# Oruka Therapeutics Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 14, 2025

*Continued operational excellence leading to acceleration of multiple timelines:*

*ORKA-001, targeting IL-23p19, Phase 1 trial dosing complete, with data expected in 3Q 2025*

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

*ORKA-002, targeting IL-17A/F, Phase 1 initiation accelerated to 2Q 2025, with initial PK data now expected around YE 2025; data will support both ORKA-002 and ORKA-021 psoriasis studies*

*Strong cash position of $373 million provides runway through 2027, over one year past anticipated ORKA-001 Phase 2a data in psoriasis*

MENLO PARK, Calif., May 14, 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 first quarter 2025 financial results and provided a corporate update.

“We are thrilled with the continued rapid progress we are making to advance our co-lead programs, which we think could set a new standard in the treatment of psoriatic disease,” said Lawrence Klein, PhD, Chief Executive Officer of Oruka. “We’re excited to soon have both of our co-lead programs, ORKA-001 and ORKA-002, in the clinic and release our first clinical data on ORKA-001. As we ramp up preparations for our first psoriasis studies, we are energized by the reception from physicians who clearly see the potential to advance the treatment paradigm in this important disease.”

**First Quarter Business and Pipeline Updates**

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

- Oruka’s Phase 1 trial of ORKA-001 is progressing, with dosing completed for all 24 subjects across three dose levels. The trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability, and pharmacokinetics (PK) of ORKA-001. The Company expects to share interim data from this trial, including initial PK data, in 3Q 2025 (previously 2H 2025).
- Based on PK modeling, the Company expects that a human half-life of 50 days or more will support dosing every six months whereas a half-life of 75 days or more could support dosing once per year. In comparison, currently approved IL-23p19 inhibitors require maintenance dosing every two or three months.
- Oruka plans to initiate a Phase 2a proof-of-concept study of ORKA-001 in 2H 2025 that will enroll approximately 80 patients with moderate-to-severe plaque 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 to test the potential for off-treatment remission in some patients. The Company expects to share efficacy and response duration data from this study in the 2H 2026. Psoriasis trials historically have low placebo rates and good reproducibility across phases of development, making this Phase 2a readout particularly impactful for derisking ORKA-001.

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

- Oruka plans to initiate a Phase 1 trial of ORKA-002 in 2Q 2025 (previously 3Q 2025). The trial is a double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability, and PK of ORKA-002 in approximately 24 healthy volunteers. The Company expects to share interim data from this trial, including initial PK data, around year end 2025 (previously 1H 2026).
- At the American Academy of Dermatology Annual Meeting in March, the Company presented data from its preclinical studies of ORKA-002. The data showed that ORKA-002 has a half-life in non-human primates of over 30 days, more than

three times longer than bimekizumab, which is expected to support a dose interval of two to three times per year. Also, ORKA-002 has similar potency to bimekizumab and binds to nearly identical epitopes on IL-17A and IL-17F with comparable affinity.

***Additional programs***

- **ORKA-021 (ORKA-002 → ORKA-001):** Oruka continues to advance a 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 for the treatment of psoriatic disease.
- **ORKA-003:** The Company continues to progress ORKA-003 through preclinical development. Based on competitive considerations, the Company is no longer planning to disclose additional details on ORKA-003 in 1H 2025.

***First Quarter 2025 Financial Results***

**Cash Position**: As of March 31, 2025, Oruka had available cash, cash equivalents, and marketable securities of $373.0 million. Net cash used in operating activities was $20.9 million for the first quarter of 2025.

**Research and Development (R&D) expenses**: R&D expenses totaled $19.9 million and $5.2 million for the first quarter of 2025 and for the period from February 6, 2024 (inception) to March 31, 2024, respectively. The increase was driven by pre-clinical and clinical development and manufacturing expenses for the Company's plaque psoriasis programs. These expenses include $3.0 million and $0.1 million of non-cash stock-based compensation for the first quarters of 2025 and 2024, respectively.

