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

FORM 10-Q

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

For the quarterly period ended June 30, 2025

OR

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

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

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

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 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, a 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 31, 2025, there were 37,450,745 shares of the registrant's common stock outstanding.

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Item 1. Financial Statements

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 65,396	$ 61,575
Marketable securities, current	263,010	314,073
Prepaid expenses and other current assets	3,606	1,221
Total current assets	332,012	376,869
Marketable securities, long-term	23,053	18,069
Property and equipment, net	174	162
Operating lease right-of-use assets	2,076	876
Other non-current assets	103	43
Total assets	$ 357,418	$ 396,019
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,664	$ 3,462
Accrued expenses and other current liabilities	3,578	3,346
Operating lease liability, current	660	213
Related party common stock warrant liability	3,089	—
Related party accounts payable and other current liabilities	119	6,022
Total current liabilities	12,110	13,043
Operating lease liability, non-current	1,666	755
Total liabilities	13,776	13,798
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Series B non-voting convertible preferred stock, $0.001 par value; 251,504 shares authorized as of June 30, 2025 and December 31, 2024; 137,138 shares issued and outstanding as of June 30, 2025 and December 31, 2024	2,931	2,931
Common stock, $0.001 par value; 545,000,000 shares authorized as of June 30, 2025 and December 31, 2024; 37,450,745 and 37,440,510 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	37	37
Additional paid-in capital	469,998	463,018
Accumulated other comprehensive loss	(27)	(41)
Accumulated deficit	(129,297)	(83,724)
Total stockholders' equity	343,642	382,221
Total liabilities, convertible preferred stock and stockholders' equity	$ 357,418	$ 396,019

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

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Operating expenses:				
Research and development[1]	$ 24,087	$ 18,673	$ 44,012	$ 23,866
General and administrative[2]	4,342	2,820	9,503	4,490
Total operating expenses	28,429	21,493	53,515	28,356
Loss from operations	(28,429)	(21,493)	(53,515)	(28,356)
Other income (expense):				
Interest income	3,857	—	7,949	—
Interest expense[3]	—	(750)	—	(964)
Other expense, net	(2)	—	(7)	—
Total other income (expense), net	3,855	(750)	7,942	(964)
Net loss	(24,574)	(22,243)	(45,573)	(29,320)
Net change in unrealized gains (losses) on marketable securities	(21)	—	14	—
Comprehensive loss	$ (24,595)	$ (22,243)	$ (45,559)	$ (29,320)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.46)	$ (6.96)	$ (0.85)	$ (9.17)
Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	$ (38.26)	$ —	$ (71.23)	$ —
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	42,095,951	3,197,975	41,888,906	3,197,975
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	137,138	—	137,138	—

(1) Includes related party amounts of $4,281 and $15,379 for the three months ended June 30, 2025 and June 30, 2024, respectively, and $6,403 and $20,430 for the six months ended June 30, 2025 and the period from February 6, 2024 (inception) to June 30, 2024, respectively

(2) Includes related party amounts of $12 and $420 for the three months ended June 30, 2025 and June 30, 2024, respectively, and $122 and $1,268 for the six months ended June 30, 2025 and the period from February 6, 2024 (inception) to June 30, 2024, respectively

(3) Includes related party amounts of nil and $750 for the three months ended June 30, 2025 and June 30, 2024, respectively, and nil and $964 for the six months ended June 30, 2025 and the period from February 6, 2024 (inception) to June 30, 2024, respectively

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

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

	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				
Balances as of December 31, 2024	137,138	$ 2,931	37,440,510	$ 37	$ 463,018	$ (41)	$ (83,724)	$ 382,221
Stock-based compensation expense	—	—	—	—	3,468	—	—	3,468
Net change in unrealized gains (losses) on marketable securities	—	—	—	—	—	35	—	35
Net loss	—	—	—	—	—	—	(20,999)	(20,999)
Balances as of March 31, 2025	137,138	$ 2,931	37,440,510	$ 37	$ 466,486	$ (6)	$ (104,723)	$ 364,725
Issuance of common stock under employee stock purchase plan	—	—	10,235	—	109	—	—	109
Stock-based compensation expense	—	—	—	—	3,403	—	—	3,403
Net change in unrealized gains (losses) on marketable securities	—	—	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	—	—	(24,574)	(24,574)
Balances as of June 30, 2025	137,138	$ 2,931	37,450,745	$ 37	$ 469,998	$ (27)	$ (129,297)	$ 343,642

	Series A 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' Deficit
	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	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	17	—	—	17
Net loss	—	—	—	—	—	—	—	—	(7,077)	(7,077)
Balances as of March 31, 2024	20,000,000	$ 2,931	—	$ —	5,405,528	$ 5	$ 13	$ —	$ (7,077)	$ (7,059)
Stock-based compensation expense	—	—	—	—	—	—	321	—	—	321
Net loss	—	—	—	—	—	—	—	—	(22,243)	(22,243)
Balances as of June 30, 2024	20,000,000	$ 2,931	—	$ —	5,405,528	$ 5	$ 334	$ —	$ (29,320)	$ (28,981)

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

ORUKA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(In thousands)

	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Cash flows from operating activities:		
Net loss	$ (45,573)	$ (29,320)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	9,960	768
Net accretion of premiums and discounts on marketable securities	(3,300)	—
Non-cash interest expense	—	3
Non-cash lease expense	187	4
Depreciation expense	35	—
Changes in operating assets and liabilities:		
Subscription receivable	—	1
Prepaid expenses and other current assets	(765)	(1,721)
Other non-current assets	(60)	(43)
Accounts payable	1,202	2,022
Accrued expenses and other current liabilities	232	683
Operating lease liability	(29)	4
Related party accounts payable and other current liabilities	(5,903)	15,437
Accrued interest payable, related party	—	961
Net cash used in operating activities	(44,014)	(11,201)
Cash flows from investing activities:		
Purchases of property and equipment	(47)	—
Purchases of marketable securities	(152,289)	—
Proceeds from maturities of marketable securities	200,062	—
Net cash provided by investing activities	47,726	—
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
Payment of deferred offering costs	—	(1,589)
Proceeds from issuance of common stock	109	—
Net cash provided by financing activities	109	26,322
Net increase in cash and cash equivalents	3,821	15,121
Cash and cash equivalents at beginning of period	61,575	—
Cash and cash equivalents at end of period	$ 65,396	$ 15,121
Supplemental disclosures of non-cash operating and financing activities:		
Operating lease liability arising from obtaining operating right-of-use asset	$ 1,387	$ 982
Deferred offering costs in accrued expenses and other current liabilities	$ —	$ 726

The accompanying notes are an integral part of these condensed 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 biopharmaceutical 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 led by the Pre-Merger Oruka management team and is focused on developing biologics for psoriasis and other inflammatory and immunology indications.

