop**" or "**Developing**" means any and all activity to discover, evaluate, test (including clinical and non-clinical testing), research, or otherwise develop an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, or Multispecific Product, as applicable. When used as a noun, "**Development**" means any and all activities involved in Developing.

1.27 "**Directed To**" means, with regard to an Antibody or product, that such Antibody or product is developed or designed to (a) [***], and (b) [***].

1.28 "**Disclosing Party**" has the meaning set forth in Section 1.21.

1.29 "**Dispute**" has the meaning set forth in Section 10.7(a).

1.30 "**Dollar**" means a U.S. dollar, and "$" shall be interpreted accordingly.

1.31 "**Effective Date**" has the meaning set forth in the preamble.

1.32 "**Exclusivity Period**" means the period commencing on the Effective Date and continuing until the fifth (5th) anniversary of the Effective Date.

1.33 "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.34 "**Field**" means the prophylaxis, palliation, treatment and diagnosis of human disease and disorders.

1.35 "**First Commercial Sale**" means the first sale of an Oruka Product by Oruka, or one of its Affiliates or its or their Sublicensees, to a Third Party after receipt of all Regulatory Approvals required to market and sell the Oruka Product have been obtained in the country in the Territory in which such Oruka Product is sold. Sales for purposes of testing the Oruka Product and sample purposes shall not be deemed a First Commercial Sale. Furthermore, for purposes of clarity, the term "First Commercial Sale" as used in this Agreement shall not include: (a) [***]; (b) [***]; nor (c) [***].

1.36 "**Force Majeure**" has the meaning set forth in Section 10.2.

1.37 "**Governmental Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.38 "**IND**" means an investigational new drug application or equivalent application that is required to commence clinical trials for a product in the Territory and filed with the applicable Regulatory Authority.

1.39 "**Indemnified Party**" has the meaning set forth in Section 9.3.

1.40 "**Indemnifying Party**" has the meaning set forth in Section 9.3.

1.41 "**Intellectual Property Rights**" means any and all proprietary rights provided under (a) patent law, including any Patents; (b) copyright law; (c) trademark law; or (d) any other applicable statutory provision or common law principle, including trade secret law, that may provide a right in Know-How, or the expression or use thereof.

1.42 "**Inventions**" means all Know-How, and all Intellectual Property Rights therein, that are conceived, reduced to practice, discovered, developed, or made by or on behalf of either Party or any Third Parties acting on their behalf (or any of their Representatives, Affiliates, licensees, or sublicensees) in the course of performing activities under this Agreement.

1.43 "**JAMS Rules**" has the meaning set forth in Section 10.7(a)(ii).

1.44 "**Know-How**" means all technical information and know-how in any tangible or intangible form, including (a) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (b) all data, instructions, processes, formulae, strategies, and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical, or otherwise and whether related to safety, quality control, manufacturing or other disciplines. Notwithstanding the foregoing, Know-How excludes any Patents.

1.45 "**Licensed Antibody**" means any and all Antibodies that are Directed To the Licensed Target and that were discovered, generated, identified or characterized by Paragon in the course of performing the Research Program. Notwithstanding the foregoing, the Licensed Antibodies shall not include (a) [***], or (b) [***].

1.46 "**Licensed Antibody Invention**" means (a) any invention or discovery, whether or not patentable, that was discovered or reduced to practice by or on behalf of Paragon under the Research Program that constitutes the composition of matter of, or any method of specifically making or using, any Licensed Antibody; and (b) all Intellectual Property Rights therein, that in each case is Controlled by Paragon or its Affiliates as of the Effective Date or during the Term. Notwithstanding the foregoing, the Licensed Antibody Inventions shall not include (i) [***], (x) [***], or (y) [***], or (ii) any Intellectual Property Rights therein.

1.47 "**Licensed Antibody Patents**" means all Patents that Cover the composition of matter of, or any method of specifically making or using, any Licensed Antibody, that in each case are Controlled by Paragon or its Affiliates as of the Effective Date or during the Term, excluding in each case any claims in such Patents that Cover the composition of matter of, or any method of specifically making or using (a) [***], or (b) [***].

1.48 "**Licensed Antibody Technology**" means (a) the Licensed Antibody Inventions; (b) the Licensed Antibody Patents; (c) the Sequence Information; (d) the Results; (e) the Research Program Materials; and (f) all Intellectual Property Rights therein Controlled by Paragon or its Affiliates as of the Effective Date and during the Term.

1.49 "**Licensed Component**" has the meaning set forth in Section 1.59.

1.50 "**Licensed Target**" means IL-17A/F.

1.51 "**Losses**" has the meaning set forth in Section 9.1.

1.52 "**MAA**" means (a) a New Drug Application in the United States, as defined in the United States Federal Food, Drug and Cosmetics Act, and applicable regulations promulgated thereunder by the FDA; (b) a Biologics License Application in the United States, as defined in the United States Public Health Service Act; or (c) any application filed with any Regulatory Authority in a country other than the United States that is equivalent to either of the foregoing.

1.53 "**Major Market Country**" means any of the following: [***].

1.54 "**Manufacture**" or "**Manufacturing**" means any and all activity to make, have made, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, or ship an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, or Multispecific Product, as applicable, or any component thereof. When used as a noun, "**Manufacture**" or "**Manufacturing**" means any and all activities involved in Manufacturing an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, or Multispecific Product, as applicable, or any component thereof.

1.55 "**Milestone**" has the meaning set forth in Section 4.1.

1.56 "**Milestone Payment**" has the meaning set forth in Section 4.1.

1.57 "**Multispecific Antibody**" means any Antibody that is comprised of (a) [***], and (b) [***].

1.58 "**Multispecific Product**" means any product that comprises or contains any Multispecific Antibody.

1.59 "**Net Sales**" means the gross amounts received for Oruka Product by Oruka, its Affiliates and Sublicensees for sales or other commercial disposition of such Oruka Product in the Territory to unrelated Third Parties, less the following, in each case related specifically to the Oruka Product and actually incurred, paid or accrued by Oruka, its Affiliates or Sublicensees and not otherwise recovered by or reimbursed to Oruka, its Affiliates or Sublicensees;

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]; and

(f) [***].

Net Sales will include [***]. Net Sales will be calculated only once for the first *bona fide* arm's length sale of the Oruka Product by Oruka, its Affiliates or its Sublicensees to a Third Party, and will not include sales between or among [***]. Net Sales shall not include any amounts invoiced for [***] (i) [***], (ii) [***], or (iii) [***].

Net Sales shall be determined from the books and records of Oruka, Affiliates of Oruka or any Sublicensee maintained in accordance with U.S. generally accepted accounting principles (GAAP) consistently applied. Oruka further agrees in determining Net Sales, it (or its applicable Affiliate or Sublicensee) will use Oruka's (or such Affiliate's or Sublicensee's) then current standard procedures and methodology.

If an Oruka Product is sold as a Combination Product (as defined below), the Net Sales of such Combination Product for the purpose of calculating royalties and sales-based milestones owed under this Agreement for sales of such Combination Product, shall be determined as follows: [***]. If any Other Component in the Combination Product is not sold separately, Net Sales shall be calculated by [***]. If both the Licensed Component and any of the Other Components are not sold separately, the adjustment to Net Sales shall be determined by the Parties [***] to reasonably reflect [***] of such Licensed Component in the Combination Product to the total fair market value of such Combination Product.

For purposes of this definition, "**Combination Product**" means any pharmaceutical product that contains two (2) or more active ingredients, including (A) one (1) or more Licensed Antibodies, Derived Antibodies or Multispecific Antibodies (the "**Licensed Component**"), and (B) one (1) or more active pharmaceutical or biological ingredients that are not (x) a Licensed Antibody, Derived Antibody or Multispecific Antibody, or (y) an Antibody owned or controlled by Paragon or its Affiliate, the rights to which have been licensed to Oruka or its Affiliate under a separate agreement ("**Other Component(s)**"), either as a [***], [***] or [***], and [***].

1.60 "**Notice of Dispute**" has the meaning set forth in 10.7(a)(i).

1.61 "**Oruka**" has the meaning set forth in the Preamble.

1.62 "**Oruka Antibody Patents**" means all Patents that Cover the composition of matter of, or any method of specifically making or using any Licensed Antibody or Derived Antibody that, in each case, are owned or in-licensed by Oruka or its Affiliates or Sublicensees as of the Effective Date or during the Term, *provided that*, if a Change of Control of Oruka occurs, the Oruka Antibody Patents shall not include any Patents owned or in-licensed by the Acquiring Entity as of the closing of such Change of Control.

1.63 "**Oruka Indemnitee**" has the meaning set forth in Section 9.2.

1.64 "**Oruka Intellectual Property**" means any Patents, Know-How or other Intellectual Property Rights that are Controlled by Oruka and are necessary for, and actually used (or held for use) by Oruka or its Affiliates as of the effective date of termination of this Agreement in the Development, Manufacturing, or Commercialization of Oruka Products.

1.65 "**Oruka Invention**" means (a) any Invention that is owned or Controlled by Oruka, and (b) all Intellectual Property Rights therein, *provided that*, in each case (a) – (b), Oruka Inventions shall not include (i) any Inventions owned or Controlled by Paragon or its Affiliate, the rights to which have been licensed to Oruka or its Affiliate under this Agreement or a separate agreement, or (ii) any Intellectual Property Rights therein.

1.66 "**Oruka Multispecific Antibody**" means any Multispecific Antibody that is Developed, Manufactured, Commercialized or otherwise exploited by Oruka, its Affiliates or Sublicensees, excluding in each case, and subject to Section 2.7, any Paragon Multispecific Antibody.

1.67 "**Oruka Multispecific Patents**" means those Patents that Cover the composition of matter of, or any method of specifically making or using, an Oruka Multispecific Antibody.

1.68 "**Oruka Multispecific Product**" means any product that comprises or contains any Oruka Multispecific Antibody.

1.69 "**Oruka Product**" means, individually or collectively, as applicable, Licensed Antibodies, Derived Antibodies, Products, Oruka Multispecific Antibodies and Oruka Multispecific Products.

1.70 "**Other Component(s)**" has the meaning set forth in Section 1.59.

1.71 "**Other Licensed Know-How**" means all Know-How Controlled by Paragon or its Affiliates on the Effective Date or during the Term that (a) was used by or on behalf of Paragon in the performance of the Research Program, and (b) is necessary to Develop, Manufacture, Commercialize or otherwise exploit (i) Licensed Antibodies, or (ii) Products, Multispecific Antibodies or Multispecific Products, in each case solely to the extent comprising or containing a Licensed Antibody. For clarity, the Other Licensed Know-How shall exclude (x) the Licensed Antibody Technology, and (y) any Know-How Controlled by Paragon or its Affiliates relating to (1) that [***], or (2) [***].

1.72 "**Other Licensed Patents**" means any Patents other than Licensed Antibody Patents Controlled by Paragon or its Affiliates as of the Effective Date or during the Term that (a) include a claim that expressly recites the sequence of a Licensed Antibody or Derived Antibody, and (b) are necessary to Develop, Manufacture or Commercialize Licensed Antibodies or Derived Antibodies in the Field in the Territory. Notwithstanding the foregoing, the Other Licensed Patents shall not include (i) Paragon Multispecific Patents, (ii) the Paragon Platform Patents (as defined in the Option Agreement), or (iii) any Patents that Cover (x) [***], or (y) [***].

1.73 "**Other Licensed Technology**" means all (a) Other Licensed Know-How, and (b) Other Licensed Patents.

1.74 "**Paragon**" has the meaning set forth in the Preamble.

1.75 "**Paragon Indemnitee**" has the meaning set forth in Section 9.1.

1.76 "**Paragon Multispecific Antibody**" means any Multispecific Antibody that is Developed, Manufactured, Commercialized or otherwise exploited by Paragon or its Affiliate or licensees (other than Oruka and its Affiliates and Sublicensees), excluding in each case any Oruka Multispecific Antibodies.

1.77 "**Paragon Multispecific Patents**" means those Patents that Cover the composition of matter of, or any method of specifically making or using, a Paragon Multispecific Antibody, in each case excluding the Licensed Antibody Patents.

1.78 "**Paragon Patents**" has the meaning set forth in Section 5.2(c).

1.79 "**Paragon Third Party Agreement**" has the meaning set forth in Section 2.8.

1.80 "**Parent Entity**" has the meaning set forth in Section 1.15.

1.81 "**Party**" has the meaning set forth in the Preamble.

1.82 "**Patent Challenge**" has the meaning set forth in Section 5.3(a).

1.83 "**Patent Infringement**" has the meaning set forth in Section 5.3(a).

1.84 "**Patents**" means (a) unexpired patents and patent applications, (b) any and all patent applications filed either from such patent or patent applications or from a patent application claiming priority from any of those, including divisionals, provisionals, continuations, continuations-in-part, and reissues, (c) substitutions, renewals, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications, and (d) any and all foreign equivalents of the foregoing.

1.85 "**Phase I Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(a), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.86 "**Phase II Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(b), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.87 "**Phase III Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(c), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.88 "**Post-Effective Date Patents**" has the meaning set forth in Section 5.2(b)(i).

1.89 "**Pre-Existing Entities**" has the meaning set forth in Section 1.3.

1.90 "**Product**" means any product that comprises or contains any Licensed Antibody or Derived Antibody other than as part of a Multispecific Antibody or a Multispecific Product.

1.91 "**Prosecute**" or "**Prosecution**" has the meaning set forth in Section 5.2(a).

1.92 "**Prosecuting Party**" has the meaning set forth in Section 5.2(b)(iii).

1.93 "**Publication**" has the meaning set forth in Section 6.6(b).

1.94 "**Receiving Party**" has the meaning set forth in Section 1.21.

1.95 "**Regulatory Approval**" means all clearances, approvals (including approval of an MAA as well as any applicable pricing and/or reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell and market a pharmaceutical product in a country or territory under this Agreement.

1.96 "**Regulatory Authority**" means any supranational, multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, manufacture marketing or sale of an Oruka Product in a country or region, including the FDA in the United States and the EMA in Europe.

1.97 "**Reimbursement Obligation**" has the meaning set forth in Section 2.8.

1.98 "**Remaining Recovery**" has the meaning set forth in Section 5.3(f).

1.99 "**Representatives**" of a Party means such Party's officers, directors, employees, contractors, subcontractors, agents and consultants.

1.100 "**Research Program**" means the Research Program (as defined in the Option Agreement) conducted by the Parties pursuant to the Option Agreement with respect to the Licensed Target.

1.101 "**Research Program Materials**" means the tangible materials resulting from the Research Program that are Controlled by Paragon or its Affiliates as of the Effective Date or during the Term that are listed in Exhibit C attached hereto, as may be amended in writing from time to time upon mutual agreement of the Parties. For clarity, Research Program Materials shall not include materials that are consumed or destroyed in the performance of the Research Program or that are not available to be transferred by Paragon to Oruka without violating the terms of any agreement or other arrangement with a Third Party.

1.102 "**Results**" means all data, results, analysis, conclusions, outcomes, information, documentation and reports that are generated by or on behalf of Paragon in performance of the Research Program, excluding in each case any other Licensed Antibody Technology.

1.103 "**Reversion Products**" has the meaning set forth in Section 8.5(c).

1.104 "**Review Period**" has the meaning set forth in Section 6.6(b).

1.105 "**ROFN Information**" has the meaning set forth in Section 2.7(a).

1.106 "**ROFN Negotiation Period**" has the meaning set forth in Section 2.7(c).

1.107 "**ROFN Period**" has the meaning set forth in Section 2.7(a).

1.108 "**Royalty Payments**" has the meaning set forth in Section 4.2(a).

1.109 "**Royalty Term**" means, on an Oruka Product-by-Oruka Product and country-by-country basis, the period commencing on First Commercial Sale of the applicable Oruka Product in the applicable country in the Territory and ending, with respect to the particular Oruka Product and country at issue on the latest of the following dates: (a) the twelfth (12th) anniversary of the date of First Commercial Sale of such Oruka Product in such country; or (b) the expiration of the last-to-expire Valid Claim of a Licensed Antibody Patent or an Oruka Antibody Patent Covering the Manufacture, use or sale of such Oruka Product in the country at issue.

1.110 "**Sequence Information**" means any files of Paragon containing all Licensed Antibody sequences generated under the Research Program.

1.111 "**Sublicensee**" means any Affiliate of Oruka or any Third Party with respect to Oruka, to whom Oruka grants a sublicense of, or other authorization or permission granted under, the rights granted to Oruka in Section 2.1.

1.112 "**Target**" means a protein molecule that (a) is chemically distinct from other molecules, and (b) wherein a binding entity derives recognized therapeutic value from binding to such molecule.

1.113 "**Term**" has the meaning set forth in Section 8.1.

1.114 "**Territory**" means worldwide.

1.115 "**Third Party**" means any person or entity other than Paragon or Oruka or an Affiliate of either Paragon or Oruka.

1.116 "**Third Party Claim**" has the meaning set forth in Section 9.1.

1.117 "**Transfer Period**" has the meaning set forth in Section 2.5(c).

1.118 "**US**" or "**United States**" means the United States of America and its possessions and territories, including Puerto Rico.

1.119 "**Valid Claim**" means, with respect to a particular country, a claim (including a process, use or composition of matter claim) of an issued and unexpired patent (or a supplementary protection certificate thereof) that has not (a) irretrievably lapsed or been abandoned, permanently revoked, dedicated to the public or disclaimed, or (b) been held invalid, unenforceable or not patentable by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, which holding, finding or decision is final and unappealable or unappealed within the time allowed for appeal.

ARTICLE II

LICENSES; TECHNOLOGY TRANSFER; MULTISPECIFIC ANTIBODIES.

2.1 **License Grants**.

(a) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a royalty-bearing, exclusive (even as to Paragon and its Affiliates, subject to Paragon's retained rights under Section 2.4) license, including the right to sublicense through multiple tiers, under the Licensed Antibody Technology to Develop, Manufacture, Commercialize, or otherwise exploit Licensed Antibodies, Derived Antibodies and Products in the Field in the Territory.

(b) Subject to the terms of this Agreement, including Section 2.7, Paragon hereby grants to Oruka a royalty-bearing, non-exclusive right and license, including the right to sublicense through multiple tiers, under the Licensed Antibody Technology to Develop, Manufacture, Commercialize or otherwise exploit Multispecific Antibodies and Multispecific Products in the Field in the Territory.

(c) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a royalty-bearing, non-exclusive license, including the right to sublicense through multiple tiers, under the Other Licensed Patents to Develop, Manufacture, Commercialize or otherwise exploit Licensed Antibodies, Derived Antibodies, Multispecific Antibodies, Products and Multispecific Products in the Field in the Territory.

(d) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a royalty-bearing, non-exclusive license, including the right to sublicense through multiple tiers, under the Other Licensed Know-How to Develop, Manufacture, Commercialize or otherwise exploit (i) Licensed Antibodies, or (ii) Products, Multispecific Antibodies or Multispecific Products, in each case solely to the extent comprising or containing a Licensed Antibody, in the Field in the Territory.

2.2 **Exclusivity**.

(a) Subject to the terms of this Section 2.2, to the maximum extent permissible under Applicable Law, during the Exclusivity Period, Paragon shall not, and shall ensure that its Affiliates do not, directly or indirectly, conduct any activity, either on its own or with, for the benefit of, or sponsored by, any Third Party, including granting any license to any Third Party that would permit such Third Party, to develop, manufacture, commercialize or otherwise exploit any monospecific Antibody that is Directed To the Licensed Target in the Field. It will not be a violation of this Section 2.2(a) if Paragon or its Affiliate, directly or through a Third Party, (i) conducts screening activities solely for the purposes of ensuring compliance with this Section 2.2(a), (ii) conducts activities in accordance with the terms of this Agreement, the Option Agreement or any other written agreement between the Parties, or (iii) conducts activities with the prior written consent of Oruka.

(b) Notwithstanding anything herein to the contrary, if a Change of Control occurs with respect to Paragon or its Parent Entity, and the Acquiring Entity (or any of such Acquiring Entity's successors or assigns, other than the relevant Pre-Existing Entities) as of the Change of Control has a program or product (or rights thereto) that would otherwise violate Section 2.2(a) (each, a "**COC Program**"), then (i) Section 2.2(a) shall not apply with respect to such COC Program, and (ii) such Acquiring Entity will be permitted to continue such COC Program after such Change of Control and such continuation will not constitute a violation of Section 2.2(a), *provided, that* the Licensed Antibody Technology and Confidential Information of Paragon and Oruka relating to the Oruka Products is not used in the COC Program.

(c) Notwithstanding anything herein to the contrary, if Paragon or its Parent Entity (i) acquires a Third Party entity that has a program or product (or rights thereto) that would otherwise violate Section 2.2(a), or (ii) acquires asset(s) from a Third Party entity that would otherwise violate Section 2.2(a) (each, an "**Acquired Program**"), then (1) Section 2.2(a) shall not apply with respect to such Acquired Program, and (2) Paragon or its Parent Entity will be permitted to continue such Acquired Program after such acquisition and such continuation will not constitute a violation of Section 2.2(a), *provided, that* the Licensed Antibody Technology and Confidential Information of Paragon and Oruka relating to the Oruka Products is not used in the Acquired Program.

2.3 **Sublicenses**. Oruka shall have the right to grant sublicenses under the rights granted to it in Section 2.1 to its Affiliates and Third Parties; *provided, that* (a) each such sublicense shall be granted in writing and each such relevant sublicense agreement shall be consistent with all relevant terms, conditions and restrictions of this Agreement, (b) Oruka will provide Paragon with a true and complete copy of each sublicense agreement (other than sublicense agreements with Third Party service providers) and any amendments thereto within [***] days following the execution thereof (which sublicense agreement and amendments may be redacted except to the extent necessary for Paragon to determine Oruka's compliance with this Agreement), and (c) Oruka shall remain responsible for all of its payments and other performance obligations due under this Agreement, notwithstanding any license or sublicense that it may grant.

2.4 **No Implied Licenses; Reservation of Rights**. Except as expressly set forth herein, no right or license under any Patents, Know-How or Intellectual Property Right of either Party is granted or shall be granted by implication hereunder. All such rights or licenses are or shall be granted only as expressly provided in this Agreement, and each Party reserves to itself all rights not expressly granted under this Agreement. Notwithstanding anything to the contrary under this Agreement, Paragon retains rights under the Licensed Antibody Technology solely to perform its obligations and exercise its rights under this Agreement and the Option Agreement.

2.5 **Information Transfer and Support to Oruka**.

(a) As soon as possible and within not more than [***] days after the Effective Date, Paragon shall provide Oruka with the Results and Sequence Information in existence as of the Effective Date not already provided to Oruka under the Option Agreement. Additionally, on a continuing basis during the term of the Research Program, as soon as possible and within not more than [***] days after additional Results or Sequence Information come into existence or are identified by Paragon that in each case have not already been provided to Oruka under the Option Agreement, Paragon shall disclose and transfer such additional Results and Sequence Information to Oruka.

(b) Upon the reasonable request of Oruka made from time to time during the Term, Paragon shall promptly disclose and transfer to Oruka tangible embodiments of the Other Licensed Know-How that is the subject of Oruka's request.

(c) The Parties acknowledge and agree that Exhibit C has been agreed by the Parties as of the Effective Date, and that materials that are different than or in addition to the materials set forth on Exhibit C may result from the Research Program to the extent that the Research Program continues to be performed following the Effective Date. Upon the reasonable request of Oruka made at any time prior to the end of the [***] day period following the expiration of the Research Term (as defined in the Option Agreement), the Parties shall update Exhibit C to reflect the tangible materials, including samples, reagents, nucleic acids and Antibodies, resulting from the Research Program that constitute Research Program Materials hereunder. During the period beginning on the Effective Date and ending [***] months after the expiration of the Research Term (the "**Transfer Period**"), at [***] request and expense, Paragon will provide Oruka or a Third Party designated by Oruka with any Research Program Materials, provided that any Third Party recipient of such Research Program Materials shall be bound by the relevant terms of this Agreement and that the Research Program Materials are used solely to further Develop, Manufacture and Commercialize the Oruka Products. For clarity, [***] shall be responsible for any out-of-pocket costs incurred by Paragon or its Affiliates to store and maintain the Research Program Materials during the Transfer Period.

(d) Each Party shall bear all costs and expenses incurred by such Party in connection with the disclosure and transfer of any Results and Sequence Information as set forth above.

(e) During the [***] day period following completion of the Research Program, in the event Oruka makes any reasonable request for assistance in order to understand the Licensed Antibody Technology and use the Licensed Antibody Technology to continue the uninterrupted Development of the Licensed Antibodies, Paragon shall provide up to [***] month of additional assistance during such period, at [***] cost and expense at the then current [***] Rate (as defined in the Option Agreement) in the Option Agreement. Paragon shall consider and discuss in good faith any additional requests for assistance made by Oruka, which assistance may be provided upon mutual agreement of the Parties.

2.6 **Paragon Rights with Respect to Multispecific Antibodies**.

(a) Subject to the terms of this Agreement, including Section 2.6(b) below and Section 2.7, Paragon reserves and retains the non-exclusive right under the Licensed Antibody Technology to Develop, Manufacture, Commercialize and otherwise exploit Multispecific Antibodies and Multispecific Products in the Field in the Territory. If Paragon exercises such right, then Paragon shall pay royalties to Oruka in accordance with Article IV (at the rate specified in Section 4.2(b)), *mutatis mutandis*, with respect to any Multispecific Antibodies and Multispecific Products that are Commercialized by Paragon or its Affiliates or sublicensees (other than Oruka and its Affiliates and Sublicensees) in the Field in the Territory, *provided, that* references to Oruka Antibody Patents in clause (b) of the Royalty Term definition and Section 4.3 shall be disregarded.

(b) Oruka has designated [***] Licensed Antibody or Derived Antibody as its lead compound and [***] Licensed Antibody or Derived Antibody as its backup compound, as set forth on Exhibit B (each such designated Licensed Antibody or Derived Antibody, a "**Designated Multispecific Antibody**"). Paragon's rights under Section 2.6(a) shall expressly exclude the right to Develop, Manufacture, Commercialize or otherwise exploit (i) Multispecific Antibodies that have identical sequence identity within their complementarity-determining regions as a Designated Multispecific Antibody, or (ii) Multispecific Products that comprise or contain any Multispecific Antibody referenced in clause (i). For the avoidance of doubt, if Paragon engaged in Development or Manufacture of a Multispecific Antibody that meets the criteria of clause (i) or (ii) above prior to the Effective Date, then Paragon shall not be in breach of this Agreement, *provided that*, Paragon ceases all such Development or Manufacture within [***] days following the Effective Date.

2.7 **Right of First Negotiation**.

(a) Commencing on the Effective Date and continuing until the [***] anniversary thereof (the "**ROFN Period**"), Paragon will promptly notify Oruka in writing if (i) Paragon has developed a descriptive research plan with respect to the Development of a Multispecific Antibody or a plan to license or grant rights in a Multispecific Antibody to a Third Party, or (ii) Paragon enters into [***] negotiations pursuant to an offer to or from any Third Party relating to the foregoing. Together with such notice, Paragon will provide to Oruka all material information and research plans developed by Paragon with respect to such Multispecific Antibody (the "**ROFN Information**"). Oruka will have [***] days from receipt of the ROFN Information to deliver a written notice to Paragon of Oruka's desire to engage in negotiations for an agreement concerning the Development, or exclusive license or grant of rights to, such Multispecific Antibody.

(b) If Oruka does not provide such written notice to Paragon of its interest to engage in such negotiations within such [***] day period, then (i) Paragon shall be free to enter into an agreement with a Third Party with respect to the grant of a license or other rights to such Multispecific Antibody and corresponding Multispecific Products without further obligation to Oruka under this Section 2.7, and (ii) Oruka's license under Section 2.1(b) shall automatically exclude any right to Develop, Manufacture, Commercialize or otherwise exploit the identical Multispecific Antibodies Developed by or on behalf of Paragon and corresponding Multispecific Products.

(c) If Oruka does provide Paragon such written notice within such [***] day period, the Parties will negotiate [***] on an exclusive basis for a period of up to [***] months from the date of Oruka's notice ("**ROFN Negotiation Period**"), an agreement for the Development, or exclusive license or grant of rights to, such Multispecific Antibody and corresponding Multispecific Products. Prior to and during the ROFN Negotiation Period, Paragon shall not enter into an agreement with respect to such Multispecific Antibody with any Third Party that will prevent Paragon from entering into an agreement with Oruka for the Development, or exclusive license or grant of rights to, such Multispecific Antibody and corresponding Multispecific Products. Unless and until the Parties have entered into an agreement with respect to such Multispecific Antibody and corresponding Multispecific Products, Oruka shall have no rights or license with respect to such Multispecific Antibody and corresponding Multispecific Products except as otherwise expressly provided in Section 2.1. In the event that the Parties have not entered into an agreement with respect to such Multispecific Antibody and corresponding Multispecific Products prior to the expiration of the ROFN Negotiation Period, then (i) Paragon shall be free to enter into an agreement with a Third Party with respect to the grant of a license or other rights to such Multispecific Antibody and corresponding Multispecific Products without further obligation to Oruka under this Section 2.7, and (ii) Oruka's license under Section 2.1(b) shall automatically exclude any right to Develop, Manufacture, Commercialize or otherwise exploit the identical Multispecific Antibodies Developed by or on behalf of Paragon and corresponding Multispecific Products.

2.8 **Third Party In-Licenses**. If Paragon (or its Affiliate) enters into any in-license agreement with a Third Party after the Effective Date with respect to any Patent that would, if Controlled by Paragon, be included within the Licensed Antibody Patents or the Other Licensed Patents (each such agreement, a "**Paragon Third Party Agreement**"), Paragon shall notify Oruka in writing that it entered into such Paragon Third Party Agreement and provide a copy of such Paragon Third Party Agreement to Oruka, which may be redacted solely concerning [***] or other confidential terms not applicable to sublicensees. Oruka shall have the right, by delivery of notice to Paragon, to elect to take a sublicense under such Patents in-licensed by Paragon under such Paragon Third Party Agreement. If Oruka elects to become a sublicensee thereunder pursuant to this Section 2.8, then (a) the applicable Patents under such Paragon Third Party Agreement shall be included within the Licensed Antibody Patents or the Other Licensed Patents, as applicable, that are licensed to Oruka under Section 2.1, (b) Oruka shall reimburse Paragon for Paragon's pro rata share of royalties or other consideration, as mutually agreed by the Parties, payable by Paragon under the Paragon Third Party Agreement for Oruka's Development, Manufacture, Commercialization or other exploitation of an Oruka Product in the Field in the Territory in connection with the grant to Oruka of such Patents (the "**Reimbursement Obligation**"), and (c) Oruka shall comply with the terms of such Paragon Third Party Agreement to the extent applicable to Oruka as a sublicensee of such Patents. In the event of any conflict between the terms of this Agreement and any Paragon Third Party Agreement applicable to a sublicense granted by Paragon to Oruka in accordance with this Section 2.8, the terms of the Paragon Third Party Agreement shall control solely to the extent necessary for the Parties to maintain compliance with such Paragon Third Party Agreement. Oruka shall comply with the Reimbursement Obligation by paying to Paragon any amounts subject to the Reimbursement Obligation within the earlier of (i) [***] days after Oruka's receipt from Paragon of an invoice for such payment, and (ii) the date when such payment is due to the counterparty licensor under the applicable Paragon Third Party Agreement, *provided that* such payment shall not be due prior to the date when such amounts are payable by Paragon to the counterparty licensor under the applicable Paragon Third Party Agreement.