**General and Administrative (G&A) expenses**: G&A expenses totaled $5.2 million and $1.7 million for the first quarter of 2025 and for the period from February 6, 2024 (inception) to March 31, 2024, respectively. The increases were primarily related to employee compensation-related expenses, including stock-based compensation, professional and consulting fees to support the growth in our operations, and costs associated with being a public company. These expenses include $1.9 million and less than $0.1 million of non-cash stock-based compensation for the first quarters of 2025 and 2024, respectively.

**Other income (expense), net**: Other income, net for the first quarter of 2025 was $4.1 million, and other expense, net for the period from February 6, 2024 (inception) to March 31, 2024 was ($0.2) million. Other income for the first quarter of 2025 relates to interest earned on the Company's investment in marketable securities. Other expenses, net for the first quarter of 2024 represent interest expense on convertible note.

**Net loss**: Net loss totaled $21.0 million and $7.1 million for the first quarter of 2025 and for the period from February 6, 2024 (inception) to March 31, 2024, respectively, which includes non-cash stock-based compensation of $4.9 million and $0.1 million, for the first quarters of 2025 and 2024, respectively

**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 ORKA-002 and the potential dosing intervals of ORKA-001 and ORKA-002, as well as Oruka's anticipated cash runway. 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, Quarterly Report on Form 10-Q 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.

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

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 83,572 | $ 61,575 |
| Marketable securities, current | 265,522 | 314,073 |
| Prepaid expenses and other current assets | 2,989 | 1,221 |
| Total current assets | 352,083 | 376,869 |
| Marketable securities, long-term | 23,953 | 18,069 |
| Property and equipment, net | 159 | 162 |
| Operating lease right-of-use assets | 814 | 876 |
| Other non-current assets | 103 | 43 |
| Total assets | $ 377,112 | $ 396,019 |
| **Liabilities, Convertible Preferred Stock and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,545 | $ 3,462 |
| Accrued expenses and other current liabilities | 5,663 | 3,346 |
| Operating lease liability, current | 283 | 213 |
| Related party common stock warrant liability | 1,415 | — |
| Related party accounts payable and other current liabilities | 817 | 6,022 |
| Total current liabilities | 11,723 | 13,043 |
| Operating lease liability, non-current | 664 | 755 |
| Total liabilities | 12,387 | 13,798 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Series B non-voting convertible preferred stock | 2,931 | 2,931 |
| Common stock | 37 | 37 |
| Additional paid-in capital | 466,486 | 463,018 |
| Accumulated other comprehensive loss | (6) | (41) |
| Accumulated deficit | (104,723) | (83,724) |
| Total stockholders' equity | 364,725 | 382,221 |
| Total liabilities, convertible preferred stock and stockholders' equity | $ 377,112 | $ 396,019 |

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

***(unaudited)***

| | Three Months Ended March 31, 2025 | Period from February 6, 2024 (Inception) to March 31, 2024 |
|---|---|---|
| Operating expenses | | |
| Research and development[(1)] | $ 19,925 | $ 5,193 |
| General and administrative[(1)] | 5,161 | 1,670 |
| Total operating expenses | 25,086 | 6,863 |
| Loss from operations | (25,086) | (6,863) |
| Other income (expense) | | |
| Interest income | 4,092 | — |
| Interest expense | — | (214) |
| Other expense, net | (5) | — |
| Total other income (expense), net | 4,087 | (214) |
| Net Loss | (20,999) | (7,077) |
| Net change in unrealized gains (losses) on marketable securities | 35 | - |
| Comprehensive loss | $ (20,964) | $ (7,077) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.40) | $ (2.21) |
| Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted | $ (32.95) | $ - |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 41,679,560 | 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 | - |

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

| | Three Months Ended March 31, 2025 | Period from February 6, 2024 (Inception) to March 31, 2024 |
|---|---|---|
| Research and development | $ 3,003 | $ 70 |
| General and administrative | 1,880 | 15 |
| Total | $ 4,883 | $ 85 |