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): February 25, 2020

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 Avenue
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 (see General Instructions A.2. below):

☐ 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 Pipeline and Business Updates

On February 25, 2020, Unity Biotechnology, Inc., a Delaware corporation ("UNITY" or the "Company"), issued a press release announcing, among other things, UNITY's cash, cash equivalents and investments (unaudited) as of December 31, 2019. The full text of the press release is furnished herewith as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for 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, or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

On February 25, 2020, UNITY announced that the its Phase 2 study of UBX0101 in patients with moderate-to-severe osteoarthritis ("OA") of the knee is now fully enrolled. Both 12- and 24-week results are now expected in the second half of 2020. In addition, UNITY announced that it had dosed the first patients in a Phase 1b study to explore the safety, tolerability and initial efficacy of a higher dose (8.0 mg) and repeated doses (4.0 mg x 2, separated by 1 month) of UBX0101. The study is expected to enroll approximately 36 patients with 12-week results expected in the second half of 2020.

UNITY further announced that its lead ophthalmology candidates, UBX1325 and UBX1967, are currently in the final phases of Investigational New Drug ("IND") enabling non-clinical toxicology studies. Both senolytic molecules are inhibitors of particular members of the Bcl-2 family of apoptosis regulatory proteins which have shown distinct pharmacokinetic profiles in preclinical studies. UNITY intends to complete IND-enabling studies for both molecules prior to selecting the first molecule to advance to a first-in-human study to explore safety and tolerability of this novel mechanism of action for age-related eye diseases. UNITY expects to initiate a Phase 1 safety study for this program in the second half of 2020. The overall clinical program is directed at multiple age-related diseases of the eye, such as age-related macular degeneration, diabetic retinopathy and diabetic macular edema.

Finally, UNITY announced that as of December 31, 2019, UNITY's cash, cash equivalents and investments were $125.0 million (unaudited). UNITY believes that cash, cash equivalents and investments are sufficient to fund operations into the second half of 2021. UNITY expects to release its audited financial results for fiscal year 2019 on March 11, 2020.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press release dated February 25, 2020.

Forward-Looking Statements

To the extent that statements contained herein are not descriptions of historical facts regarding UNITY, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements related to UNITY's understanding of cellular senescence and the role cellular senescence plays in age-related diseases; the potential for UNITY to develop medicines that eliminate senescent cells; the potential benefits, activity, effectiveness and safety of UBX0101 in patients with OA of the knee; the design of, pace of enrollment in, and timing of data read out from UNITY's Phase 2 OA study; the design of, pace of enrollment in, and timing of data read out from UNITY's Phase 1b OA study; the mechanism of action and pharmacokinetic profiles of UBX1325 and UBX1967; UNITY's ability to successfully complete ongoing pre-clinical studies of UBX1325 and UBX1967; the timing of initiation of the first Phase 1 study of UBX1325 or UBX1967 in age-related eye diseases; the potential scope of UNITY's overall clinical program in age-related eye diseases; and UNITY's expectations with regard to the sufficiency of its cash runway. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. For a 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 reports filed with the Securities and Exchange Commission ("SEC"), including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 6, as well as other documents that may be filed by the Company from time to time with the SEC.

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: February 25, 2020

By: /s/ Robert C. Goeltz II
Robert C. Goeltz II
Chief Financial Officer

Exhibit 99.1

UNITY Biotechnology Provides Pipeline and Business Updates

– Phase 2 study of UBX0101 in patients with osteoarthritis has completed enrollment –

– Topline 12- and 24-week results now expected in 2H 2020 –

– First patient dosed in phase 1b study to explore higher dose and repeat doses –

– First-in-human study initiation for ophthalmology program expected in 2H 2020 –

SAN FRANCISCO, Calif., February 25, 2020 (GLOBE NEWSWIRE) — UNITY Biotechnology, Inc. (UNITY) [NASDAQ:UBX], a biotechnology company developing therapeutics to extend healthspan by slowing, halting or reversing diseases of aging, today provided pipeline and business updates.

Recent Highlights and Business Updates

Osteoarthritis – UBX0101

In October 2019 UNITY announced that the first patient had been dosed in a Phase 2 study of UBX0101, an inhibitor of the MDM2/p53 protein-protein interaction, in patients with moderate-to-severe osteoarthritis (OA) of the knee. The study is now fully enrolled with 183 patients. The study is randomized, double-blind, and placebo-controlled and will evaluate three doses (0.5 mg, 2.0 mg and 4.0 mg) of UBX0101 administered via a single intra-articular injection. Both 12- and 24-week results are now expected in the second half of 2020.

“We are pleased to announce the completion of enrollment ahead of schedule in our Phase 2 study of UBX0101 in patients with moderate-to-severe osteoarthritis of the knee,” said Keith Leonard, chairman and chief executive officer of UNITY. “We believe the rapid enrollment of this study can, in part, be explained by the significant unmet need of patients suffering from this debilitating condition. We now anticipate that both the 12-week and 24-week data will be available in the second half of this year.”