ARTICLE III

DEVELOPMENT, MANUFACTURING & COMMERCIALIZATION.

3.1 **Oruka Responsibilities**.

(a) As between the Parties, Oruka shall be solely responsible for and shall have the sole right to control, all aspects of the Development, Manufacturing, and Commercialization of the Oruka Products in the Field in the Territory during the Term, including distribution, product positioning, product strategy, product branding, core messaging, marketing, promotion, detailing activities and all decisions relating to the setting of prices in the Territory, invoicing and booking sales, establishing all terms of sale, and all regulatory activities.

(b) As between the Parties, Oruka shall be solely responsible for, and shall have the sole right to control, the selection, registration and maintenance of all trademarks associated with the Oruka Products in the Field in the Territory. As between the Parties, Oruka shall solely own such trademarks in the Territory and pay all relevant costs thereof.

3.2 **Regulatory**. As between the Parties, Oruka shall control all regulatory matters, including the regulatory strategy, regulatory filings, regulatory activities (including clinical trials for Oruka Products) and communication with each Regulatory Authority for the Oruka Products in the Field in the Territory. Oruka shall have the right to reference any relevant data included within the Licensed Antibody Technology for the purposes of regulatory filings and safety reporting, including all nonclinical data, pre-approval and post-approval clinical use data, and regulatory data with respect thereto, and Paragon shall cooperate as reasonably requested by Oruka with respect to providing to Oruka when requested, and on a timely basis, any of the foregoing information, data filings or reporting. Oruka or its designee shall be the party to file an application to each applicable Regulatory Authority in the Territory for, and to obtain and maintain, in its own name, Regulatory Approval for the Oruka Products in each country in the Territory.

3.3 **Diligence; Reporting**. Oruka shall use Commercially Reasonable Efforts (a) to Develop and seek Regulatory Approval for at least one Oruka Product in the Field in the United States and at least one other Major Market Country, and (b) upon receipt of Regulatory Approval for a given Oruka Product in a given country, to Commercialize such Oruka Product in such country, in each case ((a) or (b)) either by itself or through its Affiliates or Sublicensees or its or their respective contractors. Additionally, on or before [***] of each year during the Term, Oruka shall deliver to Paragon a report summarizing its material development efforts with respect to the Oruka Products, including a summary of current and anticipated preclinical and clinical activities, a summary of the status of any regulatory filings and any anticipated regulatory filings, and achievement of any Milestones, during the preceding [***]; *provided, however*, that Oruka may satisfy the reporting obligations set forth in this Section 3.3 by providing Paragon with copies of any annual report or other filings with a securities exchange that include the relevant information. For the avoidance of doubt, if Oruka determines, in its sole discretion, that it is inconsistent with the use of Commercially Reasonable Efforts to pursue Commercialization of an Oruka Product in any country (other than the United States), it will not be considered a material breach of this Agreement to cease Development or Commercialization of such Oruka Product with respect to such country.

ARTICLE IV

FINANCIAL TERMS.

4.1 **Milestone Payments**. Oruka shall make the following one-time, non-refundable and non-creditable payments to Paragon (or to such other designee(s), as requested by Paragon in an invoice) (each payment, a "**Milestone Payment**"), based on the achievement of the corresponding milestone (each, a "**Milestone**") by Oruka, its Affiliates, or its Sublicensees with respect to the first Oruka Product to achieve such Milestone. Oruka shall, within [***] Business Days after it or its Affiliates achieve a Milestone, or within [***] Business Days after it learns that its or its Affiliate's Sublicensee has achieved a Milestone, notify Paragon of the achievement of such Milestone in writing. Following receipt of such notice, Paragon shall invoice Oruka for such Milestone Payment, which invoice shall specify whether Paragon or its designee should receive such Milestone Payment and the bank account information into which such Milestone Payment should be paid. Oruka shall make such Milestone Payment to Paragon or Paragon's designee within [***] days after receipt of Paragon's invoice. Each Milestone Payment shall be paid no more than once, and Oruka's total Milestone Payments hereunder shall not exceed Twenty-Two Million Dollars ($22,000,000). For avoidance of doubt, upon achievement of any Milestone, all prior unachieved Milestones shall be deemed thereby achieved and, if the Milestone Payment for any such prior Milestone has not previously been paid, it shall thereupon also be paid at the same time that the Milestone Payment for such subsequent achieved Milestone is paid.

	Milestone	Milestone Payment
#1	Achievement of Development Candidate	One Million Five Hundred Thousand Dollars ($1,500,000)
#2	First dosing of a human patient in a Phase I Trial of an Oruka Product	Two Million Five Hundred Thousand Dollars ($2,500,000)
#3	First dosing of a human patient in a Phase II Trial of an Oruka Product	Three Million Dollars ($3,000,000)
#4	First dosing of a human patient in a Phase III Trial of an Oruka Product	Five Million Dollars ($5,000,000)
#5	Receipt of Regulatory Approval from the FDA of an Oruka Product	Ten Million Dollars ($10,000,000)

4.2 **Royalties**.

(a) **Royalty Rate for Products**. During the applicable Royalty Term (which shall be measured on a country-by-country and Product-by-Product basis), Oruka shall pay tiered royalties to Paragon (or to such other designee(s), as requested by Paragon) as set forth in the table below on Annual Net Sales of all Products sold by Oruka, its Affiliates or its Sublicensees in the Field in the Territory (together with any royalties payable under Section 4.2(b), the "**Royalty Payments**").

Annual Net Sales of the Products in a Given Calendar Year	**Royalty Rate**
Portion of Annual Net Sales of the Products in a Given Calendar Year Above $0 but Up to and Including $[***]	[***]%
Portion of Annual Net Sales of the Products in a Given Calendar Year of More Than $[***], Up to and Including $1.0 Billion	[***]%
Portion of Annual Net Sales of the Products in a Given Calendar Year of More Than $[***]	[***]%

(b) **Royalty Rate for Oruka Multispecific Products**. During the applicable Royalty Term (which shall be measured on a country-by-country and Oruka Multispecific Product-by-Oruka Multispecific Product basis), Oruka shall pay royalties to Paragon (or to such other designee(s), as requested by Paragon) equal to [***] percent ([***]%) of Net Sales of all Oruka Multispecific Products sold by Oruka, its Affiliates or its Sublicensees in the Field in the Territory.

(c) If any Oruka Product contains (a) a combination of more than one Licensed Antibody, Derived Antibody and/or Multispecific Antibody, or (b) a combination of (i) one or more Licensed Antibodies, Derived Antibodies or Multispecific Antibodies, and (ii) one or more other Antibodies owned or Controlled by Paragon or its Affiliates, the rights to which have been licensed to Oruka or its Affiliates under a separate agreement, then, in each case (a) or (b) unless otherwise agreed by the Parties, the royalty rate for the Royalty Payments payable to Paragon with respect to such Oruka Product (x) shall be determined in accordance with the Royalty Rate chart set forth in Section 4.2(a) if such Oruka Product does not contain a Multispecific Antibody, and (y) shall be determined in accordance with Section 4.2(b) if such Oruka Product contains a Multispecific Antibody.

4.3 **Royalty Reductions for No Valid Claim**. If, during any Calendar Quarter during the Royalty Term for a particular Oruka Product in a particular country, no Valid Claim of a Licensed Antibody Patent Covers the Manufacture or Commercialization of such Oruka Product in such country, then the applicable royalty rate for the Royalty Payments set forth in Section 4.2 for such Calendar Quarter shall be reduced by [***].

4.4 **Payment Reports**. Within [***] days after the end of [***] days for [***] in which an Oruka Product is sold, Oruka shall provide to Paragon a written report, on an [***] basis, stating the [***], including [***]; [***]. All Royalty Payments described in such written report shall be made by Oruka at the same time it submits such written report to Paragon. All such Royalty Payments shall be paid to Paragon or Paragon's designee, *provided that* in the case of payment to a designee, Paragon has notified Oruka in writing [***] days prior to the due date for any Royalty Payment of the designee to be paid and the bank account information for such designee.

4.5 **Payment Method**. All payments due under this Agreement to Paragon shall be made in U.S. Dollars by bank wire transfer in funds to an account designated by Paragon from time to time reasonably in advance of any payment due date.

4.6 **Taxes**. The Parties agree to cooperate with one another and use reasonable efforts to minimize obligations for any and all income or other taxes required by Applicable Law to be withheld or deducted from any Royalty Payments, Milestone Payments or other payments made by Oruka to Paragon or its designee(s) under this Agreement, including by completing all procedural steps, and taking all reasonable measures, to ensure that any withholding tax is reduced or eliminated to the extent permitted under Applicable Law, including income tax treaty provisions and related procedures for claiming treaty relief. To the extent that Oruka is required to deduct and withhold taxes on any payment to Paragon or its designee(s), Oruka shall: (i) deduct such taxes from such payment to Paragon or its designee(s), (ii) pay the amounts of such taxes to the proper Governmental Authority in a timely manner, and (iii) promptly submit to Paragon an official tax certificate or other available evidence of such withholding sufficient to enable Paragon or its designee(s) to claim such payment of taxes. For the avoidance of doubt, Oruka's remittance of such withheld amounts to the appropriate Governmental Authority, together with payment to Paragon or its designee(s) of the remaining amount owed, shall constitute full satisfaction of the applicable payment due to Paragon. Oruka shall provide Paragon with any reasonably requested tax forms or certificates available to Oruka in order to allow Paragon or its designee(s) to recover, as permitted by Applicable Law, withholding taxes, value added taxes or similar obligations resulting from payments made hereunder or to obtain the benefit of any present or future treaty against double taxation that may apply to such payments. Paragon shall promptly provide Oruka with any requested tax forms that may be reasonably necessary in order for Oruka to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax income treaty.

4.7 **Foreign Exchange**. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, including in connection with the calculation of Net Sales, such conversions shall be made using the methodology used by Oruka in preparing its publicly filed financial statements.

4.8 **Late Payments**. Any amount owed by Oruka to Paragon under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the per annum rate of [***] percentage point above the then-applicable United States prime rate as quoted in the *Wall Street Journal (East Coast Edition)* (or if it no longer exists, a similarly authoritative source), calculated on a [***] basis, or, if lower, the highest rate permitted under Applicable Law.

4.9 **Blocked Currency**. If by Applicable Law of a country in which Net Sales occurred, conversion of funds into Dollars or transfer of funds from such country to the United States is restricted, forbidden or delayed for more than [***] days, then Oruka can elect, at its sole discretion, that the amounts accrued in such country and owed by Oruka to Paragon under this Agreement shall be paid to Paragon in such country in local currency by deposit in a local bank designated by Paragon, unless the Parties otherwise agree in writing.

4.10 **Records; Inspection**.

(a) Oruka shall, and shall cause its applicable Affiliates to, create and keep complete and accurate records of its sales and other dispositions of all Oruka Products, including all records that are reasonably necessary for the purposes of calculating all payments due under this Agreement.

(b) Upon reasonable advance written notice to Oruka, Paragon shall have the right to retain a nationally recognized (in the US) independent certified public accounting firm to perform on behalf of Paragon an audit, conducted in accordance with U.S. generally accepted accounting principles (GAAP), of such books and records of Oruka or its applicable Affiliates as may be reasonably necessary to verify the accuracy of any reports provided pursuant to Section 4.4 hereunder for any Calendar Quarter in which an Oruka Product was sold, ending not more than [***] calendar months prior to the date of such request. Such audits shall be conducted during normal business hours, shall not occur more frequently than [***] in each Calendar Year and shall not be conducted more than [***] with respect to any reporting period, in each case other than for cause. All information disclosed or observed during any audit pursuant to this Section 4.10 shall be the Confidential Information of Oruka, and Paragon shall cause the accounting firm to retain all such information as Confidential Information, including, if requested by Oruka, by requiring such accounting firm to enter into a customary confidentiality agreement with Oruka prior to the initiation of any such audit.

(c) Upon completion of any audit hereunder, the accounting firm shall provide both Oruka and Paragon a written report disclosing whether the reports submitted by Oruka are correct or incorrect, whether the amounts paid are correct or incorrect, and in each case, the specific details concerning any discrepancies. No other information regarding Oruka's records shall be provided to Paragon.

(d) Paragon shall bear its internal expenses and the out-of-pocket costs for engaging such accounting firm in connection with performing such audits; *provided, however*, that if any such audit uncovers an underpayment by Oruka that exceeds [***] percent ([***]%) of the total owed for such payment or payment period, as applicable, then Oruka shall reimburse Paragon or its designee(s) for the amounts actually paid to such accounting firm for performing such audit.

(e) If such accounting firm concludes that Oruka has in aggregate underpaid amounts owed to Paragon during the audited period, Oruka shall pay Paragon or its designee(s) the amount of the discrepancy within [***] days of the date Paragon delivers to Oruka such accounting firm's written report and an invoice for such amounts. If such accounting firm concludes that Oruka has in aggregate overpaid amounts owed to Paragon during the audited period, then Oruka may, at its election, either credit such overpaid amount against any future payment obligation to Paragon or require Paragon to refund such amounts within [***].

ARTICLE V

INTELLECTUAL PROPERTY.

5.1 **Ownership**. As between the Parties (a) Paragon solely owns the Licensed Antibody Technology and the Other Licensed Patents, (b) Oruka solely owns the Oruka Inventions, including any Derived Antibodies and Oruka Multispecific Antibodies to the extent they constitute Oruka Inventions, (c) each Party solely owns all Intellectual Property Rights owned or Controlled by such Party as of the Effective Date or that come into the ownership or control of such Party during the Term outside the scope of this Agreement, and (d) ownership of Inventions shall be determined in accordance with U.S. laws of inventorship. Other than rights granted to Oruka under this Agreement with respect to the Licensed Antibody Technology and the Other Licensed Patents, nothing in this Agreement shall affect Paragon's rights in any Patents, Know-How or other Intellectual Property Rights owned or controlled by Paragon or its Affiliates, now or in the future. Other than rights granted to Paragon under Section 8.5(c) of this Agreement with respect to the Oruka Intellectual Property, nothing in the Agreement shall affect Oruka's rights in any Patents, Know-How or other Intellectual Property Rights owned or controlled by Oruka or its Affiliates, now or in the future.

5.2 **Patent Prosecution**.

(a) **Prosecution Generally**. For the purpose of this Article V, "**Prosecute**" and "**Prosecution**" shall include any patent interference, opposition, pre-issuance Third Party submission, *ex parte* re-examination, post-grant review, *inter partes* review or other similar proceeding, appeals or petitions to any board of appeals in a patent office, appeals to any court for any patent office decisions, reissue proceedings and applications for patent term extensions and the like.

(b) **Prosecution of Licensed Antibody Patents**.

(i) As between the Parties, with respect to any patent applications for Licensed Antibody Patents that have not been filed prior to the Effective Date and any resulting patents (the "**Post-Effective Date Patents**"), Paragon shall have the sole right, but not the obligation, to prepare, file, Prosecute and maintain the Post-Effective Date Patents until the date on which the Final Deliverable (as defined in the Option Agreement) for the Research Program is delivered to Oruka, and during such period Paragon shall provide Oruka with drafts of all proposed filings to any patent office with respect to Post-Effective Date Patents in reasonably adequate time before submission of such filings for Oruka's review and comment.

(ii) As between the Parties, with respect to (x) any patent applications and resulting patents for Licensed Antibody Patents that were filed prior to the Effective Date, and (y) the Post-Effective Date Patents after the date on which the Final Deliverable (as defined in the Option Agreement) for the Research Program is delivered to Oruka, Oruka shall have the first right to prepare, file, Prosecute and maintain the Licensed Antibody Patents, in each case, at Oruka's sole expense. Oruka shall provide Paragon with copies of all material correspondence from and to any patent office relating to such Licensed Antibody Patents, and Oruka shall provide Paragon with drafts of all proposed filings to any patent office with respect to such Licensed Antibody Patents before submission of such filings, with reasonably adequate time for Paragon's review and comment, which review shall be at Paragon's sole expense.

(iii) Each Party, when acting as the prosecuting Party (in such capacity, the "**Prosecuting Party**") will take into consideration the non-Prosecuting Party's reasonable comments prior to submitting such filings. At the Prosecuting Party's request, the non-Prosecuting Party will sign all documents and take any other actions required for filing, maintenance and grant of Licensed Antibody Patents. Oruka shall reimburse Paragon for any costs and expenses actually incurred by Paragon to the extent Paragon is prosecuting or maintaining any Licensed Antibody Patents.

(iv) The Prosecuting Party shall notify the non-Prosecuting Party of any decision not to prepare or file, or to abandon, cease Prosecution or not maintain any Licensed Antibody Patent anywhere in the Territory. The Prosecuting Party shall provide such notice at least [***] days prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed Antibody Patent. In such event, the non-Prosecuting Party shall have a backup right, but not the obligation, to prepare, file, or continue Prosecution or maintenance of, such Licensed Antibody Patent, at its own expense.

(v) Each Party shall cooperate with the other Party in the preparation, filing, Prosecution and maintenance of Licensed Antibody Patents, including in each case by providing the prosecuting Party with data and other information as appropriate and executing all necessary affidavits, assignments and other paperwork.

(c) **Prosecution by Paragon**. Except with respect to Licensed Antibody Patents (which are addressed in Section 5.2(b)), Paragon shall be solely responsible for, and have sole discretion over, preparing, filing, Prosecuting and maintaining any Patents (including the Other Licensed Patents and Paragon Multispecific Patents) that it owns in whole or in part or otherwise Controls (the "**Paragon Patents**"). Paragon's Prosecution of any Paragon Patents shall be at Paragon's sole expense. Notwithstanding the foregoing, in Prosecuting any Paragon Multispecific Patents, Paragon hereby agrees that during the Term, neither Paragon nor any of its Affiliates or licensees will file, or assist any Third Party in filing, any Patent that includes a claim that expressly recites the sequence of a Licensed Antibody or Derived Antibody other than as part of a Paragon Multispecific Antibody.

(d) **Patent Prosecution Costs Prior to the Effective Date**. No later than [***] days after the Effective Date, Oruka shall reimburse Paragon for any actual costs and expenses incurred by Paragon that are related to the Prosecution of any Licensed Antibody Patents prior to the Effective Date and that have not already been paid by Oruka. Oruka will promptly reimburse Paragon for any future Prosecution costs and expenses incurred by Paragon with respect to the Licensed Antibody Patents.

(e) **CREATE Act**. Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the "**CREATE Act**") when exercising its rights under Article V of this Agreement, without the prior written consent of the other Party. Where such Party intends to invoke the CREATE Act, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a joint research agreement (JRA) as defined in the CREATE Act.

(f) **Disclosure of Antibody Patents**. Upon the request of Paragon, Oruka shall deliver to Paragon a list of the then-existing Oruka Antibody Patents.

5.3 **Patent Enforcement and Defense**.

(a) **Notice of Patent Infringement and Patent Challenge**. Each Party shall give the other Party notice of any known or suspected infringement by a Third Party ("**Patent Infringement**") of any Licensed Antibody Patent and any known or suspected challenge by a Third Party against the validity or enforceability ("**Patent Challenge**") of any Licensed Antibody Patent within [***] days after such Patent Infringement or Patent Challenge comes to such Party's attention.

(b) **Oruka's First Right to Enforce or Defend**. Oruka shall have the first right, but not the obligation, to bring and control any legal action, including by declaratory judgment action, patent litigation or similar proceeding, in connection with any Patent Infringement or Patent Challenge with respect to the Licensed Antibody Patents in the Territory at its own expense and discretion as it reasonably determines appropriate. Oruka shall keep Paragon informed and reasonably consult with Paragon in the course of such legal action. Paragon shall have the right to be represented in any such legal action by counsel of its choice at its own expense.

(c) **Paragon's First Right to Enforce or Defend**. Paragon shall have the sole right, but not the obligation, to bring and control any legal action, including by declaratory judgment action, patent litigation or similar proceeding, in connection with any Patent Infringement or Patent Challenge with respect to the Paragon Patents in the Territory at its own expense and discretion as it reasonably determines appropriate.

(d) **Settlement**. In connection with any such legal action or proceeding, Oruka shall not enter into any settlement admitting the invalidity or unenforceability of Licensed Antibody Patents without the prior written consent of Paragon (such consent not to be unreasonably conditioned, withheld, or delayed).

(e) **Paragon's Backup Right to Enforce or Defend**. If Oruka does not initiate a legal action for Patent Infringement or Patent Challenge with respect to any Licensed Antibody Patent within [***] days after a notice from Paragon under Section 5.3(a), then Paragon shall have a backup right, but not the obligation, to initiate such legal action at its own expense.

(f) **Allocation of Recoveries**. Any recoveries resulting from such legal action initiated by Oruka or Paragon hereunder relating to Patent Infringement or Patent Challenge in each case solely with respect to the Licensed Antibody Patents, including pursuant to a settlement, shall be applied as follows: (i) first to reimburse the [***] of each of the Parties in such action; and (ii) second, any amounts remaining after paying the amounts due each Party under clause (i) (the "**Remaining Recovery**") shall be allocated as follows: (1) [***]; or (2) [***].

(g) **Cooperation with Patent Enforcement**. At the request of the enforcing Party (and at the requesting Party's expense), the other Party shall reasonably cooperate and provide any information or assistance in connection with any legal action under this Section 5.3, including executing reasonably appropriate documents, cooperating in discovery and, if required by Applicable Law, joining as a party to the legal action at its own expense.

5.4 **Third Party Patent Proceedings**.

(a) **Oruka's First Right to Challenge Third Party Patents**. Oruka shall have the sole and exclusive right, but not the obligation, to bring and control any legal action to challenge any Patents controlled by a Third Party, including by declaratory judgment action, patent interference, opposition, pre-issuance submission, *ex parte* re-examination, post-grant review, *inter partes* review, patent litigation or similar proceeding, in each case that are necessary or useful to Develop, Manufacture, Commercialize or otherwise exploit any Oruka Product.

(b) **Cooperation by Paragon**. At the request of Oruka, Paragon shall cooperate and provide any information or assistance in connection with any legal action under this Section 5.4, including executing reasonably appropriate documents, cooperating in discovery and, if required by Applicable Law, joining as a party to the action at Oruka's cost and expense.

5.5 **Common Interest Agreement**. At the request of either Party to conduct the activities under this Article V, the Parties shall cooperate in good faith to enter into a customary, mutually-agreed common-interest agreement intended to preserve attorney-client privilege with respect to disclosures and communications by or on behalf of either Party or its Affiliates in connection with such activities.

ARTICLE VI

PROTECTION OF CONFIDENTIAL INFORMATION.

6.1 **Confidentiality**. Except to the extent expressly authorized by this Agreement, the Receiving Party agrees that, during the Term, for [***] years thereafter, and, with respect to any Know-How that constitutes a trade secret, for long as such Know-How constitutes a trade secret, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party may disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Representatives who have a need for such information, *provided that* the Receiving Party shall advise such Representatives of the confidential nature thereof, shall ensure that each such Representative is bound in writing by obligations of confidentiality and non-use at least as stringent as those contained in this Agreement, and shall be responsible for the compliance of its Representatives with the terms of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information of the Disclosing Party. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the Disclosing Party.

6.2 **Exceptions**. The Receiving Party's obligations under Section 6.1 shall not apply to any Confidential Information of the Disclosing Party that the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available; (b) is known by the Receiving Party at the time of receiving such information from the Disclosing Party; (c) is hereafter furnished to the Receiving Party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the aid, use or application of any Confidential Information of the Disclosing Party.

6.3 **Authorized Disclosure**. Notwithstanding the provisions of this Article VI, the Receiving Party may disclose Confidential Information of the Disclosing Party, without violating its obligations under this Agreement, to the extent the disclosure is:

(a) required by a valid order of a court or other Governmental Authority of competent jurisdiction or as otherwise required by Applicable Law, rule, regulation (including securities laws), government requirement, or as may be required in connection with any filings made with, or by the disclosure policies of, a stock exchange (including, for clarity, any such disclosures required to be made by Paragon or its Affiliates or licensees in connection with the Development, Manufacture, Commercialization or other exploitation of Multispecific Antibodies), *provided that* the Receiving Party shall give reasonable prior written notice to the Disclosing Party of such required disclosure and, at the [***] request and expense, shall cooperate with the Disclosing Party's efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law required, or to obtain other confidential treatment of such Confidential Information;

(b) reasonably necessary to file or Prosecute patent applications, Prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, or obtain or maintain approval to conduct clinical trials or Regulatory Approvals, in each case, in accordance with this Agreement (including, for clarity, any such disclosures that are reasonably necessary to made by Paragon or its Affiliates or licensees in connection with the Development, Manufacture, Commercialization or other exploitation of Multispecific Antibodies); or

(c) under appropriate confidentiality provisions substantially equivalent to those in this Agreement (but of shorter duration if customary in the case of subclause (ii)): (i) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder and the right to Develop, Manufacture, Commercialize and otherwise exploit Antibodies and products (including Multispecific Antibodies and Multispecific Products) to which it has rights hereunder, or (ii) to actual or *bona fide* potential licensees, acquirers, merger partners, assignees, collaborators, investment bankers, investors or lenders.

6.4 **Use of Names**. Except as set forth in Section 6.6(b), neither Party shall use the other Party's name or trademarks in any advertising, sales, or promotional material or in any publication without the prior written consent of the other Party.

6.5 **Confidentiality of this Agreement**. This Agreement and its terms are considered Confidential Information of both Parties, and each Party shall keep confidential and shall not publish or otherwise disclose the terms of this Agreement without the prior written consent of the other Party, except as expressly permitted by Section 6.3, and except that both Parties may disclose this Agreement and its terms to its legal, financial and investment banking advisors; *bona fide* potential and actual investors, acquirers, merger partners, assignees, collaborators, investment bankers, lenders, licensees, sublicensees or strategic partners in connection with license or partnering transactions, due diligence or similar investigations by such Third Parties or in confidential financing documents; and counsel or other advisors for the foregoing; *provided*, in each case, that any such Third Party agrees to be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article VI (*provided that* the confidentiality term applicable to such Third Party may be shorter so long as it is commercially reasonable).

6.6 **Publicity**.

(a) Subject to Section 6.6(b), neither Party will generate or allow any publicity regarding this Agreement or the transactions contemplated hereunder without the other Party first approving such press release or publication in writing, except for any public disclosure by or on behalf of a Party that is, upon the advice of such Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of such Party are listed (or to which an application for listing has been submitted) and except that a Party may, once a press release or other public written statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other public written statement without the further approval of the other Party.

(b) The Parties shall collaborate and cooperate [***] to devise a Publication (as defined below) strategy for the Oruka Products that is acceptable to both Parties. Prior to publicly presenting or publishing any data, results or analyses relating to an Oruka Product generated by or on behalf of Oruka pursuant to this Agreement (each such proposed presentation or publication, a "**Publication**"), Oruka will provide Paragon with a copy of such proposed Publication to review with adequate time for Paragon's review and comment prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). Oruka will take into consideration Paragon's reasonable comments prior to finalizing the Publication. Upon Paragon's request, Oruka shall remove any Confidential Information of Paragon from such Publication that Oruka is not required to disclose pursuant to Applicable Law or the rules of a stock exchange on which the securities of Oruka are listed. In addition, Paragon shall have the right to request the delay of such Publication for up to [***] days to enable filing of Patents, which request Oruka will take into consideration and discuss with Paragon before release of the Publication. Paragon will not publicly present or publish any Publication including Confidential Information of Oruka relating specifically to the Licensed Antibodies or Derived Antibodies without Oruka's prior written consent, which consent may be withheld for any reason or no reason; *provided, that* the foregoing shall not limit Paragon's right to publicly present or publish any Publication relating to Multispecific Antibodies. Each Publication shall include proper attribution, including the use of such Party's trademarks and name, to the non-publishing Party, as applicable, and each non-publishing Party expressly authorizes the inclusion of such reference in the applicable Publication and licenses the use of such trademarks and name solely for inclusion in any such Publication.

ARTICLE VII

REPRESENTATIONS, WARRANTIES AND COVENANTS.

7.1 **Mutual Representations**. Each Party represents and warrants to the other Party that:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder;

(c) no consent, approval, permit, governmental order, declaration or filing with, or notice to, any Governmental Authority or any Third Party is required by or with respect to such in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby; and

(d) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not and will not conflict with any agreement, instrument, or understanding, oral or written, to which it is or may become a party or by which it may be or become bound.

