Oruka Therapeutics Reports Third Quarter 2024 Financial Results and Provides Corporate Update

November 13, 2024

Successful go-public transaction and over $475 million raised this year provides cash runway through multiple clinical inflection points

ORKA-001 non-human primate (NHP) pharmacokinetic and in vitro *potency data, presented at EADV in September, further support and derisk the program*

Strong execution allowed for acceleration of clinical timelines for both ORKA-001 and ORKA-002, as previously announced

MENLO PARK, Calif., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Oruka Therapeutics, Inc. ("Oruka") (Nasdaq: ORKA), a biotechnology company developing novel biologics designed to set a new standard for the treatment of chronic skin diseases including plaque psoriasis, today reported third quarter 2024 financial results and provided a corporate update.

"We had a highly eventful third quarter which included going public, closing on over $475 million in proceeds across two transactions and continuing to progress our very promising co-lead programs," said Lawrence Klein, PhD, Chief Executive Officer of Oruka. "We are excited to soon transition to a clinical stage company and show the potential of our programs to raise the bar on what is possible in psoriatic disease."

Third Quarter Business and Pipeline Updates

Corporate

- Oruka consummated its go-public transaction and began trading on the Nasdaq under the ticker ORKA.
- The Company raised over $475 million, including a $275 million private placement previously announced in April that closed concurrently with the merger and an additional $200 million private placement shortly thereafter from a group of new and existing investors.

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

- Oruka plans to initiate a Phase 1 trial of ORKA-001 in the first quarter of 2025, which was accelerated from the first half of 2025. The Company expects to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the second half of 2025 and initial efficacy data in psoriasis patients in the second half of 2026.
- Data presented at the European Academy of Dermatology and Venereology (EADV) Congress showed that ORKA-001 has a half-life in NHP 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 even once a year while maintaining high antibody exposures and further derisk its development path.

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, which was accelerated from the second half of 2025. The Company expects to share interim data from the first-in-human trial in healthy volunteers, including initial pharmacokinetic data, in the first half of 2026.
- A precursor antibody to ORKA-002 showed a half-life in NHP of approximately 20 days, double that seen with bimekizumab, supporting the potential to achieve significantly longer dosing intervals than currently marketed agents targeting IL-17. This extended half-life could enable a dosing interval of once every four to six months for ORKA-002.

Third Quarter 2024 Financial Results

Cash Position: As of September 30, 2024, Oruka had available cash and cash equivalents of $410.9 million. Net cash used in operating activities was $27.8 million for the third quarter of 2024. The Company expects this cash to provide runway through

2027.

Research and Development (R&D) expenses: R&D expenses totaled $25.7 million for the third quarter of 2024. This expense includes $7.8 million of non-cash stock-based compensation. During the third quarter of 2024, the Company incurred $11.8 million and $4.1 million on the development of ORKA-001 and ORKA-002, respectively.

General and Administrative (G&A) expenses: G&A expenses totaled $3.8 million for the third quarter of 2024. This expense includes $2.4 million of personnel-related costs, including $1.2 million of non-cash stock-based compensation related to equity awards to employees and service providers, and $1.3 million for professional, consulting, and other costs to operate a public company and support R&D activities.

Other income (expense): Other income, net for the third quarter of 2024 was $0.8 million. Interest earned on the Company's investment in money market funds was $1.3 million for the third quarter of 2024, partly offset by interest expense of $0.5 million on convertible notes before their conversion to common stock.

Net loss: Net loss totaled $28.6 million for the third quarter of 2024, which includes non-cash stock-based compensation of $9.0 million.

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 Series A and Series B 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, the potency, binding affinity, efficacy and antibody exposures of ORKA-001, including vis-à-vis risankizumab, the potential half-life of ORKA-001 and ORKA-002 and their potential dosing intervals, and Oruka's cash runway. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. 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, including its 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. 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)

Assets	September 30, 2024	February 6, 2024
Current assets:		
Cash and cash equivalents	$ 410,875	$ —
Subscription receivables	—	1
Prepaid expenses and other current assets	2,074	
Total current assets	412,949	1
Property and equipment, net	160	—
Operating lease right-of-use assets	938	—
Other non-current assets	43	—
Total assets	$ 414,090	$ 1
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,145	$ —
Accrued expenses and other current liabilities	1,710	—
Operating lease liability, current	146	—
Related party common stock warrant liability	7,681	—
Related party accounts payable and current liabilities	6,357	—
Total current liabilities	18,039	—
Operating lease liability, non-current	842	—
Total liabilities	18,881	—
Commitments and contingencies		
Preferred stock	52,841	—
Stockholders' equity:		
Preferred stock	2,931	—
Common stock	35	—
Additional paid-in capital	397,345	1
Accumulated deficit	(57,943)	—
Total stockholders' equity	342,368	1
Total liabilities, convertible preferred stock and stockholders' equity	$ 414,090	$ 1

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

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Operating expenses		
Research and development[(1)]	$ 25,691	$ 49,557
General and administrative[(1)]	3,758	8,248
Total operating expenses	29,449	57,805
Loss from operations	(29,449)	(57,805)
Other income (expense)		
Interest income	1,330	1,330
Interest expense	(504)	(1,468)
Total other income (expense), net	826	(138)
Net loss and comprehensive loss	$ (28,623)	$ (57,943)
Net loss per share attributable to common stockholders, basic and diluted	$ 1.46	$ 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	$ 121.76	$ 506.44

Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	15,013,655	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	49,191	19,015

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

	Three Months Ended September 30, 2024	Period from February 6, 2024 (Inception) to September 30, 2024
Research and development	$ 7,772	$ 8,310
General and administrative	1,229	1,459
Total	$ 9,001	$ 9,769