Oruka Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

March 6, 2025

ORKA-001, targeting IL-23p19, Phase 1 trial ongoing, with pharmacokinetic (PK) data expected in 2H 2025

ORKA-001 Phase 2a initiation expected in 2H 2025, with efficacy readout in 2H 2026 that provides multiple opportunities to show differentiation over standard of care

ORKA-002, targeting IL-17A/F, preclinical data to be presented at the 2025 AAD Annual Meeting; Phase 1 initiation expected in Q3 2025, with PK data in 1H 2026

Successful go-public transaction and over $475 million raised in 2024

$394 million of cash, cash equivalents, and marketable securities at year-end 2024, projected to fund company through 2027, over one year past anticipated ORKA-001 Phase 2a data in psoriasis

MENLO PARK, Calif.,, March 06, 2025 (GLOBE NEWSWIRE) -- Oruka Therapeutics, Inc. (“Oruka”) (Nasdaq: ORKA), a clinical-stage biotechnology company developing novel biologics designed to set a new standard for the treatment of chronic skin diseases including plaque psoriasis, today reported fourth quarter and full year 2024 financial results and provided a corporate update.

“We made tremendous progress in our first year as a company, including our successful public debut, raising over $475 million to fund the company through 2027, and advancing ORKA-001 into the clinic,” said Lawrence Klein, PhD, Chief Executive Officer of Oruka. “As we move into 2025, we are excited about the momentum ahead, with our first clinical data readout anticipated later this year as well as our plans to advance ORKA-002 into the clinic and ORKA-001 into Phase 2 development. Looking forward, we expect to deliver a clinical catalyst every six months, which could progressively establish ORKA-001 and ORKA-002 as the best treatment options in the incredibly important therapeutic area of psoriatic disease.”

Fourth Quarter and Full Year Business and Pipeline Updates

ORKA-001: a novel half-life extended IL-23p19 monoclonal antibody

- Oruka initiated a Phase 1 trial of ORKA-001 in December 2024, ahead of schedule. The trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability, and pharmacokinetics (PK) of ORKA-001 in approximately 24 healthy volunteers. The Company expects to share interim data from this trial, including initial PK data, in the second half of 2025.
- Oruka plans to initiate a Phase 2a proof-of-concept study of ORKA-001 in the second half of 2025 that will enroll approximately 80 patients with moderate-to-severe psoriasis. The planned study design is innovative, with a primary endpoint of PASI 100 at week 16 (versus PASI 90 for prior biologics studies) and maintenance arms evaluating a six-month dosing interval alongside a cohort of patients who are not re-dosed until disease recurrence to test the potential for ultra-long responses. The Company expects to share efficacy and response duration data from this study in the second half of 2026. Psoriasis trials historically have had low placebo rates and good reproducibility across phases of development, making this Phase 2a readout particularly impactful for derisking ORKA-001.
- Preclinical data presented at the European Academy of Dermatology and Venereology (EADV) Congress in September 2024 showed that ORKA-001 has a half-life in non-human primates (NHPs) of more than 30 days, over three times longer than risankizumab and one of the longest NHP half-lives observed for an extended half-life antibody. In addition, the data showed that ORKA-001 binds to a similar epitope as risankizumab and displays similar binding affinity and potency across a variety of *in vitro* assays. These findings support the potential for ORKA-001 to achieve extended dosing intervals of once every six months or longer.
- Updated long-term data from KNOCKOUT, an investigator-initiated trial evaluating high induction doses of risankizumab, was presented in December 2024 and showed that ~44% of patients retained PASI 100 at one year and ~10% retained PASI 100 at two years despite receiving their last dose at week 16. This data demonstrates the potential for longer term "remission"-like responses following treatment with a higher dose IL-23 inhibitor. The Company believes that ORKA-001 can build on these results and potentially enable long-lasting responses in a significant portion of patients.

ORKA-002: a novel half-life extended IL-17A/F monoclonal antibody

- Oruka plans to initiate a Phase 1 trial of ORKA-002 in the third quarter of 2025. The Company expects to share interim data from the first-in-human trial in healthy volunteers, including initial PK data, in the first half of 2026.
- Preclinical data on ORKA-002 will be presented at the American Academy of Dermatology (AAD) Annual Meeting this month. ORKA-002 has the potential to achieve extended dosing intervals of once every four to six months, significantly longer than currently approved therapies targeting IL-17.

  Title: #64919 Characterization of ORKA-002, a Novel Extended Half-Life Monoclonal Antibody Targeting IL-17A/F for the Treatment of Psoriasis and Other Indications
  Presentation Information: 8:30am ET, Friday, March 7, 2025

Additional programs

- **ORKA-021:** Oruka disclosed a new sequential combination regimen of ORKA-002 and ORKA-001, which could deliver rapid and deep responses with an ideal maintenance profile. ORKA-021 could create another opportunity for the Company to define the best possible regimen in psoriatic disease.
- **ORKA-003:** The Company is on track to disclose additional program details in the first half of 2025.

Corporate

- Oruka successfully completed its go-public transaction and began trading on the Nasdaq under the ticker ORKA. As part of this process, the Company raised over $475 million in 2024, including two oversubscribed private placements of $275 million and $200 million, respectively. The Company has cash runway through 2027, over one year past anticipated Phase 2a data for ORKA-001 in plaque psoriasis.
- Oruka entered into license agreements with Paragon Therapeutics granting it worldwide exclusive rights to ORKA-001 in all indications other than inflammatory bowel disease, and to ORKA-002 in all indications.

Fourth Quarter 2024 and Full Year 2024 Financial Results

Cash Position: As of December 31, 2024, Oruka had available cash, cash equivalents, and marketable securities of $393.7 million. Net cash used in operating activities was $18.8 million for the fourth quarter of 2024 and $57.8 million for the period from February 6, 2024 (inception) to December 31, 2024.