The condensed consolidated financial statements and accompanying notes are prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for interim financial reporting and the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") and therefore do not include all information and disclosures normally included in the annual consolidated financial statements. The accompanying condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Certain information and footnote disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the period ended December 31, 2024 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 6, 2025 (the "Annual Report"). The information as of December 31, 2024, included in the condensed consolidated balance sheets was derived from the Company's audited financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements, and in the opinion of the Company's management, reflect all adjustments, which include only normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial statements.

The results for the three and six months ended June 30, 2025 are not necessarily indicative of results that may be expected for the year ending December 31, 2025 or for any other interim period or for any other future year.

Reverse Recapitalization, Pre-Closing Financing, and Reverse Stock Split

On August 29, 2024 (the "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, on August 29, 2024, the Company changed its name from "ARCA biopharma, Inc." to "Oruka Therapeutics, Inc." and 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. 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 condensed 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.

Immediately prior to the execution and delivery of the Merger Agreement, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (that was subsequently amended and restated in July 2024, 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 6) 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 were recorded as a reduction to additional paid-in capital in the condensed consolidated financial statements.

In connection with the Closing, the shares of Pre-Merger Oruka Common Stock were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock in accordance with the Exchange Ratio (as defined below and determined by the terms of the Merger Agreement). Moreover, as part of the Closing, (i) then-issued and outstanding shares 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") 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 after the Reverse Stock Split, (iii) each outstanding option to purchase Pre-Merger Oruka Common Stock was converted into an option to purchase shares of Company Common Stock, and (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.

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 owned a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Oruka's largest stockholders retained 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: (a) the Merger was treated as the equivalent of Pre-Merger Oruka issuing stock to acquire the net assets of ARCA, and (b) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Oruka. As part of the reverse recapitalization, the Company acquired a cash balance of $4.94 million from ARCA.

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 share of Company Series A Preferred Stock was 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). 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.

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 it will need additional financing to fund its operating activities.

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 three and six months ended June 30, 2025, the Company incurred net losses of $24.6 million and $45.6 million, respectively, and used net cash of $44.0 million for its operating activities during the first six months of 2025.

As of June 30, 2025, the Company had cash, cash equivalents, and marketable securities of $351.5 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 condensed 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 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

The Company's significant accounting policies are detailed in the Notes titled "1. Nature of the Business and Basis of Presentation" and "2. Summary of Significant Accounting Policies" of the Company's Annual Report. The Company uses the same accounting policies in preparing its quarterly and annual financial statements. There have been no material changes to significant accounting policies during the six months ended June 30, 2025.

Use of Estimates

The preparation of the Company's condensed 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 condensed consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected within these condensed 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.

Recently Issued Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 condensed 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 condensed consolidated financial statements.

3. Fair Value Measurements

The following tables present the Company's fair value hierarchy for financial assets measured as of June 30, 2025 and December 31, 2024 (in thousands):

	June 30, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 20,931	$ —	$ —	$ 20,931
U.S. treasury securities	—	6,952	—	6,952
Commercial papers	—	35,405	—	35,405
Total cash equivalents	20,931	42,357	—	63,288
Marketable securities				
Marketable securities, current				
U.S. treasury securities	—	203,806	—	203,806
U.S. government agency securities	—	14,183	—	14,183
Commercial papers	—	5,391	—	5,391
Corporate debt securities	—	39,630	—	39,630
Total marketable securities, current	—	263,010	—	263,010
Marketable securities, long-term				
U.S. treasury securities	—	18,608	—	18,608
U.S. government agency securities	—	4,445	—	4,445
Total marketable securities, long-term	—	23,053	—	23,053
Total cash equivalents and marketable securities	$ 20,931	$ 328,420	$ —	$ 349,351

There were no transfers in or out of Level 3 during the three and six months ended June 30, 2025.

	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

4. Cash Equivalents and Marketable Securities

The following tables summarize the cash equivalents and marketable securities, which are classified as available-for-sale as of June 30, 2025 and December 31, 2024 (in thousands):

	June 30, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents				
Money market funds	$ 20,931	$ —	$ —	$ 20,931
U.S. treasury securities	6,951	1	—	6,952
Commercial papers	35,412	—	(7)	35,405
Total cash equivalents	63,294	1	(7)	63,288
Marketable securities				
Marketable securities, current				
U.S. treasury securities	203,839	14	(47)	203,806
U.S. government agency securities	14,188	—	(5)	14,183
Commercial papers	5,394	—	(3)	5,391
Corporate debt securities	39,630	9	(9)	39,630
Total marketable securities, current	263,051	23	(64)	263,010
Marketable securities, long-term				
U.S. treasury securities	18,589	19	—	18,608
U.S. government agency securities	4,444	2	(1)	4,445
Total marketable securities, long-term	23,033	21	(1)	23,053
Total cash equivalents and marketable securities	$ 349,378	$ 45	$ (72)	$ 349,351

	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 June 30, 2025 and December 31, 2024 (in thousands):

	June 30, 2025					
	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	$ 35,405	$ (7)	$ —	$ —	$ 35,405	$ (7)
Marketable securities						
Marketable securities, current						
U.S. treasury securities	148,432	(47)	—	—	148,432	(47)
U.S. government agency securities	14,183	(5)	—	—	14,183	(5)
Commercial papers	5,391	(3)	—	—	5,391	(3)
Corporate debt securities	26,193	(9)	—	—	26,193	(9)
Marketable securities, long-term						
U.S. treasury securities	1,038	(1)	—	—	1,038	(1)
Total	$ 230,642	$ (72)	$ —	$ —	$ 230,642	$ (72)

	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 periods 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 June 30, 2025 and December 31, 2024. As of June 30, 2025 and 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):

	June 30, 2025	December 31, 2024
Due in one year or less	$ 263,010	$ 314,073
Due in 1-2 years	23,053	18,069
Total	$ 286,063	$ 332,142

5. Accrued Expenses and Other Current Liabilities

The following table summarizes accrued expenses and other current liabilities (in thousands):

	June 30, 2025	December 31, 2024
Accrued research and development	$ 1,756	$ 1,084
Accrued employee compensation and benefits	1,684	2,041
Accrued professional and consulting	138	221
Total	$ 3,578	$ 3,346

6. 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. 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.

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 three months ended June 30, 2024 and the period from February 6, 2024 (inception) to June 30, 2024, the Company recognized interest expenses related to the Convertible Note of $0.8 million and $1.0 million, respectively, which included non-cash interest expense related to the amortization of debt issuance of less than $0.1 million, for each of the three months ended June 30, 2024 and the period from February 6, 2024 (inception) to June 30, 2024. As of December 31, 2024 and June 30, 2025, the Convertible Note was not outstanding.

7. 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 and after the Closing, are now 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. Collectively, 6,202,207 pre-funded warrants were outstanding as of June 30, 2025 and December 31, 2024.