7.2 **Representations of Paragon**. Paragon hereby represents and warrants to Oruka as of the Effective Date that:

(a) Paragon has set forth in Exhibit A a true, correct and complete list of all the Licensed Antibody Patents existing as of the Effective Date (including title, all inventors, owners, assignees, filing date, grant date, expiration date and status);

(b) Unless otherwise set forth in Exhibit A, Paragon exclusively owns all Licensed Antibody Patents;

(c) There are no licenses or sublicenses pursuant to which Paragon licenses as of the Effective Date any of the Licensed Antibody Technology, nor, to Paragon's actual knowledge, are any such licenses necessary to Develop, Manufacture and Commercialize the Licensed Antibodies;

(d) Paragon has the right under the Licensed Antibody Technology to grant to Oruka the licenses and other rights set forth in this Agreement, and it has not granted any license or other right under the Licensed Antibody Technology that is inconsistent with the licenses and other rights granted to Oruka hereunder;

(e) There is no pending or, to Paragon's knowledge, threatened litigation, nor has Paragon received any written notice from any Third Party, asserting or alleging that the development, manufacture or commercialization of the Licensed Antibody Technology prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(f) To Paragon's knowledge, Paragon has not withheld from Oruka any information with respect to the Licensed Antibody Technology that would reasonably be expected to be materially adverse to Oruka's Development, Manufacture, or Commercialization of any Product in the Territory as contemplated under this Agreement;

(g) To Paragon's knowledge, Paragon has, and any of Paragon's Affiliates involved in the Research Program have, (i) conducted all research and development under the Research Program in accordance with Research Plan (as defined in the Option Agreement), and (ii) conducted the Research Program in compliance with all Applicable Laws;

(h) To Paragon's knowledge, Paragon has provided true, correct and complete copies of all Results developed under the Research Program and all other deliverables required under the Research Program have been provided or delivered to Oruka and are true, correct and complete in all material respects;

(i) Paragon has properly filed, Prosecuted and maintained all Licensed Antibody Patents;

(j) Paragon has complied with all duties of disclosure and has not engaged in any inequitable conduct with respect to all Licensed Antibody Patents that were filed prior to the Effective Date;

(k) All Licensed Antibody Patents listed in Exhibit A that have been issued as of the Effective Date are in full force and effect and are, to Paragon's knowledge, valid and enforceable;

(l) Other than the Patents listed in Exhibit A, as of the Effective Date, neither Paragon nor any of its Affiliates own or have any rights in, to or under any Patents Covering the composition of matter of, or any method of specifically making or using, any Licensed Antibody;

(m) There are no judgments against or awards or settlements against Paragon or any of its Affiliates, and there are no claims, actions, or proceedings pending or, to Paragon's knowledge, threatened, nor to Paragon's knowledge are there any formal inquiries initiated or written notices received that are reasonably likely to lead to the institution of any such legal proceedings, in each case (i) relating to any Licensed Antibodies, Derived Antibodies or Licensed Antibody Technology or alleging that any Third Party has any right to or under any Products, Licensed Antibodies, Derived Antibodies or Licensed Antibody Technology that would conflict with the rights granted in this Agreement; or (ii) alleging that any Licensed Antibody Patent is unpatentable, invalid, unenforceable or infringed;

(n) (i) Each Representative employed or engaged by Paragon or its Affiliate to conduct the activities under the Research Program have assigned or licensed, or are under contractual obligations to assign or license, to Paragon all inventions conceived, reduced to practice or otherwise related to Licensed Antibodies, Derived Antibodies and Licensed Antibody Technology; (ii) to Paragon's knowledge, no Representative employed by Paragon or its Affiliate that conducts activities under a Research Program has any obligations under agreements or Applicable Law to assign any interest in any such inventions to any Third Party; and (iii) each Representative employed or engaged by Paragon or its Affiliate to conduct the activities under a Research Program have existing obligations under agreements or Applicable Law to maintain as confidential Paragon's Confidential Information as well as confidential information of other parties (including of Oruka and its Affiliates);

(o) None of Paragon, its Representatives, or any other person used by Paragon in the performance of the Research Program or otherwise in connection with this Agreement has been or is (i) debarred, convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (ii) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program, or (iii) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Paragon agrees to inform Oruka in writing promptly if Paragon or any person who is performing activities on its behalf under the Agreement is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending or threatened;

(p) No funding, facilities, or personnel of any Governmental Authority or any public or private educational or research institutions were used to develop or create any Licensed Antibody Technology, and neither Paragon nor any of its Affiliates has entered into a government funding relationship that would result in rights to any Products, Licensed Antibodies, Derived Antibodies or Licensed Antibody Technology residing in the U.S. Government, the National Institutes of Health, or other agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in Public Law 96-517 (35 U.S.C. §§ 200-204), or any similar obligations under the laws of any other country in the Territory; and

(q) To the [***] knowledge of [***] of Paragon, with respect to this Agreement and the Option Agreement, neither Paragon nor any of its directors, officers, employees, distributors, consultants, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Paragon or any of its Affiliates:

(i) has taken any action in violation of any applicable anti-corruption laws, anti-money laundering laws or laws restricting or regulating global trade (collectively, "**Anti-Corruption Laws**");

(ii) has conducted or initiated any internal investigation with respect to any alleged act or omission arising under or relating to any potential noncompliance with any Anti-Corruption Law, or been the subject of current, pending, or threatened investigation, formal or informal inquiry, enforcement proceedings, or received any notice, request, or citation for alleged violations of such laws;

(iii) has engaged in any direct or indirect dealings or transactions in or with a person, entity or country found on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Office of Foreign Assets Control, or engaged in any direct or indirect dealings with Sudan, individuals ordinarily resident in Sudan, or entities incorporated under the laws of Sudan prior to October 12, 2017; or

(iv) has offered, paid, given, promised to pay or give, or authorized the payment or gift of, received, or solicited anything of value, directly or indirectly, to any public official, for the purposes of: influencing any act or decision of any public official in his or her official capacity; inducing any public official to do or omit to do any act in violation of his or her lawful duty; securing any improper or undue advantage; or inducing any public official to use his or her influence with a government, Governmental Authority, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

7.3 **Covenants of Paragon**. Paragon hereby covenants to Oruka during the Term that:

(a) Paragon will not grant a Third Party any license or other right in the Licensed Antibody Technology or the Other Licensed Technology that would conflict with the rights and licenses granted to Oruka hereunder with respect to such Licensed Antibody Technology;

(b) Paragon will, and will direct each Affiliate of Paragon and subcontractor conducting activities under this Agreement to, conduct all such activities in compliance with Applicable Laws, including all applicable Anti-Corruption Laws and U.S. sanctions;

(c) Paragon will comply with the terms of each Paragon Third Party Agreement, will maintain each Paragon Third Party Agreement, will not amend a Paragon Third Party Agreement in a manner that (i) adversely effects Oruka in any material respect, or (ii) increases any financial obligations under a Paragon Third Party Agreement that will result in an increase in Oruka's Reimbursement Obligation, in each case of (i) and (ii) without Oruka's prior written consent, and will not take any actions that could reasonably cause any Paragon Third Party Agreement to lapse or terminate; and

(d) Paragon will, and will direct each applicable Affiliate of Paragon to, execute and deliver such additional documents and instruments and to perform such additional acts as may be necessary or appropriate to enable Oruka to exercise its rights and obligations under Sections 5.2, 5.3 and 5.4.

7.4 **Compliance with Laws**. Each Party shall, and shall ensure that its Affiliates and its and its Affiliates' Representatives and sublicensees, comply with Applicable Laws in all material respects in the performance of its obligations and the exercise of its rights under this Agreement.

7.5 **DISCLAIMER OF WARRANTIES**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, DURABILITY, MERCHANTABLE QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE VIII

TERM; TERMINATION.

8.1 **Term**. The term of this Agreement shall commence on the Effective Date and shall expire on a country-by-country and Oruka Product-by-Oruka Product basis on the expiration of the Royalty Term for such Oruka Product in such country, in each case, unless earlier terminated by a Party as set forth below in this Article VIII (the "**Term**"). Upon expiration (but not termination) of the Agreement, the licenses granted in Section 2.1 shall survive and become royalty-free, fully paid-up, perpetual and irrevocable with respect to the applicable Oruka Product in the applicable country.

8.2 **Termination by Oruka**. Oruka shall have the right to terminate this Agreement in its entirety or on a country-by-country or Oruka Product-by-Oruka Product basis for any or no reason upon sixty (60) days' prior written notice to Paragon.

8.3 **Material Breach**. Either Party may terminate this Agreement in its entirety for the material breach of this Agreement by the other Party, if such material breach remains uncured ninety (90) days (or thirty (30) days with respect to any failure to make any payments owing to a Party hereunder) following notice from the non-breaching Party to the breaching Party specifying such breach, *provided that*, in the event of a dispute regarding the existence or cure of a material breach, no termination shall become effective until such dispute is finally resolved pursuant to Section 10.7 in favor of the non-breaching Party and the breaching Party fails to cure such material breach within ninety (90) days thereafter.

8.4 **Insolvency**. Each Party will have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [***] days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, or (d) appointment of a receiver for all or substantially all of a Party's assets.

8.5 **Effect of Termination of this Agreement**. If this Agreement terminates for any reason (excluding expiration under Section 8.1), whether with respect to a particular Oruka Product, particular country or in its entirety, then the following shall apply:

(a) All licenses and other rights granted by Paragon under this Agreement with respect to the terminated Oruka Product(s) and terminated country(ies) shall terminate, except as required for Oruka, its Affiliates and/or its Sublicensees to perform any of its obligations that survive termination, including to continue to complete or wind down (at [***] expense in the event of a termination by Oruka under Section 8.3) any ongoing clinical trials for any Oruka Product, as may be required by Applicable Law or ethical principles.

(b) No later than [***] days after the effective date of such termination, each Party shall return or cause to be returned to the other Party, or destroy, all Confidential Information received from the other Party and all copies thereof related to the terminated Oruka Product(s) in the terminated country(ies); *provided, however*, that each Party may retain any Confidential Information reasonably necessary for such Party's ongoing obligations and rights under this Agreement which do not terminate, and each Party may keep one (1) copy of Confidential Information received from the other Party in its confidential files for record purposes and such copy shall remain subject to Article VI of this Agreement.

(c) Upon Paragon's written request to Oruka (which must be provided to Oruka within [***] days after the effective date of termination), Paragon and Oruka shall [***] discuss [***], for a period of up to [***] days following such written request, terms and conditions under which Oruka may be willing to grant to Paragon [***], [***] license under the Oruka Intellectual Property to Develop, Manufacture, Commercialize or otherwise exploit the terminated Oruka Products in the Field in the terminated countries that were the subject of any Development, Manufacturing or Commercialization activities performed by Oruka or its Affiliates under this Agreement prior to such termination, ("**Reversion Products**"), as well as the potential transfer of materials, ongoing clinical trials, and applicable regulatory filings and relevant data generated by Oruka with respect to the Reversion Products and necessary for the continued Development, Manufacture, Commercialization and exploitation of such Reversion Products, such agreement to include commercially reasonable financial and other terms, which terms shall take into consideration Oruka's contributions made in the Development, Manufacture, Commercialization and other exploitation of the Reversion Products, provided, that Oruka is under no obligation to enter into such license.

8.6 **Survival of Sublicenses**. Upon termination of this Agreement, at the written request of any Sublicensee who is not then in breach of its sublicense agreement, such sublicense agreement will survive such termination of this Agreement, and Paragon will negotiate [***] the terms and conditions of a direct license with such Sublicensee that is consistent with the terms of this Agreement (as adjusted for the scope of license, products, field of use and other provisions of the original sublicense). Each sublicense that may be amended to become a direct license between Paragon and a Sublicensee shall ensure that any and all economic rights, payments or benefits due to Oruka will be preserved and payable to Oruka and will designate Oruka a third-party beneficiary to enforce such rights. In each such instance, Oruka will have the right to review and approve the terms of such agreement between Paragon and such Sublicensee as related to Oruka's economic rights, which approval shall not be unreasonably withheld, conditioned or delayed.

8.7 **Accrued Rights; Survival**. The expiration or termination of this Agreement for any reason shall not release either Party from any liability or obligation that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination, nor will expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement. In the event of expiration or any termination of this Agreement, the following provisions of this Agreement shall survive such expiration or termination in accordance with their respective terms and conditions: Article I (Definitions); Section 2.1 (License Grant from Paragon) (upon expiration (but not termination) of this Agreement as set forth in Section 8.1 (Term)); Section 2.3 (Sublicenses) (with respect to any payments or other performance obligations prior to conversion (if any) to a direct license pursuant to Section 8.6); Section 2.4 (No Implied Licenses; Reservation of Rights); Section 4.1 (Milestone Payments) (with respect to any outstanding payment obligations incurred prior to the date of termination or expiration); Section 4.2 (Royalties) (with respect to any outstanding payments accrued prior to the effective date of termination); Section 4.4 (Payment Reports) (with respect to the last Calendar Quarter of the Term to the extent not already reported and any outstanding payment obligation with respect to any royalty payments accrued prior to the date of termination or expiration); Section 4.5 (Payment Method) to 4.9 (Blocked Currency) (for the duration of any outstanding payment obligations under this Agreement); Section 4.10 (Records; Inspection) (for the duration set forth therein); Section 5.1 (Ownership); Section 7.5 (Disclaimer of Warranties); Article VI (Protection of Confidential Information) (for the duration set forth therein); Section 8.5 (Effect of Termination of this Agreement); Section 8.6 (Survival of Sublicenses); Section 8.7 (Accrued Rights; Survival); Article IX (Indemnification); and Article X (Miscellaneous).

ARTICLE IX

INDEMNIFICATION.

9.1 **By Oruka**. Oruka hereby agrees to defend, indemnify and hold harmless Paragon, its Affiliates and its or their Representatives (each, an "**Paragon Indemnitee**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees (collectively, "**Losses**"), to which any Paragon Indemnitee may become subject (a) as a result of any claim, demand, action, or other proceeding by any Third Party ("**Third Party Claim**") to the extent such Losses result from: (i) the gross negligence, recklessness or willful misconduct of any Oruka Indemnitee in the performance of this Agreement; (ii) Oruka's breach of any of its representations, warranties or covenants under this Agreement; or (iii) Oruka's Development, Manufacture and Commercialization of the Oruka Products; and (b) to the extent such Losses result from the termination, suspension, revocation or other loss of any Licensed Antibody Patents as a result of any negligence or breach of this Agreement by Oruka, its Affiliates or Sublicensees, in each case ((a) to (b)), except in each case to the extent that any Losses are attributable to the breach of this Agreement by, or the negligence, recklessness or willful misconduct of, or otherwise indemnifiable by, any Paragon Indemnitee.

9.2 **By Paragon**. Paragon hereby agrees to defend, indemnify, and hold harmless Oruka, its Affiliates, and its or their Representatives (each, a "**Oruka Indemnitee**") from and against any and all Losses to which any Oruka Indemnitee may become subject (a) as a result of any Third Party Claim to the extent such Losses result from: (i) the gross negligence, recklessness or willful misconduct of any Paragon Indemnitee in the performance of this Agreement; or (ii) Paragon's breach of any of its representations, warranties or covenants under this Agreement; and (b) to the extent such Losses result from: (i) the termination, suspension, revocation or other loss of any Licensed Antibody Patents as a result of any negligence or breach of this Agreement by Paragon or its Affiliates; or (ii) any claim or demand from any employee or contractor of Paragon or its Affiliates who is an inventor of any Licensed Antibody Patents with respect to ownership thereof, in each case ((a) to (b)), except to the extent that any Losses are attributable to the breach of this Agreement by, or the negligence, recklessness or willful misconduct of, or otherwise indemnifiable by, any Oruka Indemnitee.

9.3 **Indemnification Procedures**. The Party claiming indemnity under this Article IX (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of the Third Party Claim for which indemnity is being sought ("**Claim**"). The Indemnifying Party's obligation to defend, indemnify and hold harmless pursuant to Section 9.1 or Section 9.2, as applicable, will be reduced to the extent the Indemnified Party's delay in providing notification pursuant to the previous sentence results in material prejudice to the Indemnifying Party; *provided, however,* that the failure by an Indemnified Party to give such notice or otherwise meet its obligations under this Section 9.3 will not relieve the Indemnifying Party of its indemnification obligation under this Agreement. At its option, the Indemnifying Party may assume the defense and have exclusive control, at its own expense, of any Claim for which indemnity is being sought by giving written notice to the Indemnified Party within [***] days after receipt of the notice of the Claim. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however,* the Indemnifying Party will have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. The Indemnified Party will not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate, *provided, that* the Indemnified Party reasonably consults with the Indemnifying Party prior to entering into any settlement, and (ii) the Indemnified Party reserves any right it may have under this Article IX to obtain indemnification from the Indemnifying Party.

9.4 **Limitation of Liability**. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE VI, FOR BREACH OF SECTIONS 2.1 OR 2.2, FOR BREACH OF ANY INTELLECTUAL PROPERTY RIGHTS HELD BY A PARTY, FOR THE FRAUD OR WILLFUL MISCONDUCT OF A PARTY OR FOR INDEMNIFICATION CLAIMS UNDER THIS ARTICLE IX, IN NO EVENT SHALL EITHER PARTY BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, EVEN IF THE OTHER PARTY HAD NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

9.5 **Insurance**. During the Term and for a period of [***] years thereafter, each Party shall maintain at its expense insurance coverage consistent with normal business practices and adequate to cover the risks associated with its performance of any activities hereunder. Each Party hereby expressly acknowledges and agrees that the maintenance of such insurance coverage shall not relieve it of its obligations under this Agreement.

ARTICLE X

MISCELLANEOUS.

10.1 **Independent Contractor Relationship**. Paragon's relationship with Oruka is that of an independent contractor, and nothing in this Agreement should be construed to create a partnership, joint venture, or employer-employee relationship. Neither Party is an agent of the other Party or authorized to make any representation, contract, or commitment on behalf of the other Party.

10.2 **Force Majeure**. Neither Party will be charged with any liability for delay or failure in performance of an obligation under this Agreement (other than any obligation to pay monies when due) to the extent such delay or failure is due to a cause beyond the reasonable control of the affected Party, such as war, riots, labor disturbances, epidemic, pandemic, fire, explosion, and compliance in good faith with any Applicable Law (in each case, a "**Force Majeure**"). In addition, a Force Majeure event may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to the COVID-19 pandemic or any other pandemic (or other Force Majeure event), such as requiring employees to stay home, closures of facilities, delays of clinical trials, or cessation of activities in response to the pandemic. The Party affected by a Force Majeure will give prompt written notice to the other Party of the nature of the cause of any material delay or failure to perform, its anticipated duration and any action being taken to avoid or minimize the effect. The Party affected will use its diligent efforts to avoid or remove such causes of delay or failure to perform and to mitigate the effect of such occurrence, and will continue performance in accordance with the terms of this Agreement whenever such causes are removed. The Party affected will give prompt written notice to the other Party of such resumed performance.

10.3 **Entire Agreement; Amendment**. This Agreement and the Option Agreement, together with all Exhibits attached hereto, constitutes the final, complete, and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements, relating to its subject matter. This Agreement (including its Exhibits) may not be changed, modified, amended, or supplemented except by a written instrument signed by both Parties.

10.4 **Non-Waiver**. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

10.5 **Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

10.6 **Assignment**. Neither this Agreement nor any rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however*, that (a) Paragon may assign to an Affiliate or a Third Party financing source its rights to receive some or all of the payments payable hereunder together with the right to receive Confidential Information of Oruka, *provided* Paragon shall not be permitted to share Oruka Confidential Information unless and except to the extent necessary to obtain Affiliate or Third-Party financing, *provided, further, that* any such Affiliate or Third Party agrees to be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in Article VI; and (b) either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent to (i) its Affiliates or (ii) its successor to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. The assigning Party shall provide the other Party with prompt written notice of any such assignment set forth in clauses (a) and (b) above. Except for an assignment pursuant to clause (a) above, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.

10.7 **Dispute Resolution**.

(a) The Parties recognize that a *bona fide* dispute as to certain matters may arise from time to time during the Term relating to either Party's rights or obligations hereunder or otherwise relating to the validity, enforceability or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any disputes relating to Article VI or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights (hereinafter, a "**Dispute**"). In the event of the occurrence of any Dispute, the Parties will follow the following procedures in an attempt to resolve the dispute or disagreement:

(i) The Party claiming that such a Dispute exists will give notice in writing (a "**Notice of Dispute**") to the other Party of the nature of the Dispute. The Dispute will be referred to the then Chief Executive Officer of Paragon and the then Chief Executive Officer of Oruka who will meet no later than [***] days following the initial receipt of the Notice of Dispute and use reasonable endeavors to resolve the Dispute.

(ii) If, within [***] days of initial receipt of the Notice of Dispute, the Dispute has not been resolved, or if, for any reason, the meeting described in Section 10.7(a)(i) hereof has not been held within [***] days of initial receipt of the Notice of Dispute, then the Parties agree that such Dispute will be finally resolved through binding arbitration to be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the Expedited Procedures in those Rules (the "**JAMS Rules**"), as specifically modified by the provisions of this Section 10.7(a)(ii) and Section 10.7(a)(iii).

(iii) The arbitration will be conducted by a panel of three arbitrators. Within [***] days after the initiation of the arbitration, each Party will nominate one person to act as arbitrator, and the two arbitrators so named will then jointly appoint the third arbitrator within [***] days of their appointment, who will serve as chairman of the panel. All three arbitrators must be independent Third Parties having at least [***] years of dispute resolution experience (which may include judicial experience) or legal or business experience in the biotech or pharmaceutical industry. If either Party fails to nominate its arbitrator, or if the arbitrators selected by the Parties cannot agree on a person to be named as chairman within such [***]-day period, JAMS will make the necessary appointments for such arbitrator(s) or the chairman. Once appointed by a Party, such Party will have no *ex parte* communication with its appointed arbitrator.

(iv) Notwithstanding the provisions of Section 10.7(a)(iii), if the Dispute involves an amount in question of less than $[***], then the arbitration will be conducted by one arbitrator, selected in accordance with the JAMS Rules.

(v) The place of arbitration will be in Boston, Massachusetts or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrator(s) shall have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 *et seq.,* and judgment upon the award rendered by the arbitrators may be entered in any court having competent jurisdiction thereof. The existence, content and results of any arbitration proceedings pursuant to this Section 10.7 will be deemed the Confidential Information of both Parties.

(b) Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement.

(c) The Parties agree that any disputes relating to Article VI or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights shall be subject to the exclusive jurisdiction of the state and federal courts in Boston, Massachusetts and each Party hereby submits to such jurisdiction.

10.8 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without reference to conflicts of laws principles.

10.9 **Notices**. Any notice to be given under this Agreement must be in writing and delivered either in person, by internationally recognized express courier, or by email, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by express courier, the next Business Day the express courier regularly makes deliveries; or (c) if delivered by email, upon the date upon which the receipt of such email is confirmed by return email. Together with any notice provided by a Party to the other Party in accordance with this Section 10.9, the Party shall send a copy of such notice by email to the other Party.

If to Paragon: Paragon Therapeutics, Inc.
221 Crescent Street
Building 23, Suite 105
Waltham, MA 02453
Attn: Chief Operating Officer
Email: [***]

If to Oruka: Oruka Therapeutics, Inc.
855 Oak Grove Avenue, Suite 100
Menlo Park, CA 94025
Attn: General Counsel
Email: [***]

10.10 **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity shall be construed to include such person's or entity's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "or." The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language. To the extent there is any inconsistency or conflict between the terms and conditions of this Agreement and any Exhibit, the terms and conditions of this Agreement will prevail.

10.11 **No Third-Party Rights**. The provisions of this Agreement are for the exclusive benefit of the Parties and their successors and permitted assigns, and no other person shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

10.12 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, or electronic signatures complying with the ESIGN Act of 2000 (such as DocuSign), which signatures shall have the same force and effect as original signatures.

10.13 **Expenses**. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

10.14 **Binding Effect**. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

10.15 **Construction**. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

10.16 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

10.17 **Performance by Affiliates**. A Party may perform some or all of its obligations under this Agreement through Affiliate(s) or may exercise some or all of its rights under this Agreement through Affiliates, subject to the terms of this Agreement. However, each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance as if such Party were performing such obligations itself, and references to a Party in this Agreement shall be deemed to also reference such Affiliate. In particular and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in Article VI, and shall be subject to the intellectual property provisions of Article V as if they were the original Party to this Agreement (and be deemed included in the actual Party to this Agreement for purposes of all intellectual property-related definitions). A Party and its Affiliates shall be jointly and severally liable for their performance under this Agreement.

[*Remainder of Page Left Intentionally Blank; Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have by duly authorized persons executed this Agreement as of the Effective Date.

PARAGON THERAPEUTICS, INC.

By: /s/ K. Evan Thompson
Name: K. Evan Thompson
Title: Chief Operating Officer

ORUKA THERAPEUTICS, INC.

By: /s/ Lawrence Klein
Name: Lawrence Klein
Title: Chief Executive Officer

[SIGNATURE PAGE TO LICENSE AGREEMENT]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

IL-23 LICENSE AGREEMENT

This License Agreement ("**Agreement**") is entered into and effective as of December 17, 2024 (the "**Effective Date**"), by and between Paragon Therapeutics, Inc., a Delaware corporation ("**Paragon**"), and Oruka Therapeutics, Inc., a Delaware corporation ("**Oruka**"). Paragon and Oruka are also referred to herein individually as a "**Party**", or collectively as the "**Parties**."

RECITALS

Whereas, Paragon has developed a proprietary platform technology for the discovery and development of antibodies against therapeutically relevant targets;

Whereas, pursuant to that certain Amended and Restated Antibody Discovery and Option Agreement by and among Paragon, Oruka and Paruka Holding, LLC, a Delaware limited liability company, dated as of March 28, 2024 (as such agreement may be further amended from time to time, the "**Option Agreement**"), Oruka has engaged Paragon to identify, evaluate and develop one or more antibody candidates directed to certain therapeutic targets and has been granted an exclusive option to enter into one or more separate license agreements to develop, manufacture and commercialize the resulting antibodies with respect to a given target;

Whereas, Oruka has exercised such option with respect to the Licensed Target (as defined below), and the Parties desire to memorialize the exclusive license from Paragon to Oruka with respect to such Licensed Target, all on the terms and subject to the conditions set forth in this Agreement.

Now Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE I

DEFINITIONS.

The following initially capitalized terms have the following meanings (and derivative forms of them shall be interpreted accordingly):

1.1 "**Achievement of Development Candidate**" means the first to occur of: (a) nomination by Oruka's Board of Directors of an Oruka Product as a "Development Candidate"; and (b) the initiation by or on behalf of Oruka or its Affiliate or Sublicensee of a toxicology study with respect to an Oruka Product that employs applicable then-current good laboratory practice standards, the results of which are intended to be submitted as part of an IND.

1.2 "**Acquired Program**" has the meaning set forth in Section 2.2(c).

1.3 "**Acquiring Entity**" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than (a) the applicable Party in the definition of Change of Control, and (b) such Party's Affiliates, determined immediately prior to the closing of such Change of Control ((a) and (b) collectively, the "**Pre-Existing Entities**").

1.4 "**Affiliate**" means any entity controlled by, controlling, or under common control with a Party hereto. For the purpose of this definition, "control" (including, with correlative meaning, the terms "controlled by" or "under common control") means the direct or indirect ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) in the equity of, or the right to appoint more than fifty percent (50%) of the directors or management of, such corporation or other business entity. Notwithstanding the foregoing, (a) with respect to either Party, Affiliates of such Party do not include [***] or its Affiliates other than such Party and its subsidiaries, (b) Paragon and its Affiliates, on the one hand, and Oruka and its subsidiaries, on the other hand, shall not be deemed to be Affiliates of each other, and (c) Affiliates of Paragon do not include new entities formed by or on behalf of Paragon for the sole *bona fide* purpose of further developing, manufacturing, commercializing or otherwise exploiting Antibodies and Antibody products (excluding any Licensed Antibody Technology or Other Licensed Technology) using, among other sources, funds from Third Party investors.

1.5 "**Agreement**" has the meaning set forth in the preamble.

1.6 "**Annual Net Sales**" means total Net Sales by Oruka, its Affiliates and Sublicensees in the Territory of all of the Products in a particular Calendar Year, calculated in accordance with U.S. generally accepted accounting principles (GAAP) consistently applied.

1.7 "**Anti-Corruption Laws**" has the meaning set forth in Section 7.2(q)(i).

1.8 "**Antibody**" means any molecule, including [***].

1.9 "**Applicable Law**" means any national, supra-national, federal, state or local laws, rules, guidances, and regulations, in each case, as applicable to the subject matter and the Party at issue.

1.10 "**Bankruptcy Code**" has the meaning set forth in Section 8.4.

1.11 "**Bankruptcy Event**" has the meaning set forth in Section 8.4.

1.12 "**Business Day**" means any day other than Saturday, Sunday or a national holiday in the United States.

1.13 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.14 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.

1.15 "**Change of Control**" means, with respect to any entity, any of the following: (a) the sale or disposition of all or substantially all of the assets of such entity or its direct or indirect controlling Affiliate to a Third Party; or (b) (i) the acquisition by a Third Party, alone or together with any of its Affiliates, other than an employee benefit plan (or related trust) sponsored or maintained by such entity or any of its Affiliates, of more than fifty percent (50%) of the then-outstanding shares of voting capital stock of such entity or its direct or indirect parent entity that holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then-outstanding shares of voting capital stock of such entity (a "**Parent Entity**"), or (ii) the acquisition, merger or consolidation of such entity or its Parent Entity with or into another entity, other than, in the case of clause (i) or (ii), an acquisition or a merger or consolidation of such entity or its Parent Entity in which the holders of shares of voting capital stock of such entity or its Parent Entity, as the case may be, immediately prior to such acquisition, merger or consolidation will beneficially own, directly or indirectly, at least fifty percent (50%) of the shares of voting capital stock of the acquiring Third Party or the surviving corporation in such acquisition, merger or consolidation, as the case may be, immediately after such acquisition, merger or consolidation, and in each case of (a) or (b), whether through a single transaction or a series of related transactions, but excluding any and all *bona fide* financing transactions or internal reorganizations for tax purposes (including the change of place of incorporation or domicile of such entity).

1.16 "**Claim**" has the meaning set forth in Section 9.3.

1.17 "**COC Program**" has the meaning set forth in Section 2.2(b).

1.18 "**Combination Product**" has the meaning set forth in Section 1.59.

1.19 "**Commercialize**" or "**Commercializing**" means any and all activity to market, promote, distribute, offer for sale, sell, have sold, seek reimbursement, import, have imported, export, have exported, or otherwise commercialize an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, Multispecific Product, as applicable, and including interacting with Regulatory Authorities following receipt of Regulatory Approval and seeking and maintaining any required Reimbursement Approval. When used as a noun, "**Commercialization**" means any and all activities involved in Commercializing.

1.20 "**Commercially Reasonable Efforts**" means those efforts and resources, including reasonably necessary and qualified personnel, equivalent to the efforts and resources that a reasonable international biopharmaceutical company or a pharmaceutical company, in each case, that is of comparable size and resources to the applicable Party would typically devote as part of an active and continuing program of development and commercialization of a pharmaceutical or biologic product of similar market potential, at a similar stage of its product life, taking into account the competitiveness of the marketplace and the proprietary position, regulatory status, and relative safety and efficacy of such product. Commercially Reasonable Efforts requires, with respect to an obligation, that the applicable Party (a) assign responsibility for such obligation to specific employees who are held accountable for progress and monitor such progress on an on-going basis, (b) set and seek to achieve reasonable objectives for carrying out such obligation, and (c) make and implement reasonable decisions and allocate resources designed to advance progress with respect to such objectives.

1.21 "**Confidential Information**" of a Party means Know-How and any and all non-public scientific, business, regulatory or technical information that is disclosed or made available by or on behalf of one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") in connection with this Agreement, regardless of whether such information is specifically marked or designated confidential, whether in writing, orally, visually, or otherwise. Notwithstanding any provision of this Agreement to the contrary, the Licensed Antibody Technology shall be the Confidential Information of Oruka.