Research and Development (R&D) expenses: R&D expenses totaled $25.5 million for the fourth quarter of 2024 and $75.1 million for the period from February 6, 2024 (inception) to December 31, 2024. This expense includes $3.7 million and $12.0 million of non-cash stock-based compensation for the fourth quarter and inception to December 31, 2024, respectively.

General and Administrative (G&A) expenses: G&A expenses totaled $4.8 million for the fourth quarter of 2024 and $13.1 million for the period from February 6, 2024 (inception) to December 31, 2024. This expense includes $1.5 million and $2.9 million of non-cash stock-based compensation for the fourth quarter and inception to December 31, 2024, respectively.

Other income, net: Other income, net for the fourth quarter of 2024 was $4.5 million and $4.4 million for the period from February 6, 2024 (inception) to December 31, 2024. Other income for the fourth quarter relates to interest earned on the Company's investment in marketable securities. Other income for the period from February 6, 2024 (inception) to December 31, 2024, includes $5.9 million of interest income earned on the Company's investment in marketable securities, partly offset by $1.5 million of interest expense on convertible notes before their conversion to common stock.

Net loss: Net loss totaled $25.8 million for the fourth quarter of 2024 and $83.7 million for the period from February 6, 2024 (inception) to December 31, 2024.

Shares Outstanding: Oruka has approximately 55.1 million shares of the Company's common stock and common stock equivalents issued and outstanding, including shares of common stock underlying pre-funded warrants and non-voting convertible preferred stock.

About Oruka Therapeutics

Oruka Therapeutics is developing novel biologics designed to set a new standard for the treatment of chronic skin diseases. Oruka's mission is to offer patients suffering from chronic skin diseases like plaque psoriasis the greatest possible freedom from their condition by achieving high rates of complete disease clearance with dosing as infrequently as once or twice a year. Oruka is advancing a proprietary portfolio of potentially best-in-class antibodies that were engineered by Paragon Therapeutics and target the core mechanisms underlying plaque psoriasis and other dermatologic and inflammatory diseases. For more information, visit www.orukatx.com and follow Oruka on LinkedIn.

Forward Looking Statements

Certain statements in this press release, other than purely historical information, may constitute "forward-looking statements" within

the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements relating to Oruka's expectations, hopes, beliefs, intentions or strategies regarding the future of its pipeline and business including, without limitation, Oruka's ability to achieve the expected benefits or opportunities with respect to ORKA-001 and ORKA-002, including timelines to clinical and data release milestones as well as trial initiation timelines, the details of its planned clinical studies, the potential half-life of ORKA-001 and the potential dosing intervals of ORKA-001 and ORKA-002, as well as Oruka's anticipated cash runway and timeline for clinical catalysts. 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 Oruka will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Oruka's 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. These risks and uncertainties include, but are not limited to, those uncertainties and factors described under the heading "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in Oruka's most recent filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K and its registration statement on Form S-1. Should one or more of these risks or uncertainties materialize, or should any of Oruka's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth therein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein and in Oruka's SEC filings. Oruka does not undertake or accept any duty to make any updates or revisions to any forward-looking statements.

Investor Contact:
Alan Lada
(650)-606-7911
alan.lada@orukatx.com

ORUKA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

Assets	**December 31, 2024**	**February 6, 2024**
Current assets:		
Cash and cash equivalents	$ 61,575	$ —
Marketable securities, current	314,073	—
Subscription receivables	—	1
Prepaid expenses and other current assets	1,221	
Total current assets	376,869	1
Marketable securities, long-term	18,069	—
Property and equipment, net	162	—
Operating lease right-of-use assets	876	—
Other non-current assets	43	—
Total assets	$ 396,019	$ 1
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,462	$ —
Accrued expenses and other current liabilities	3,346	—
Operating lease liability, current	213	—
Related party accounts payable and current liabilities	6,022	—
Total current liabilities	13,043	—
Operating lease liability, non-current	755	—
Total liabilities	13,798	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	2,931	—
Common stock	37	—
Additional paid-in capital	463,018	1
Accumulated other comprehensive loss	(41)	—
Accumulated deficit	(83,724)	—

Total stockholders' equity	382,221	1
Total liabilities, convertible preferred stock and stockholders' equity	$ 396,019	$ 1

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

	Three Months Ended December 31, 2024	Period from February 6, 2024 (Inception) to December 31, 2024
Operating expenses		
Research and development[(1)]	$ 25,503	$ 75,060
General and administrative[(1)]	4,815	13,063
Total operating expenses	30,318	88,123
Loss from operations	(30,318)	(88,123)
Other income (expense)		
Interest income	4,533	5,863
Interest expense	—	(1,468)
Other income, net	4	4
Total other income, net	4,537	4,399
Net Loss	(25,781)	(83,724)
Unrealized loss on marketable securities, net	(41)	(41)
Comprehensive loss	$ (25,822)	$ (83,765)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (3.87)
Net loss per share attributable to Series A non-voting convertible preferred Stockholders, basic and diluted	$ (488.06)	$ (3,873.25)
Net loss per share attributable to Series B non-voting convertible preferred Stockholders, basic and diluted	$ (40.64)	$ (322.81)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	40,134,008	16,789,362
Weighted-average shares used in computing net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	1,299	495
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	137,138	51,946

(1) Amounts include non-cash stock based compensation expense as follows (in thousands):

	Three Months Ended December 31, 2024	Period from February 6, 2024 (Inception) to December 31, 2024
Research and development	$ 3,682	$ 11,992
General and administrative	1,468	2,927
Total	$ 5,150	$ 14,919