Employee Warrants

The Subscription Agreement provided for, among other things, the issuance of warrants to certain of Pre-Merger Oruka's employees and directors immediately prior to the Closing. 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. 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. 3,054,358 warrants were outstanding as of June 30, 2025 and December 31, 2024.

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, 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 Closing, the Pre-Merger Oruka Series A Preferred Stock converted 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 June 30, 2025 and December 31, 2024, there were no outstanding shares of Company Series A Preferred Stock.

As of June 30, 2025, Company Series B Preferred Stock consisted of the following (in thousands, except share data):

	June 30, 2025			
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Common Stock Issuable Upon Conversion
Company Series B 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 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 June 30, 2025, 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 Holding LLC ("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 June 30, 2025, the warrant issued to settle the 2024 Paruka Warrant Obligation was outstanding and unexercised. See Note 8 for additional information on the Paruka Warrant Obligation.

Common Stock

As of June 30, 2025, the Certificate of Incorporation provided for 545,000,000 authorized shares of Company Common Stock. As of June 30, 2025, 37,450,745 shares of Company Common Stock were issued and outstanding, including 2,207,553 shares of restricted common stock awards ("RSAs") issued and outstanding.

As of June 30, 2025 and December 31, 2024, the Company had common stock reserved for future issuance as follows:

	June 30, 2025	December 31, 2024
Shares issuable on conversion of Company Series B Preferred Stock	11,428,149	11,428,149
Shares issuable upon exercise of pre-funded warrants	6,202,207	6,202,207
Shares issuable upon exercise of warrant under the Paruka Warrant Obligation	596,930	596,930
Outstanding and issued stock options	3,668,560	1,567,760
Outstanding and issued employee warrants	3,054,358	3,054,358
Shares available for grant under 2024 Stock Incentive Plan	4,899,067	4,246,324
Shares available for grant under 2024 Employee Stock Purchase Plan	1,001,003	460,529
Total shares of common stock reserved	30,850,274	27,556,257

8. 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 June 30, 2025, 1,179,193 shares were subject to options outstanding under the 2024 Plan and will become available under the 2024 Stock Incentive Plan (defined below) to the extent the options are forfeited or lapse unexercised.

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. An additional 2,753,543 shares became available for issuance under the 2024 Stock Plan on January 1, 2025 as a result of the annual increase pursuant to the evergreen provision.

As of June 30, 2025, 7,388,434 shares were reserved for issuance under the 2024 Stock Plan, of which 4,899,067 shares were available for future grant and 2,489,367 shares were subject to outstanding options.

2024 Employee Stock Purchase Plan

The 2024 Employee Stock Purchase Plan (the "ESPP") became effective in August 2024. 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. An additional 550,709 shares became available for issuance under the ESPP on January 1, 2025 as a result of the annual increase pursuant to the evergreen provision.

The Company issued 10,235 shares during the three and six months ended June 30, 2025 out of the ESPP, and as of June 30, 2025, there were 1,001,003 shares of Company Common Stock available in the pool for future issuances.

For each of the three and six months ended June 30, 2025, 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 three and six months ended June 30, 2025 and for the three months ended June 30, 2024 and the period from February 6, 2024 (inception) to June 30, 2024:

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Expected term (in years)	5.9	6.0	6.0	6.0
Expected volatility	93.4%	100.6%	95.5%	101.4%
Risk-free interest rate	4.1%	4.5%	4.4%	4.4%
Expected dividend yield	—	—	—	—

Stock Options

The following table summarizes the stock option activities under the 2024 Plan and the 2024 Stock Plan for the six months ended June 30, 2025:

	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 December 31, 2024	1,567,760	$ 11.39	9.4	$ 15,470
Granted	2,100,800	$ 11.97		
Exercised	—	$ —		
Canceled/forfeited	—	$ —		
Balance as of June 30, 2025	3,668,560	$ 11.72	9.3	$ 6,634
Vested and expected to vest, June 30, 2025	3,668,560	$ 11.72	9.3	$ 6,634
Exercisable, June 30, 2025	470,276	$ 8.04	9.0	$ 1,661

The weighted average grant-date fair value per share of stock options granted during the six months ended June 30, 2025 was $9.44 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. 137,972 and 714,543 RSAs vested during the three and six months ended June 30, 2025, respectively. As of June 30, 2025, 1,493,010 of RSAs remain unvested. For each of the three and six months ended June 30, 2025, the three months ended June 30, 2024, and from February 6, 2024 (inception) to June 30, 2024, stock-based compensation expense related to RSAs was less than $0.1 million.

The following table summarizes the RSA activity for the six months ended June 30, 2025:

	Number of RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2024	2,207,553	$ —
Granted	—	$ —
Vested	(714,543)	$ —
Unvested balance as of June 30, 2025	1,493,010	$ —

Option Agreements and Paruka Warrant Obligation

As part of the Option Agreements, (defined in Note 10 below) 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 condensed consolidated statement of operations and comprehensive loss as stock-based compensation expense under research and development expenses. For the period from February 6, 2024 (inception) to June 30, 2024, $0.4 million was recognized as stock-based compensation expenses related to the December 31, 2024 Paruka Warrant Obligation. On issuance of the warrant to Paruka on December 31, 2024, the fair value of the warrant issued on December 31, 2024 of $10.4 million was reclassified from liability to equity on the condensed consolidated balance sheet as of December 31, 2024.

As of June 30, 2025, the estimated fair value of the warrant to be granted on December 31, 2025 was $6.2 million. For the three and six months ended June 30, 2025 $1.7 million and $3.1 million, respectively, was recognized as stock-based compensation expense related to the December 31, 2025 Paruka Warrant Obligation. As of June 30, 2025, there was $3.1 million in unamortized expense related to the December 31, 2025 Paruka Warrant Obligation.

Employee Warrants

As stated above, in July 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 prior to the Closing. 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 condensed 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. During the three and six months ended June 30, 2025, no employee warrants were granted.

The following table summarizes the employee warrant activity during the six months ended June 30, 2025:

	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 December 31, 2024	3,054,358	$ 7.80	9.5	$ 35,400
Granted	—	$ —		
Exercised	—	$ —		
Canceled/forfeited	—	$ —		
Balance as of June 30, 2025	3,054,358	$ 7.80	9.0	$ 10,415
Vested and expected to vest, June 30, 2025	3,054,358	$ 7.80	9.0	$ 10,415
Exercisable, June 30, 2025	797,307	$ 7.80	9.0	$ 2,719

Stock-Based Compensation Expense

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Research and development	$ 3,368	$ 468	$ 6,371	$ 538
General and administrative	1,709	215	3,589	230
Total	$ 5,077	$ 683	$ 9,960	$ 768

As of June 30, 2025, total unrecognized compensation cost related to the unvested stock options was $28.5 million, which is expected to be recognized over a weighted average period of approximately 3.2 years.

