Oruka Therapeutics Reports Third Quarter 2026 Financial Results and Provides Corporate Update

November 9, 2026

EVERLAST-B Week 16 results showed 61% PASI 100 and 86% PASI 90 in the ORKA-001 high-dose group, highly consistent with EVERLAST-A

EVERLAST-A responses continued to deepen to 71% PASI 100 at Week 28, 6 months after last dose

EVERLAST-A 52-week data expected in December 2026; Phase 3 program on track to begin 1H 2027

ORKA-002 ORCA-SURGE Phase 2 enrollment completed with Week 16 data in psoriasis expected in 1Q 2027

MENLO PARK, Calif., Nov. 09, 2026 (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) and hidradenitis suppurativa (HS), today reported third quarter 2026 financial results and provided a corporate update.

“We continued to make rapid progress in the third quarter and shared two new datasets from the EVERLAST program with ORKA-001 that further strengthen our belief that it can set a new standard in psoriatic disease,” said Lawrence Klein, PhD, Chief Executive Officer of Oruka. “We look forward to sharing 52-week data from EVERLAST-A later this year and then working to rapidly initiate pivotal studies with this very promising asset. In parallel, we are building depth in our portfolio with ORKA-002 advancing in two Phase 2 studies, and ORKA-004 nearing first-in-human initiation.”

Third Quarter 2026 and Recent Business and Pipeline Updates

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

- In October 2026, the Company announced positive Week 16 results from EVERLAST-B, a Phase 2b dose-ranging trial of ORKA-001 in moderate-to-severe PsO. Efficacy increased across dose levels in a dose-dependent manner, with 61% of patients in the high-dose group (600 mg at Weeks 0 and 4) achieving the primary endpoint of PASI 100 at Week 16, and 86% of patients achieving each of PASI 90 and IGA 0/1 at Week 16. Placebo rates were at the lower end of what is typically seen in psoriasis studies, with no patients in the placebo group reaching PASI 100, PASI 90, or IGA 0/1 at Week 16. These results were highly consistent with the results observed in EVERLAST-A. ORKA-001 continued to be well tolerated, with a safety profile consistent with the IL-23p19 class.
- In September 2026, the Company presented Week 28 data from EVERLAST-A, a Phase 2a trial testing ORKA-001 600 mg at Weeks 0 and 4 versus placebo in moderate-to-severe PsO. Clinical responses continued to deepen through Week 28 despite participants receiving no further doses since Week 4, with PASI 100 rates increasing to 71% and PASI 90 rates increasing to 87%. ORKA-001 maintained a favorable safety and tolerability profile.
- Based on these results and pending discussions with regulatory authorities, the Company plans to initiate Phase 3 trials of ORKA-001 in moderate-to-severe PsO in the first half of 2027 with the 600 mg dose.
- The Company expects to report 52-week data from EVERLAST-A in December 2026, and 52-week data from EVERLAST-B in the second half of 2027.

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

- ORCA-SURGE, a Phase 2 dose-ranging trial of ORKA-002 in moderate-to-severe PsO, has completed enrollment of 171 patients, and the Company remains on track to report Week 16 data in the first quarter of 2027.
- ORCA-SPLASH, a Phase 2 trial of ORKA-002 in moderate-to-severe HS, is progressing well. ORCA-SPLASH is a randomized, double-blind, placebo-controlled trial of ORKA-002 versus placebo being conducted in the United States and Canada. The primary endpoint is HiSCR75 at Week 16, after which participants enter an open-label maintenance period evaluating ORKA-002 administered every 12 weeks.

Additional updates

- ORKA-004, a novel, subcutaneously administered, half-life extended monoclonal antibody targeting TL1A, remains on track

for initiation of clinical development in the fourth quarter of 2026. The Company plans to initiate Phase 2 combination studies of ORKA-004 with ORKA-001 or ORKA-002 in 2027.

- In August 2026, the Company appointed Todd Edwards as Chief Commercial Officer. Mr. Edwards brings more than 25 years of commercial leadership experience across immunology and dermatology, joining Oruka from Arcutis Biotherapeutics, where he served as Executive Vice President and Chief Commercial Officer.

Third Quarter 2026 Financial Results

Cash Position: As of September 30, 2026, Oruka had cash, cash equivalents, and marketable securities of $1.2 billion. Net cash used in operating activities was $44.3 million for the third quarter of 2026 compared to $21.6 million for the third quarter of 2025.