1.22 "**Control**" (including any variations such as "**Controlled**" and "**Controlling**") means, with respect to any technology (including Know-How) or other Intellectual Property Rights, possession by a Party or one of its Affiliates of the ability (whether by ownership, license or otherwise (other than by a license, sublicense or other right granted pursuant to this Agreement)) to grant a license or a sublicense of or under such technology or Intellectual Property Rights without violating the terms of any agreement or other arrangement with any Third Party; *provided, that* if following the Effective Date (a) Paragon would Control any Patent that would be included in the Licensed Antibody Technology or Other Licensed Patents but for an obligation to pay royalties or other consideration for the Development, Manufacture or Commercialization of an Oruka Product in the Territory in connection with a grant to Oruka of a license under such Patent, and (b) Oruka, pursuant to Section 2.8, consents to being a sublicensee of such Patent and complies with the Reimbursement Obligation, then such Patent shall be deemed Controlled by Paragon. Notwithstanding the foregoing, a Party and its Affiliates shall not be deemed to "Control" any technology or Intellectual Property Rights that (i) prior to the consummation of a Change of Control of such Party is owned or in-licensed, or (ii) after the consummation of a Change of Control of such Party, becomes owned or in-licensed (to the extent such technology or Intellectual Property Rights are developed outside of the scope of the activities conducted hereunder and without use of or reference to any technology or Intellectual Property Rights Controlled by such Party or any Affiliate of such Party immediately before such Change of Control, or any Confidential Information of the other Party), in each case ((i) or (ii)), by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Change of Control or an assignee of such Party after the Effective Date as the result of an assignment of this Agreement in connection with a Change of Control unless prior to the consummation of such Change of Control or assignment, such Party or any of its Affiliates also Controlled such technology or Intellectual Property Rights.

1.23 "**Cover**" or "**Covering**" means, with respect to a particular product, any Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, importation, or exportation of such product would infringe a valid and unexpired claim of such Patent.

1.24 **"Derived Antibody"** means any Antibody that is created by or on behalf of Oruka (other than an Antibody created by Paragon under the Option Agreement), its Affiliates or its or their licensees and: (a) is derived from or constitutes a modification of a Licensed Antibody, including [***], (b) [***] and (c) [***]. For avoidance of doubt, any Antibody that [***] will be deemed a Derived Antibody, irrespective of origin, so long as such Antibody satisfies the requirements of (a), (b) and (c). Notwithstanding the foregoing, a Derived Antibody shall not include (i) [***], or (ii) [***].

1.25 "**Designated Multispecific Antibody**" has the meaning set forth in Section 2.6(b).

1.26 "**Develop**" or "**Developing**" means any and all activity to discover, evaluate, test (including clinical and non-clinical testing), research, or otherwise develop an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, or Multispecific Product, as applicable. When used as a noun, "**Development**" means any and all activities involved in Developing.

1.27 "**Directed To**" means, with regard to an Antibody or product, that such Antibody or product is developed or designed to (a) [***], and (b) [***].

1.28 "**Disclosing Party**" has the meaning set forth in Section 1.21.

1.29 "**Dispute**" has the meaning set forth in Section 10.7(a).

1.30 "**Dollar**" means a U.S. dollar, and "$" shall be interpreted accordingly.

1.31 "**Effective Date**" has the meaning set forth in the preamble.

1.32 "**Exclusivity Period**" means the period commencing on the Effective Date and continuing until the fifth (5th) anniversary of the Effective Date.

1.33 "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.34 "**Field**" means the prophylaxis, palliation, treatment and diagnosis of human disease and disorders except the therapeutic area of inflammatory bowel disease.

1.35 "**First Commercial Sale**" means the first sale of an Oruka Product by Oruka, or one of its Affiliates or its or their Sublicensees, to a Third Party after receipt of all Regulatory Approvals required to market and sell the Oruka Product have been obtained in the country in the Territory in which such Oruka Product is sold. Sales for purposes of testing the Oruka Product and sample purposes shall not be deemed a First Commercial Sale. Furthermore, for purposes of clarity, the term "First Commercial Sale" as used in this Agreement shall not include: (a) [***]; (b) [***]; nor (c) [***].

1.36 "**Force Majeure**" has the meaning set forth in Section 10.2.

1.37 "**Governmental Authority**" means any national, international, federal, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.38 "**IND**" means an investigational new drug application or equivalent application that is required to commence clinical trials for a product in the Territory and filed with the applicable Regulatory Authority.

1.39 "**Indemnified Party**" has the meaning set forth in Section 9.3.

1.40 "**Indemnifying Party**" has the meaning set forth in Section 9.3.

1.41 "**Intellectual Property Rights**" means any and all proprietary rights provided under (a) patent law, including any Patents; (b) copyright law; (c) trademark law; or (d) any other applicable statutory provision or common law principle, including trade secret law, that may provide a right in Know-How, or the expression or use thereof.

1.42 "**Inventions**" means all Know-How, and all Intellectual Property Rights therein, that are conceived, reduced to practice, discovered, developed, or made by or on behalf of either Party or any Third Parties acting on their behalf (or any of their Representatives, Affiliates, licensees, or sublicensees) in the course of performing activities under this Agreement.

1.43 "**JAMS Rules**" has the meaning set forth in Section 10.7(a)(ii).

1.44 "**Know-How**" means all technical information and know-how in any tangible or intangible form, including (a) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (b) all data, instructions, processes, formulae, strategies, and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical, or otherwise and whether related to safety, quality control, manufacturing or other disciplines. Notwithstanding the foregoing, Know-How excludes any Patents.

1.45 "**Licensed Antibody**" means the Antibodies listed in Exhibit B as "Licensed Antibodies" that are Directed To the Licensed Target and that were discovered, generated, identified or characterized by Paragon in the course of performing the Research Program. Notwithstanding the foregoing, the Licensed Antibodies shall not include (a) [***], or (b) [***].

1.46 "**Licensed Antibody Invention**" means (a) any invention or discovery, whether or not patentable, that was discovered or reduced to practice by or on behalf of Paragon under the Research Program that constitutes the composition of matter of, or any method of specifically making or using, any Licensed Antibody; and (b) all Intellectual Property Rights therein, that in each case is Controlled by Paragon or its Affiliates as of the Effective Date or during the Term. Notwithstanding the foregoing, the Licensed Antibody Inventions shall not include (i) [***], (x) [***], or (y) [***], or (ii) any Intellectual Property Rights therein.

1.47 "**Licensed Antibody Patents**" means all Patents that Cover the composition of matter of, or any method of specifically making or using, any Licensed Antibody, that in each case are Controlled by Paragon or its Affiliates as of the Effective Date or during the Term, excluding in each case any claims in such Patents that Cover the composition of matter of, or any method of specifically making or using (a) [***], or (b) [***].

1.48 "**Licensed Antibody Technology**" means (a) the Licensed Antibody Inventions; (b) the Licensed Antibody Patents; (c) the Sequence Information; (d) the Results; (e) the Research Program Materials; and (f) all Intellectual Property Rights therein Controlled by Paragon or its Affiliates as of the Effective Date and during the Term.

1.49 "**Licensed Component**" has the meaning set forth in Section 1.59.

1.50 "**Licensed Target**" means IL-23.

1.51 "**Losses**" has the meaning set forth in Section 9.1.

1.52 "**MAA**" means (a) a New Drug Application in the United States, as defined in the United States Federal Food, Drug and Cosmetics Act, and applicable regulations promulgated thereunder by the FDA; (b) a Biologics License Application in the United States, as defined in the United States Public Health Service Act; or (c) any application filed with any Regulatory Authority in a country other than the United States that is equivalent to either of the foregoing.

1.53 "**Major Market Country**" means any of the following: [***].

1.54 "**Manufacture**" or "**Manufacturing**" means any and all activity to make, have made, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, or ship an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, or Multispecific Product, as applicable, or any component thereof. When used as a noun, "**Manufacture**" or "**Manufacturing**" means any and all activities involved in Manufacturing an Antibody or product, including any Licensed Antibody, Derived Antibody, Product, Multispecific Antibody, or Multispecific Product, as applicable, or any component thereof.

1.55 "**Milestone**" has the meaning set forth in Section 4.1.

1.56 "**Milestone Payment**" has the meaning set forth in Section 4.1.

1.57 "**Multispecific Antibody**" means any Antibody that is comprised of (a) [***], and (b) [***].

1.58 "**Multispecific Product**" means any product that comprises or contains any Multispecific Antibody.

1.59 "**Net Sales**" means the gross amounts received for Oruka Product by Oruka, its Affiliates and Sublicensees for sales or other commercial disposition of such Oruka Product in the Territory to unrelated Third Parties, less the following, in each case related specifically to the Oruka Product and actually incurred, paid or accrued by Oruka, its Affiliates or Sublicensees and not otherwise recovered by or reimbursed to Oruka, its Affiliates or Sublicensees;

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]; and

(f) [***].

Net Sales will include [***]. Net Sales will be calculated only once for the first *bona fide* arm's length sale of the Oruka Product by Oruka, its Affiliates or its Sublicensees to a Third Party, and will not include sales between or among [***]. Net Sales shall not include any amounts invoiced for [***], (ii) [***], or (iii) [***].

Net Sales shall be determined from the books and records of Oruka, Affiliates of Oruka or any Sublicensee maintained in accordance with U.S. generally accepted accounting principles (GAAP) consistently applied. Oruka further agrees in determining Net Sales, it (or its applicable Affiliate or Sublicensee) will use Oruka's (or such Affiliate's or Sublicensee's) then current standard procedures and methodology.

If an Oruka Product is sold as a Combination Product (as defined below), the Net Sales of such Combination Product for the purpose of calculating royalties and sales-based milestones owed under this Agreement for sales of such Combination Product, shall be determined as follows: [***]. If any Other Component in the Combination Product is not sold separately, Net Sales shall be calculated by [***]. If both the Licensed Component and any of the Other Components are not sold separately, the adjustment to Net Sales shall be determined by the Parties [***] to reasonably reflect [***] of such Licensed Component in the Combination Product to the total fair market value of such Combination Product.

For purposes of this definition, "**Combination Product**" means any pharmaceutical product that contains two (2) or more active ingredients, including (A) one (1) or more Licensed Antibodies, Derived Antibodies or Multispecific Antibodies (the "**Licensed Component**"), and (B) one (1) or more active pharmaceutical or biological ingredients that are not (x) a Licensed Antibody, Derived Antibody or Multispecific Antibody, or (y) an Antibody owned or controlled by Paragon or its Affiliate, the rights to which have been licensed to Oruka or its Affiliate under a separate agreement ("**Other Component(s)**"), either as a [***], [***] or [***], and [***].

1.60 "**Notice of Dispute**" has the meaning set forth in 10.7(a)(i).

1.61 "**Oruka**" has the meaning set forth in the Preamble.

1.62 "**Oruka Antibody Patents**" means all Patents that Cover the composition of matter of, or any method of specifically making or using any Licensed Antibody or Derived Antibody that, in each case, are owned or in-licensed by Oruka or its Affiliates or Sublicensees as of the Effective Date or during the Term, *provided that*, if a Change of Control of Oruka occurs, the Oruka Antibody Patents shall not include any Patents owned or in-licensed by the Acquiring Entity as of the closing of such Change of Control.

1.63 "**Oruka Cross License Patents**" means any Patents Controlled by Oruka or its Affiliates as of the Effective Date or during the Term that Cover the composition of matter or method of treatment of the Retained IL-23 Project Antibodies. Notwithstanding the foregoing, the Oruka Cross License Patents shall not include any Patents that Cover (a) [***], or (b) [***].

1.64 "**Oruka Indemnitee**" has the meaning set forth in Section 9.2.

1.65 "**Oruka Intellectual Property**" means any Patents, Know-How or other Intellectual Property Rights that are Controlled by Oruka and are necessary for, and actually used (or held for use) by Oruka or its Affiliates as of the effective date of termination of this Agreement in the Development, Manufacturing, or Commercialization of Oruka Products.

1.66 "**Oruka Invention**" means (a) any Invention that is owned or Controlled by Oruka, and (b) all Intellectual Property Rights therein, *provided that*, in each case (a) – (b), Oruka Inventions shall not include (i) any Inventions owned or Controlled by Paragon or its Affiliate, the rights to which have been licensed to Oruka or its Affiliate under this Agreement or a separate agreement, or (ii) any Intellectual Property Rights therein.

1.67 "**Oruka Multispecific Antibody**" means any Multispecific Antibody that is Developed, Manufactured, Commercialized or otherwise exploited by Oruka, its Affiliates or Sublicensees, excluding in each case, and subject to Section 2.7, any Paragon Multispecific Antibody.

1.68 "**Oruka Multispecific Patents**" means those Patents that Cover the composition of matter of, or any method of specifically making or using, an Oruka Multispecific Antibody.

1.69 "**Oruka Multispecific Product**" means any product that comprises or contains any Oruka Multispecific Antibody.

1.70 "**Oruka Product**" means, individually or collectively, as applicable, Licensed Antibodies, Derived Antibodies, Products, Oruka Multispecific Antibodies and Oruka Multispecific Products.

1.71 "**Other Component(s)**" has the meaning set forth in Section 1.59.

1.72 "**Other Licensed Know-How**" means all Know-How Controlled by Paragon or its Affiliates on the Effective Date or during the Term that (a) was used by or on behalf of Paragon in the performance of the Research Program, and (b) is necessary to Develop, Manufacture, Commercialize or otherwise exploit (i) Licensed Antibodies, or (ii) Products, Multispecific Antibodies or Multispecific Products, in each case solely to the extent comprising or containing a Licensed Antibody. For clarity, the Other Licensed Know-How shall exclude (x) the Licensed Antibody Technology, and (y) any Know-How Controlled by Paragon or its Affiliates relating to (1) that [***], or (2) [***].

1.73 "**Other Licensed Patents**" means any Patents other than Licensed Antibody Patents Controlled by Paragon or its Affiliates as of the Effective Date or during the Term that (a) include a claim that expressly recites the sequence of a Licensed Antibody or Derived Antibody, and (b) are necessary to Develop, Manufacture or Commercialize Licensed Antibodies or Derived Antibodies in the Field in the Territory. Notwithstanding the foregoing, the Other Licensed Patents shall not include (i) Paragon Multispecific Patents, (ii) the Paragon Platform Patents (as defined in the Option Agreement), or (iii) any Patents that Cover (x) that [***], or (y) [***].

1.74 "**Other Licensed Technology**" means all (a) Other Licensed Know-How, and (b) Other Licensed Patents.

1.75 "**Paragon**" has the meaning set forth in the Preamble.

1.76 "**Paragon Cross License Patents**" means any Patents (other than Licensed Antibody Patents or Other Licensed Patents) Controlled by Paragon or its Affiliates as of the Effective Date or during the Term that Cover the composition of matter or method of treatment of the Licensed Antibodies. Notwithstanding the foregoing, the Paragon Cross License Patents shall not include (a) the Paragon Multispecific Patents, (b) the Paragon Platform Patents (as defined in the Option Agreement), or (c) any Patents that Cover (i) [***], or (ii) [***].

1.77 "**Paragon Indemnitee**" has the meaning set forth in Section 9.1.

1.78 "**Paragon Multispecific Antibody**" means any Multispecific Antibody that is Developed, Manufactured, Commercialized or otherwise exploited by Paragon or its Affiliate or licensees (other than Oruka and its Affiliates and Sublicensees), excluding in each case any Oruka Multispecific Antibodies.

1.79 "**Paragon Multispecific Patents**" means those Patents that Cover the composition of matter of, or any method of specifically making or using, a Paragon Multispecific Antibody, in each case excluding the Licensed Antibody Patents.

1.80 "**Paragon Patents**" has the meaning set forth in Section 5.2(c).

1.81 "**Paragon Third Party Agreement**" has the meaning set forth in Section 2.8.

1.82 "**Parent Entity**" has the meaning set forth in Section 1.15.

1.83 "**Party**" has the meaning set forth in the Preamble.

1.84 "**Patent Challenge**" has the meaning set forth in Section 5.3(a).

1.85 "**Patent Infringement**" has the meaning set forth in Section 5.3(a).

1.86 "**Patents**" means (a) unexpired patents and patent applications, (b) any and all patent applications filed either from such patent or patent applications or from a patent application claiming priority from any of those, including divisionals, provisionals, continuations, continuations-in-part, and reissues, (c) substitutions, renewals, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications, and (d) any and all foreign equivalents of the foregoing.

1.87 "**Phase I Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(a), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.88 "**Phase II Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(b), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.89 "**Phase III Trial**" means a human clinical trial in any country of the type described in 21 C.F.R. §312.21(c), or the foreign equivalent thereof, regardless of where such clinical trial is conducted.

1.90 "**Post-Effective Date Patents**" has the meaning set forth in Section 5.2(b)(i).

1.91 "**Pre-Existing Entities**" has the meaning set forth in Section 1.3.

1.92 "**Product**" means any product that comprises or contains any Licensed Antibody or Derived Antibody other than as part of a Multispecific Antibody or a Multispecific Product.

1.93 "**Prosecute**" or "**Prosecution**" has the meaning set forth in Section 5.2(a).

1.94 "**Prosecuting Party**" has the meaning set forth in Section 5.2(b)(iii).

1.95 "**Publication**" has the meaning set forth in Section 6.6(b).

1.96 "**Receiving Party**" has the meaning set forth in Section 1.21.

1.97 "**Regulatory Approval**" means all clearances, approvals (including approval of an MAA as well as any applicable pricing and/or reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell and market a pharmaceutical product in a country or territory under this Agreement.

1.98 "**Regulatory Authority**" means any supranational, multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, manufacture marketing or sale of an Oruka Product in a country or region, including the FDA in the United States and the EMA in Europe.

1.99 "**Reimbursement Obligation**" has the meaning set forth in Section 2.8.

1.100 "**Remaining Recovery**" has the meaning set forth in Section 5.3(f).

1.101 "**Representatives**" of a Party means such Party's officers, directors, employees, contractors, subcontractors, agents and consultants.

1.102 "**Research Program**" means the Research Program (as defined in the Option Agreement) conducted by the Parties pursuant to the Option Agreement with respect to the Licensed Target.

1.103 "**Research Program Materials**" means the tangible materials resulting from the Research Program that are Controlled by Paragon or its Affiliates as of the Effective Date or during the Term that are listed in Exhibit C attached hereto, as may be amended in writing from time to time upon mutual agreement of the Parties. For clarity, Research Program Materials shall not include materials that are consumed or destroyed in the performance of the Research Program or that are not available to be transferred by Paragon to Oruka without violating the terms of any agreement or other arrangement with a Third Party.

1.104 "**Results**" means all data, results, analysis, conclusions, outcomes, information, documentation and reports that are generated by or on behalf of Paragon in performance of the Research Program, excluding in each case any other Licensed Antibody Technology.

1.105 "**Retained IL-23 Antibody Patents**" means all Patents that Cover the composition of matter of, or any method of specifically making or using, the Retained IL-23 Project Antibodies that in each case are owned by Paragon as of the Effective Date and are set forth on Exhibit E.

1.106 "**Retained IL-23 Project Antibodies**" has the meaning set forth in the Option Agreement. A list of the Retained IL-23 Project Antibodies, identified by individual sequence identifier numbers, is set forth on Exhibit D.

1.107 "**Retained IL-23 Project Antibody Licensee**" means any assignee or licensee of Paragon with respect to Paragon's rights in the Retained IL-23 Project Antibodies and the Retained IL-23 Antibody Patents.

1.108 "**Reversion Products**" has the meaning set forth in Section 8.5(c).

1.109 "**Review Period**" has the meaning set forth in Section 6.6(b).

1.110 "**ROFN Information**" has the meaning set forth in Section 2.7(a).

1.111 "**ROFN Negotiation Period**" has the meaning set forth in Section 2.7(c).

1.112 "**ROFN Period**" has the meaning set forth in Section 2.7(a).

1.113 "**Royalty Payments**" has the meaning set forth in Section 4.2(a).

1.114 "**Royalty Term**" means, on an Oruka Product-by-Oruka Product and country-by-country basis, the period commencing on First Commercial Sale of the applicable Oruka Product in the applicable country in the Territory and ending, with respect to the particular Oruka Product and country at issue on the latest of the following dates: (a) the twelfth (12th) anniversary of the date of First Commercial Sale of such Oruka Product in such country; or (b) the expiration of the last-to-expire Valid Claim of a Licensed Antibody Patent or an Oruka Antibody Patent Covering the Manufacture, use or sale of such Oruka Product in the country at issue.

1.115 "**Sequence Information**" means any files of Paragon containing all Licensed Antibody sequences generated under the Research Program.

1.116 "**Sublicensee**" means any Affiliate of Oruka or any Third Party with respect to Oruka, to whom Oruka grants a sublicense of, or other authorization or permission granted under, the rights granted to Oruka in Section 2.1.

1.117 "**Target**" means a protein molecule that (a) is chemically distinct from other molecules, and (b) wherein a binding entity derives recognized therapeutic value from binding to such molecule.

1.118 "**Term**" has the meaning set forth in Section 8.1.

1.119 "**Territory**" means worldwide.

1.120 "**Third Party**" means any person or entity other than Paragon or Oruka or an Affiliate of either Paragon or Oruka.

1.121 "**Third Party Claim**" has the meaning set forth in Section 9.1.

1.122 "**Transfer Period**" has the meaning set forth in Section 2.5(c).

1.123 "**US**" or "**United States**" means the United States of America and its possessions and territories, including Puerto Rico.

1.124 "**Valid Claim**" means, with respect to a particular country, a claim (including a process, use or composition of matter claim) of an issued and unexpired patent (or a supplementary protection certificate thereof) that has not (a) irretrievably lapsed or been abandoned, permanently revoked, dedicated to the public or disclaimed, or (b) been held invalid, unenforceable or not patentable by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, which holding, finding or decision is final and unappealable or unappealed within the time allowed for appeal.

ARTICLE II

LICENSES; TECHNOLOGY TRANSFER; MULTISPECIFIC ANTIBODIES.

2.1 **License Grants**.

(a) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a royalty-bearing, exclusive (even as to Paragon and its Affiliates, subject to Paragon's retained rights under Section 2.4) license, including the right to sublicense through multiple tiers, under the Licensed Antibody Technology to Develop, Manufacture, Commercialize, or otherwise exploit Licensed Antibodies, Derived Antibodies and Products in the Field in the Territory.

(b) Subject to the terms of this Agreement, including Section 2.7, Paragon hereby grants to Oruka a royalty-bearing, non-exclusive right and license, including the right to sublicense through multiple tiers, under the Licensed Antibody Technology to Develop, Manufacture, Commercialize or otherwise exploit Multispecific Antibodies and Multispecific Products in the Field in the Territory.

(c) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a royalty-bearing, non-exclusive license, including the right to sublicense through multiple tiers, under the Other Licensed Patents to Develop, Manufacture, Commercialize or otherwise exploit Licensed Antibodies, Derived Antibodies, Multispecific Antibodies, Products and Multispecific Products in the Field in the Territory.

(d) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a royalty-bearing, non-exclusive license, including the right to sublicense through multiple tiers, under the Other Licensed Know-How to Develop, Manufacture, Commercialize or otherwise exploit (i) Licensed Antibodies, or (ii) Products, Multispecific Antibodies or Multispecific Products, in each case solely to the extent comprising or containing a Licensed Antibody, in the Field in the Territory.

(e) Subject to the terms of this Agreement, Paragon hereby grants to Oruka a non-exclusive license, including the right to sublicense through multiple tiers, under the Paragon Cross License Patents to Develop, Manufacture, Commercialize or otherwise exploit the Licensed Antibodies solely in the Field in the Territory.

(f) Subject to the terms of this Agreement, Oruka hereby grants to Paragon a non-exclusive license, including the right to sublicense through multiple tiers, under the Oruka Cross License Patents to Develop, Manufacture, Commercialize or otherwise exploit the Retained IL-23 Project Antibodies solely in the Territory in the therapeutic area of inflammatory bowel disease.

2.2 **Exclusivity**.

(a) Subject to the terms of this Section 2.2, to the maximum extent permissible under Applicable Law, during the Exclusivity Period, Paragon shall not, and shall ensure that its Affiliates do not, directly or indirectly, conduct any activity, either on its own or with, for the benefit of, or sponsored by, any Third Party, including granting any license to any Third Party that would permit such Third Party, to develop, manufacture, commercialize or otherwise exploit any monospecific Antibody that is Directed To the Licensed Target in the Field. It will not be a violation of this Section 2.2(a) if Paragon or its Affiliate, directly or through a Third Party, (i) conducts screening activities solely for the purposes of ensuring compliance with this Section 2.2(a), (ii) conducts activities in accordance with the terms of this Agreement, the Option Agreement or any other written agreement between the Parties, or (iii) conducts activities with the prior written consent of Oruka.

(b) Notwithstanding anything herein to the contrary, if a Change of Control occurs with respect to Paragon or its Parent Entity, and the Acquiring Entity (or any of such Acquiring Entity's successors or assigns, other than the relevant Pre-Existing Entities) as of the Change of Control has a program or product (or rights thereto) that would otherwise violate Section 2.2(a) (each, a "**COC Program**"), then (i) Section 2.2(a) shall not apply with respect to such COC Program, and (ii) such Acquiring Entity will be permitted to continue such COC Program after such Change of Control and such continuation will not constitute a violation of Section 2.2(a), *provided, that* the Licensed Antibody Technology and Confidential Information of Paragon and Oruka relating to the Oruka Products is not used in the COC Program.

(c) Notwithstanding anything herein to the contrary, if Paragon or its Parent Entity (i) acquires a Third Party entity that has a program or product (or rights thereto) that would otherwise violate Section 2.2(a), or (ii) acquires asset(s) from a Third Party entity that would otherwise violate Section 2.2(a) (each, an "**Acquired Program**"), then (1) Section 2.2(a) shall not apply with respect to such Acquired Program, and (2) Paragon or its Parent Entity will be permitted to continue such Acquired Program after such acquisition and such continuation will not constitute a violation of Section 2.2(a), *provided, that* the Licensed Antibody Technology and Confidential Information of Paragon and Oruka relating to the Oruka Products is not used in the Acquired Program.

2.3 **Sublicenses**. Oruka shall have the right to grant sublicenses under the rights granted to it in Section 2.1 to its Affiliates and Third Parties; *provided, that* (a) each such sublicense shall be granted in writing and each such relevant sublicense agreement shall be consistent with all relevant terms, conditions and restrictions of this Agreement, (b) Oruka will provide Paragon with a true and complete copy of each sublicense agreement (other than sublicense agreements with Third Party service providers) and any amendments thereto within [***] days following the execution thereof (which sublicense agreement and amendments may be redacted except to the extent necessary for Paragon to determine Oruka's compliance with this Agreement), and (c) Oruka shall remain responsible for all of its payments and other performance obligations due under this Agreement, notwithstanding any license or sublicense that it may grant.

2.4 **No Implied Licenses; Reservation of Rights**. Except as expressly set forth herein, no right or license under any Patents, Know-How or Intellectual Property Right of either Party is granted or shall be granted by implication hereunder. All such rights or licenses are or shall be granted only as expressly provided in this Agreement, and each Party reserves to itself all rights not expressly granted under this Agreement. Notwithstanding anything to the contrary under this Agreement, Paragon retains rights under the Licensed Antibody Technology solely to perform its obligations and exercise its rights under this Agreement and the Option Agreement; provided, that during the Term, Paragon shall not, and shall ensure that its Affiliates do not, (a) use the Licensed Antibody Technology to, or (b) grant a license to a Third Party under the Licensed Antibody Technology to, Develop, Manufacture, Commercialize, or otherwise exploit the Licensed Antibodies or Derived Antibodies, in each case as part of a Product, in the Territory for the therapeutic area of inflammatory bowel disease; provided, further, that the foregoing proviso does not, and is not intended to, limit Paragon's rights under Section 2.6. Oruka acknowledges and agrees that it has no rights under this Agreement or the Option Agreement with respect to any Antibodies that were discovered, generated, identified or characterized by Paragon in the course of performing the Research Program (including the Retained IL-23 Project Antibodies) other than the Licensed Antibodies and the Derived Antibodies.

2.5 **Information Transfer and Support to Oruka**.

(a) As soon as possible and within not more than [***] days after the Effective Date, Paragon shall provide Oruka with the Results and Sequence Information in existence as of the Effective Date not already provided to Oruka under the Option Agreement. Additionally, on a continuing basis during the term of the Research Program, as soon as possible and within not more than [***] days after additional Results or Sequence Information come into existence or are identified by Paragon that in each case have not already been provided to Oruka under the Option Agreement, Paragon shall disclose and transfer such additional Results and Sequence Information to Oruka.

(b) Upon the reasonable request of Oruka made from time to time during the Term, Paragon shall promptly disclose and transfer to Oruka tangible embodiments of the Other Licensed Know-How that is the subject of Oruka's request.

(c) The Parties acknowledge and agree that Exhibit C has been agreed by the Parties as of the Effective Date, and that materials that are different than or in addition to the materials set forth on Exhibit C may result from the Research Program to the extent that the Research Program continues to be performed following the Effective Date. Upon the reasonable request of Oruka made at any time prior to the end of the [***] day period following the expiration of the Research Term (as defined in the Option Agreement), the Parties shall update Exhibit C to reflect the tangible materials, including samples, reagents, nucleic acids and Antibodies, resulting from the Research Program that constitute Research Program Materials hereunder. During the period beginning on the Effective Date and ending [***] months after the expiration of the Research Term (the "**Transfer Period**"), at [***] request and expense, Paragon will provide Oruka or a Third Party designated by Oruka with any Research Program Materials, provided that any Third Party recipient of such Research Program Materials shall be bound by the relevant terms of this Agreement and that the Research Program Materials are used solely to further Develop, Manufacture and Commercialize the Oruka Products. For clarity, [***] shall be responsible for any out-of-pocket costs incurred by Paragon or its Affiliates to store and maintain the Research Program Materials during the Transfer Period.

(d) Each Party shall bear all costs and expenses incurred by such Party in connection with the disclosure and transfer of any Results and Sequence Information as set forth above.

(e) During the [***] day period following completion of the Research Program, in the event Oruka makes any reasonable request for assistance in order to understand the Licensed Antibody Technology and use the Licensed Antibody Technology to continue the uninterrupted Development of the Licensed Antibodies, Paragon shall provide up to [***] month of additional assistance during such period, at [***] cost and expense at the then current [***] Rate (as defined in the Option Agreement) in the Option Agreement. Paragon shall consider and discuss in good faith any additional requests for assistance made by Oruka, which assistance may be provided upon mutual agreement of the Parties.