As of June 30, 2025, 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 2.6 years.

As of June 30, 2025, the unrecognized compensation cost related to the employee warrants was $13.5 million, which is expected to be recognized over a weighted average period of 2.8 years.

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Paruka Warrant Obligation	$ 1,674	$ 362	$ 3,089	$ 430
Employee warrants	1,238	—	2,789	—
Stock options	2,130	321	4,019	338
Employee stock purchase plan	35	—	63	—
Total	$ 5,077	$ 683	$ 9,960	$ 768

9. 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 June 30, 2025 and December 31, 2024 all long-lived assets were in the U.S.

The following table summarizes the segment loss from operations, including significant segment expenses (in thousands):

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Research and development personnel-related (excluding stock-based compensation)	$ 3,301	$ 876	$ 5,764	$ 1,070
General and administrative personnel-related (excluding stock-based compensation)	1,717	1,159	3,411	1,925
Research and development stock-based compensation	3,368	468	6,371	538
General and administrative stock-based compensation	1,709	215	3,589	230
External research and development	16,416	17,113	30,026	22,018
Other research and development	1,002	216	1,851	240
General and administrative, excluding personnel-related and stock-based compensation	916	1,446	2,503	2,335
Total operating expenses	28,429	21,493	53,515	28,356
Loss from operations	$ (28,429)	$ (21,493)	$ (53,515)	$ (28,356)

10. Option Agreements and License Agreements

Option Agreements – Paragon Therapeutics

In March 2024, the Company entered into two antibody discovery and option agreements (the "Option Agreements") with Paragon Therapeutics, Inc. ("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 rights, titles, 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). 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 agreement, 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 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.

License Agreements – Paragon Therapeutics

In September 2024, the Company exercised its exclusive option to acquire certain rights to ORKA-001, and in December 2024, it entered into a 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 its exclusive option to acquire certain rights to ORKA-002, 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"). Pursuant to each of the two License Agreements, Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies in the respective agreed-upon 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 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 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. 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. Each of the 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. As of June 30, 2025, the Company has incurred and expensed milestone payments of $4.0 million for each of the License Agreements. Subsequent to the quarter end, the Company dosed the first patient in a Phase 2a clinical trial for ORKA-001. In the third quarter of 2025, the Company accrued for the additional milestone payment of $3.0 million under the ORKA-001 License Agreement, as it became probable that the milestone would be achieved.

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 is required to pay certain initiation fees, development costs and milestone payments to Paragon. For the ORKA-001 program, the Company recognized research and development expenses related to the following milestones during the period from February 6, 2024 (inception) to December 31, 2024: a one-time, nonrefundable research initiation fee of $0.8 million; $1.5 million related to exercising its option and achievement of development candidate; and $2.5 million related to completing the first dosing of a human subject in a Phase 1 trial. The Company was responsible for 50% of the development costs incurred through the completion of the IL-23 selection process, which was completed in June 2024.

For the ORKA-002 program, the Company recognized research and development expenses related to the following milestones during the period from February 6, 2024 (inception) to December 31, 2024: a one-time, nonrefundable research initiation fee of $0.8 million and $1.5 million related to exercising its option and achievement of development candidate. The Company was responsible for the development costs incurred through the completion of the IL-23 selection process, which was completed in December 2024.

Pursuant to the Option Agreements, during the three and six months ended June 30, 2025, the Company's share of research and development expenses for ORKA-001 program for the periods were nil. For the three months ended June 30, 2024, and the period from February 6, 2024 (inception) to June 30, 2024, the Company's share of research and development expenses, including research initiation fee, incurred for ORKA-001 program for the periods were $12.4 million and $13.2 million, respectively. These costs were recorded as research and development expenses. As of June 30, 2025 and December 31, 2024, nil and $12.4 million, respectively, related to ORKA-001 were included in related party accounts payable and other current liabilities.

Pursuant to the Option Agreements, during the three and six months ended June 30, 2025, the Company's share of research and development expenses for ORKA-002 program was nil and $0.1 million, respectively. For the three months ended June 30, 2024, and the period from February 6, 2024 (inception) to June 30, 2024, the Company's share of research and development expense, including research initiation fee, incurred for ORKA-002 program for the periods were $2.7 million and $6.9 million, respectively. The Company recognized a milestone payment of $2.5 million related to completing the first dosing of a human subject in a Phase 1 trial milestone during the three and six months ended June 30, 2025. These costs were recorded as research and development expenses. As of June 30, 2025 and December 31, 2024, nil and $2.7 million, respectively, related to ORKA-002 were included in related party accounts payable and other current liabilities.

For the three and six months ended June 30, 2025, the Company recognized $4.2 million and $5.7 million, respectively, of expenses in connection with services provided by Paragon and Paruka under the Option Agreements. For the three months ended June 30, 2024, and the period from February 6, 2024 (inception) to June 30, 2024, the Company recognized $15.4 million and $20.4 million, respectively.

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 condensed consolidated statements 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.

11. Commitments 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. In February 2025, the Company entered into an operating lease agreement in Waltham, Massachusetts, which commenced on April 1, 2025 with an initial term of 54 months. The Company leases office spaces under noncancelable operating lease agreements. Lease liabilities are based on the net present value of the remaining lease payments over the remaining lease terms. 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 June 30, 2025, the operating lease arrangement for the Company's headquarters in Menlo Park, California had a remaining lease term of 27 months and a discount rate of 17.95%. As of June 30, 2025, the operating lease arrangement for the Company's lease in Waltham, Massachusetts had a remaining lease term of 51 months and a discount rate of 9.95%. For the three and six months ended June 30, 2025, the Company recorded operating and variable lease expenses of $0.3 million and $0.4 million, respectively, in general and administrative expenses in its condensed consolidated statement of operations and comprehensive loss. For the three months ended June 30, 2024 and the period from February 6, 2024 (inception) to June 30, 2024, the Company recorded operating and variable lease expenses of less than $0.1 million.

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

	Six Months Ended June 30, 2025
Cash paid for amounts included in the measurement of lease liabilities	$ 147

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of June 30, 2025 (in thousands):

Year ending December 31,	Amount
2025 (remainder of the year)	$ 527
2026	822
2027	768
2028	397
2029	304
Total undiscounted lease payments	2,818
Less: imputed interest	(492)
Total discounted lease payments	2,326
Less: current portion of lease liability	(660)
Non-current portion of lease liability	$ 1,666

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.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of FASB ASC Topic 450, Contingencies ("ASC 450"). The Company expenses as incurred the costs related to its legal proceedings.