UNITY has also dosed the first patients in a Phase 1b study to explore the safety, tolerability and initial efficacy of a higher dose (8.0 mg) and repeated doses (4.0 mg x 2, separated by 1 month) of UBX0101. The study is expected to enroll approximately 36 patients with 12-week results expected in the second half of 2020.

Ophthalmology

UNITY’s lead ophthalmology candidates, UBX1325 and UBX1967, are currently in the final phases of Investigational New Drug (IND) enabling non-clinical toxicology studies. Both senolytic molecules are inhibitors of particular members of the Bcl-2 family of apoptosis regulatory proteins which have shown distinct pharmacokinetic profiles in preclinical studies. UNITY intends to complete IND-enabling studies for both molecules prior to selecting the first molecule to advance to a first-in-human study to explore safety and tolerability of this novel mechanism of action for age-related eye diseases. UNITY expects to initiate a Phase 1 safety study for this program in the second half of 2020. The overall clinical program is directed at multiple age-related diseases of the eye, such as age-related macular degeneration, diabetic retinopathy and diabetic macular edema.

Cash Update

As of December 31, 2019 cash, cash equivalents and investments were $125.0 million (unaudited). UNITY expects this is sufficient to fund operations into the second half of 2021.

UNITY expects to release its audited financial results for 2019 on March 11, 2020.

About UBX0101

UBX0101 is being evaluated for the treatment of musculoskeletal disease, with an initial focus on osteoarthritis (OA) of the knee. UBX0101 is a small molecule inhibitor of the MDM2/p53 protein-protein interaction. UBX0101 binds to MDM2, raising p53 levels which in turn, we believe, causes the elimination of senescent cells. Initial results from a Phase 1 clinical trial in patients with moderate-to-severe OA of the knee were announced in June 2019. The study demonstrated that UBX0101 was well-tolerated. Dose-dependent improvement in several clinical measures, including pain and function, as well as modulation of multiple senescence-associated secretory phenotype (SASP) factors and disease-related biomarkers, was observed after a single dose of UBX0101.

About Osteoarthritis

OA is a degenerative disease that negatively impacts cartilage, subchondral bone and the synovial tissue lining the joint, causing pain and physical impairment. OA is a highly prevalent disease, symptomatically affecting as many as 10% to 15% of the world's population over age 60, and results in a decline in quality of life. The most common joint affected by OA is the knee. Importantly, the current standard of care addresses only the symptoms of OA, which temporarily reduces joint inflammation and pain.

About Opthalmology (Age-Related Eye Diseases)

The majority of significant eye diseases are age-related, with the prevalence of vision-threatening disease increasing significantly over the age of 75. Of the 285 million individuals worldwide living with visual impairment, 65% are over the age of 50. The individual diseases that are associated with these figures include age-related macular degeneration, diabetic eye diseases and glaucoma, all of which have a high prevalence and significant unmet need in either prevention or therapeutic options.

About UNITY

UNITY is developing therapeutics to extend healthspan with an initial focus on cellular senescence. UNITY believes that the accumulation of senescent cells is a fundamental mechanism of aging and a driver of many common age-related diseases. Cellular senescence is a natural biological state in which a cell permanently halts division. As senescent cells accumulate with age, they begin secreting inflammatory factors, proteases, fibrotic factors, and growth factors, that disturb the tissue micro-environment. This collection of secreted proteins is referred to as the Senescence Associated Secretory Phenotype, or SASP. UNITY is developing senolytic

medicines to eliminate senescent cells and thereby stop the production of the SASP, which UNITY believes addresses a root cause of age-related diseases. By stopping the production of the SASP at it source, UNITY believes senolytic medicines could slow, halt, or reverse diseases such as osteoarthritis and age-related eye diseases. More information is available at www.unitybiotechnology.com or follow us on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements, including: statements related to UNITY's understanding of cellular senescence and the role cellular senescence plays in age-related diseases; the potential for UNITY to develop medicines that eliminate senescent cells; the potential benefits, activity, effectiveness and safety of UBX0101 in patients with OA of the knee; the design of, pace of enrollment in, and timing of data read out from UNITY's Phase 2 OA study; the design of and timing of data read out from UNITY's Phase 1b OA study; the mechanism of action and pharmacokinetic profiles of UBX1325 and UBX1967; UNITY's ability to successfully complete ongoing pre-clinical studies of UBX1325 and UBX1967; the timing of initiation of the first Phase 1 study of UBX1325 or UBX1967 in age-related eye diseases; the potential scope of UNITY's overall clinical program in age-related eye diseases; and UNITY's expectations with regard to 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. 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 recently filed Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the Securities and Exchange Commission on November 6, 2019, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission. This press release concerns drug candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

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