2.6 **Paragon Rights with Respect to Multispecific Antibodies**.

(a) Subject to the terms of this Agreement, including Section 2.6(b) below and Section 2.7, Paragon reserves and retains the non-exclusive right under the Licensed Antibody Technology to Develop, Manufacture, Commercialize and otherwise exploit Multispecific Antibodies and Multispecific Products in the Field in the Territory. If Paragon exercises such right, then Paragon shall pay royalties to Oruka in accordance with Article IV (at the rate specified in Section 4.2(b)), *mutatis mutandis*, with respect to any Multispecific Antibodies and Multispecific Products that are Commercialized by Paragon or its Affiliates or sublicensees (other than Oruka and its Affiliates and Sublicensees) in the Field in the Territory, *provided, that* references to Oruka Antibody Patents in clause (b) of the Royalty Term definition and Section 4.3 shall be disregarded.

(b) Oruka has designated [***] Licensed Antibody or Derived Antibody as its lead compound and [***] Licensed Antibody or Derived Antibody as its backup compound, as set forth on Exhibit B (each such designated Licensed Antibody or Derived Antibody, a "**Designated Multispecific Antibody**"). Paragon's rights under Section 2.6(a) shall expressly exclude the right to Develop, Manufacture, Commercialize or otherwise exploit (i) Multispecific Antibodies that have identical sequence identity within their variable regions as a Designated Multispecific Antibody, or (ii) Multispecific Products that comprise or contain any Multispecific Antibody referenced in clause (i). For the avoidance of doubt, if Paragon engaged in Development or Manufacture of a Multispecific Antibody that meets the criteria of clause (i) or (ii) above prior to the Effective Date, then Paragon shall not be in breach of this Agreement, *provided that*, Paragon ceases all such Development or Manufacture within [***] days following the Effective Date.

2.7 **Right of First Negotiation**.

(a) Commencing on the Effective Date and continuing until the [***] anniversary thereof (the "**ROFN Period**"), Paragon will promptly notify Oruka in writing if (i) Paragon has developed a descriptive research plan with respect to the Development of a Multispecific Antibody or a plan to license or grant rights in a Multispecific Antibody to a Third Party, or (ii) Paragon enters into [***] negotiations pursuant to an offer to or from any Third Party relating to the foregoing. Together with such notice, Paragon will provide to Oruka all material information and research plans developed by Paragon with respect to such Multispecific Antibody (the "**ROFN Information**"). Oruka will have [***] days from receipt of the ROFN Information to deliver a written notice to Paragon of Oruka's desire to engage in negotiations for an agreement concerning the Development, or exclusive license or grant of rights to, such Multispecific Antibody.

(b) If Oruka does not provide such written notice to Paragon of its interest to engage in such negotiations within such [***] day period, then (i) Paragon shall be free to enter into an agreement with a Third Party with respect to the grant of a license or other rights to such Multispecific Antibody and corresponding Multispecific Products without further obligation to Oruka under this Section 2.7, and (ii) Oruka's license under Section 2.1(b) shall automatically exclude any right to Develop, Manufacture, Commercialize or otherwise exploit the identical Multispecific Antibodies Developed by or on behalf of Paragon and corresponding Multispecific Products.

(c) If Oruka does provide Paragon such written notice within such [***] day period, the Parties will negotiate [***] on an exclusive basis for a period of up to [***] months from the date of Oruka's notice ("**ROFN Negotiation Period**"), an agreement for the Development, or exclusive license or grant of rights to, such Multispecific Antibody and corresponding Multispecific Products. Prior to and during the ROFN Negotiation Period, Paragon shall not enter into an agreement with respect to such Multispecific Antibody with any Third Party that will prevent Paragon from entering into an agreement with Oruka for the Development, or exclusive license or grant of rights to, such Multispecific Antibody and corresponding Multispecific Products. Unless and until the Parties have entered into an agreement with respect to such Multispecific Antibody and corresponding Multispecific Products, Oruka shall have no rights or license with respect to such Multispecific Antibody and corresponding Multispecific Products except as otherwise expressly provided in Section 2.1. In the event that the Parties have not entered into an agreement with respect to such Multispecific Antibody and corresponding Multispecific Products prior to the expiration of the ROFN Negotiation Period, then (i) Paragon shall be free to enter into an agreement with a Third Party with respect to the grant of a license or other rights to such Multispecific Antibody and corresponding Multispecific Products without further obligation to Oruka under this Section 2.7, and (ii) Oruka's license under Section 2.1(b) shall automatically exclude any right to Develop, Manufacture, Commercialize or otherwise exploit the identical Multispecific Antibodies Developed by or on behalf of Paragon and corresponding Multispecific Products.

2.8 **Third Party In-Licenses**. If Paragon (or its Affiliate) enters into any in-license agreement with a Third Party after the Effective Date with respect to any Patent that would, if Controlled by Paragon, be included within the Licensed Antibody Patents or the Other Licensed Patents (each such agreement, a "**Paragon Third Party Agreement**"), Paragon shall notify Oruka in writing that it entered into such Paragon Third Party Agreement and provide a copy of such Paragon Third Party Agreement to Oruka, which may be redacted solely concerning [***] or other confidential terms not applicable to sublicensees. Oruka shall have the right, by delivery of notice to Paragon, to elect to take a sublicense under such Patents in-licensed by Paragon under such Paragon Third Party Agreement. If Oruka elects to become a sublicensee thereunder pursuant to this Section 2.8, then (a) the applicable Patents under such Paragon Third Party Agreement shall be included within the Licensed Antibody Patents or the Other Licensed Patents, as applicable, that are licensed to Oruka under Section 2.1, (b) Oruka shall reimburse Paragon for Paragon's pro rata share of royalties or other consideration, as mutually agreed by the Parties, payable by Paragon under the Paragon Third Party Agreement for Oruka's Development, Manufacture, Commercialization or other exploitation of an Oruka Product in the Field in the Territory in connection with the grant to Oruka of such Patents (the "**Reimbursement Obligation**"), and (c) Oruka shall comply with the terms of such Paragon Third Party Agreement to the extent applicable to Oruka as a sublicensee of such Patents. In the event of any conflict between the terms of this Agreement and any Paragon Third Party Agreement applicable to a sublicense granted by Paragon to Oruka in accordance with this Section 2.8, the terms of the Paragon Third Party Agreement shall control solely to the extent necessary for the Parties to maintain compliance with such Paragon Third Party Agreement. Oruka shall comply with the Reimbursement Obligation by paying to Paragon any amounts subject to the Reimbursement Obligation within the earlier of (i) [***] days after Oruka's receipt from Paragon of an invoice for such payment, and (ii) the date when such payment is due to the counterparty licensor under the applicable Paragon Third Party Agreement, *provided that* such payment shall not be due prior to the date when such amounts are payable by Paragon to the counterparty licensor under the applicable Paragon Third Party Agreement.

ARTICLE III

DEVELOPMENT, MANUFACTURING & COMMERCIALIZATION.

3.1 **Oruka Responsibilities**.

(a) As between the Parties, Oruka shall be solely responsible for and shall have the sole right to control, all aspects of the Development, Manufacturing, and Commercialization of the Oruka Products in the Field in the Territory during the Term, including distribution, product positioning, product strategy, product branding, core messaging, marketing, promotion, detailing activities and all decisions relating to the setting of prices in the Territory, invoicing and booking sales, establishing all terms of sale, and all regulatory activities.

(b) As between the Parties, Oruka shall be solely responsible for, and shall have the sole right to control, the selection, registration and maintenance of all trademarks associated with the Oruka Products in the Field in the Territory. As between the Parties, Oruka shall solely own such trademarks in the Territory and pay all relevant costs thereof.

3.2 **Regulatory**. As between the Parties, Oruka shall control all regulatory matters, including the regulatory strategy, regulatory filings, regulatory activities (including clinical trials for Oruka Products) and communication with each Regulatory Authority for the Oruka Products in the Field in the Territory. Oruka shall have the right to reference any relevant data included within the Licensed Antibody Technology for the purposes of regulatory filings and safety reporting, including all nonclinical data, pre-approval and post-approval clinical use data, and regulatory data with respect thereto, and Paragon shall cooperate as reasonably requested by Oruka with respect to providing to Oruka when requested, and on a timely basis, any of the foregoing information, data filings or reporting. Oruka or its designee shall be the party to file an application to each applicable Regulatory Authority in the Territory for, and to obtain and maintain, in its own name, Regulatory Approval for the Oruka Products in each country in the Territory.

3.3 **Diligence; Reporting**. Oruka shall use Commercially Reasonable Efforts (a) to Develop and seek Regulatory Approval for at least one Oruka Product in the Field in the United States and at least one other Major Market Country, and (b) upon receipt of Regulatory Approval for a given Oruka Product in a given country, to Commercialize such Oruka Product in such country, in each case ((a) or (b)) either by itself or through its Affiliates or Sublicensees or its or their respective contractors. Additionally, on or before [***] of each year during the Term, Oruka shall deliver to Paragon a report summarizing its material development efforts with respect to the Oruka Products, including a summary of current and anticipated preclinical and clinical activities, a summary of the status of any regulatory filings and any anticipated regulatory filings, and achievement of any Milestones, during the preceding [***]; *provided, however*, that Oruka may satisfy the reporting obligations set forth in this Section 3.3 by providing Paragon with copies of any annual report or other filings with a securities exchange that include the relevant information. For the avoidance of doubt, if Oruka determines, in its sole discretion, that it is inconsistent with the use of Commercially Reasonable Efforts to pursue Commercialization of an Oruka Product in any country (other than the United States), it will not be considered a material breach of this Agreement to cease Development or Commercialization of such Oruka Product with respect to such country.

ARTICLE IV

FINANCIAL TERMS.

4.1 **Milestone Payments**. Oruka shall make the following one-time, non-refundable and non-creditable payments to Paragon (or to such other designee(s), as requested by Paragon in an invoice) (each payment, a "**Milestone Payment**"), based on the achievement of the corresponding milestone (each, a "**Milestone**") by Oruka, its Affiliates, or its Sublicensees with respect to the first Oruka Product to achieve such Milestone. Oruka shall, within [***] Business Days after it or its Affiliates achieve a Milestone, or within [***] Business Days after it learns that its or its Affiliate's Sublicensee has achieved a Milestone, notify Paragon of the achievement of such Milestone in writing. Following receipt of such notice, Paragon shall invoice Oruka for such Milestone Payment, which invoice shall specify whether Paragon or its designee should receive such Milestone Payment and the bank account information into which such Milestone Payment should be paid. Oruka shall make such Milestone Payment to Paragon or Paragon's designee within [***] days after receipt of Paragon's invoice. Each Milestone Payment shall be paid no more than once, and Oruka's total Milestone Payments hereunder shall not exceed Twenty-Two Million Dollars ($22,000,000). For avoidance of doubt, upon achievement of any Milestone, all prior unachieved Milestones shall be deemed thereby achieved and, if the Milestone Payment for any such prior Milestone has not previously been paid, it shall thereupon also be paid at the same time that the Milestone Payment for such subsequent achieved Milestone is paid.

	Milestone	Milestone Payment
#1	Achievement of Development Candidate	One Million Five Hundred Thousand Dollars ($1,500,000)
#2	First dosing of a human patient in a Phase I Trial of an Oruka Product	Two Million Five Hundred Thousand Dollars ($2,500,000)
#3	First dosing of a human patient in a Phase II Trial of an Oruka Product	Three Million Dollars ($3,000,000)
#4	First dosing of a human patient in a Phase III Trial of an Oruka Product	Five Million Dollars ($5,000,000)
#5	Receipt of Regulatory Approval from the FDA of an Oruka Product	Ten Million Dollars ($10,000,000)

4.2 **Royalties**.

(a) **Royalty Rate for Products**. During the applicable Royalty Term (which shall be measured on a country-by-country and Product-by-Product basis), Oruka shall pay tiered royalties to Paragon (or to such other designee(s), as requested by Paragon) as set forth in the table below on Annual Net Sales of all Products sold by Oruka, its Affiliates or its Sublicensees in the Field in the Territory (together with any royalties payable under Section 4.2(b), the "**Royalty Payments**").

Annual Net Sales of the Products in a Given Calendar Year	Royalty Rate
Portion Of Annual Net Sales Of The Products In A Given Calendar Year Above $0 But Up To And Including $[***]	[***]%
Portion Of Annual Net Sales Of The Products In A Given Calendar Year Of More Than $[***], Up To And Including $[***]	[***]%
Portion Of Annual Net Sales Of The Products In A Given Calendar Year Of More Than $[***]	[***]%

(b) **Royalty Rate for Oruka Multispecific Products**. During the applicable Royalty Term (which shall be measured on a country-by-country and Oruka Multispecific Product-by-Oruka Multispecific Product basis), Oruka shall pay royalties to Paragon (or to such other designee(s), as requested by Paragon) equal to [***] percent ([***]%) of Net Sales of all Oruka Multispecific Products sold by Oruka, its Affiliates or its Sublicensees in the Field in the Territory.

(c) If any Oruka Product contains (a) a combination of more than one Licensed Antibody, Derived Antibody and/or Multispecific Antibody, or (b) a combination of (i) one or more Licensed Antibodies, Derived Antibodies or Multispecific Antibodies, and (ii) one or more other Antibodies owned or Controlled by Paragon or its Affiliates, the rights to which have been licensed to Oruka or its Affiliates under a separate agreement, then, in each case (a) or (b) unless otherwise agreed by the Parties, the royalty rate for the Royalty Payments payable to Paragon with respect to such Oruka Product (x) shall be determined in accordance with the Royalty Rate chart set forth in Section 4.2(a) if such Oruka Product does not contain a Multispecific Antibody, and (y) shall be determined in accordance with Section 4.2(b) if such Oruka Product contains a Multispecific Antibody.

4.3 **Royalty Reductions for No Valid Claim**. If, during any Calendar Quarter during the Royalty Term for a particular Oruka Product in a particular country, no Valid Claim of a Licensed Antibody Patent Covers the Manufacture or Commercialization of such Oruka Product in such country, then the applicable royalty rate for the Royalty Payments set forth in Section 4.2 for such Calendar Quarter shall be reduced by [***].

4.4 **Payment Reports**. Within [***] days after the end of [***] days for [***] in which an Oruka Product is sold, Oruka shall provide to Paragon a written report, on an [***] basis, stating the [***], including [***]; [***]. All Royalty Payments described in such written report shall be made by Oruka at the same time it submits such written report to Paragon. All such Royalty Payments shall be paid to Paragon or Paragon's designee, *provided that* in the case of payment to a designee, Paragon has notified Oruka in writing [***] days prior to the due date for any Royalty Payment of the designee to be paid and the bank account information for such designee.

4.5 **Payment Method**. All payments due under this Agreement to Paragon shall be made in U.S. Dollars by bank wire transfer in funds to an account designated by Paragon from time to time reasonably in advance of any payment due date.

4.6 **Taxes**. The Parties agree to cooperate with one another and use reasonable efforts to minimize obligations for any and all income or other taxes required by Applicable Law to be withheld or deducted from any Royalty Payments, Milestone Payments or other payments made by Oruka to Paragon or its designee(s) under this Agreement, including by completing all procedural steps, and taking all reasonable measures, to ensure that any withholding tax is reduced or eliminated to the extent permitted under Applicable Law, including income tax treaty provisions and related procedures for claiming treaty relief. To the extent that Oruka is required to deduct and withhold taxes on any payment to Paragon or its designee(s), Oruka shall: (i) deduct such taxes from such payment to Paragon or its designee(s), (ii) pay the amounts of such taxes to the proper Governmental Authority in a timely manner, and (iii) promptly submit to Paragon an official tax certificate or other available evidence of such withholding sufficient to enable Paragon or its designee(s) to claim such payment of taxes. For the avoidance of doubt, Oruka's remittance of such withheld amounts to the appropriate Governmental Authority, together with payment to Paragon or its designee(s) of the remaining amount owed, shall constitute full satisfaction of the applicable payment due to Paragon. Oruka shall provide Paragon with any reasonably requested tax forms or certificates available to Oruka in order to allow Paragon or its designee(s) to recover, as permitted by Applicable Law, withholding taxes, value added taxes or similar obligations resulting from payments made hereunder or to obtain the benefit of any present or future treaty against double taxation that may apply to such payments. Paragon shall promptly provide Oruka with any requested tax forms that may be reasonably necessary in order for Oruka to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax income treaty.

4.7 **Foreign Exchange**. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, including in connection with the calculation of Net Sales, such conversions shall be made using the methodology used by Oruka in preparing its publicly filed financial statements.

4.8 **Late Payments**. Any amount owed by Oruka to Paragon under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the per annum rate of [***] percentage point above the then-applicable United States prime rate as quoted in the *Wall Street Journal (East Coast Edition)* (or if it no longer exists, a similarly authoritative source), calculated on a [***] basis, or, if lower, the highest rate permitted under Applicable Law.

4.9 **Blocked Currency**. If by Applicable Law of a country in which Net Sales occurred, conversion of funds into Dollars or transfer of funds from such country to the United States is restricted, forbidden or delayed for more than [***] days, then Oruka can elect, at its sole discretion, that the amounts accrued in such country and owed by Oruka to Paragon under this Agreement shall be paid to Paragon in such country in local currency by deposit in a local bank designated by Paragon, unless the Parties otherwise agree in writing.

4.10 **Records; Inspection**.

(a) Oruka shall, and shall cause its applicable Affiliates to, create and keep complete and accurate records of its sales and other dispositions of all Oruka Products, including all records that are reasonably necessary for the purposes of calculating all payments due under this Agreement.

(b) Upon reasonable advance written notice to Oruka, Paragon shall have the right to retain a nationally recognized (in the US) independent certified public accounting firm to perform on behalf of Paragon an audit, conducted in accordance with U.S. generally accepted accounting principles (GAAP), of such books and records of Oruka or its applicable Affiliates as may be reasonably necessary to verify the accuracy of any reports provided pursuant to Section 4.4 hereunder for any Calendar Quarter in which an Oruka Product was sold, ending not more than [***] calendar months prior to the date of such request. Such audits shall be conducted during normal business hours, shall not occur more frequently than [***] in each Calendar Year and shall not be conducted more than [***] with respect to any reporting period, in each case other than for cause. All information disclosed or observed during any audit pursuant to this Section 4.10 shall be the Confidential Information of Oruka, and Paragon shall cause the accounting firm to retain all such information as Confidential Information, including, if requested by Oruka, by requiring such accounting firm to enter into a customary confidentiality agreement with Oruka prior to the initiation of any such audit.

(c) Upon completion of any audit hereunder, the accounting firm shall provide both Oruka and Paragon a written report disclosing whether the reports submitted by Oruka are correct or incorrect, whether the amounts paid are correct or incorrect, and in each case, the specific details concerning any discrepancies. No other information regarding Oruka's records shall be provided to Paragon.

(d) Paragon shall bear its internal expenses and the out-of-pocket costs for engaging such accounting firm in connection with performing such audits; *provided, however*, that if any such audit uncovers an underpayment by Oruka that exceeds [***] percent ([***]%) of the total owed for such payment or payment period, as applicable, then Oruka shall reimburse Paragon or its designee(s) for the amounts actually paid to such accounting firm for performing such audit.

(e) If such accounting firm concludes that Oruka has in aggregate underpaid amounts owed to Paragon during the audited period, Oruka shall pay Paragon or its designee(s) the amount of the discrepancy within [***] days of the date Paragon delivers to Oruka such accounting firm's written report and an invoice for such amounts. If such accounting firm concludes that Oruka has in aggregate overpaid amounts owed to Paragon during the audited period, then Oruka may, at its election, either credit such overpaid amount against any future payment obligation to Paragon or require Paragon to refund such amounts within [***].

ARTICLE V

INTELLECTUAL PROPERTY.

5.1 **Ownership**. As between the Parties (a) Paragon solely owns the Licensed Antibody Technology, the Other Licensed Patents and the Retained IL-23 Antibody Patents, (b) Oruka solely owns the Oruka Inventions, including any Derived Antibodies and Oruka Multispecific Antibodies to the extent they constitute Oruka Inventions, (c) each Party solely owns all Intellectual Property Rights owned or Controlled by such Party as of the Effective Date or that come into the ownership or control of such Party during the Term outside the scope of this Agreement, and (d) ownership of Inventions shall be determined in accordance with U.S. laws of inventorship. Other than rights granted to Oruka under this Agreement with respect to the Licensed Antibody Technology and the Other Licensed Patents, nothing in this Agreement shall affect Paragon's rights in any Patents, Know-How or other Intellectual Property Rights owned or controlled by Paragon or its Affiliates, now or in the future. Other than rights granted to Paragon under Section 8.5(c) of this Agreement with respect to the Oruka Intellectual Property, nothing in the Agreement shall affect Oruka's rights in any Patents, Know-How or other Intellectual Property Rights owned or controlled by Oruka or its Affiliates, now or in the future.

5.2 **Patent Prosecution**.

(a) **Prosecution Generally**. For the purpose of this Article V, "**Prosecute**" and "**Prosecution**" shall include any patent interference, opposition, pre-issuance Third Party submission, *ex parte* re-examination, post-grant review, *inter partes* review or other similar proceeding, appeals or petitions to any board of appeals in a patent office, appeals to any court for any patent office decisions, reissue proceedings and applications for patent term extensions and the like.

(b) **Prosecution of Licensed Antibody Patents**.

(i) As between the Parties, with respect to any patent applications for Licensed Antibody Patents that have not been filed prior to the Effective Date and any resulting patents (the "**Post-Effective Date Patents**"), Paragon shall have the sole right, but not the obligation, to prepare, file, Prosecute and maintain the Post-Effective Date Patents until the date on which the Final Deliverable (as defined in the Option Agreement) for the Research Program is delivered to Oruka, and during such period Paragon shall provide Oruka with drafts of all proposed filings to any patent office with respect to Post-Effective Date Patents in reasonably adequate time before submission of such filings for Oruka's review and comment.

(ii) As between the Parties, with respect to (x) any patent applications and resulting patents for Licensed Antibody Patents that were filed prior to the Effective Date, and (y) the Post-Effective Date Patents after the date on which the Final Deliverable (as defined in the Option Agreement) for the Research Program is delivered to Oruka, Oruka shall have the first right to prepare, file, Prosecute and maintain the Licensed Antibody Patents, in each case, at Oruka's sole expense. Oruka shall provide Paragon (and, at the direction of Paragon, shall also provide directly to the Retained IL-23 Project Antibody Licensee) with copies of all material correspondence from and to any patent office relating to such Licensed Antibody Patents, and Oruka shall provide Paragon (and, at the direction of Paragon, shall also provide directly to the Retained IL-23 Project Antibody Licensee) with drafts of all proposed filings to any patent office with respect to such Licensed Antibody Patents before submission of such filings, with reasonably adequate time for Paragon's (and the Retained IL-23 Project Antibody Licensee's) review and comment, which review shall be at Paragon's (and the Retained IL-23 Project Antibody Licensee's) sole expense.

(iii) Each Party, when acting as the prosecuting Party (in such capacity, the "**Prosecuting Party**") will take into consideration the non-Prosecuting Party's reasonable comments (and, if Oruka is the Prosecuting Party, the Retained IL-23 Project Antibody Licensee's reasonable comments) prior to submitting such filings. At the Prosecuting Party's request, the non-Prosecuting Party will sign all documents and take any other actions required for filing, maintenance and grant of Licensed Antibody Patents. Oruka shall reimburse Paragon for any costs and expenses actually incurred by Paragon to the extent Paragon is prosecuting or maintaining any Licensed Antibody Patents.

(iv) The Prosecuting Party shall notify the non-Prosecuting Party of any decision not to prepare or file, or to abandon, cease Prosecution or not maintain any Licensed Antibody Patent anywhere in the Territory. The Prosecuting Party shall provide such notice at least [***] days prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed Antibody Patent. In such event, the non-Prosecuting Party shall have a backup right, but not the obligation, to prepare, file, or continue Prosecution or maintenance of, such Licensed Antibody Patent, at its own expense.

(v) Each Party shall cooperate with the other Party in the preparation, filing, Prosecution and maintenance of Licensed Antibody Patents, including in each case by providing the prosecuting Party with data and other information as appropriate and executing all necessary affidavits, assignments and other paperwork.

(c) **Prosecution by Paragon**. Except with respect to Licensed Antibody Patents (which are addressed in Section 5.2(b)), Paragon (directly or indirectly through the Retained IL-23 Project Antibody Licensee) shall be solely responsible for, and have sole discretion over, preparing, filing, Prosecuting and maintaining any Patents (including the Other Licensed Patents, Paragon Multispecific Patents and Retained IL-23 Antibody Patents) that it owns in whole or in part or otherwise Controls (the "**Paragon Patents**"). Paragon's Prosecution of any Paragon Patents shall be at Paragon's sole expense. Notwithstanding the foregoing, in Prosecuting any Paragon Multispecific Patents, Paragon hereby agrees that during the Term, neither Paragon nor any of its Affiliates or licensees will file, or assist any Third Party in filing, any Patent that includes a claim that expressly recites the sequence of a Licensed Antibody or Derived Antibody other than as part of a Paragon Multispecific Antibody. In the Prosecution by Paragon or the Retained IL-23 Project Antibody Licensee of any Retained IL-23 Antibody Patents, (i) Paragon shall provide or cause to be provided (directly or indirectly through the Retained IL-23 Project Antibody Licensee) to Oruka copies of all material correspondence from and to any patent office relating to such Retained IL-23 Antibody Patents, and (ii) Paragon shall provide or cause to be provided (directly or indirectly through the Retained IL-23 Project Antibody Licensee) to Oruka drafts of all proposed filings to any patent office with respect to such Retained IL-23 Antibody Patents before submission of such filings, with reasonably adequate time for Oruka's review and comment, and Paragon or the Retained IL-23 Project Antibody Licensee, as applicable, will take into consideration Oruka's reasonable comments prior to submitting such filings.

(d) **Patent Prosecution Costs Prior to the Effective Date**. No later than [***] days after the Effective Date, Oruka shall reimburse Paragon for any actual costs and expenses incurred by Paragon that are related to the Prosecution of any Licensed Antibody Patents prior to the Effective Date and that have not already been paid by Oruka. Oruka will promptly reimburse Paragon for any future Prosecution costs and expenses incurred by Paragon with respect to the Licensed Antibody Patents.

(e) **CREATE Act**. Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the "**CREATE Act**") when exercising its rights under Article V of this Agreement, without the prior written consent of the other Party. Where such Party intends to invoke the CREATE Act, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a joint research agreement (JRA) as defined in the CREATE Act.

(f) **Disclosure of Antibody Patents**. Upon the request of Paragon, Oruka shall deliver to Paragon a list of the then-existing Oruka Antibody Patents. Upon the request of Oruka, Paragon shall deliver to Oruka a list of the then-existing Retained IL-23 Antibody Patents.

5.3 **Patent Enforcement and Defense**.

(a) **Notice of Patent Infringement and Patent Challenge**. Each Party shall give the other Party notice of any known or suspected infringement by a Third Party ("**Patent Infringement**") of any Licensed Antibody Patent and any known or suspected challenge by a Third Party against the validity or enforceability ("**Patent Challenge**") of any Licensed Antibody Patent or Retained IL-23 Antibody Patent within [***] days after such Patent Infringement or Patent Challenge comes to such Party's attention.

(b) **Oruka's First Right to Enforce or Defend**. Oruka shall have the first right, but not the obligation, to bring and control any legal action, including by declaratory judgment action, patent litigation or similar proceeding, in connection with any Patent Infringement or Patent Challenge with respect to the Licensed Antibody Patents in the Territory at its own expense and discretion as it reasonably determines appropriate. Oruka shall keep Paragon (and, at the direction of Paragon, the Retained IL-23 Project Antibody Licensee) informed and reasonably consult with Paragon (and, at the direction of Paragon, the Retained IL-23 Project Antibody Licensee) in the course of such legal action. Paragon shall have the right to be represented in any such legal action by counsel of its choice at its own expense.

(c) **Paragon's First Right to Enforce or Defend**. Paragon (or, at Paragon's discretion, the Retained IL-23 Project Antibody Licensee) shall have the sole right, but not the obligation, to bring and control any legal action, including by declaratory judgment action, patent litigation or similar proceeding, in connection with any Patent Infringement or Patent Challenge with respect to the Paragon Patents in the Territory at its own expense and discretion as it reasonably determines appropriate. Paragon (directly or indirectly through the Retained IL-23 Project Antibody Licensee) shall keep Oruka informed and reasonably consult with Oruka in the course of legal action to enforce or defend any Retained IL-23 Antibody Patent.

(d) **Settlement**. In connection with any such legal action or proceeding, Oruka shall not enter into any settlement admitting the invalidity or unenforceability of Licensed Antibody Patents without the prior written consent of Paragon (such consent not to be unreasonably conditioned, withheld, or delayed), and Paragon shall not enter into any settlement admitting the invalidity or unenforceability of the Retained IL-23 Antibody Patents without the prior written consent of Oruka (such consent not to be unreasonably conditioned, withheld, or delayed).

(e) **Paragon's Backup Right to Enforce or Defend**. If Oruka does not initiate a legal action for Patent Infringement or Patent Challenge with respect to any Licensed Antibody Patent within [***] days after a notice from Paragon under Section 5.3(a), then Paragon shall have a backup right, but not the obligation, to initiate such legal action at its own expense.

(f) **Allocation of Recoveries**. Any recoveries resulting from such legal action initiated by Oruka or Paragon hereunder relating to Patent Infringement or Patent Challenge in each case solely with respect to the Licensed Antibody Patents, including pursuant to a settlement, shall be applied as follows: (i) first to reimburse the [***] of each of the Parties in such action; and (ii) second, any amounts remaining after paying the amounts due each Party under clause (i) (the "**Remaining Recovery**") shall be allocated as follows: (1) [***]; or (2) [***].

(g) **Cooperation with Patent Enforcement**. At the request of the enforcing Party (and at the requesting Party's expense), the other Party shall reasonably cooperate and provide any information or assistance in connection with any legal action under this Section 5.3, including executing reasonably appropriate documents, cooperating in discovery and, if required by Applicable Law, joining as a party to the legal action at its own expense.

5.4 **Third Party Patent Proceedings**.

(a) **Oruka's First Right to Challenge Third Party Patents**. Oruka shall have the sole and exclusive right, but not the obligation, to bring and control any legal action to challenge any Patents controlled by a Third Party, including by declaratory judgment action, patent interference, opposition, pre-issuance submission, *ex parte* re-examination, post-grant review, *inter partes* review, patent litigation or similar proceeding, in each case that are necessary or useful to Develop, Manufacture, Commercialize or otherwise exploit any Oruka Product.