12. Net Loss per Share

The following table summarizes the basic and diluted net loss per share attributable to stockholders (in thousands, except share and per share data):

	Three Months Ended June 30, 2025			Three Months Ended June 30, 2024		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted
Common Stock	$ (19,327)	42,095,951	$ (0.46)	$ (22,243)	3,197,975	$ (6.96)
Company Series B Preferred Stock[(1)]	(5,247)	137,138	$ (38.26)	—	—	$ —
Net loss	$ (24,574)			$ (22,243)		

(1) The weighted-average number of shares of as-converted Company Series B Preferred Stock used in the loss allocation was 11,428,129 for the three months ended June 30, 2025.

	Six Months Ended June 30, 2025			Period from February 6, 2024 (Inception) to June 30, 2024		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share, Basic and Diluted
Common Stock	$ (35,805)	41,888,906	$ (0.85)	$ (29,320)	3,197,975	$ (9.17)
Company Series B Preferred Stock[(1)]	(9,768)	137,138	$ (71.23)	—	—	$ —
Net loss	$ (45,573)			$ (29,320)		

(1) The weighted-average number of shares of as-converted Company Series B Preferred Stock used in the loss allocation was 11,428,129 for the six months ended June 30, 2025.

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:

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Outstanding convertible preferred stock (as converted to common stock)	—	11,428,149	—	11,428,149
Outstanding employee warrants to purchase common stock	3,054,358	—	3,054,358	—
Outstanding unvested restricted stock awards	1,493,010	2,207,553	1,493,010	2,207,553
Outstanding and issued common stock options	3,668,560	1,179,193	3,668,560	1,179,193
Outstanding and issued warrant to Paruka	596,930	—	596,930	—
Total	8,812,858	14,814,895	8,812,858	14,814,895

13. 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 stock, 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):

	June 30, 2025	December 31, 2024
Paragon reimbursable Option Agreements' fees	$ —	$ 1,482
Paragon milestone payments for License Agreement	—	4,000
Paragon reimbursable other research expenses	107	515
Paragon reimbursable patent expenses	12	25
Total	$ 119	$ 6,022

14. Income Taxes

On July 4, 2025, the One Big Beautiful Bill Act (the "Act") was signed into law. The Act makes permanent key elements of the Tax Cuts and Jobs Act, including 100% bonus depreciation, domestic research cost expensing, and the business interest expense limitation. The Company is currently evaluating the impact of the Act.

Item 2. 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 unaudited condensed consolidated financial statements and the related notes included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 (this "Quarterly Report") and with the audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the Securities and Exchange Commission ("SEC") on March 6, 2025. 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 Quarterly Report entitled "Risk Factors" and elsewhere in this Quarterly 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 Quarterly Report. As used in this Quarterly 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, taken as a whole.

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.

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 our company, business and scientific planning, conducting discovery and research activities, establishing and protecting our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our programs and component materials, developing and progressing our pipeline, and providing general and administrative support for these operations. We do not have any products 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, 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. During the three and six months ended June 30, 2025, we generated net losses of $24.6 million and $45.6 million, respectively, and for the six months ended June 30, 2025, we used net cash of $44.0 million for our operating activities.

We had cash, cash equivalents, and marketable securities of $351.5 million as of June 30, 2025. 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 Quarterly 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 injection as infrequently as once or twice per 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, at the European Academy of Dermatology & Venereology (EADV) Congress in September 2025.

In July 2025, the United States Food and Drug Administration ("FDA") cleared our investigational new drug ("IND") application and Health Canada cleared our Clinical Trial Application ("CTA") for our Phase 2a trial of ORKA-001 in moderate-to-severe PsO, called EVERLAST-A. In the third quarter of 2025, we commenced dosing in a Phase 2a clinical trial of ORKA-001 in patients with moderate-to-severe PsO. We expect to share efficacy and response duration data from this study 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 the 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 initiated the dosing of healthy volunteers in a Phase 1 trial of ORKA-002 in the second quarter of 2025. We expect to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, around year end 2025.

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 plan to pursue a sequential combination regimen of ORKA-002 followed by ORKA-001, called ORKA-021. ORKA-021 has the potential to combine the rapid response of an IL-17 inhibitor with the ideal maintenance profile of an IL-23 inhibitor in a single regimen. 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 "Closing"), we completed the acquisition (the "Merger") of the private company, Oruka Therapeutics, Inc. ("Pre-Merger Oruka"), 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, 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." to "Oruka Therapeutics, Inc." and our Nasdaq ticker symbol from "ABIO" to "ORKA". Following consummation of the Merger, we 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"). The Company Common Stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the opening of trading on September 3, 2024.

Pre-Closing Financing and Closing

In April 2024, certain new and existing investors of Pre-Merger Oruka entered into a subscription agreement with Pre-Merger Oruka (as amended, 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 and Pre-Merger Oruka pre-funded warrants for gross proceeds of approximately $275.0 million. We incurred transaction costs of $20.5 million. At the Closing, those shares of common stock of Pre-Merger Oruka and the Pre-Merger Oruka pre-funded warrants were converted into shares of Company Common Stock and pre-funded warrants of Company Common Stock.

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 our 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).

Option Agreements and License Agreements – Paragon Therapeutics

In March 2024, we entered into two Antibody Discovery and Option Agreements with Paragon and Paruka Holding, LLC ("Paruka") (each, an "Option Agreement"), pursuant to which we initiated certain research programs with Paragon focusing on discovering, generating, identifying and/or characterizing antibodies directed to a particular target, including for IL-23 and IL-17A/F for ORKA-001 and ORKA-002, respectively. In September 2024, we exercised our exclusive option to acquire certain rights to ORKA-001, and in December 2024, we entered into a corresponding license agreement 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 in all fields other than the field of inflammatory bowel disease. In December 2024, we exercised our exclusive option to acquire certain rights to ORKA-002, and in February 2025, we entered into the corresponding license agreement 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-17A/F in all fields (collectively, the "License Agreements").

Pursuant to each of the License Agreements, Paragon has agreed not to conduct any new campaigns that generate anti-IL-23 monospecific antibodies or anti-IL-17A/F monospecific antibodies in the respective agreed-upon fields. 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 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. 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 our product. There is also a royalty step-down if there is no Paragon patent in effect during the royalty term for each program.

Pursuant to the License Agreements, as of June 30, 2025, we have incurred and expensed milestone payments of $4.0 million for each of ORKA-001 and ORKA-002. Subsequent to the quarter end, we dosed the first patient in a Phase 2a clinical trial for ORKA-001. In the third quarter of 2025, we accrued for the additional milestone payment of $3.0 million under the ORKA-001 License Agreement, as it became probable that the milestone would be achieved.

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 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; 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. See Note 10 to the condensed consolidated financial statements included in Part I - Item 1 of this Quarterly Report 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 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 (Expense), Net

Total other income (expense), 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.

