# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

## CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 11, 2021**

# UNITY BIOTECHNOLOGY, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-38470** | **26-4726035** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification Number)** |

**285 East Grand Ave.**
**South San Francisco, CA 94080**
**(Address of principal executive offices, including Zip Code)**

**Registrant's telephone number, including area code: (650) 416-1192**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.0001 per share | UBX | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02 Results of Operations and Financial Condition.**

On May 11, 2021, Unity Biotechnology, Inc. (the "Company") announced its financial results for the first quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including the attached Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

Reference is made to the Exhibit Index attached hereto.

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated May 11, 2021. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**UNITY BIOTECHNOLOGY, INC.**

Date: May 11, 2021

By: /s/ Anirvan Ghosh
Anirvan Ghosh, Ph.D.
Chief Executive Officer

# UNITY Biotechnology, Inc. Reports First Quarter 2021 Financial Results and Business Updates

***- UBX1325 demonstrates favorable tolerability in Phase 1 safety study with initial evidence of relevant biological activity***

***- Phase 2a proof-of-concept study initiated in patients with diabetic macular edema; data expected first half of 2022***

***- Cash balance sufficient to fund operations into second half of 2022***

**SOUTH SAN FRANCISCO, Calif., May 11, 2021 (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 first quarter ended March 31, 2021.

“The highlight of the quarter was the completion of the initial assessment of patients in our Phase 1 safety study of UBX1325, a senolytic molecule that has the potential to promote reparative vascular remodeling in the retina in various age-related eye diseases such as diabetic macular edema and age-related macular degeneration and could provide a disease-modifying alternative to current VEGF-targeting therapies,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “We are excited by this safety and tolerability data as well as initial evidence of relevant biological activity, and are very pleased to have initiated a Phase 2a proof-of-concept study of UBX1325.”

## Key Business Highlights

*Ophthalmology – UBX1325*

In October 2020, UNITY began its Phase 1 study of UBX1325 in patients with diabetic macular edema (DME) and wet age-related macular degeneration (AMD). The ongoing Phase 1 study includes patients with a diagnosis of DME or AMD with significant visual impairment and who are no longer candidates for anti-vascular endothelial growth factor (VEGF) therapy. UBX1325, the first senolytic agent to be administered to these patient populations, has been well tolerated with no significant treatment-associated adverse events in either disease population.

The initial assessment of the Phase 1, first-in-human, open-label, single-ascending dose study included 12 patients with advanced DME or wet AMD. The primary outcome measure is ocular and systemic safety and tolerability of a single intravitreal injection of UBX1325 evaluated by the incidence of dose limiting toxicities (DLTs) and treatment emergent adverse events (TEAEs) reported up to 24 weeks after administration. The single intravitreal injection of UBX1325 was well tolerated and had no adverse findings that would limit advancement of UBX1325 into further clinical investigation. Based on prospectively determined safety criteria, the Phase 1 study was able to dose-escalate beyond the originally planned 5 mcg dose up to 10 mcg, which will inform the final dose for the Phase 2a study in DME which is expected to read out in 2022. In addition, based on encouraging early data, UNITY intends to recruit additional patients with wet AMD into the Phase 1 study to potentially support an additional, independent Phase 2a study in wet AMD, which could also read out in 2022. The company intends to share details of the activity profile of UBX1325 from this Phase 1 study, including data on best-corrected visual acuity (BCVA), central subfield thickness (CST), and sub-retinal fluid (SRF), in the coming months.

Based on this initial data, UNITY has initiated a Phase 2a proof-of-concept study to evaluate the safety, efficacy, and durability of a single intravitreal injection of UBX1325 in a broader population of patients with DME. Approximately 60 patients will be enrolled in the study, randomized evenly between UBX1325 and sham-injected patients, and followed for 24 weeks post-injection. Endpoints being explored in the study include safety and tolerability, improvements in BCVA, CST, SRF, and durability of effect. UNITY anticipates receiving initial results from the Phase 2a proof-of-concept study in patients with DME in the first of half of 2022.

“Mounting evidence shows an accumulation of senescent cells in diseased retinal and choroidal tissue associated with the vasculature – hallmarks of diabetic eye disease and other age-related eye diseases,” said Jamie Dananberg, M.D., chief medical officer of UNITY. “Senolytics represent a potential new class of medicine designed to selectively target diseased blood vessels to reduce vascular leakage, allow healthy vascular remodeling, and restore retinal function. We find the data we have seen to date very promising and look forward to evaluating both the safety and efficacy of UBX1325 in advanced clinical studies.”

*Operational Highlights*

**First Quarter Financial Results**

Cash, cash equivalents, and marketable securities totaled $110.2 million as of March 31, 2021 compared with $115.6 million as of December 31, 2020. UNITY believes that current cash, cash equivalents, and marketable securities are sufficient to fund operations into the second half of 2022.