(b) **Cooperation by Paragon**. At the request of Oruka, Paragon shall cooperate and provide any information or assistance in connection with any legal action under this Section 5.4, including executing reasonably appropriate documents, cooperating in discovery and, if required by Applicable Law, joining as a party to the action at Oruka's cost and expense.

5.5 **Common Interest Agreement**. At the request of either Party to conduct the activities under this Article V, the Parties shall cooperate in good faith to enter into a customary, mutually-agreed common-interest agreement intended to preserve attorney-client privilege with respect to disclosures and communications by or on behalf of either Party or its Affiliates in connection with such activities.

ARTICLE VI

PROTECTION OF CONFIDENTIAL INFORMATION.

6.1 **Confidentiality**. Except to the extent expressly authorized by this Agreement, the Receiving Party agrees that, during the Term, for [***] years thereafter, and, with respect to any Know-How that constitutes a trade secret, for long as such Know-How constitutes a trade secret, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the Disclosing Party. The Receiving Party may disclose Confidential Information of the Disclosing Party to those of the Receiving Party's Representatives who have a need for such information, *provided that* the Receiving Party shall advise such Representatives of the confidential nature thereof, shall ensure that each such Representative is bound in writing by obligations of confidentiality and non-use at least as stringent as those contained in this Agreement, and shall be responsible for the compliance of its Representatives with the terms of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information of the Disclosing Party. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Confidential Information of the Disclosing Party.

6.2 **Exceptions**. The Receiving Party's obligations under Section 6.1 shall not apply to any Confidential Information of the Disclosing Party that the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in breach of this Agreement, generally known or available; (b) is known by the Receiving Party at the time of receiving such information from the Disclosing Party; (c) is hereafter furnished to the Receiving Party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the aid, use or application of any Confidential Information of the Disclosing Party.

6.3 **Authorized Disclosure**. Notwithstanding the provisions of this Article VI, the Receiving Party may disclose Confidential Information of the Disclosing Party, without violating its obligations under this Agreement, to the extent the disclosure is:

(a) required by a valid order of a court or other Governmental Authority of competent jurisdiction or as otherwise required by Applicable Law, rule, regulation (including securities laws), government requirement, or as may be required in connection with any filings made with, or by the disclosure policies of, a stock exchange (including, for clarity, any such disclosures required to be made by Paragon or its Affiliates or licensees in connection with the Development, Manufacture, Commercialization or other exploitation of Multispecific Antibodies), *provided that* the Receiving Party shall give reasonable prior written notice to the Disclosing Party of such required disclosure and, at the [***] request and expense, shall cooperate with the Disclosing Party's efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law required, or to obtain other confidential treatment of such Confidential Information;

(b) reasonably necessary to file or Prosecute patent applications, Prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, or obtain or maintain approval to conduct clinical trials or Regulatory Approvals, in each case, in accordance with this Agreement (including, for clarity, any such disclosures that are reasonably necessary to made by Paragon or its Affiliates or licensees in connection with the Development, Manufacture, Commercialization or other exploitation of Multispecific Antibodies); or

(c) under appropriate confidentiality provisions substantially equivalent to those in this Agreement (but of shorter duration if customary in the case of subclause (ii)): (i) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder and the right to Develop, Manufacture, Commercialize and otherwise exploit Antibodies and products (including Multispecific Antibodies and Multispecific Products) to which it has rights hereunder, or (ii) to actual or *bona fide* potential licensees, acquirers, merger partners, assignees, collaborators, investment bankers, investors or lenders.

6.4 **Use of Names**. Except as set forth in Section 6.6(b), neither Party shall use the other Party's name or trademarks in any advertising, sales, or promotional material or in any publication without the prior written consent of the other Party.

6.5 **Confidentiality of this Agreement**. This Agreement and its terms are considered Confidential Information of both Parties, and each Party shall keep confidential and shall not publish or otherwise disclose the terms of this Agreement without the prior written consent of the other Party, except as expressly permitted by Section 6.3, and except that both Parties may disclose this Agreement and its terms to its legal, financial and investment banking advisors; *bona fide* potential and actual investors, acquirers, merger partners, assignees, collaborators, investment bankers, lenders, licensees, sublicensees or strategic partners in connection with license or partnering transactions, due diligence or similar investigations by such Third Parties or in confidential financing documents; and counsel or other advisors for the foregoing; *provided*, in each case, that any such Third Party agrees to be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article VI (*provided that* the confidentiality term applicable to such Third Party may be shorter so long as it is commercially reasonable).

6.6 **Publicity**.

(a) Subject to Section 6.6(b), neither Party will generate or allow any publicity regarding this Agreement or the transactions contemplated hereunder without the other Party first approving such press release or publication in writing, except for any public disclosure by or on behalf of a Party that is, upon the advice of such Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of such Party are listed (or to which an application for listing has been submitted) and except that a Party may, once a press release or other public written statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other public written statement without the further approval of the other Party.

(b) The Parties shall collaborate and cooperate [***] to devise a Publication (as defined below) strategy for the Oruka Products that is acceptable to both Parties. Prior to publicly presenting or publishing any data, results or analyses relating to an Oruka Product generated by or on behalf of Oruka pursuant to this Agreement (each such proposed presentation or publication, a "**Publication**"), Oruka will provide Paragon with a copy of such proposed Publication to review with adequate time for Paragon's review and comment prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). Oruka will take into consideration Paragon's reasonable comments prior to finalizing the Publication. Upon Paragon's request, Oruka shall remove any Confidential Information of Paragon from such Publication that Oruka is not required to disclose pursuant to Applicable Law or the rules of a stock exchange on which the securities of Oruka are listed. In addition, Paragon shall have the right to request the delay of such Publication for up to [***] days to enable filing of Patents, which request Oruka will take into consideration and discuss with Paragon before release of the Publication. Paragon will not publicly present or publish any Publication including Confidential Information of Oruka relating specifically to the Licensed Antibodies or Derived Antibodies without Oruka's prior written consent, which consent may be withheld for any reason or no reason; *provided, that* the foregoing shall not limit Paragon's right to publicly present or publish any Publication relating to Multispecific Antibodies. Each Publication shall include proper attribution, including the use of such Party's trademarks and name, to the non-publishing Party, as applicable, and each non-publishing Party expressly authorizes the inclusion of such reference in the applicable Publication and licenses the use of such trademarks and name solely for inclusion in any such Publication.

ARTICLE VII

REPRESENTATIONS, WARRANTIES AND COVENANTS.

7.1 **Mutual Representations**. Each Party represents and warrants to the other Party that:

(a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder;

(c) no consent, approval, permit, governmental order, declaration or filing with, or notice to, any Governmental Authority or any Third Party is required by or with respect to such in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby; and

(d) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not and will not conflict with any agreement, instrument, or understanding, oral or written, to which it is or may become a party or by which it may be or become bound.

7.2 **Representations of Paragon**. Paragon hereby represents and warrants to Oruka as of the Effective Date that:

(a) Paragon has set forth in Exhibit A a true, correct and complete list of all the Licensed Antibody Patents existing as of the Effective Date (including title, all inventors, owners, assignees, filing date, grant date, expiration date and status);

(b) Unless otherwise set forth in Exhibit A, Paragon exclusively owns all Licensed Antibody Patents;

(c) There are no licenses or sublicenses pursuant to which Paragon licenses as of the Effective Date any of the Licensed Antibody Technology, nor, to Paragon's actual knowledge, are any such licenses necessary to Develop, Manufacture and Commercialize the Licensed Antibodies;

(d) Paragon has the right under the Licensed Antibody Technology to grant to Oruka the licenses and other rights set forth in this Agreement, and it has not granted any license or other right under the Licensed Antibody Technology that is inconsistent with the licenses and other rights granted to Oruka hereunder;

(e) There is no pending or, to Paragon's knowledge, threatened litigation, nor has Paragon received any written notice from any Third Party, asserting or alleging that the development, manufacture or commercialization of the Licensed Antibody Technology prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(f) To Paragon's knowledge, Paragon has not withheld from Oruka any information with respect to the Licensed Antibody Technology that would reasonably be expected to be materially adverse to Oruka's Development, Manufacture, or Commercialization of any Product in the Territory as contemplated under this Agreement;

(g) To Paragon's knowledge, Paragon has, and any of Paragon's Affiliates involved in the Research Program have, (i) conducted all research and development under the Research Program in accordance with Research Plan (as defined in the Option Agreement), and (ii) conducted the Research Program in compliance with all Applicable Laws;

(h) To Paragon's knowledge, Paragon has provided true, correct and complete copies of all Results developed under the Research Program and all other deliverables required under the Research Program have been provided or delivered to Oruka and are true, correct and complete in all material respects;

(i) Paragon has properly filed, Prosecuted and maintained all Licensed Antibody Patents;

(j) Paragon has complied with all duties of disclosure and has not engaged in any inequitable conduct with respect to all Licensed Antibody Patents that were filed prior to the Effective Date;

(k) All Licensed Antibody Patents listed in Exhibit A that have been issued as of the Effective Date are in full force and effect and are, to Paragon's knowledge, valid and enforceable;

(l) Other than the Patents listed in Exhibit A, as of the Effective Date, neither Paragon nor any of its Affiliates own or have any rights in, to or under any Patents Covering the composition of matter of, or any method of specifically making or using, any Licensed Antibody;

(m) There are no judgments against or awards or settlements against Paragon or any of its Affiliates, and there are no claims, actions, or proceedings pending or, to Paragon's knowledge, threatened, nor to Paragon's knowledge are there any formal inquiries initiated or written notices received that are reasonably likely to lead to the institution of any such legal proceedings, in each case (i) relating to any Licensed Antibodies, Derived Antibodies or Licensed Antibody Technology or alleging that any Third Party has any right to or under any Products, Licensed Antibodies, Derived Antibodies or Licensed Antibody Technology that would conflict with the rights granted in this Agreement; or (ii) alleging that any Licensed Antibody Patent is unpatentable, invalid, unenforceable or infringed;

(n) (i) Each Representative employed or engaged by Paragon or its Affiliate to conduct the activities under the Research Program have assigned or licensed, or are under contractual obligations to assign or license, to Paragon all inventions conceived, reduced to practice or otherwise related to Licensed Antibodies, Derived Antibodies and Licensed Antibody Technology; (ii) to Paragon's knowledge, no Representative employed by Paragon or its Affiliate that conducts activities under a Research Program has any obligations under agreements or Applicable Law to assign any interest in any such inventions to any Third Party; and (iii) each Representative employed or engaged by Paragon or its Affiliate to conduct the activities under a Research Program have existing obligations under agreements or Applicable Law to maintain as confidential Paragon's Confidential Information as well as confidential information of other parties (including of Oruka and its Affiliates);

(o) None of Paragon, its Representatives, or any other person used by Paragon in the performance of the Research Program or otherwise in connection with this Agreement has been or is (i) debarred, convicted, or is subject to a pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (ii) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program, or (iii) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Paragon agrees to inform Oruka in writing promptly if Paragon or any person who is performing activities on its behalf under the Agreement is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending or threatened;

(p) No funding, facilities, or personnel of any Governmental Authority or any public or private educational or research institutions were used to develop or create any Licensed Antibody Technology, and neither Paragon nor any of its Affiliates has entered into a government funding relationship that would result in rights to any Products, Licensed Antibodies, Derived Antibodies or Licensed Antibody Technology residing in the U.S. Government, the National Institutes of Health, or other agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in Public Law 96-517 (35 U.S.C. §§ 200-204), or any similar obligations under the laws of any other country in the Territory; and

(q) To the [***] knowledge of [***] of Paragon, with respect to this Agreement and the Option Agreement, neither Paragon nor any of its directors, officers, employees, distributors, consultants, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Paragon or any of its Affiliates:

(i) has taken any action in violation of any applicable anti-corruption laws, anti-money laundering laws or laws restricting or regulating global trade (collectively, "**Anti-Corruption Laws**");

(ii) has conducted or initiated any internal investigation with respect to any alleged act or omission arising under or relating to any potential noncompliance with any Anti-Corruption Law, or been the subject of current, pending, or threatened investigation, formal or informal inquiry, enforcement proceedings, or received any notice, request, or citation for alleged violations of such laws;

(iii) has engaged in any direct or indirect dealings or transactions in or with a person, entity or country found on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Office of Foreign Assets Control, or engaged in any direct or indirect dealings with Sudan, individuals ordinarily resident in Sudan, or entities incorporated under the laws of Sudan prior to October 12, 2017; or

(iv) has offered, paid, given, promised to pay or give, or authorized the payment or gift of, received, or solicited anything of value, directly or indirectly, to any public official, for the purposes of: influencing any act or decision of any public official in his or her official capacity; inducing any public official to do or omit to do any act in violation of his or her lawful duty; securing any improper or undue advantage; or inducing any public official to use his or her influence with a government, Governmental Authority, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

7.3 **Covenants of Paragon**. Paragon hereby covenants to Oruka during the Term that:

(a) Paragon will not grant a Third Party any license or other right in the Licensed Antibody Technology or the Other Licensed Technology that would conflict with the rights and licenses granted to Oruka hereunder with respect to such Licensed Antibody Technology;

(b) Paragon will, and will direct each Affiliate of Paragon and subcontractor conducting activities under this Agreement to, conduct all such activities in compliance with Applicable Laws, including all applicable Anti-Corruption Laws and U.S. sanctions;

(c) Paragon will comply with the terms of each Paragon Third Party Agreement, will maintain each Paragon Third Party Agreement, will not amend a Paragon Third Party Agreement in a manner that (i) adversely effects Oruka in any material respect, or (ii) increases any financial obligations under a Paragon Third Party Agreement that will result in an increase in Oruka's Reimbursement Obligation, in each case of (i) and (ii) without Oruka's prior written consent, and will not take any actions that could reasonably cause any Paragon Third Party Agreement to lapse or terminate; and

(d) Paragon will, and will direct each applicable Affiliate of Paragon to, execute and deliver such additional documents and instruments and to perform such additional acts as may be necessary or appropriate to enable Oruka to exercise its rights and obligations under Sections 5.2, 5.3 and 5.4.

7.4 **Compliance with Laws**. Each Party shall, and shall ensure that its Affiliates and its and its Affiliates' Representatives and sublicensees, comply with Applicable Laws in all material respects in the performance of its obligations and the exercise of its rights under this Agreement.

7.5 **DISCLAIMER OF WARRANTIES**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, DURABILITY, MERCHANTABLE QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE VIII

TERM; TERMINATION.

8.1 **Term**. The term of this Agreement shall commence on the Effective Date and shall expire on a country-by-country and Oruka Product-by-Oruka Product basis on the expiration of the Royalty Term for such Oruka Product in such country, in each case, unless earlier terminated by a Party as set forth below in this Article VIII (the "**Term**"). Upon expiration (but not termination) of the Agreement, the licenses granted in Section 2.1 shall survive and become royalty-free, fully paid-up, perpetual and irrevocable with respect to the applicable Oruka Product in the applicable country.

8.2 **Termination by Oruka**. Oruka shall have the right to terminate this Agreement in its entirety or on a country-by-country or Oruka Product-by-Oruka Product basis for any or no reason upon sixty (60) days' prior written notice to Paragon.

8.3 **Material Breach**. Either Party may terminate this Agreement in its entirety for the material breach of this Agreement by the other Party, if such material breach remains uncured ninety (90) days (or thirty (30) days with respect to any failure to make any payments owing to a Party hereunder) following notice from the non-breaching Party to the breaching Party specifying such breach, *provided that*, in the event of a dispute regarding the existence or cure of a material breach, no termination shall become effective until such dispute is finally resolved pursuant to Section 10.7 in favor of the non-breaching Party and the breaching Party fails to cure such material breach within ninety (90) days thereafter.

8.4 **Insolvency**. Each Party will have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [***] days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, or (d) appointment of a receiver for all or substantially all of a Party's assets.

8.5 **Effect of Termination of this Agreement**. If this Agreement terminates for any reason (excluding expiration under Section 8.1), whether with respect to a particular Oruka Product, particular country or in its entirety, then the following shall apply:

(a) All licenses and other rights granted by Paragon under this Agreement with respect to the terminated Oruka Product(s) and terminated country(ies) shall terminate, except as required for Oruka, its Affiliates and/or its Sublicensees to perform any of its obligations that survive termination, including to continue to complete or wind down (at [***] expense in the event of a termination by Oruka under Section 8.3) any ongoing clinical trials for any Oruka Product, as may be required by Applicable Law or ethical principles.

(b) No later than [***] days after the effective date of such termination, each Party shall return or cause to be returned to the other Party, or destroy, all Confidential Information received from the other Party and all copies thereof related to the terminated Oruka Product(s) in the terminated country(ies); *provided, however*, that each Party may retain any Confidential Information reasonably necessary for such Party's ongoing obligations and rights under this Agreement which do not terminate, and each Party may keep one (1) copy of Confidential Information received from the other Party in its confidential files for record purposes and such copy shall remain subject to Article VI of this Agreement.

(c) Upon Paragon's written request to Oruka (which must be provided to Oruka within [***] days after the effective date of termination), Paragon and Oruka shall [***] discuss [***], for a period of up to [***] days following such written request, terms and conditions under which Oruka may be willing to grant to Paragon [***], [***] license under the Oruka Intellectual Property to Develop, Manufacture, Commercialize or otherwise exploit the terminated Oruka Products in the Field in the terminated countries that were the subject of any Development, Manufacturing or Commercialization activities performed by Oruka or its Affiliates under this Agreement prior to such termination, ("**Reversion Products**"), as well as the potential transfer of materials, ongoing clinical trials, and applicable regulatory filings and relevant data generated by Oruka with respect to the Reversion Products and necessary for the continued Development, Manufacture, Commercialization and exploitation of such Reversion Products, such agreement to include commercially reasonable financial and other terms, which terms shall take into consideration Oruka's contributions made in the Development, Manufacture, Commercialization and other exploitation of the Reversion Products, provided, that Oruka is under no obligation to enter into such license.

8.6 **Survival of Sublicenses**. Upon termination of this Agreement, at the written request of any Sublicensee who is not then in breach of its sublicense agreement, such sublicense agreement will survive such termination of this Agreement, and Paragon will negotiate [***] the terms and conditions of a direct license with such Sublicensee that is consistent with the terms of this Agreement (as adjusted for the scope of license, products, field of use and other provisions of the original sublicense). Each sublicense that may be amended to become a direct license between Paragon and a Sublicensee shall ensure that any and all economic rights, payments or benefits due to Oruka will be preserved and payable to Oruka and will designate Oruka a third-party beneficiary to enforce such rights. In each such instance, Oruka will have the right to review and approve the terms of such agreement between Paragon and such Sublicensee as related to Oruka's economic rights, which approval shall not be unreasonably withheld, conditioned or delayed.

8.7 **Accrued Rights; Survival**. The expiration or termination of this Agreement for any reason shall not release either Party from any liability or obligation that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination, nor will expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement. In the event of expiration or any termination of this Agreement, the following provisions of this Agreement shall survive such expiration or termination in accordance with their respective terms and conditions: Article I (Definitions); Section 2.1 (License Grant from Paragon) (upon expiration (but not termination) of this Agreement as set forth in Section 8.1 (Term)); Section 2.3 (Sublicenses) (with respect to any payments or other performance obligations prior to conversion (if any) to a direct license pursuant to Section 8.6); Section 2.4 (No Implied Licenses; Reservation of Rights); Section 4.1 (Milestone Payments) (with respect to any outstanding payment obligations incurred prior to the date of termination or expiration); Section 4.2 (Royalties) (with respect to any outstanding payments accrued prior to the effective date of termination); Section 4.4 (Payment Reports) (with respect to the last Calendar Quarter of the Term to the extent not already reported and any outstanding payment obligation with respect to any royalty payments accrued prior to the date of termination or expiration); Section 4.5 (Payment Method) to 4.9 (Blocked Currency) (for the duration of any outstanding payment obligations under this Agreement); Section 4.10 (Records; Inspection) (for the duration set forth therein); Section 5.1 (Ownership); Section 7.5 (Disclaimer of Warranties); Article VI (Protection of Confidential Information) (for the duration set forth therein); Section 8.5 (Effect of Termination of this Agreement); Section 8.6 (Survival of Sublicenses); Section 8.7 (Accrued Rights; Survival); Article IX (Indemnification); and Article X (Miscellaneous).

ARTICLE IX

INDEMNIFICATION.

9.1 **By Oruka**. Oruka hereby agrees to defend, indemnify and hold harmless Paragon, its Affiliates and its or their Representatives (each, an "**Paragon Indemnitee**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees (collectively, "**Losses**"), to which any Paragon Indemnitee may become subject (a) as a result of any claim, demand, action, or other proceeding by any Third Party ("**Third Party Claim**") to the extent such Losses result from: (i) the gross negligence, recklessness or willful misconduct of any Oruka Indemnitee in the performance of this Agreement; (ii) Oruka's breach of any of its representations, warranties or covenants under this Agreement; or (iii) Oruka's Development, Manufacture and Commercialization of the Oruka Products; and (b) to the extent such Losses result from the termination, suspension, revocation or other loss of any Licensed Antibody Patents as a result of any negligence or breach of this Agreement by Oruka, its Affiliates or Sublicensees, in each case ((a) to (b)), except in each case to the extent that any Losses are attributable to the breach of this Agreement by, or the negligence, recklessness or willful misconduct of, or otherwise indemnifiable by, any Paragon Indemnitee.

9.2 **By Paragon**. Paragon hereby agrees to defend, indemnify, and hold harmless Oruka, its Affiliates, and its or their Representatives (each, a "**Oruka Indemnitee**") from and against any and all Losses to which any Oruka Indemnitee may become subject (a) as a result of any Third Party Claim to the extent such Losses result from: (i) the gross negligence, recklessness or willful misconduct of any Paragon Indemnitee in the performance of this Agreement; or (ii) Paragon's breach of any of its representations, warranties or covenants under this Agreement; and (b) to the extent such Losses result from: (i) the termination, suspension, revocation or other loss of any Licensed Antibody Patents as a result of any negligence or breach of this Agreement by Paragon or its Affiliates; or (ii) any claim or demand from any employee or contractor of Paragon or its Affiliates who is an inventor of any Licensed Antibody Patents with respect to ownership thereof, in each case ((a) to (b)), except to the extent that any Losses are attributable to the breach of this Agreement by, or the negligence, recklessness or willful misconduct of, or otherwise indemnifiable by, any Oruka Indemnitee.

9.3 **Indemnification Procedures**. The Party claiming indemnity under this Article IX (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of the Third Party Claim for which indemnity is being sought ("**Claim**"). The Indemnifying Party's obligation to defend, indemnify and hold harmless pursuant to Section 9.1 or Section 9.2, as applicable, will be reduced to the extent the Indemnified Party's delay in providing notification pursuant to the previous sentence results in material prejudice to the Indemnifying Party; *provided, however,* that the failure by an Indemnified Party to give such notice or otherwise meet its obligations under this Section 9.3 will not relieve the Indemnifying Party of its indemnification obligation under this Agreement. At its option, the Indemnifying Party may assume the defense and have exclusive control, at its own expense, of any Claim for which indemnity is being sought by giving written notice to the Indemnified Party within [***] days after receipt of the notice of the Claim. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however,* the Indemnifying Party will have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. The Indemnified Party will not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate, *provided, that* the Indemnified Party reasonably consults with the Indemnifying Party prior to entering into any settlement, and (ii) the Indemnified Party reserves any right it may have under this Article IX to obtain indemnification from the Indemnifying Party.

9.4 **Limitation of Liability**. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE VI, FOR BREACH OF SECTIONS 2.1 OR 2.2, FOR BREACH OF ANY INTELLECTUAL PROPERTY RIGHTS HELD BY A PARTY, FOR THE FRAUD OR WILLFUL MISCONDUCT OF A PARTY OR FOR INDEMNIFICATION CLAIMS UNDER THIS ARTICLE IX, IN NO EVENT SHALL EITHER PARTY BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, EVEN IF THE OTHER PARTY HAD NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

9.5 **Insurance**. During the Term and for a period of [***] years thereafter, each Party shall maintain at its expense insurance coverage consistent with normal business practices and adequate to cover the risks associated with its performance of any activities hereunder. Each Party hereby expressly acknowledges and agrees that the maintenance of such insurance coverage shall not relieve it of its obligations under this Agreement.

ARTICLE X

MISCELLANEOUS.

10.1 **Independent Contractor Relationship**. Paragon's relationship with Oruka is that of an independent contractor, and nothing in this Agreement should be construed to create a partnership, joint venture, or employer-employee relationship. Neither Party is an agent of the other Party or authorized to make any representation, contract, or commitment on behalf of the other Party.

10.2 **Force Majeure**. Neither Party will be charged with any liability for delay or failure in performance of an obligation under this Agreement (other than any obligation to pay monies when due) to the extent such delay or failure is due to a cause beyond the reasonable control of the affected Party, such as war, riots, labor disturbances, epidemic, pandemic, fire, explosion, and compliance in good faith with any Applicable Law (in each case, a "**Force Majeure**"). In addition, a Force Majeure event may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to the COVID-19 pandemic or any other pandemic (or other Force Majeure event), such as requiring employees to stay home, closures of facilities, delays of clinical trials, or cessation of activities in response to the pandemic. The Party affected by a Force Majeure will give prompt written notice to the other Party of the nature of the cause of any material delay or failure to perform, its anticipated duration and any action being taken to avoid or minimize the effect. The Party affected will use its diligent efforts to avoid or remove such causes of delay or failure to perform and to mitigate the effect of such occurrence, and will continue performance in accordance with the terms of this Agreement whenever such causes are removed. The Party affected will give prompt written notice to the other Party of such resumed performance.

10.3 **Entire Agreement; Amendment**. This Agreement and the Option Agreement, together with all Exhibits attached hereto, constitutes the final, complete, and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements, relating to its subject matter. This Agreement (including its Exhibits) may not be changed, modified, amended, or supplemented except by a written instrument signed by both Parties.

10.4 **Non-Waiver**. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

10.5 **Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

10.6 **Assignment**. Neither this Agreement nor any rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however*, that (a) Paragon may assign to an Affiliate or a Third Party financing source its rights to receive some or all of the payments payable hereunder together with the right to receive Confidential Information of Oruka, *provided* Paragon shall not be permitted to share Oruka Confidential Information unless and except to the extent necessary to obtain Affiliate or Third-Party financing, *provided, further, that* any such Affiliate or Third Party agrees to be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in Article VI; and (b) either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent to (i) its Affiliates or (ii) its successor to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. The assigning Party shall provide the other Party with prompt written notice of any such assignment set forth in clauses (a) and (b) above. Except for an assignment pursuant to clause (a) above, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.

10.7 **Dispute Resolution**.

(a) The Parties recognize that a *bona fide* dispute as to certain matters may arise from time to time during the Term relating to either Party's rights or obligations hereunder or otherwise relating to the validity, enforceability or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any disputes relating to Article VI or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights (hereinafter, a "**Dispute**"). In the event of the occurrence of any Dispute, the Parties will follow the following procedures in an attempt to resolve the dispute or disagreement:

(i) The Party claiming that such a Dispute exists will give notice in writing (a "**Notice of Dispute**") to the other Party of the nature of the Dispute. The Dispute will be referred to the then Chief Executive Officer of Paragon and the then Chief Executive Officer of Oruka who will meet no later than [***] days following the initial receipt of the Notice of Dispute and use reasonable endeavors to resolve the Dispute.

(ii) If, within [***] days of initial receipt of the Notice of Dispute, the Dispute has not been resolved, or if, for any reason, the meeting described in Section 10.7(a)(i) hereof has not been held within [***] days of initial receipt of the Notice of Dispute, then the Parties agree that such Dispute will be finally resolved through binding arbitration to be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the Expedited Procedures in those Rules (the "**JAMS Rules**"), as specifically modified by the provisions of this Section 10.7(a)(ii) and Section 10.7(a)(iii).

(iii) The arbitration will be conducted by a panel of three arbitrators. Within [***] days after the initiation of the arbitration, each Party will nominate one person to act as arbitrator, and the two arbitrators so named will then jointly appoint the third arbitrator within [***] days of their appointment, who will serve as chairman of the panel. All three arbitrators must be independent Third Parties having at least [***] years of dispute resolution experience (which may include judicial experience) or legal or business experience in the biotech or pharmaceutical industry. If either Party fails to nominate its arbitrator, or if the arbitrators selected by the Parties cannot agree on a person to be named as chairman within such [***]-day period, JAMS will make the necessary appointments for such arbitrator(s) or the chairman. Once appointed by a Party, such Party will have no *ex parte* communication with its appointed arbitrator.

(iv) Notwithstanding the provisions of Section 10.7(a)(iii), if the Dispute involves an amount in question of less than $[***], then the arbitration will be conducted by one arbitrator, selected in accordance with the JAMS Rules.

(v) The place of arbitration will be in Boston, Massachusetts or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrator(s) shall have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 *et seq.,* and judgment upon the award rendered by the arbitrators may be entered in any court having competent jurisdiction thereof. The existence, content and results of any arbitration proceedings pursuant to this Section 10.7 will be deemed the Confidential Information of both Parties.

(b) Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement.

(c) The Parties agree that any disputes relating to Article VI or disputes relating to the determination of the validity, scope, infringement, enforceability, inventorship or ownership of the Parties' respective Intellectual Property Rights shall be subject to the exclusive jurisdiction of the state and federal courts in Boston, Massachusetts and each Party hereby submits to such jurisdiction.

10.8 **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without reference to conflicts of laws principles.

10.9 **Notices**. Any notice to be given under this Agreement must be in writing and delivered either in person, by internationally recognized express courier, or by email, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by express courier, the next Business Day the express courier regularly makes deliveries; or (c) if delivered by email, upon the date upon which the receipt of such email is confirmed by return email. Together with any notice provided by a Party to the other Party in accordance with this Section 10.9, the Party shall send a copy of such notice by email to the other Party.

If to Paragon: Paragon Therapeutics, Inc.
221 Crescent Street
Building 23, Suite 105
Waltham, MA 02453
Attn: Chief Operating Officer
Email: [***]

If to Oruka: Oruka Therapeutics, Inc.
855 Oak Grove Avenue, Suite 100
Menlo Park, CA 94025
Attn: General Counsel
Email: [***]

10.10 **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity shall be construed to include such person's or entity's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "or." The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement or have any effect on its interpretation or construction. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language. To the extent there is any inconsistency or conflict between the terms and conditions of this Agreement and any Exhibit, the terms and conditions of this Agreement will prevail.

10.11 **No Third-Party Rights**. The provisions of this Agreement are for the exclusive benefit of the Parties and their successors and permitted assigns, and no other person shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

10.12 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, or electronic signatures complying with the ESIGN Act of 2000 (such as DocuSign), which signatures shall have the same force and effect as original signatures.