Research and Development (R&D) Expenses: R&D expenses were $53.7 million for the third quarter of 2026, compared to $29.0 million for the third quarter of 2025. The increase was primarily related to additional clinical trials and associated costs of Oruka's programs and higher employee compensation expenses, including stock-based compensation driven by increased headcount. The increase in stock-based compensation was offset by the absence of expense related to the Paruka warrant obligation from the prior year.

General and Administrative (G&A) Expenses: G&A expenses were $8.4 million for the third quarter of 2026, compared to $5.1 million for the third quarter of 2025. The increase was primarily related to higher employee compensation-related expenses, including stock-based compensation, to support the operations of a growing public company.

Other income, net: Other income, net was $12.2 million for the third quarter of 2026, compared to $3.8 million for the third quarter of 2025. The increase was primarily driven by interest earned on higher cash and marketable securities balances.

Net Loss: Net loss was $50.0 million and $30.3 million for the third quarters of 2026 and 2025, respectively, which includes non-cash stock-based compensation of $9.1 million and $10.2 million for the third quarters of 2026 and 2025, respectively.

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 inflammatory diseases like plaque psoriasis and hidradenitis suppurativa the greatest possible freedom from their condition by achieving high rates of disease clearance with dosing as infrequently as once or twice a year. 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 regarding Oruka's plans and expectations for its pipeline and business including the potential benefits, efficacy, safety, durability of response, dosing profile and therapeutic potential of its product candidates; the design, initiation, enrollment, conduct, timing, progress and results of the Company's clinical studies, including EVERLAST-A, EVERLAST-B, ORCA-SURGE and ORCA-SPLASH; the expected timing of 52-week data from EVERLAST-A and EVERLAST-B and Week 16 data from ORCA-SURGE; the planned initiation of Phase 3 trials of ORKA-001 in the first half of 2027; the anticipated initiation of clinical development of ORKA-004 in the fourth quarter of 2026 and the planned initiation of combination studies of ORKA-004 with ORKA-001 or ORKA-002 in 2027; and the Company's development plans and expectations for ORKA-001, ORKA-002 and ORKA-004. 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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 191,519	$ 46,935
Marketable securities, current	728,758	290,109
Prepaid expenses and other current assets	21,216	6,813
Total current assets	941,493	343,857
Marketable securities, long-term	286,310	142,539
Property and equipment, net	309	288
Operating lease right-of-use assets	2,786	1,830
Other non-current assets	128	103
Total assets	$ 1,231,026	$ 488,617
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 14,377	$ 4,155
Accrued expenses and other current liabilities	16,516	10,591
Operating lease liability, current	838	619
Related party accounts payable and other current liabilities	50	9
Total current liabilities	31,781	15,374
Operating lease liability, non-current	2,094	1,313
Total liabilities	33,875	16,687
Commitments and contingencies		
Stockholders' equity:		
Series B non-voting convertible preferred stock	2,020	2,931
Common stock	67	49
Additional paid-in capital	1,512,253	657,561
Accumulated other comprehensive income (loss)	(5,041)	546
Accumulated deficit	(312,148)	(189,157)
Total stockholders' equity	1,197,151	471,930
Total liabilities and stockholders' equity	$ 1,231,026	$ 488,617

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development[(1)]	$ 53,696	$ 28,988	$ 126,098	$ 73,000
General and administrative[(1)]	8,440	5,117	22,579	14,620
Total operating expenses	62,136	34,105	148,677	87,620
Loss from operations	(62,136)	(34,105)	(148,677)	(87,620)
Other income (expense):				
Interest income	12,166	3,832	25,669	11,781
Other income (expense), net	5	(4)	17	(11)
Total other income, net	12,171	3,828	25,686	11,770
Net Loss	$ (49,965)	$ (30,277)	$ (122,991)	$ (75,850)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.63)	$ (0.55)	$ (1.67)	$ (1.40)
Net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	$ (52.40)	$ (45.46)	$ (139.45)	$ (116.94)

Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	71,590,343	44,067,059	63,268,180	42,622,935
Weighted-average shares used in computing net loss per share attributable to Series B non-voting convertible preferred stockholders, basic and diluted	94,497	137,138	122,768	137,138

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 4,740	$ 8,341	$ 12,232	$ 14,712
General and administrative	4,391	1,824	11,151	5,413
Total	$ 9,131	$ 10,165	$ 23,383	$ 20,125