Results of Operations

Comparison of the Three Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations and comprehensive loss for the periods presented (in thousands):

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Change	
			$	%
Operating expenses				
Research and development[(1)]	$ 24,087	$ 18,673	$ 5,414	29%
General and administrative[(2)]	4,342	2,820	1,522	54%
Total operating expenses	28,429	21,493	6,936	32%
Loss from operations	(28,429)	(21,493)	(6,936)	32%
Other income (expense)				
Interest income	3,857	—	3,857	100%
Interest expense[(3)]	—	(750)	750	(100)%
Other expense, net	(2)	—	(2)	100%
Total other income (expense), net	3,855	(750)	4,605	*
Net loss	$ (24,574)	$ (22,243)	$ (2,331)	10%

* Percentage not meaningful

(1) Includes related party amounts of $4,281 and $15,379 for the three months ended June 30, 2025 and June 30, 2024, respectively

(2) Includes related party amounts of $12 and $420 for the three months ended June 30, 2025 and June 30, 2024, respectively

(3) Includes related party amounts of nil and $750 for the three months ended June 30, 2025 and June 30, 2024, respectively

Research and Development Expenses

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Change	
			$	%
External research and development expenses	$ 16,416	$ 17,113	$ (697)	(4)%
Other research and development expenses:				
Personnel-related (excluding stock-based compensation)	3,301	876	2,425	*
Stock-based compensation	3,368	468	2,900	*
Other	1,002	216	786	*
Total research and development expenses	$ 24,087	$ 18,673	$ 5,414	29%

* Percentage not meaningful

Research and development expenses increased by $5.4 million, from $18.7 million for the three months ended June 30, 2024 to $24.1 million for the three months ended June 30, 2025.

External research and development expenses, including CROs, CMOs and other third-party preclinical studies and clinical trials expenses decreased by $0.7 million, from $17.1 million for the three months ended June 30, 2024 to $16.4 million for the three months ended June 30, 2025. The decrease is primarily related to the decrease in research expenses incurred by Paragon partially offset by increased CMO product development and manufacturing expenses and an increase in our CRO expenses related to our ongoing clinical trials and toxicology studies.

Personnel-related expenses increased by $2.4 million, from $0.9 million for the three months ended June 30, 2024 to $3.3 million for the three months ended June 30, 2025, as we continue hiring employees in our research and development organization. Stock-based compensation expense increased by $2.9 million, from $0.5 million for the three months ended June 30, 2024 to $3.4 million for the three months ended June 30, 2025. The increase in stock-based compensation expense is related to the $1.3 million increase in Paruka warrant liability under the Option Agreements and $1.6 million related to the increase in employee awards. Other research and development expenses increased by $0.8 million, from $0.2 million for the three months ended June 30, 2024 to $1.0 million for the three months ended June 30, 2025, primarily due to increases to facilities and allocated overhead expenses as we commenced using our leased Menlo Park office space from June 2024 and Waltham office from April 2025, as well as an increase in our research and development employee count.

General and Administrative Expenses

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Change	
			$	%
Personnel-related (including stock-based compensation)	$ 3,426	$ 1,374	$ 2,052	149%
Professional and consulting services	758	1,419	(661)	(47)%
Other	158	27	131	*
Total general and administrative expenses	$ 4,342	$ 2,820	$ 1,522	54%

General and administrative expenses increased by $1.5 million, from $2.8 million for the three months ended June 30, 2024 to $4.3 million for the three months ended June 30, 2025.

Personnel-related expenses increased by $2.1 million, from $1.3 million for the three months ended June 30, 2024 to $3.4 million for the three months ended June 30, 2025, as a result of continued hiring of executives and administrative employees. Stock-based compensation expense increased by $1.5 million, from $0.2 million for the three months ended June 30, 2024 to $1.7 million for three months ended June 30, 2025.

Expenses related to professional and consulting services decreased by $0.6 million, from $1.4 million for the three months ended June 30, 2024 to $0.8 million for the three months ended June 30, 2025, due to higher spending in the prior period on accounting, audit, and legal fees as we began preparation to become a public company.

Other general and administrative expenses increased by $0.1 million primarily due to facilities and allocated overhead expenses as we commenced using our leased Menlo Park office space from June 2024 and Waltham office from April 2025, as well as an increase in our employee count.

Total Other Income (Expense), Net

Interest income from cash equivalents and marketable securities was $3.9 million for the three months ended June 30, 2025. No interest income was recorded for the three months ended June 30, 2024.

No interest expense was recorded during the three months ended June 30, 2025. Interest expense of $0.8 million was incurred for the three months ended June 30, 2024 relating to the Convertible Note issued to Fairmount in March 2024.

Comparison of the Six Months Ended June 30, 2025, and the period from February 6 (inception) to June 30, 2024

The following table summarizes our results of operations and comprehensive loss for the periods presented (in thousands):

	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024	Change	
			$	%
Operating expenses				
Research and development[(1)]	$ 44,012	$ 23,866	$ 20,146	84%
General and administrative[(2)]	9,503	4,490	5,013	112%
Total operating expenses	53,515	28,356	25,159	89%
Loss from operations	(53,515)	(28,356)	(25,159)	89%
Other income (expense)				
Interest income	7,949	—	7,949	100%
Interest expense[(3)]	—	(964)	964	(100)%
Other expense, net	(7)	—	(7)	100%
Total other income (expense), net	7,942	(964)	8,906	*
Net loss	$ (45,573)	$ (29,320)	$ (16,253)	55%

* Percentage not meaningful

(1) Includes related party amounts of $6,403 and $20,430 for the six months ended June 30, 2025 and the period from February 6, 2024 (inception) to June 30, 2024, respectively

(2) Includes related party amounts of $122 and $1,268 for the six months ended June 30, 2025 and the period from February 6, 2024 (inception) to June 30, 2024, respectively

(3) Includes related party amounts of nil and $964 for the six months ended June 30, 2025 and the period from February 6, 2024 (inception) to June 30, 2024, respectively

Research and Development Expenses

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

	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024	Change	
			$	%
External research and development expenses	$ 30,026	$ 22,018	$ 8,008	36%
Other research and development expenses:				
Personnel-related (excluding stock-based compensation)	5,764	1,070	4,694	*
Stock-based compensation	6,371	538	5,833	*
Other	1,851	240	1,611	*
Total research and development expenses	$ 44,012	$ 23,866	$ 20,146	84%

* Percentage not meaningful

Research and development expenses increased by $20.1 million, from $23.9 million for the period from February 6, 2024 (inception) to June 30, 2024 to $44.0 million for the six months ended June 30, 2025.

External research and development expenses, including CROs, CMOs and other third-party preclinical studies and clinical trials expenses increased by $8.0 million, from $22.0 million for the period from February 6, 2024 (inception) to June 30, 2024 to $30.0 million for the six months ended June 30, 2025. The increase is primarily related to increased CMO product development and manufacturing expenses, an increase in our CRO expenses related to our ongoing clinical trials and toxicology studies, partially offset by a reduction of research expenses incurred by Paragon.