10.13 **Expenses**. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

10.14 **Binding Effect**. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

10.15 **Construction**. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

10.16 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

10.17 **Performance by Affiliates**. A Party may perform some or all of its obligations under this Agreement through Affiliate(s) or may exercise some or all of its rights under this Agreement through Affiliates, subject to the terms of this Agreement. However, each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance as if such Party were performing such obligations itself, and references to a Party in this Agreement shall be deemed to also reference such Affiliate. In particular and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in Article VI, and shall be subject to the intellectual property provisions of Article V as if they were the original Party to this Agreement (and be deemed included in the actual Party to this Agreement for purposes of all intellectual property-related definitions). A Party and its Affiliates shall be jointly and severally liable for their performance under this Agreement.

[*Remainder of Page Left Intentionally Blank; Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have by duly authorized persons executed this Agreement as of the Effective Date.

PARAGON THERAPEUTICS, INC.

By: /s/ K. Evan Thompson
Name: K. Evan Thompson
Title: Chief Operating Officer

ORUKA THERAPEUTICS, INC.

By: /s/ Lawrence Klein
Name: Lawrence Klein
Title: Chief Executive Officer

[SIGNATURE PAGE TO LICENSE AGREEMENT]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

CELL LINE LICENSE AGREEMENT

This Cell Line License Agreement ("Agreement"), effective as of March 4, 2024 ("EFFECTIVE DATE"), is entered and made by and between WuXi Biologics Ireland Limited, having an address at Dundalk Science & Technology Park, Mullagharlin, Dundalk, Co Louth A91 X56F, Ireland (collectively, "WuXi Biologics") and Oruka Therapeutics, Inc., a Delaware corporation, with an office at 221 Crescent Street, Building 23, Suite 105, Waltham, MA 02453 ("Licensee"). WuXi Biologics and Licensee may be referred to herein individually as a "Party" and collectively as the "Parties."

The Parties agree as follows:

1. Definitions

1.1 "**Affiliate**" of a person means any other person that directly or indirectly Controls, is Controlled by, or is under common Control with, the person.

1.2 "**Client Product**" means [***] of interest to Licensee, which is designated by the Licensee to be produced by the Licensed Cell Line. Each different Client Product covered under this Agreement shall be specified in Appendix I. An amendment to this Agreement is required for each new Client Product produced by the Licensed Cell Line.

1.3 "**Confidential Information**" of a Party (the "**Disclosing Party**") means all non- public scientific, technical, financial regulatory or business information and materials disclosed by or on behalf of the Disclosing Party to the other Party (the "**Receiving Party**") or its Related Persons (defined below) in connection with this Agreement. Confidential information shall be identified as confidential in writing or, if disclosed verbally or by observation, summarized in writing and submitted to the Receiving Party within [***] of the oral or visual disclosure thereof; provided, however, information need not be labeled or marked "confidential" to be deemed Confidential Information hereunder, if under the circumstances it is, or should be, understood to be confidential. The Confidential Information of both Parties includes the existence, terms and objectives of this Agreement, and the nature of any dispute and the outcome of any arbitration proceedings arising out of or in connection with this Agreement.

1.4 "**Construct**" means a [***] developed by WuXi Biologics that is used for delivering genetic code and for transfecting and/or transforming the Host Cell Line for purposes of creating the Licensed Cell Line.

1.5 "**Control**" over an entity means (a) owning 50% or more of the voting securities or other ownership interests of such entity or (b) having the power to direct the management or policies of such entity.

1.6 "**Drug Product**" means the final dosage form which contains Client Product, in association with other active or inactive ingredients.

1.7 "**Drug Substance**" means bulk Client Product, which has not yet been packaged into its final dosage form.

1.8 "**Host Cell Line**" means the proprietary host cell line developed by WuXi Biologics, and designated by WuXi Biologics as the [***], that is used to make the Licensed Cell Line.

1.9 "**Licensed Cell Line**" means a transformed or transfected (using WuXi Biologics' Construct(s)) version of the Host Cell Line that produces the Client Product.

1.10 "**Licensed Know-How**" means any know-how and non-public information owned or controlled by WuXi Biologics that is used or incorporated in the Process, and that is necessary or useful to operate the Process as further described in the Technology Transfer Package. The word "control" when used in connection with Licensed Know-How includes both exclusively and non-exclusively licensed know-how and non-public information, as well a right of WuXi Biologics to transfer such know-how and non-public information to Licensee. As used in this definition "know-how" means all confidential and proprietary commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, and including study designs and protocols).

1.11 "**Marketing Authorization Approval**" means, with respect to a country or extra-national territory, any and all approvals (including a New Drug Application or Biologics License Application approved by the FDA), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, including any pricing or reimbursement approvals.

1.12 "**Materials**" means the biological materials, including the Licensed Cell Line, provided to Licensee pursuant to the license granted under this Agreement.

1.13 "**Media and Feeds**" means any proprietary media and feeds used in the Process.

1.14 "**Net Sales**" means the amount [***] by Licensee and its Affiliates or sublicensees for bona fide sales of Client Product to a third-party [***], less:

- [***];
- [***];
- [***];
- [***];
- [***];
- [***]; and
- [***].

Net Sales will not include [***]. Such amounts will be determined from the books and records of [***], maintained in accordance with GAAP consistently applied.

1.15 "**Process**" means a process for manufacture of Client Product utilizing Licensed Know-How, Materials and Media and Feeds as described in the Technology Transfer Package.

1.16 "**Regulatory Authority**" means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council, or other government entity involved in regulating development of and granting regulatory approval for a pharmaceutical product, including the FDA and EMA.

1.17 "**Related Persons**" means a Party's Affiliates and their respective directors, officers, employees and agents.

1.18 "**Research Cell Bank**" is a [***].

1.19 "**Technology Transfer Package**" means all information and data describing the Process, together with all Licensed Know-How, Materials and Media and Feeds necessary or useful for the development and manufacture of Client Product using the Licensed Cell Line and/or the Process.

1.20 "**Third Party**" means any person other than the Parties to this Agreement.

1.21 "**Third Party Manufacturer**" means (i) a Third Party whose primary business is contract manufacturing, or (ii) a Third Party who has a contractual arrangement with Licensee or with a sublicensee of Licensee that includes manufacturing of Client Product and/or Drug Product by such Third Party for Licensee or such sublicensee.

2. License

2.1 WuXi Biologics hereby grants to Licensee and its Affiliates a non-exclusive, worldwide license, with the right to grant sublicenses as provided in Section 2.3, to the Licensed Know-How and the Licensed Cell Line, Materials, and Media and Feeds, for the purpose of conducting the Process, including the following licensed activities:

i. to make, have made, import, sell and otherwise use Client Product; and

ii. to make, have made, use, sell, have sold, offer for sale, import, keep and otherwise deal in and further commercialize Drug Substance and Drug Product for any and all purposes.

2.2 The Licensee or its Affiliates may contract with a Third Party Manufacturer for the limited purpose of developing and manufacturing Client Product on behalf of the Licensee or its Affiliates, provided that, such Third Party Manufacturers are bound by the contract to comply with the confidentiality and use terms of this Agreement, and that the Licensee or its Affiliates will remain liable for any Third Party Manufacturers' breach of this Agreement.

2.2.1 For the benefit of doubt, a Third Party Manufacturer cannot manufacture Client Product, Drug Substance or Drug Product utilizing the Licensed Cell Line and Licensed Know-How without first being contracted with a Licensee, its Affiliates or sublicensee.

2.2.2 A Third Party Manufacturer that has been granted a sublicense cannot grant, issue or transfer a sublicense to another Third Party.

2.3 Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant sublicenses to a Third Party for the rights granted to Licensee under this Agreement. Each sublicense agreement shall be in writing and provided that the applicable sublicensee is bound by all applicable terms and conditions of this Agreement, and Licensee or its Affiliates shall remain liable for any sublicensee's breach of this Agreement. Licensee shall inform WuXi Biologics in writing any and all such sublicenses. [***]. Licensee will notify WuXi Biologics in writing of any sublicense agreement with a sublicensee within [***] of the execution of such agreement. Any sublicense granted by Licensee to any rights licensed to it hereunder will terminate [***] upon the termination of the license by WuXi Biologics under the terms of this Agreement; provided, that such sublicensed rights will not terminate if, as of the effective date of such termination, a sublicensee is not in material default of its obligations under its sublicense agreement, and within [***] of such termination, the sublicensee agrees in writing to be bound directly to WuXi Biologics under a license agreement substantially similar to this Agreement with respect to the rights sublicensed hereunder.

2.4 Except as expressly provided in this Agreement, nothing in this Agreement shall be deemed to have granted Licensee (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any intellectual property, Know-How or information owned or controlled by WuXi Biologics.

2.5 Invoicing of License fees will commence [***].

3. <u>Transfer of Materials and Licensed Know-How</u>

WuXi Biologics shall notify Licensee in writing within [***] following the date on which WuXi Biologics completes transfection of the Host Cell Line to generate the Licensed Cell Line. Thereafter, [***] upon written request and the completion of due payment by Licensee (and in any event within [***] following designation of a Third Party Manufacturer), WuXi Biologics shall disclose, make available, and conduct a full transfer, and shall cause its Affiliates to disclose, make available, and conduct a full transfer to Licensee, its Affiliates, or any one or more of its Third Party Manufacturers designated by Licensee, all Materials and Licensed Know-How, that is necessary or reasonably useful for Licensee and Third Party Manufacturers to solely develop and manufacture the Client Product. The Parties shall agree to a schedule for such transfer of the Materials and Licensed Know-How. WuXi Biologics will provide [***] assistance to enable such Third Party Manufacturer to manufacture Client Product, provided, however, it is the Third Party Manufacturer's full responsibility to manufacture such Client Product after the transfer, WuXi Biologics will not be responsible for the Third Party Manufacturer's success or failure to manufacture any Client Products. Initiation of such technology transfer will be determined by Licensee. WuXi Biologics will be reimbursed for such activities by Licensee on an [***] rate. WuXi Biologics will provide [***] requested ongoing technical support if requested by Licensee with such support reimbursed [***] rate basis.

4. License Fee

As consideration for the license granted in Section 2 of this Agreement, and the representation and warranty set forth in Section 10 of this Agreement, Licensee agrees to pay WuXi Biologics a fixed non-creditable, non-refundable license fee of USD [***] for the Licensed Cell Line used in Client Product.

5. Cell Line Royalties.

If Licensee manufactures [***] commercial supplies of the applicable Drug Substance using manufacturing facilities other than WuXi Biologics' or its Affiliates' manufacturing facilities, Licensee shall pay to WuXi Biologics a Royalty of [***] on the applicable Drug Product's global Net Sales sold by Licensee, its Affiliates, or sublicensees, paid to WuXi Biologics [***]. If Licensee manufactures [***] commercial supplies of the applicable Drug Substance using WuXi Biologics' or its Affiliates' manufacturing facilities, the Royalty shall be [***], depending on [***]. If Licensee manufactures all of its commercial supplies of the applicable Drug Substance by WuXi Biologics or its Affiliates, no Royalty is applicable and no Royalty payment shall be due hereunder.

6. Payment Terms

Licensee shall pay WuXi Biologics' undisputed invoice(s) within [***] of receipt by Licensee. Such payments will be made by wire transfer to the account designated by WuXi Biologics. Invoices must be submitted, and payment must be made, [***].

7. Bank Account Details

Unless the Parties otherwise mutually agree in writing, and such mutual agreement is set forth in a particular invoice, Licensee shall pay each invoice by wire transfer to the account designated by WuXi Biologics. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on standard methodologies employed by Licensee or its Affiliates or sublicensees for consolidation purposes for the [***] for which remittance is made for Royalties.

8. Restriction

Licensee agrees that no attempt will be made by or on behalf of Licensee to modify or reverse engineer the Licensed Cell Line or attempt to reverse engineer, recreate or assemble the Construct(s). Licensee shall only use the Licensed Cell Line in the way as permitted by this Agreement and shall not use or have used the Licensed Cell Line for any purpose other than as provided hereunder, including operating the Process, the manufacture of Client Product, Drug Substance and Drug Product, and for other purposes reasonably related to securing Marketing Authorization Approval for the Client Product and/or Drug Product. Licensee shall not transfer the Licensed Cell Line to any Third Party except to a permitted sublicensee, as described in Section 2.2 above, permitted Third Party Manufacturer, or an assignee.

9. Indemnity

9.1 Licensee agrees to indemnify, hold harmless and defend WuXi Biologics, its Affiliates, and their respective directors, officers, employees and agents harmless (collectively, "WuXi Indemnitees") from and against any and all liabilities and damages (including reasonable attorneys' fees) resulting from any and all claims from any Third Party ("Claims") to the extent arising from the use of the Licensed Cell Line, Client Product, Drug Substance or Drug Product by Licensee; except to the extent WuXi Biologics is obligated to indemnify Licensee in accordance with Section 9.2 of this Agreement, and provided further that Licensee shall have no obligation to indemnify any such Claims that arise from WuXi Biologics' (i) negligence or intentional misconduct in connection with the Licensed Cell Line (ii) material breach of this Agreement (including the representations and warranties set forth in Section 10); or (iii) Host Cell Line components of the Licensed Cell Line or any Media and Feeds.

9.2 WuXi Biologics will indemnify Licensee, its Affiliates, its sublicensees and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, "Licensee Indemnitees"), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third-Party Claims against Licensee Indemnitees to the extent arising from or occurring as a result of: (i) the breach by WuXi Biologics of any provision of this Agreement; or (ii) any negligence or willful misconduct on the part of any WuXi Indemnitee in connection with the Host Cell Line components of the Licensed Cell Line, except in each case to the extent Licensee is obligated to indemnify WuXi Biologics in accordance with Section 9.1 of this Agreement.

9.3 Each party must notify the other party within [***] of receipt of any claims made for which the other party might be liable hereunder. The indemnifying party will have the sole right to defend, negotiate, and settle such claims. The indemnified party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense. No compromise or settlement of any Claim may be made by the indemnifying Party without the indemnified Party's written consent; provided, however, that the indemnifying party will have final decision-making authority regarding all aspects of the defense of any claim. The party seeking indemnification will provide the indemnifying party with such information and assistance as the indemnifying party may reasonably request, at the expense of the indemnifying party.

9.4 Limitation of Liability. NEITHER PARTY WILL BE LIABLE UNDER ANY LEGAL THEORY (WHETHER TORT, CONTRACT OR OTHERWISE) FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, HOWEVER CAUSED, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, EXCEPT AS A RESULT OF A BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN SECTION 11. NOTHING IN THIS SECTION 9.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

10. Representations and Warranties

10.1 WuXi Biologics represents and warrants that: (i) it is a corporation duly organized validly existing and in good standing under the laws of the Republic of Ireland; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of WuXi Biologics; (iii) the performance of WuXi Biologics' obligations under this Agreement will not conflict with its charter documents or result in a material breach of any agreements, contracts or other arrangements to which it is a party; (iv) WuXi Biologics will not before the termination of this Agreement enter into any agreements, contracts or other arrangements that would be materially inconsistent with its obligations under this Agreement; (v) WuXi Biologics has sufficient facilities, experienced personnel and other capabilities reasonably suited to enable it to perform its obligations under this Agreement; (vi) WuXi Biologics has the right to grant the licenses or sublicenses, as the case may be, therefor granted under this Agreement; (vii) WuXi Biologics is the sole and exclusive owner of the Licensed Know-how and Licensed Cell Line, or otherwise has the right to license the Licensed Know-how and Licensed Cell Line and grant rights to Licensee as set forth in this Agreement and during the Term of the Agreement, (viii) to the best of its knowledge WuXi Biologics is and will remain entitled to grant to Licensee the licenses and rights specified or contemplated by this Agreement, and to the Licensed Know-How, (ix) as of the Effective Date, neither WuXi Biologics nor any of its Affiliates has received any notice challenging WuXi Biologics' ownership or right to use the Licensed Know-How in relation to the Licensed Cell Line and, Host Cell Line component of the Licensed Cell Line, (x) to the best of WuXi Biologics's knowledge, there are no valid grounds for any claim against WuXi Biologics or any of its Affiliates except for any claims caused by Licensee's DNA sequence related to the Client Product incorporated into the Licensed Cell Line.

10.2 Licensee represents and warrants that: (i) it is a corporation duly organized validly existing and in good standing under the laws of the Commonwealth of Massachusetts; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of Licensee; (iii) the performance of Licensee's obligations under this Agreement will not conflict with its charter documents or result in a material breach of any agreements, contracts or other arrangements to which it is a party; (iv) Licensee has sufficient facilities, experienced personnel and other capabilities reasonably suited to enable it to perform its obligations under this Agreement; and (v) Licensee will not before the termination of this Agreement enter into any agreements, contracts or other arrangements that would be materially inconsistent with its obligations under this Agreement.

10.3 Disclaimer of Warranties. OTHER THAN AS PROVIDED IN THIS AGREEMENT, THE LICENSED KNOW-HOW, AND LICENSED CELL LINES ARE PROVIDED AND LICENSED TO LICENSEE "AS IS", THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT THERETO OR TO THE PRODUCTS, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSEVALIDITY OF THE RIGHTS LICENSED HEREUNDER, OR NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

11. Confidentiality

11.1 Subject to the exceptions listed below, during the term of this Agreement and for [***] thereafter, the Receiving Party shall, and shall ensure that its Related Persons will, (a) maintain the Disclosing Party's Confidential Information in confidence, (b) not use such Confidential Information other than in connection with this Agreement, and (c) not disclose such Confidential Information to any Third Party other than (i) those of its Related Persons that have a need to know such Confidential Information in connection with the Activities conducted pursuant to the Agreement and are obligated to maintain such Confidential Information in confidence and (ii) to the extent required by applicable law or judicial order, or to the extent reasonably necessary to prosecute or defend litigation or arbitration in relation to this Agreement, and, in either case, only after the Receiving Party gives the Disclosing Party [***] advance written notice of such requirement and [***] cooperates with the Disclosing Party's efforts to limit or avoid such disclosure, to seek a protective order or secure confidential treatment of the Confidential Information, and/or to seek any other remedies available to the Disclosing Party at law or in equity. Notwithstanding the foregoing, the existence of this Agreement and its non-technical terms may be disclosed confidentially in connection with a potential financing, collaboration or acquisition or in discussion with a potential acquirer of Client Product.

11.2 The Receiving Party's obligations set forth in Section 11.1 do not apply to Confidential Information if (a) the information is public knowledge or becomes public knowledge after disclosure through no act or omission of the Receiving Party or any of its Related Persons, (b) the information can be shown by the Receiving Party to have been lawfully in its possession prior to disclosure, (c) the information was rightfully received on a non-confidential basis from a Third Party that was not obligated to maintain the information in confidence, or (d) the Receiving Party can show that equivalent information was developed independently by the Receiving Party without reference to the Disclosing Party' Confidential Information.

11.3 Licensee may disclose the Confidential Information of WuXi Biologics to a Third Party for the purpose of exercising Licensee's license rights hereunder (including disclosure to potential Third Party sublicensees), provided that Licensee shall, prior to such disclosure, ensure that each Third Party to which disclosure is to be made is made aware of the obligations contained in this Agreement and agrees to be subject to obligations of confidentiality and non-use no less onerous than those contained in this Agreement. Any breaches of the obligations of confidentiality and non-use contained in this Agreement by such Third Party shall be treated as a breach of such obligations by Licensee.

11.4 Notwithstanding anything to the contrary in this Agreement, a Party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in securities filings with the U.S. Securities and Exchange Commission (or equivalent foreign agency) and any rules of stock exchanges where the Parties may be listed to the extent required by applicable law after complying with the procedure set forth in this Section 11.4. In such event, unless otherwise required to comply with applicable law, the Party seeking such disclosure will prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party will [***] give its input in a [***] in order to allow the Party seeking disclosure to file its request within the timelines proscribed by applicable laws and regulations. The Party seeking such disclosure shall exercise [***] to obtain confidential treatment of this Agreement from the U.S. Securities and Exchange Commission (or equivalent foreign agency) as represented by the redacted version reviewed by the other Party.

11.5 The provisions of this Section 11 shall survive termination or expiry of this Agreement.

12. Termination

12.1 Voluntary Termination by Licensee.

Licensee shall have the right to terminate this Agreement upon [***] prior written notice to WuXi Biologics, and upon payment of all undisputed amounts due to WuXi Biologics through such termination effective date.

12.2 Termination for Default

(a) Nonpayment. In the event Licensee fails to pay any undisputed amounts due and payable to WuXi Biologics hereunder, and fails to make such payments within thirty (30) days after receiving written notice of such failure, WuXi Biologics may terminate this Agreement [***] upon written notice to Licensee.

(b) Material Breach. In the event Licensee commits a material breach of its obligation under this Agreement and fails to cure that breach within [***] after receiving written notice thereof, WuXi Biologics may terminate this Agreement [***] upon written notice to Licensee.

12.3 Termination Upon Bankruptcy. If either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition or commences a proceeding under any bankruptcy or insolvency act in any state or country or has any such petition or application filed against it which is not discharged within [***] of the filing thereof, then the other Party may thereafter terminate this Agreement effective [***] upon written notice to such Party. All rights and licenses granted under or pursuant to this Agreement by WuXi Biologics are, and will otherwise be deemed to be, for purposes of the relevant provisions of the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3 ("BIA"), including Sections 65.11(7), 65.13(9), 72.1 and 246.1 of the BIA; and the relevant provisions of the Companies' Creditors Arrangement Act, R.S.C. 1985, c. C-36 ("CCAA"), including Sections 32(6) and 36(8) of the CCAA (the BIA and CCAA being referred to collectively as the "Insolvency Legislation"), a grant of a "right to use" "intellectual property" as used in the Insolvency Legislation. The Parties agree that Licensee and its Affiliates and sublicensees, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Insolvency Legislation subject to the payment of amounts provided for herein. Without limiting Licensee's rights under the Insolvency Legislation, if WuXi Biologics becomes insolvent or makes an assignment for the benefit of its creditors or there is filed by or against it any bankruptcy, receivership, reorganization or similar proceeding pursuant to or under the Insolvency Legislation or otherwise, Licensee will be entitled to a copy of any and all information specified in the Technology Transfer Package unless WuXi Biologics, or its trustee or receiver, elects within [***] to continue to perform all of its obligations under this Agreement.

12.4 Expiration or termination of this Agreement for any reason will not relieve either party of any obligation accruing prior to such expiration or termination, including section 5 (Cell Line Royalties) shall survive termination or expiry of this Agreement.

13. Miscellaneous.

13.1 Assignment. This Agreement may not be assigned or otherwise transferred by either Party (subject to Licensee's right to sublicense its rights hereunder) without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; *provided, however*, that a Party may, without such consent, assign this Agreement in its entirety (a) to an Affiliate, or (b) to a Third Party in connection with a merger, acquisition, consolidation or a sale involving all or substantially all of the assets or business of such Party. Any attempted assignment or transfer in violation of this Section 13.1 shall be void.

13.2 Regulatory Assistance. WuXi Biologics will provide assistance to Licensee, and any sublicensee, in respect of Licensee's or such sublicensee's regulatory filing activities for the Client Product and/or Drug Product, at Licensee's or such sublicensee's reasonable cost and expense on [***] rate.

13.3 Governing Law. The laws of the State of New York, USA, without regard to any choice of law principle that would require the application of the law of another jurisdiction, govern all matters relating to this Agreement and the enforcement thereof. The parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980.

13.4 Arbitration. The parties shall engage in good faith consultation to resolve any dispute arising out of or in connection with this agreement. Such consultation will begin [***] after one party has delivered to the other party a request for consultation. If the dispute cannot be resolved within [***] following the date on which the request for consultation is delivered, then either party may submit the dispute to JAMS International Arbitration Rules ("Arbitration"). The Arbitration tribunal will consist of three arbitrators. Within [***] after the commencement of the Arbitration, each Party shall select one person to act as arbitrator, each of whom must be a practicing or retired attorney or judge have at least [***] of litigation experience within the biopharmaceutical industry. The two arbitrators so selected shall select the chair within [***] of the commencement of the Arbitration, whom must a practicing or retired attorney or judge have at least [***] of litigation experience within the biopharmaceutical industry. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator within the allotted time, the third arbitrator shall be appointed by JAMS in accordance with the JAMS International Arbitration Rules. All arbitrators shall serve as neutral, independent and impartial arbitrators. (ii) The Arbitration shall be conducted in accordance with the expedited procedures set forth in the JAMS International Arbitration Rules. The place of arbitration will be Manhattan, New York. The official language of the arbitration will be English. The arbitration proceedings will be confidential, and the arbitrator may issue appropriate protective orders to safeguard each party's Confidential Information. During the course of arbitration, the parties shall continue to implement the terms of this agreement. The arbitral award will be final and binding upon the parties, and the party to the award may apply to a court of competent jurisdiction for enforcement of the award. Notwithstanding the foregoing, each party has the right to institute an action in a court of proper jurisdiction for injunctive or other equitable relief pending a final decision by the arbitrator.

13.5 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

IN WITNESS WHEREOF, the Parties hereto have caused this AGREEMENT to be duly executed as of the Effective Date set forth above.

WuXi Biologics Ireland Limited

By: /s/ Zhisheng Chen
Name: Zhisheng Chen
Title: Director

Oruka Therapeutics, Inc.

By: /s/ Lawrence Klein
Name: Lawrence Klein
Title: CEO

Appendix I

[***]

Exhibit 10.33

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NO. 1 TO THE CELL LICENSE AGREEMENT

THIS AMENDMENT NO. 1 TO THE CELL LINE LICENSE AGREEMENT ("**Amendment**"), effective as of November 20, 2024 (the "Amendment Effective Date"), is entered into and made by and between **WuXi Biologics Ireland Limited**, ("WuXi Biologics"), and **Oruka Therapeutics,** Inc. ("Licensee"). WuXi Biologics and Licensee may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, WuXi Biologics (and Licensee have entered into that certain Cell Line License Agreement, dated as of March 4, 2024, (the "**License Agreement**"); and

WHEREAS, the Parties now desire to amend the License Agreement;

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending legally to be bound, hereby agree as follows:

1. The current *Section 5 Cell Line Royalties* shall be re-numbered to Section 5.1

2. A new *Section 5.2 Buy-out Payment* is hereby added into the License Agreement as the following:

5.2. **Buy-Out Payment**

Notwithstanding the foregoing, in lieu of Licensee paying WuXi Biologics the Royalty provided for in Section 5.1, Licensee, or its sublicensee or assignee may, at any time, in its sole discretion, pay to WuXi Biologics, on a Drug Product-by-Drug Product basis, a fixed non-creditable, non-refundable royalty buyout payment as set forth below (a "Royalty Buyout Payment"). Once WuXi Biologics has received the Royalty Buyout Payment from Licensee, or its sublicensee or assignee, all future royalty obligations with respect to such Drug Product will be extinguished and Licensee will no longer owe any Royalty with respect to such Drug Product. Upon the applicable Royalty Buyout Payment being fully paid with respect to a Drug Product, the rights and licenses granted with respect to such Drug Product under this Agreement (including for clarity in Section 2.1) shall become fully paid-up, royalty free, perpetual and irrevocable.

5.2.1 For the [***] Drug Product [***], the Royalty Buyout Payment shall be [***].

5.2.2 For the [***], Drug Product(s) [***], the Royalty Buyout Payment shall be [***].

5.2.3 For clarity, [***].

3. Except as expressly modified by this Amendment, the License Agreement shall remain unchanged and in full force and effect in accordance with its terms and the Parties hereby ratify and reaffirm the License Agreement as amended hereby.

4. This Amendment may be executed in any number of counterparts, with each counterpart constituting an original, but all of which shall together constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Amendment by facsimile or electronic transmission (including .pdf file) shall be effective as delivery of a manually executed counterpart of this Amendment.

5. Any capitalized term used in this Amendment and not otherwise defined herein shall have the meaning given to that term in the License Agreement. This Amendment and the rights and obligations of the Parties hereto shall be governed, construed, and enforced in accordance with the governing law as stated in the License Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed as of the Amendment Effective Date set forth above.

WuXi Biologics Ireland Limited

By: /s/ Zhisheng CHEN
Name: Zhisheng CHEN
Title: Director

Oruka Therapeutics, Inc.

By: /s/ Lawrence Klein
Name: Lawrence Klein
Title: President and Chief Executive Officer

INSIDER TRADING POLICY

August 29, 2024

I. INTRODUCTION

Federal and state laws prohibit buying, selling or making other transfers of securities by persons who have material information that is not generally known or available to the public. These laws also prohibit persons with such material nonpublic information ("MNPI") from disclosing this information to others who trade. Trading while in possession of MNPI is often referred to as "insider trading."

Who Is Subject to this Policy. Oruka Therapeutics, Inc. (the "Company") has adopted the following policy (this "Policy") regarding trading in securities by all of its directors, officers and employees, as well as certain contractors and consultants who are so designated by the General Counsel ("GC")[1] from time to time (together, "Company Personnel") as well as their family members who reside with them, anyone else who lives in their household and any family members who do not live in their household but whose transactions in Company securities (as defined below) are directed by them or are subject to their influence or control (collectively, "Family Members"), and corporations or other business entities controlled, influenced or managed by them or their Family Members, and trusts for which such persons are a trustee or in which they have a beneficial or pecuniary interest (collectively, "Controlled Entities," and together with Company Personnel and Family Members, "Insiders"). Unless otherwise indicated, all references to "you" in this Policy should be read to include all of your Family Members and Controlled Entities.

Which Securities Are Subject to this Policy. This Policy applies to transactions, whether direct or indirect, in the Company's securities, including its common stock, options to purchase common stock, restricted stock or restricted stock units or any other type of securities that Company may issue from time to time, including but not limited to preferred stock and convertible debentures, as well as derivative securities relating to the Company but that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities (collectively, "Company securities"). Similarly, this Policy applies to all securities, including common stock, options to purchase common stock or any other type of securities, that are issued by a Company Counterparty (as defined below), as well as any derivative securities that are relating to the Company Counterparty but that are not issued by such Company Counterparty, such as puts, calls or swaps.

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1 At any time when the Company does not have an active GC, the duties and responsibilities assigned to the GC under this Policy shall be fulfilled by the Chief Financial Officer ("CFO"). At any time when the Company does not have an active CFO, the duties and responsibilities assigned to the CFO under this Policy shall be fulfilled by the principal financial officer.

