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

November 12, 2025

ORKA-001 Phase 1 results presented at EADV show potential for once-per-year dosing, higher efficacy and off-treatment remission

Over $500M cash and equivalents provides runway over one year past three key readouts: ORKA-001 Phase 2a and 2b (EVERLAST-A and -B), and ORKA-002 Phase 2

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

ORKA-001 Phase 2a trial enrolling well with data expected 2H 2026

MENLO PARK, Calif., Nov. 12, 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 (PsO), today reported third quarter 2025 financial results and provided a corporate update.

“We had a very successful quarter where we released our first clinical data as a company and extended our cash runway beyond additional Phase 2 clinical readouts,” commented Lawrence Klein, PhD, Chief Executive Officer of Oruka. “We are seeing increased interest in both of our co-lead programs, with additional appreciation that each could become a very impactful medicine in psoriatic disease and beyond. We’re excited by our continued rapid progress advancing both ORKA-001 and -002 and look forward to sharing our first Phase 2 data in 2026.”

Third Quarter Business and Pipeline Updates

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

- In September 2025, at the European Academy of Dermatology and Venerology (EADV) Congress, the Company presented interim Phase 1 results in a late-breaking oral session. ORKA-001 demonstrated a half-life of approximately 100 days, greater than three times that of risankizumab, and a Cmax that exceeded risankizumab at an equivalent dose, both of which increase the likelihood of achieving once-yearly dosing, higher efficacy, and extended off-treatment remissions. Single doses of ORKA-001 also showed complete and sustained inhibition of STAT3 signaling, a downstream marker of IL-23 activity. ORKA-001 was well tolerated across all dose levels, with a favorable safety profile consistent with the anti-IL-23 class. The study is ongoing.
- Enrollment is progressing well in EVERLAST-A, a randomized, double-blind, placebo-controlled Phase 2a trial of ORKA-001 in moderate to severe PsO. Additional details of the study design were presented in an oral presentation at the EADV Congress. EVERLAST-A is designed to provide evidence of ORKA-001’s potential for yearly dosing, greater efficacy, and extended off-treatment remissions. The Company expects to share PASI 100 data at Week 16 for all patients, as well as response duration data out to approximately one year for some patients, in 2H 2026.
- Oruka plans to initiate a dose-ranging Phase 2b trial of ORKA-001, EVERLAST-B, in 1H 2026. EVERLAST-B will evaluate three dose levels of ORKA-001: 37.5 mg at Week 0, 300 mg at Weeks 0 and 4, and 600 mg at Weeks 0 and 4, versus placebo. The primary endpoint is PASI 100 at Week 16. To expedite development, EVERLAST-B dosing is projected to begin enrolling before the completion of EVERLAST-A.

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

- The Phase 1 trial of ORKA-002 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.
- The Company intends to begin a Phase 2 trial of ORKA-002 in moderate-to-severe PsO in 1H 2026. The Company also is planning for a Phase 2 trial in hidradenitis suppurativa (HS), which is included in cash runway forecasts.

Additional programs and updates

- The Company completed a $180M PIPE financing, extending runway over one year past three Phase 2 catalysts: the

ORKA-001 Phase 2a and 2b studies (EVERLAST-A and -B), and the ORKA-002 Phase 2 study in PsO.

- **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.

Third Quarter 2025 Financial Results

Cash Position: As of September 30, 2025, Oruka had available cash, cash equivalents, and marketable securities of $500.9 million. Net cash used in operating activities was $21.6 million for the third quarter of 2025.

Research and Development (R&D) expenses: R&D expenses totaled $29.0 million and $25.7 million for the third 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 $8.3 million and $7.8 million of non-cash stock-based compensation for the third quarters of 2025 and 2024, respectively, of which $6.6 million and $7.3 million, respectively, relate to Paruka warrant obligation.

General and Administrative (G&A) expenses: G&A expenses totaled $5.1 million and $3.8 million for the third 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, net: Other income, net was $3.8 million and $0.8 million for the third quarters of 2025 and 2024, respectively. The increase is primarily due to higher interest income in the third quarter of 2025 from the Company's investment in marketable securities.

Net loss: Net loss totaled $30.3 million and $28.6 million for the third quarters of 2025 and 2024, respectively, which includes non-cash stock-based compensation of $10.2 million and $9.0 million for the third quarters of 2025 and 2024, respectively

Shares Outstanding: Oruka has approximately 67.1 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 and 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 and Quarterly Reports on Form 10-Q. 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)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 91,253	$ 61,575
Marketable securities, current	257,902	314,073
Prepaid expenses and other current assets	6,008	1,221
Total current assets	355,163	376,869
Marketable securities, long-term	151,763	18,069
Property and equipment, net	253	162
Operating lease right-of-use assets	1,969	876
Other non-current assets	103	43
Total assets	$ 509,251	$ 396,019
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,208	$ 3,462
Accrued expenses and other current liabilities	8,648	3,346
Operating lease liability, current	419	213
Related party common stock warrant liability	9,684	—
Related party accounts payable and other current liabilities	8	6,022
Total current liabilities	20,967	13,043
Operating lease liability, non-current	1,493	755
Total liabilities	22,460	13,798
Commitments and contingencies		
Stockholders' equity:		
Series B non-voting convertible preferred stock	2,931	2,931
Common stock	48	37
Additional paid-in capital	643,201	463,018
Accumulated other comprehensive income (loss)	185	(41)
Accumulated deficit	(159,574)	(83,724)
Total stockholders' equity	486,791	382,221
Total liabilities and stockholders' equity	$ 509,251	$ 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 September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Period from February 6, 2024 (inception) to September 30, 2024
Operating expenses:				
Research and development[(1)]	$ 28,988	$ 25,691	$ 73,000	$ 49,557

General and administrative[1]	5,117	3,758	14,620	8,248
Total operating expenses	34,105	29,449	87,620	57,805
Loss from operations	(34,105)	(29,449)	(87,620)	(57,805)
Other income (expense):				
Interest income	3,832	1,330	11,781	1,330
Interest expense	—	(504)	—	(1,468)
Other expense, net	(4)	—	(11)	—
Total other income (expense), net	3,828	826	11,770	(138)
Net Loss	(30,277)	(28,623)	(75,850)	(57,943)
Net change in unrealized gains (losses) on marketable securities	212	—	226	—
Comprehensive loss	$ (30,065)	$ (28,623)	$ (75,624)	$ (57,943)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.55)	$ (1.46)	$ (1.40)	$ (6.08)
Net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	$ —	$ (1,461.10)	$ —	$ (6,077.25)
Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	$ (45.46)	$ (121.76)	$ (116.94)	$ (506.44)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	44,067,059	15,013,655	42,622,935	7,765,381
Weighted-average shares used in computing net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	—	477	—	184
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	137,138	49,191	137,138	19,015

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

	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Period from February 6, 2024 (inception) to September 30, 2024
Research and development	$ 8,341	$ 7,772	$ 14,712	$ 8,310
General and administrative	1,824	1,229	5,413	1,459
Total	$ 10,165	$ 9,001	$ 20,125	$ 9,769