

UNITY Biotechnology, Inc. Reports Third Quarter 2024 Financial Results and Business Updates

November 4, 2024

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2024 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. (UNITY) [NASDAQ:UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today reported financial results for the third quarter ended September 30, 2024.

"As recently discussed on our Ophthalmology Day for investors and analysts, diabetic macular edema represents a large underserved market due to inadequate response to anti-VEGF standard of care, continued vision loss over time despite treatment, and high treatment burden leading to discontinuation," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "We believe that UBX1325 (foselutoclax) with its novel mechanism of action has the potential to improve long-term visual outcomes for DME patients, via a proven and safe intravitreal route of administration. We believe that the readouts from the Phase 2b ASPIRE study comparing UBX1325 to the aflibercept standard of care will provide a definitive dataset to inform the design of a potential pivotal study."

In the third quarter of 2024, UNITY had a Type C interaction with the U.S. Food and Drug Administration, or FDA, regarding the development of UBX1325 (foselutoclax) for DME. Based on that interaction, UNITY expects that a pivotal study would need to be a non-inferiority trial comparing UBX1325 to an approved anti-VEGF agent such as aflibercept. The endpoint for regulatory approval is expected to be an assessment of best-corrected visual acuity (BCVA), as assessed by the ETDRS scale with a non-inferiority margin of 4 letters.

The webcast presentation from the Company's Ophthalmology Investor and Analyst Day is available here.

UBX1325 (foselutoclax) is designed as a novel and durable therapeutic option in diabetic macular edema (DME) that acts via a senolytic mechanism of action, with the potential to address shortcomings of the current standard of care, such as high treatment burden and sub-optimal response to treatment.

UNITY expects topline 24-week primary endpoint data in the first quarter of 2025 and 36-week data in the second quarter of 2025. The Phase 2b ASPIRE study in DME is a multi-center, randomized, double-masked, active-controlled study designed to evaluate the safety and efficacy of UBX1325 in a head-to-head comparison to aflibercept. More information about ASPIRE (NCT06011798) can be found here.

Third Quarter Financial Results

Cash, cash equivalents and marketable securities totaled \$29.0 million as of September 30, 2024 compared with \$43.2 million as of December 31, 2023. UNITY believes that current cash, cash equivalents and marketable securities are sufficient to fund operations into the third quarter of 2025.

Net loss for the three months ended September 30, 2024, was \$6.5 million compared to \$14.8 million for the three months ended September 30, 2023. Cash used in operations during the first, second and third quarters of 2024 was \$15.0 million compared to \$29.5 million during the first, second, and third quarters of 2023.

Research and development expenses decreased by \$1.8 million, to \$2.8 million for three months ended September 30, 2024, from \$4.6 million for the three months ended September 30, 2023. The decrease was primarily due to \$0.9 million in personnel costs due to our reduced headcount related to our reduction in force, \$0.8 million in direct research and development expenses mainly due to the completion of the Phase 2 BEHOLD study of UBX1325 in patients with DME and the Phase 2 ENVISION study of UBX1325 in patients with AMD, and \$0.1 million in operating costs due to reduced fixed assets depreciation and reduced office space.

General and administrative expenses decreased by \$0.5 million, to \$3.8 million for the three months ended September 30, 2024, from \$4.3 million for the three months ended September 30, 2023. The decrease was primarily due to decreases of \$0.5 million in personnel-related expenses due to reduced headcount and the reduction in bonus and severance amounts paid as compared to 2023 and \$0.1 million in operating costs mainly from the continuation of sublease income generated from the East Grand property, partially offset by an increase of \$0.1 million in professional fees and accounting service fees.

About UNITY

UNITY is developing a new class of therapeutics to slow, halt, or reverse diseases of aging. UNITY's current focus is on creating medicines to selectively eliminate or modulate senescent cells and thereby provide transformative benefit in age-related ophthalmologic and neurologic diseases. More information is available at www.unitybiotechnology.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements including statements related to UNITY's understanding of cellular senescence and the role it plays in diseases of aging, the potential for UNITY to develop therapeutics to slow, halt, or reverse diseases of aging, including for ophthalmologic and neurologic diseases, the potential for UNITY to successfully commence and complete clinical studies of UBX1325 for DME, AMD, and other ophthalmologic diseases, the expected timing of enrollment and results of the clinical trials in UBX1325, and UNITY's expectations regarding the sufficiency of its cash runway. These statements involve substantial known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements, including risks related to delay or disruption in the enrollment of patients in clinical trials, risks relating to the uncertainties inherent in the drug development process, and risks relating to UNITY's understanding of senescence biology. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this press release represent our views as of the date of this release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this release. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see UNITY's most recent Quarterly Report on Form 10-Q for the guarter ended September 30, 2024, filed with the Securities and Exchange Commission on November 4, 2024, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission.