Personnel-related expenses increased by $4.7 million, from $1.1 million for the period from February 6, 2024 (inception) to June 30, 2024 to $5.8 million for the six months ended June 30, 2025, as we continue hiring employees in our research and development organization. Stock-based compensation expense increased by $5.8 million, from $0.5 million for the period from February 6, 2024 (inception) to June 30, 2024 to $6.4 million for the six months ended June 30, 2025. Stock-based compensation expense increased by $3.2 million due to the increase in employee awards and $2.6 million due to an increase in Paruka warrant liability under the Option Agreements. Other research and development expenses increased by $1.6 million, from $0.2 million for the period from February 6, 2024 (inception) to June 30, 2024 to $1.8 million for the six months ended June 30, 2025, primarily due to facilities and allocated overhead expenses as we commenced using our leased Menlo Park office space from June 2024 and Waltham office from April 2025, as well as increased our research and development employee count.

General and Administrative Expenses

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

	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024	Change	
			$	%
Personnel-related (including stock-based compensation)	$ 7,000	$ 2,155	$ 4,845	225%
Professional and consulting services	2,120	2,119	1	0%
Other	383	216	167	77%
Total general and administrative expenses	$ 9,503	$ 4,490	$ 5,013	112%

General and administrative expenses increased by $5.0 million, from $4.5 million for the period from February 6, 2024 (inception) to June 30, 2024 to $9.5 million for the six months ended June 30, 2025.

Personnel-related expenses increased by $4.8 million, from $2.2 million for the period from February 6, 2024 (inception) to June 30, 2024 to $7.0 million for the six months ended June 30, 2025, as a result of continued hiring of executives and administrative employees. Stock-based compensation expense was $0.2 million and $3.6 million for the period from February 6, 2024 (inception) to June 30, 2024 and for the six months ended June 30, 2025, respectively.

Expenses related to professional and consulting services remained relatively consistent at $2.1 million for the period from February 6, 2024 (inception) to June 30, 2024 compared to $2.1 million for the six months ended June 30, 2025.

Other general and administrative expenses increased by $0.2 million primarily due to facilities and allocated overhead expenses as we commenced using our leased Menlo Park office space from June 2024 and Waltham office from April 2025, as well as an increase in our employee count.

Total Other Income (Expense), Net

Interest income from cash equivalents and marketable securities was $7.9 million for the six months ended June 30, 2025. No interest income was recorded for the period from February 6, 2024 (inception) to June 30, 2024.

No interest expense was recorded during the six months ended June 30, 2025. Interest expense was $1.0 million for the period from February 6, 2024 (inception) to June 30, 2024 relating to the Convertible Note issued to Fairmount in March 2024.

Liquidity and Capital Resources

As of June 30, 2025, we had $351.5 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 June 30, 2025, 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 biopharmaceutical 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 Quarterly 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. At this time, due to the inherently unpredictable nature of clinical development, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval, and commercialize our current product candidate or any future product candidates. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or our current or any future license agreements which we may enter into or whether, or when, if ever, we may achieve profitability. In addition, with a change in the presidential administration in 2025, there has been an economic policy shift towards increasing tariffs, which in turn has led and could lead to further retaliatory tariffs. These may have the potential to impact expenses as well as our ability to, if ever, generate revenue or achieve profitability. 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 periods presented (in thousands):

	Six Months Ended June 30, 2025	Period from February 6, 2024 (Inception) to June 30, 2024
Net cash used in operating activities	$ (44,014)	$ (11,201)
Net cash provided by investing activities	47,726	—
Net cash provided by financing activities	109	26,322
Net increase in cash and cash equivalents	$ 3,821	$ 15,121

Operating Activities

For the six months ended June 30, 2025, net cash used in operating activities was $44.0 million, which was primarily attributable to a net loss of $45.6 million and net changes in our operating assets and liabilities of $5.3 million, partially offset by net non-cash charges of $6.9 million. Net changes in our operating assets and liabilities were primarily comprised of a decrease of $5.9 million in related party accounts payable and other current liabilities and an increase of $1.2 million in accounts payable. Net non-cash charges primarily comprised of an increase of $10.0 million in stock-based compensation expense, partially offset by $3.3 million in net accretion of premiums and discounts on marketable securities.

From February 6, 2024 (inception) to June 30, 2024, net cash used in operating activities was $11.2 million, which was primarily attributable to a net loss of $29.3 million, partially offset by non-cash charges of $0.8 million and net cash provided by changes in operating activities of $17.3 million. Non-cash charges consisted of a $0.8 million increase in stock-based compensation expense. Net cash provided by changes in our operating activities primarily consisted of a $15.4 million increase in related parties accounts payable and other current liabilities, $2.0 million increase in accounts payable, $1.0 million increase in accrued interest, related party, $0.6 million increase in accrued expenses and other current liabilities, partially offset by a $1.7 million increase in prepaid expenses and other current assets.

Investing Activities

For the six months ended June 30, 2025, net cash provided by investing activities was $47.7 million, which included $200.1 million in proceeds from maturities of marketable securities, offset by $152.3 million in purchases of marketable securities.

From February 6, 2024 (inception) to June 30, 2024, no cash was used in or provided by investing activities.

Financing Activities

For the six months ended June 30, 2025, net cash provided by financing activities was $0.1 million due to proceeds from the issuance of shares of common stock in connection with purchases under our employee stock purchase plan.

From February 6, 2024 (inception) to June 30, 2024, net cash provided by financing activities was $26.3 million, consisting of $2.9 million of net proceeds from the issuance of Pre-Merger Oruka Series A Preferred Stock and $25.0 million of net proceeds from the issuance of the Convertible Note, partially offset by $1.6 million of payments in deferred offering costs.

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 the contract 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 June 30, 2025. See Notes 10 and 11 to the condensed consolidated financial statements included in Part I - Item 1 of this Quarterly Report for further information on our contractual lease obligations for our headquarters in Menlo Park, California, and our office in Waltham, Massachusetts, and other commitments, including the commitments under the Option and License Agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed 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 our 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.

Our significant accounting policies are described in more detail in Note 2 to our condensed consolidated financial statements included in Part I - Item 1 of this Quarterly Report. During the three months ended June 30, 2025, there were no changes to our critical accounting policies and significant judgments and estimates as disclosed in our Annual Report on Form 10-K for the period from February 6 (inception) to December 31, 2024.

Off-Balance Sheet Arrangements

As of June 30, 2025, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. 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 4. Controls and Procedures

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our 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 under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, believes that our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Part II - Other Information

Item 1. 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 1A. Risk Factors

RISK FACTOR 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 Quarterly Report 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 summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in Item 1A of this Quarterly Report "Risk Factors". Please carefully consider all the information in this Quarterly Report, including the full set of risks set forth in the "Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding the Company.

