Oruka Therapeutics Reports Second Quarter 2025 Financial Results and Provides Corporate Update

August 11, 2025

First patients dosed in the EVERLAST-A Phase 2a trial of ORKA-001, with data expected in 2H 2026

ORKA-001 Phase 1 data and EVERLAST-A design to be presented at EADV in September 2025

ORKA-002 Phase 1 trial ongoing, with data to be presented around YE 2025

MENLO PARK, Calif., Aug. 11, 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 second quarter 2025 financial results and provided a corporate update.

“We are very pleased to have initiated our EVERLAST-A study, and we expect nearly all our sites to be open and enrolling by the end of the month,” said Lawrence Klein, PhD, Chief Executive Officer of Oruka. “This study could demonstrate three different aspects of ORKA-001’s differentiation – an ultra-long dosing interval, higher efficacy than other IL-23 inhibitors, and the potential for off-treatment remissions. Together with our ORKA-002 program and ORKA-021 sequential combination that are following close behind, we are confident we can have the best biologic regimens in psoriatic disease, an area that continues to reward innovation in biologics.”

Second Quarter Business and Pipeline Updates

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

- Enrollment is ongoing in EVERLAST-A following clearance from both the U.S. FDA and Health Canada in July, and the first patients have been dosed in the study. EVERLAST-A is a randomized, double-blind, placebo-controlled Phase 2a trial designed to enroll approximately 80 patients with moderate-to-severe plaque psoriasis. Patients will be randomized 3:1 to receive ORKA-001 or placebo with a primary endpoint of PASI 100 at Week 16. At Week 28, patients who have achieved PASI 100, or completely clear skin, will be randomized 2:1 to either (1) an arm where they do not receive another dose until disease recurs or (2) ORKA-001 every six months. This “no-dose” arm will provide evidence for both yearly dosing and the potential for extended off-treatment remissions. Additional details on the EVERLAST-A design will be presented at the European Academy of Dermatology and Venereology (EADV) Congress in September. The Company expects to share efficacy and response duration data from EVERLAST-A in 2H 2026. Psoriasis trials historically have low placebo rates and high reproducibility across phases of development, making this Phase 2a readout particularly impactful for demonstrating ORKA-001’s differentiation.
- Oruka’s Phase 1 trial of ORKA-001 is ongoing, 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 will present data from this trial at EADV in September.

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

- The first participants were dosed in a Phase 1 trial of ORKA-002 in May, and the trial is ongoing. 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 YE 2025, and to initiate a Phase 2 trial in psoriasis in 1H 2026.

Additional programs and updates

- Laura Sandler, who joined Oruka in 2024 as SVP of Operations, was promoted to Chief Operating Officer.
- **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.

Second Quarter 2025 Financial Results

Cash Position: As of June 30, 2025, Oruka had available cash, cash equivalents, and marketable securities of $351.5 million. Net cash used in operating activities was $23.1 million for the second quarter of 2025.

Research and Development (R&D) expenses: R&D expenses totaled $24.1 million and $18.7 million for the second quarters of 2025 and 2024, respectively. The increase was primarily related to employee compensation-related expenses, including stock-based compensation to support the Company's plaque psoriasis programs. These expenses include $3.4 million and $0.5 million of non-cash stock-based compensation for the second quarters of 2025 and 2024, respectively.

General and Administrative (G&A) expenses: G&A expenses totaled $4.3 million and $2.8 million for the second quarters of 2025 and 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.

Other income (expense), net: Other income, net for the second quarter of 2025 was $3.9 million, and other expense, net for second quarter of 2024 was ($0.8) million. Other income for the second quarter of 2025 relates to interest earned from the Company's investment in marketable securities.

Net loss: Net loss totaled $24.6 million and $22.2 million for the second quarters of 2025 and 2024, respectively, which includes non-cash stock-based compensation of $5.1 million and $0.7 million for the second 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, ORKA-002 and ORKA-021, including timelines to clinical and data release milestones, trial and site initiation timelines, and the details of its planned clinical studies, as well as the potential exposures and dosing interval of ORKA-001. 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 Reports 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
(unaudited)
(in thousands)

	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		
Stockholders' equity:		
Series B non-voting convertible preferred stock	2,931	2,931
Common stock	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

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[(1)]	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	—	(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) Amounts include non-cash stock based compensation expense as follows (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