Unity Biotechnology, Inc. Statements of Operations and Comprehensive Loss (In thousands, except share and per share amounts)

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | | | |
|---|----------------------------------|------------|-----|------------------------------------|----|-------------|----|------------|
| | | 2024 | | 2023 | | 2024 | | 2023 |
| | | (Unau | dit | ed) | | (Unaudited) | | |
| Operating expenses: | | | | | | | | |
| Research and development | \$ | 2,787 | \$ | 4,632 | \$ | 9,971 | \$ | 16,828 |
| General and administrative | | 3,815 | | 4,347 | | 11,209 | | 14,560 |
| Impairment of long-lived assets | | <u> </u> | _ | 5,602 | | <u> </u> | | 5,602 |
| Total operating expenses | | 6,602 | | 14,581 | | 21,180 | | 36,990 |
| Loss from operations | | (6,602) | | (14,581) | | (21,180) | | (36,990) |
| Interest income | | 396 | | 689 | | 1,424 | | 2,349 |
| Interest expense | | _ | | (566) | | _ | | (2,451) |
| Gain (loss) on warrant liability | | (215) | | 253 | | 2,407 | | 2,283 |
| Other income (expense), net | | (60) | _ | (577) | | (201) | | (711) |
| Net loss | | (6,481) | | (14,782) | | (17,550) | | (35,520) |
| Other comprehensive gain (loss) | | _ | | <u> </u> | | <u> </u> | | |
| Unrealized gain (loss) on marketable debt securities | | 74 | | 81 | | 63 | | 196 |
| Comprehensive loss | \$ | (6,407) | \$ | (14,701) | \$ | (17,487) | \$ | (35,324) |
| Net loss per share, basic and diluted | \$ | (0.38) | \$ | (1.01) | \$ | (1.04) | \$ | (2.46) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | | 16,849,283 | | 14,598,218 | | 16,816,706 | | 14,446,672 |

Unity Biotechnology, Inc. Condensed Balance Sheets (In thousands)

| | September 30, 2024 | | December 31, 2023 | |
|---|-----------------------|-----------|----------------------|-----------|
| | (Una | udited) | | |
| Assets | • | - | | |
| Current Assets: | | | | |
| Cash and cash equivalents | \$ | 8,898 | \$ | 19,803 |
| Short-term marketable securities | | 20,139 | | 23,398 |
| Prepaid expenses and other current assets | | 1,226 | | 3,404 |
| Total current assets | | 30,263 | | 46,605 |
| Property and equipment, net | | 4,414 | | 5,082 |
| Operating lease right-of-use assets | | 11,359 | | 12,981 |
| Long-term restricted cash | | 896 | | 896 |
| Other long-term assets | | 200 | | 126 |
| Total assets | \$ | 47,132 | \$ | 65,690 |
| Liabilities and Stockholders' Equity | | | | |
| Current liabilities: | | | | |
| Accounts payable | \$ | 1,804 | \$ | 1,380 |
| Accrued compensation | | 1,704 | | 1,841 |
| Accrued and other current liabilities | | 5,276 | | 4,619 |
| Total current liabilities | | 8,784 | | 7,840 |
| Operating lease liability, net of current portion | | 20,698 | | 23,539 |
| Warrant liability | | 3,506 | | 5,913 |
| Total liabilities | | 32,988 | | 37,292 |
| Commitments and contingencies | | | | _ |
| Stockholders' equity: | | | | |
| Common stock | | 2 | | 2 |
| Additional paid-in capital | | 516,006 | | 512,773 |
| Accumulated other comprehensive gain | | 39 | | (24) |
| Accumulated deficit | | (501,903) | | (484,353) |
| Total stockholders' equity | | 14,144 | | 28,398 |
| Total liabilities and stockholders' equity | \$ | 47,132 | \$ | 65,690 |

Media

Inizio Evoke Comms Katherine Smith katherine.smith@inizioevoke.com

Investor Contact LifeSci Advisors, LLC Joyce Allaire

jallaire@lifesciadvisors.com



Source: Unity Biotechnology, Inc.