Operating loss for the three months ended March 31, 2021 was $14.9 million compared to $27.2 million for the three months ended March 31, 2020. Cash used in operations during the first quarter of 2021 was $15.1 million compared to $25.1 million for the first quarter of 2020.

Research and development expenses decreased by $10.6 million, to $8.7 million for the three months ended March 31, 2021, from $19.3 million for the three months ended March 31, 2020. The decrease was primarily due to decreases of $6.0 million in direct research and development expenses due to termination of osteoarthritis studies, $2.8 million in personnel costs due to reduction in force, $0.9 million in laboratory supplies, and $0.9 million in facilities-related costs.

General and administrative expenses increased by $0.3 million, to $6.2 million for the three months ended March 31, 2021, from $5.9 million for the three months ended March 31, 2020. The increase was primarily due to increases of $0.4 million in facilities-related costs and $0.1 million in insurance-related expense, offset by a decrease of $0.2 million in professional 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.

**About UBX1325**

UBX1325 is an investigational compound being studied for age-related diseases of the eye, including diabetic macular edema (DME), age-related macular degeneration (AMD), and diabetic retinopathy (DR). UBX1325 is a potent small molecule inhibitor of Bcl-xL, a member of the Bcl-2 family of apoptosis-regulatory proteins. UBX1325 is designed to inhibit the function of proteins senescent cells rely on for survival. In preclinical studies, UNITY has demonstrated that targeting Bcl-xL with UBX1325 preferentially eliminates senescent cells from diseased tissue while sparing healthy cells. UNITY's goal with UBX1325 is to transformationally improve real-world outcomes for patients with DME, AMD, and DR.

**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, our expectations regarding potential benefits, activity, effectiveness, and safety of UBX1325, the potential for UNITY to successfully commence and complete clinical studies of UBX1325 for DME, AMD, and other ophthalmologic diseases, the expected timing of results of our studies of UBX1325, the timing of the expected commencement, progression, and conclusion of our studies including those of 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 the risk that the COVID-19 worldwide pandemic may continue to negatively impact the development of preclinical and clinical drug candidates, including delaying or disrupting 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 UNITY in general, see UNITY's most recent Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the Securities and Exchange Commission on May 11, 2021, 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 March 31, | |
|---|---|---|
| | 2021 | 2020 |
| | (Unaudited) | |
| Operating expenses: | | |
| Research and development | $ 8,717 | $ 19,265 |
| General and administrative | 6,226 | 5,953 |
| Change in fair value of contingent consideration | — | (221) |
| Impairment of long-lived assets | — | 2,159 |
| Total operating expenses | 14,943 | 27,156 |
| Loss from operations | (14,943) | (27,156) |
| Interest income | 36 | 527 |
| Interest expense | (775) | — |
| Other expense | (74) | (1,409) |
| Net loss | (15,756) | (28,038) |
| Other comprehensive loss | | |
| Unrealized gain on marketable debt securities | 10 | 283 |
| Comprehensive loss | $ (15,746) | $ (27,755) |
| Net loss per share, basic and diluted | $ (0.29) | $ (0.59) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 54,169,349 | 47,544,401 |

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

| | March 31, 2021 (Unaudited) | December 31, 2020 |
|---|---|---|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 26,842 | $ 17,807 |
| Short-term marketable securities | 73,617 | 79,892 |
| Prepaid expenses and other current assets | 1,582 | 3,167 |
| Total current assets | 102,041 | 100,866 |
| Property and equipment, net | 11,941 | 12,627 |
| Operating lease right-of-use assets | 22,967 | 23,509 |
| Long-term marketable securities | 9,790 | 17,871 |
| Restricted cash | 1,446 | 1,446 |
| Total assets | $ 148,185 | $ 156,319 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | $ 1,975 | $ 2,558 |
| Accrued compensation | 1,839 | 5,355 |
| Accrued and other current liabilities | 6,455 | 6,550 |
| Total current liabilities | 10,269 | 14,463 |
| Operating lease liability, net of current portion | 33,264 | 34,468 |
| Long-term debt, net | 24,699 | 24,508 |
| Total liabilities | 68,232 | 73,439 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock | 5 | 5 |
| Additional paid-in capital | 435,198 | 422,379 |
| Related party promissory notes for purchase of common stock | — | (210) |
| Promissory notes for purchase of common stock | (210) | — |
| Accumulated other comprehensive gain | 15 | 5 |
| Accumulated deficit | (355,055) | (339,299) |
| Total stockholders' equity | 79,953 | 82,880 |
| Total liabilities and stockholders' equity | $ 148,185 | $ 156,319 |

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