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 Clinical Development, Regulatory Approval and Commercialization

- 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. We may not achieve our projected development goals in the time frames we announce and expect, or at all.
- We face competition from entities that have developed or may develop programs for the diseases addressed by our product candidates.

Risks Related to Government Regulations

- 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.

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. Our business could be negatively impacted if we are unable to maintain these arrangements or if these arrangements are not successful.
- Third parties we rely on for the execution of nonclinical studies and clinical trials may fail to carry out their contractual duties.
- Our third-party manufacturing partners and manufacturing sites may fail to perform adequately in their efforts to support the manufacture of our product candidates and we may need to switch or create third-party manufacturer redundancies.

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

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 identifying, acquiring, and developing our product candidates, organizing and staffing our company, and providing general and administrative support for our operations.

Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. The current market environment for small and midcap biotechnology companies and broader macroeconomic factors may preclude us from successfully raising additional capital. For example, escalating geopolitical tensions, elevated interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries, which such volatility can have an adverse effect on the ability to raise capital.

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 ceasing 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.

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, Institutional Review Boards ("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;

- 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 the 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 have also initiated a Phase 2 clinical trial of ORKA-001 in patients with moderate-to-severe psoriasis in the third quarter of 2025. In addition, we have initiated a Phase 1 clinical trial of ORKA-002 in healthy volunteers and plan to initiate a Phase 2 clinical trial of ORKA-002 in the first half of 2026. Currently, we believe that the success of our programs is dependent on observing a longer half-life of our product candidates in humans than 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 non-human primates 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 announce 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 the data results from our clinical trials, as well as the submission of regulatory filings. 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 or the timing of the 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 currently 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 in the applicable 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.

Clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. 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 trial 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 or difficulties in recruiting trial patients; 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 Good Clinical Practice ("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 a 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 current or 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 that 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.

Moreover, negative or inconclusive results of clinical trials involving our product candidates could require that we repeat or conduct additional clinical trials. We do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates. If the preliminary, topline or interim data that we report differ from actual results, or if final data or data from later stage clinical trials do not produce favorable results, 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, third-party payors or others in 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 United States 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 United States. 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. Further, the FDA and comparable foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations or revise existing regulations, or take other actions, such as those implemented by the recently established Department of Government Efficiency, which may impact our clinical development plans or prevent or delay approval of our programs under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance. 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 Biologics Price Competition and Innovation Act (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 Risk Evaluation and Mitigation Strategy ("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 Good Manufacturing Practices ("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 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, statutory, regulatory and policy changes, disruptions caused by government shutdowns and public health crises. There have been mass layoffs of federal government employees since the start of the Trump administration in January 2025, the full impact of which is unclear at this time. 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. Furthermore, the Trump administration has made and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA.

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 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.

We are unable to predict the extent to which the Trump administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting our business and operations. It is unclear how these executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or manufacturing of our product candidates, which could have a material adverse effect on our business.

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 third-party 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 Inflation Reduction Act ("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. In addition, we may be subject to data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable laws and regulations include the following:

- foreign privacy, data protection, and data security laws and regulations, such as the European Union's General Data Protection Regulation (EU GDPR), which imposes comprehensive obligations on covered businesses to, among other things, make contractual privacy, data protection and data security commitments, cooperate with European data protection authorities, implement security measures, give data breach notifications, and keep records of personal information processing activities; and

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof.

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, we may be subject to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, and 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 composition, 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 composition, 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 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 patent 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 without limitation: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes may 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 or delay the development of 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 litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they may 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 ("marks") 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 of, affect the 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 and independent contractors to assist us in the development of our programs. Many of these consultants, independent contractors 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, our consultants or our independent contractors 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, consultants and independent contractors 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, consultants or independent contractors, 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 impact the validity of the patents issuing thereon. 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 time 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, including for ORKA-001 and ORKA-002.

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 do not control the manufacturing process of, and are 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 Biologics 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. For example, in April 2025, the United States government imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or other countries or impose other restrictions on companies' ability to work with Chinese or other foreign counterparties. To the extent these or future tariffs are applicable to the material we import from China and other countries or if we are not able to secure supply of our product candidates as a result of applicable legislation, our business and financial condition could be adversely affected.

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 employees, independent contractors, consultants, advisors, 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, advisors, 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, 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 U.S. 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 product liability claims 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, either at the clinical or commercial stage. 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, especially in light of recent executive orders made by the Trump administration, 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 biotechnology areas), political and military conflict, and uncertainty about economic stability. In recent months, the U.S. has announced tariffs on imports from most countries, including significant tariffs on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. There is substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. 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 economic or political uncertainty, 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. 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. For example, escalating trade tensions, elevated interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries. 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. Class action securities litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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;
- general market, macroeconomic or geopolitical conditions or market conditions in the pharmaceutical and biotechnology sectors;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- 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.

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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Plans

During the quarter ended June 30, 2025, no director or Section 16 officer 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 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report are set forth below.

EXHIBIT NUMBER	DESCRIPTION	FORM	EXHIBIT	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	April 3, 2024
3.1	Second Amended and Restated Certificate of Incorporation of the Company, filed September 3, 2024.	8-K	3.5	September 5, 2024
3.2	Amended and Restated Bylaws of the Company.	8-K	3.6	September 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)	May 24, 2013
3.4	Certificate of Elimination of Series A Convertible Preferred Stock, effective August 29, 2024.	8-K	3.8	September 5, 2024
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock.	8-K	3.9	September 5, 2024
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock.	8-K	3.1	September 13, 2024
4.1	Description of Securities.	10-K	4.1	March 6, 2025
4.2	Form of Pre-Funded Warrant, dated August 29, 2024.	10-K	4.3	March 6, 2025
4.3	Form of Pre-Funded Warrant, dated September 13, 2024.	8-K	4.1	September 13, 2024
4.4	Paruka Warrant, dated December 31, 2024	10-Q	4.5	May 14, 2025
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			
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			
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			
101.INS	Inline XBRL Instance Document			
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbases Document			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Oruka Therapeutics, Inc.

Date: August 11, 2025

By: /s/ Lawrence Klein

Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2025

By: /s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lawrence Klein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: August 11, 2025

By: /s/ Lawrence Klein

Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Arjun Agarwal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: August 11, 2025

By: /s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance and Treasurer
(Principal Financial Officer and
Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 Quarterly Report on Form 10-Q of Oruka Therapeutics, Inc. (the "Company") for the quarterly period ending June 30, 2025, 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. § 1350, as adopted pursuant to § 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: August 11, 2025 By: /s/ Lawrence Klein

Lawrence Klein
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2025 By: /s/ Arjun Agarwal

Arjun Agarwal
Senior Vice President, Finance and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Oruka Therapeutics, Inc. and will be retained by Oruka Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.