Application of this Policy to Company Counterparties. The principles discussed in this Policy also apply to nonpublic information that you obtain in the course of your employment or other involvement with the Company about another public company with which the Company has a preexisting or prospective relationship, such as the Company's customers, suppliers, contract research, manufacturing, licensing or other collaboration partners, companies in which the Company has an investment or a firm with which the Company is negotiating a major transaction, such as a joint venture, licensing transaction, collaboration arrangement or material acquisition or disposition (a "Company Counterparty" or "Company Counterparties").

No Exceptions. The prohibition against trading while in possession of MNPI is absolute and unconditional. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to high standards of conduct. There is no exception for small transactions or transactions that may seem necessary or justifiable for independent reasons, such as the need to raise money for an emergency expenditure.

Individual Responsibility. You are responsible for ensuring that you (as well as your Family Members and Controlled Entities) do not violate federal or state securities laws or this Policy. The Company has designed this Policy to promote compliance with the federal securities laws and to protect the Company and you from the serious liabilities and penalties that can result from violations of these laws.

Consequences for Violating Insider Trading Laws. If you violate insider trading laws, you may have to pay civil fines for up to three times the profit gained or loss avoided by such trading, as well as criminal fines of up to $5 million. You also may be subject to criminal charges and may have to serve a jail sentence of up to 20 years. In addition, the Company may face civil penalties up to the greater of $1 million, or three times the profit gained or loss avoided as a result of your insider trading violations, as well as criminal fines of up to $25 million. Both the Securities and Exchange Commission ("SEC") and The Nasdaq Stock Market ("Nasdaq") are very effective at detecting and pursuing insider trading cases. The SEC has successfully prosecuted cases against employees trading through foreign accounts, trading by family members and friends and trading involving only a small number of shares. Therefore, it is important that you understand the breadth of activities that constitute illegal insider trading. This Policy sets out the Company's policy in the area of insider trading and should be read carefully and complied with fully.

Administrative Provisions. All Company Personnel will be required to certify their understanding of and intent to comply with this Policy by signing the Receipt and Acknowledgment attached hereto periodically. This Policy will be reviewed, evaluated and revised by the Company from time to time in light of regulatory changes, developments in the Company's business and other factors.

II. POLICIES AND PROCEDURES

A. Trading Policy

1. *General Prohibition.* You may not buy, sell, gift or otherwise transact in securities of the Company or a Company Counterparty when you are in possession of MNPI about that company.

2. *No Tipping.* You may not convey MNPI about the Company or a Company Counterparty to anyone else, including family members. You also may not suggest that anyone purchase or sell any company's securities while you are aware of MNPI about that company. These practices, known as "tipping," also violate U.S. securities laws and can result in the same civil and criminal penalties that apply if you engage in insider trading directly, even if you do not receive any money or derive any benefit from trades made by persons to whom you passed MNPI. This policy against "tipping" applies to information about the Company and its securities, as well as to information about Company Counterparties. Persons with whom you have a history, pattern or practice of sharing confidences—such as family members, close friends and financial and personal counselors—may be presumed to act on the basis of information known to you; therefore, special care should be taken so that MNPI is not disclosed to such persons. This policy does not restrict legitimate business communications on a "need to know" basis. MNPI, however, should not be disclosed to persons outside the Company unless you are specifically authorized to disclose such information and such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company.

3. *No Speculative Trading.* It is against Company policy for you to engage in speculative transactions in Company securities. As such, you may not engage in: (a) short sales (selling Company securities you do not own); (b) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (c) other hedging transactions (such as "cashless" collars, forward sales, equity swaps and other similar arrangements). Additionally, securities held in a margin account or pledged as collateral may be sold without your consent, if you fail to meet a margin call or if you default on a loan, and thus a margin or foreclosure sale may result in unlawful insider trading. Because of this danger, you are also prohibited from including Company securities in a margin account or pledging Company securities as collateral for a loan.

4. *Applying the Trading Policy.* As stated above, these restrictions also apply to your Family Members and Controlled Entities. For purposes of this Policy, references to "trading," "transact" and "transactions" include, among other things:

- purchases and/or sales of securities in public markets;
- sales of securities obtained through the exercise of stock options or vesting of other equity awards granted by the Company;
- making gifts of securities; and
- using securities to secure a loan.

Transactions in mutual funds that are invested in Company or Company Counterparty securities are not transactions subject to this Policy as long as (a) the Insider does not control the investment decisions on individual stocks within the fund and (b) Company or Company Counterparty securities do not represent a substantial portion of the assets of the fund.

In addition, transactions pursuant to a Rule 10b5-1 Trading Plan (as defined below) are subject to certain exceptions and requirements set forth below.

Insiders should consult the GC if they have any questions.

5. *Company Transactions.* From time to time, the Company may engage in transactions in its own securities. When engaging in transactions in Company securities, it is the Company's policy to comply with all applicable securities laws and regulations and state corporate laws. This includes consultation, as appropriate, with the CEO, CFO, GC and outside counsel, and, if required or advisable, approval by the Board of Directors or appropriate board committee.

B. What is "**Material Nonpublic Information**"**? When is Information "Public"?**

1. *Material Information*

Information is generally considered "material" if there is a likelihood a reasonable investor would consider such information important in making an investment decision to buy, hold or sell securities. Either positive or negative information may be material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances. The GC or other attorneys designated by the GC should be consulted and shall determine whether information is material, but, in general, any information that could reasonably be expected to affect the Company's or a Company Counterparty's stock price should be considered material. Depending on the circumstances, common examples of information that may be material include:

- significant new product or product candidate developments, innovations or discoveries (including new targets and new indications);
- pending U.S. Food and Drug Administration, European Medicines Agency or other regulatory action;
- clinical data or significant interactions, filings, approval or rulings by a regulatory agency relating to the Company or a Company product;
- clinical trial enrollment status and results (including interim results) and status of pre-clinical or clinical studies;
- changes in intellectual property status, including patent filings, issuances or potential interference and infringement proceedings;
- changes in research or business strategies;
- financial and operating results, estimates, forecasts and projections, including earnings, cash runway, revenue or similar financial information;

- unpublished financial reports or projections, including knowledge of changes of research analyst views or ratings;
- extraordinary borrowing or liquidity problems;
- changes in control or sale of all or part of the Company's business, including potential partnerships;
- changes in directors, senior management or auditors;
- information about current, proposed or contemplated transactions, business plans, financial restructurings, acquisition targets or significant expansions or contractions of operations;
- changes in dividend policies, the declaration of a stock split or the proposed or contemplated issuance, redemption or repurchase of securities;
- public or private debt or equity offerings;
- negotiations regarding an important license, distribution agreement, joint venture or collaboration agreement;
- material defaults under agreements or actions by creditors, clients or suppliers relating to the Company's credit rating;
- information about major contracts;
- gain or loss of a significant customer or supplier;
- significant product pricing or reimbursement changes;
- significant cybersecurity incidents, events or risks that affect the Company or third-party providers that support the Company's business operations, including computer system or network compromises, viruses or other destructive software, and data breach incidents that may disclose personal, business or other confidential information;
- product recalls;
- impending financial problems such as impending bankruptcy or liquidity problems;
- the interruption of production or other aspects of a company's business as a result of an accident, fire, natural disaster, public health emergency or breakdown of labor negotiations;
- major environmental incidents;

- institution of, or developments in, major actual or threatened litigation, investigations or regulatory actions or proceedings;

- information about Company affiliates and Company Counterparties; and

- the imposition of a trading "blackout" by the Company on transactions in Company securities or the securities of a Company Counterparty.

Federal and Nasdaq investigators will scrutinize a questionable trade after the fact with the benefit of hindsight, so you should always err on the side of deciding that the information is material and not trade. The mere fact that a person is aware of MNPI is a bar to trading. It is no excuse that such person's reasons for trading were not based on the MNPI. If you have questions regarding specific transactions, please contact the GC.

2. *Nonpublic Information*

Nonpublic information is information that is not generally known by or available to the public. We consider information to be available to the public only when:

- it has been released to the public by the Company through appropriate channels (e.g., by means of a press release, a filing with the SEC or a widely disseminated statement from a senior officer); and

- enough time has elapsed to permit the investment market to absorb and evaluate the information. As a general rule, you should consider information to be nonpublic until two full trading days have lapsed following the time of public disclosure.

The fact that rumors, speculation or statements attributed to unidentified sources are public is insufficient to be considered "generally available to the public" even when the information is accurate.

C. Unauthorized Disclosure; Prohibition on Certain Public Speaking

All Company Personnel must maintain the confidentiality of Company information for competitive, security and other business reasons, as well as to comply with securities laws. All information you learn about the Company or its business plans is potentially nonpublic information until it is publicly disclosed. You should treat this information as confidential and proprietary to the Company. You may not disclose it to others, such as Family Members, other relatives or business or social acquaintances.

In addition, you are prohibited from participating as an "expert," consultant, advisor and/or in any capacity for an "expert network" and/or any other outside firm that compensates individuals for speaking with investors and other investment professionals. This prohibition is designed to protect the Company, its stockholders and you. Indeed, United States criminal authorities and the SEC have prosecuted numerous public company employees who received monetary compensation by expert networks to speak with investors and disclose confidential company information that investors then used for trading purposes.

Legal rules govern the timing and nature of our disclosure of material information to outsiders or the public. Violation of these rules could result in substantial liability for you, the Company and its management. For this reason, we permit only specifically designated representatives of the Company to discuss the Company with the news media, securities analysts and investors and only in accordance with the Company's Policy On Public Disclosures And Communications With The Investment Community. If you receive inquiries of this nature, refer them to the CEO.

D. When and How to Trade Company Stock

1. *Overview*

Directors, officers, as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") (such officers, "Section 16 Officers", and together with directors, "Section 16 Persons"), and certain other employees, contractors and consultants who are so designated by the GC from time to time (such designated employees, contractors and consultants, together with Section 16 Persons, and each of their respective Family Members and Controlled Entities, "Restricted Persons") are for purposes of this Policy required to comply with the restrictions covered below. Even if you are not a Restricted Person, however, following the procedures listed below may assist you in complying with this Policy.

2. *Blackout Periods*

From time to time, due to certain developments (such as a significant event or transaction) during which there may exist MNPI about the Company or a Company Counterparty, the Company may implement special blackout periods during which the Company may notify particular individuals that they should not transact in Company securities or the securities of a Company Counterparty, as applicable (subject to the exceptions set forth in Section II.D.4 or pursuant to an approved Rule 10b5-1 Trading Plan pursuant to Section II.E). If you are subject to a special blackout period, you should not trade in the applicable company's securities during such time and you should not disclose to others the fact that you are prohibited from trading, as the existence of a special blackout period may, itself, be deemed MNPI. These special blackout periods, which may vary in length, will be determined by the GC and be communicated to the appropriate personnel via e-mail. Termination of a blackout period will also be communicated to the appropriate personnel via e-mail.

However, it is not the Company's policy to impose special blackout periods every time that MNPI exists or every time that an Insider may be in the possession of MNPI. Thus, the absence of a special blackout period should not be interpreted as permission to trade. In addition, if you are subject to the Company's pre-clearance policy (described below), you must pre-clear transactions even if you initiate them while a blackout period is not in place.

Even if a special blackout period is in place, you may exercise Company stock options if no shares are to be sold – you may not, however, effect sales of stock issued upon the exercise of stock options (including same-day sales and cashless exercises). Generally, all pending purchase and sale orders regarding Company securities must be executed or cancelled before a special blackout period is implemented so as to avoid any transactions during such period.

In light of these restrictions, if you expect a need to sell Company stock at a specific time in the future, including executing sales to satisfy tax withholding obligations in connection with the exercise of stock options, vesting of restricted stock or settlement of restricted stock units in the future, you may wish to consider entering into a prearranged Rule 10b5-1 Trading Plan (as discussed below).

3. *Pre-clearance*

The Company requires all Restricted Persons to contact the GC[2] in advance of effecting any purchase, sale, gift or other trading of Company securities and to obtain prior approval of the transaction, other than transactions made under an approved Rule 10b5-1 Trading Plan pursuant to Section II.E below. All requests must be submitted to the GC at least two business days in advance of the proposed transaction.[3] **This pre-clearance policy applies to Restricted Persons even if they are initiating a transaction while a blackout period is not in place.**

If a transaction is approved under the pre-clearance policy, the transaction must be executed during the cleared trading period approved by the GC (not to exceed five (5) trading days), but regardless may not be executed if you acquire MNPI concerning the Company during that time. If a transaction is not completed within the period described above, the transaction must be approved again before it may be executed.

If a proposed transaction is not approved under the pre-clearance policy, you may not transact in Company securities, and you should not inform anyone within or outside of the Company of the restriction. For the avoidance of doubt, there should be no presumption that the GC will grant any or all pre-clearance requests and there shall be no obligation to inform a Restricted Person of the reasons for any request approval or denial. Any transaction under a Rule 10b5-1 Trading Plan will not require pre-clearance at the time of the transaction, but the adoption, amendment, modification or termination of any such Rule 10b5-1 Trading Plan is subject to the pre-clearance and other restrictions set forth in Section II.E and Appendix A, "Guidelines for Rule 10b5-1 Trading Plans" below.

4. *Exceptions*

The restrictions contained in this Policy shall not apply to:

- the exercise of Company stock options if (a) no shares are to be sold to third parties or (b) there is only a "net exercise" (defined as the Company withholding shares to satisfy your tax obligations or to cover the exercise price or equivalent);

- "sell to cover" transactions involving a sale of shares of common stock directed by the Company in its sole discretion in order to cover the Company's or such individual's or entity's withholding tax obligations in connection with the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;

2 For the purposes of this Section D.3, GC includes a person delegated authority by the GC to pre-clear trades.

3 Transactions by the GC (or the GC's Family Members and Controlled Entities) are required to be approved in advance by the Chief Executive Officer ("CEO") or CFO.

- the vesting of Company stock options, restricted stock, restricted stock units or other equity incentive awards according to their terms;

- the withholding of shares to satisfy the exercise price or a tax withholding obligation upon the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans;

- purchases of shares through the Company's Employee Stock Purchase Plan in accordance with your pre-established participation elections;

- transferring shares to an entity that does not involve a change in the beneficial ownership of the shares (for example, transferring shares from one brokerage account to another brokerage account that you control);

- sales of Company securities as a selling stockholder in a registered public offering, including a "synthetic secondary" offering, in accordance with applicable securities laws; or

- any other purchase of Company securities from the Company or sale of Company securities to the Company in accordance with applicable securities and state laws.

To the extent applicable and such elections are permitted, your elections regarding (1) participation in "net exercise" or "sell to cover" transactions or (2) participation in or an increase in contributions to the Company's Employee Stock Purchase Plan, in each case, including changes from any defaults established by the Company, may only be made when you are not subject to a blackout period and are not in possession of MNPI.

E. Rule 10b5-1 Trading Plans

Rule 10b5-1 under the Exchange Act provides an affirmative defense from insider trading liability if trades occur pursuant to a pre-arranged trading plan that meets specified conditions (a "Rule 10b5-1 Trading Plan"). A Rule 10b5-1 Trading Plan is a written trading plan between you and your broker and must either specify the number of securities to be bought or sold, along with the price and the date, or provide a written formula for determining this information. Alternatively, such Rule 10b5-1 Trading Plan can delegate investment discretion to a third party, such as a broker, who then makes trading decisions without further input from the person implementing the plan. A Rule 10b5-1 Trading Plan must be established at a time when you are not aware of any MNPI and must not permit you to exercise any subsequent control or influence over how, when or whether the purchases or sales are made. Under this Policy, the adoption, amendment, modification or termination of a Rule 10b5-1 Trading Plan must meet the requirements set forth in Appendix A, "Guidelines for Rule 10b5-1 Trading Plans," including applicable pre-clearance procedures.

Because the SEC rules on trading plans are complex, you should consult with your broker and be sure you fully understand the limitations and conditions of the rules before you establish a Rule 10b5-1 Trading Plan (or a transaction that is intended to constitute a "non-Rule 10b5-1 trading arrangement" within the meaning of SEC rules).

F. Noncompliance

Anyone subject to this Policy who fails to comply with this Policy will be subject to appropriate disciplinary action, up to and including termination of employment.

G. Post-Termination Transactions

This Policy, other than the pre-clearance provisions, will continue to apply to your transactions in Company securities after your employment or service with the Company has terminated until such time as you are no longer aware of MNPI or until that information has been publicly disclosed or is no longer material.

Questions about this Policy should be directed to the GC.

RECEIPT AND ACKNOWLEDGMENT

I, _____, hereby acknowledge that I have received and read a copy of the Oruka Therapeutics, Inc. Insider Trading Policy (this "Policy"). I agree to comply with this Policy and certify that I will communicate with all members of my household to inform them of the obligations in this Policy that apply to them. I understand that violation of SEC regulations may subject me to severe civil and/or criminal penalties, and that violation of this Policy may subject me to discipline by Oruka Therapeutics, Inc. up to and including termination for cause.

Signature

Date

[RECEIPT AND ACKNOWLEDGMENT]

APPENDIX A

Oruka Therapeutics, Inc. Guidelines for Rule 10b5-1 Trading Plans

As discussed in the Policy, Rule 10b5-1 under the Exchange Act provides an affirmative defense from insider trading liability. In order to be eligible to rely on this affirmative defense, you must enter into a Rule 10b5-1 Trading Plan for transactions in Company securities that meets certain conditions specified in Rule 10b5-1, including the guidelines set forth below. These guidelines generally do not apply to any transactions that are intended to constitute "non-Rule 10b5-1 trading arrangements" within the meaning of SEC rules. Capitalized terms used in these guidelines without definition have the meaning set forth in the Policy.

These guidelines are in addition to, and not in lieu of, the requirements and conditions of Rule 10b5-1. The GC will interpret and administer these guidelines for compliance with Rule 10b5-1 and the Policy. No personal legal or financial advice is being provided by the GC or other members of the Company regarding any Rule 10b5-1 Trading Plan or proposed trades. You remain ultimately responsible for ensuring that your Rule 10b5-1 Trading Plans and contemplated transactions fully comply with applicable securities laws. It is recommended that you consult with your own attorney or other advisor about any contemplated Rule 10b5-1 Trading Plan. **Note that for any Section 16 Persons, the Company is required to disclose the material terms of his or her (and any Family Members' and Controlled Entities') Rule 10b5-1 Trading Plan, other than with respect to price, in its periodic report for the quarter in which the Rule 10b5-1 Trading Plan is adopted or terminated or modified (as described below).**

1. **Pre-Clearance Requirement.** The Rule 10b5-1 Trading Plan must be submitted for pre-approval in advance to the GC (or, in the case of the GC, to the CEO or CFO) at least five trading days prior to the entry into the plan in accordance with the procedures set forth in the Policy and these guidelines. The Company may require that you use a standardized form of Rule 10b5-1 Trading Plan.

2. **Time of Adoption.** Subject to pre-clearance requirements described above, the Rule 10b5-1 Trading Plan must be adopted at a time:

    - when you are not aware of any MNPI; and

    - when you are not subject to a blackout period.

3. **Plan Instructions.** Any Rule 10b5-1 Trading Plan must be in writing, signed and either:

    - specify the amount, price and date of the sales (or purchases) of Company securities to be effected;

    - provide a formula, algorithm or computer program for determining when to sell (or purchase) the Company's securities, the quantity to sell (or purchase) and the price; or

    - delegate decision-making authority with regard to these transactions to a broker or other agent without any MNPI about the Company or its securities.

    For the avoidance of doubt, you may not subsequently influence how, when or whether to effect purchases or sales with respect to the securities subject to an approved and adopted Rule 10b5-1 Trading Plan.

4. **No Hedging.** You may not have entered into or alter a corresponding or hedging transaction or position with respect to the securities subject to the Rule 10b5-1 Trading Plan and must agree not to enter into any such transaction while the Rule 10b5-1 Trading Plan is in effect.

5. **Good Faith Requirements.** You must enter into the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Exchange Act. You must act in good faith with respect to the Rule 10b5-1 Trading Plan for the entirety of its duration.

6. **Certifications for Section 16 Persons.** Section 16 Persons and their Family Members and Controlled Entities that enter into Rule 10b5-1 Trading Plans must certify that they are: (1) not aware of any MNPI about the Company or the Company securities; and (2) adopting the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Exchange Act.

7. **Cooling Off Periods.** The first trade under the Rule 10b5-1 Trading Plan may not occur until the expiration of a cooling-off period as follows:

    - For Section 16 Persons (as well as their Family Members and Controlled Entities), the later of (1) two business days following the filing of the Company's Form 10-Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Trading Plan was adopted and (2) 90 calendar days after adoption of the Rule 10b5-1 Trading Plan; provided, however, that the required cooling-off period shall in no event exceed 120 days.

    - For other Insiders, 30 days after adoption of the Rule 10b5-1 Trading Plan.

8. **No Overlapping Rule 10b5-1 Trading Plans.** You may not enter into overlapping Rule 10b5-1 Trading Plans (subject to certain exceptions). Please consult with the GC for any questions regarding overlapping Rule 10b5-1 Trading Plans.

9. **Single Transaction Plans.** You may not enter into more than one Rule 10b5-1 Trading Plan designed to effect the open-market purchase or sale of the total amount of securities as a single transaction during any rolling 12-month period (subject to certain exceptions). A single-transaction plan is "designed to effect" the purchase or sale of securities as a single transaction when the terms of the plan would, for practical purposes, directly or indirectly require execution in a single transaction.

10. **Modifications and Terminations.** Modifications/amendments and terminations of an existing Rule 10b5-1 Trading Plan are strongly discouraged due to legal risks, and can affect the validity of trades that have taken place under the plan prior to such modification/amendment or termination. Under Rule 10b5-1 and these guidelines, any modification/amendment to the amount, price or timing of the purchase or sale of the securities underlying the Rule 10b5-1 Trading Plan (a "Material Modification") will be deemed to be a termination of the current Rule 10b5-1 Trading Plan and creation of a new Rule 10b5-1 Trading Plan. As such, the modification/amendment of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the GC in accordance with the pre-clearance procedures set forth in the Policy and these guidelines, and any Material Modification will be subject to all the other requirements set forth in these guidelines regarding the adoption of a new Rule 10b5-1 Trading Plan.

    The termination (other than through an amendment or modification) of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the GC in accordance with the pre-clearance procedures set forth in the Policy and these guidelines. Except in limited circumstances, the GC will not approve the termination of a Rule 10b5-1 Trading Plan unless:

    - you are not aware of any MNPI; and

    - when you are not subject to a blackout period.

Exhibit 21.1

Subsidiaries of Oruka Therapeutics, Inc.

Name of Subsidiary	State or Jurisdiction in Which Incorporated or Organized
Oruka Therapeutics Operating Company, LLC	Delaware
Oruka Therapeutics Australia Pty Ltd.	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-283243) of Oruka Therapeutics, Inc. of our report dated March 6, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 6, 2025

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Lawrence Klein, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oruka Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2025

/s/ Lawrence Klein

Lawrence Klein
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Arjun Agarwal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oruka Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2025

/s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 32.1

Certifications of the
Principal Executive Officer and Principal Financial Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 of The Sarbanes-Oxley Act Of 2002

In connection with the Annual Report on Form 10-K of Oruka Therapeutics, Inc. (the "Company") for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 6, 2025

/s/ Lawrence Klein

Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)

INCENTIVE COMPENSATION CLAWBACK POLICY

August 29, 2024

I. Recoupment of Incentive-Based Compensation

It is the policy of Oruka Therapeutics, Inc. (the "Company") that, in the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws (including any such correction that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Company will recover on a reasonably prompt basis the amount of any Incentive-Based Compensation Received by a Covered Executive during the Recovery Period that exceeds the amount that otherwise would have been Received had it been determined based on the restated financial statements. This Incentive Compensation Clawback Policy (this "Policy") has been adopted by the Board of Directors (the "Board") of the Company and the Compensation Committee (the "Committee") of the Board. The Committee may amend or change the terms of this Policy at any time for any reason, including as required to comply with any laws, rules, regulations and listing standards that may be applicable to the Company.

II. Policy Administration and Definitions

This Policy is administered by the Committee and is intended to comply with, and as applicable to be administered and interpreted consistent with, and subject to the exceptions set forth in, Listing Rule 5608 adopted by The Nasdaq Stock Market ("Nasdaq") to implement Rule 10D-1 under the Securities Exchange Act of 1934, as amended (collectively, "Rule 10D-1").

For purposes of this Policy:

"Covered Executive" means any "executive officer" of the Company as defined under Rule 10D-1.

A "Financial Reporting Measure" is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total stockholder return.

"Incentive-Based Compensation" means any compensation granted, earned or vested based in whole or in part on the Company's attainment of a Financial Reporting Measure that was Received by a person (i) on or after October 2, 2023, and after the person began service as a Covered Executive, and (ii) who served as a Covered Executive at any time during the performance period for the Incentive-Based Compensation.

Incentive-Based Compensation is deemed to be "Received" in the fiscal period during which the relevant Financial Reporting Measure is attained, regardless of when the compensation is actually paid or awarded.

"Recovery Period" means the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement described in this Policy and any transition period of less than nine months that is within or immediately following such three fiscal years, all as determined pursuant to Rule 10D-1.

III. Determination by the Committee

If the Committee determines the amount of Incentive-Based Compensation Received by a Covered Executive during a Recovery Period exceeds the amount that would have been Received if determined or calculated based on the Company's restated financial results, such excess amount of Incentive-Based Compensation shall be subject to recoupment by the Company pursuant to this Policy. For Incentive-Based Compensation based on stock price or total stockholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the Committee will determine the amount based on a reasonable estimate of the effect of the accounting restatement on the relevant stock price or total stockholder return. In all cases, the calculation of the excess amount of Incentive-Based Compensation to be recovered will be determined on a pre-tax basis (i.e., without regard to any taxes paid with respect to such compensation). The Company will maintain and will provide to Nasdaq documentation of all determinations and actions taken in complying with this Policy. Any determinations made by the Committee under this Policy shall be final and binding on all affected individuals.

IV. Methods of Clawback

The Company may effect any recovery pursuant to this Policy in any manner consistent with applicable law, including by requiring payment of such amount(s) to the Company, by set-off, by reducing future compensation, or by such other means or combination of means as the Committee determines to be appropriate. The Company need not recover the excess amount of Incentive-Based Compensation if and to the extent that the Committee determines that such recovery is impracticable, subject to and in accordance with any applicable exceptions under the Nasdaq listing rules and not required under Rule 10D-1, including if the Committee determines that the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to recover such amounts. The Company is authorized to take appropriate steps to implement this Policy with respect to Incentive-Based Compensation arrangements with Covered Executives.

V. Not Exclusive Remedy

Any right of recoupment or recovery pursuant to this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any other policy, any employment agreement or plan or award terms, and any other legal remedies available to the Company (including, but not limited to, Section 304 of the Sarbanes-Oxley Act of 2002); provided that the Company shall not recoup amounts pursuant to such other policy, terms or remedies to the extent it is recovered pursuant to this Policy. The Company shall not indemnify any Covered Executive against the loss of any Incentive-Based Compensation pursuant to this Policy (or provide any advancement of expenses in such instance), nor will the Company pay or reimburse or agree to pay or reimburse any insurance premium to cover any such loss.

VI. Certification

All Covered Executives subject to this Policy will be required to certify their understanding of and intent to comply with this Policy periodically.

ACKNOWLEDGMENT AND CERTIFICATION

By signing below, the undersigned covered executive (the "Covered Executive") acknowledges and confirms that the Covered Executive has received and reviewed a copy of the Oruka Therapeutics, Inc. (the "Company") Incentive Compensation Clawback Policy (as interpreted or modified from time to time pursuant to the terms hereof, the "Policy"), and in addition, the Covered Executive acknowledges and agrees that, for good and valid consideration, including continuing participation in the Company's incentive compensation programs, the receipt and sufficiency of which the Covered Executive hereby acknowledges, the Covered Executive will be bound by and abide by the Policy as follows:

(a) the Covered Executive is and will continue to be subject to the Policy and the Policy will apply both during and after the Covered Executive's employment with the Company;

(b) to the extent necessary to comply with the Policy, the Company hereby amends any employment agreement, equity award agreement or similar agreement that the Covered Executive is a party to with the Company;

(c) the Covered Executive shall abide by the terms of the Policy, including, without limitation, by returning any compensation to the Company to the extent required by, and in a manner permitted by, the Policy, and understands and agrees that the Covered Executive shall not be entitled to any (i) indemnification for any liability (including any amounts owed by the Covered Executive in a judgment or settlement of any Clawback Proceeding (as defined below)), or loss (including judgments, fines, taxes, penalties or amounts paid in settlement by or on behalf of the Covered Executive) incurred by the Covered Executive in connection with or as a result of any action taken by the Board of Directors (the "Board") of the Company or the Compensation Committee (the "Committee") of the Board to enforce the Policy (such action, a "Clawback Proceeding") or (ii) indemnification or advancement of any expenses (including attorneys' fees) from the Company and or any subsidiary of the Company incurred by the Covered Executive in connection with any Clawback Proceeding; *provided, however*, that if the Covered Executive is successful on the merits in the defense of any claim asserted against the Covered Executive in a Clawback Proceeding, the Covered Executive shall be indemnified for the expenses (including attorneys' fees) the Covered Executive reasonably incurred to defend such claim;

(d) any amounts payable to the Covered Executive shall be subject to the Policy as may be in effect and reasonably interpreted, or modified from time to time in the sole discretion of the Committee or as required by applicable law or the requirements of any securities exchange on which the Company's securities are listed, and that such reasonable interpretation, or modification will be covered by this acknowledgment;

(e) the Company may recover compensation paid to the Covered Executive through any method of recovery the Committee or its delegate deems appropriate, including without limitation, by reducing any amount that is or may become payable to the Covered Executive, and the Covered Executive agrees to comply with any reasonable request or reasonable demand for repayment by the Company in order to comply with the Policy;

[ACKNOWLEDGMENT AND CERTIFICATION]

(f) the Company is not responsible for and shall not make the Covered Executive whole for any effect under any tax law or regulation of the recovery of any compensation pursuant to the Policy or for any taxes paid by the Covered Executive on compensation that is subject to recovery or is recovered pursuant to the Policy; and

(g) the Covered Executive hereby knowingly, voluntarily and intentionally waives, and agrees not to assert any claim regarding, any and all rights to indemnification, advancement and other rights from the Company or any subsidiary of the Company to which the Covered Executive is now or may become entitled under any indemnification agreement between the Covered Executive and the Company (including any provisions related to non-exclusivity of rights contained therein), the Company's Certificate of Incorporation and Bylaws, the governing documents of each subsidiary of the Company and the Delaware General Corporation Law, in each case to the extent such waiver and agreement is necessary to give effect to the preceding provisions of this Acknowledgment and Certification.

Signature

Print Name

Date

[ACKNOWLEDGMENT AND CERTIFICATION]