# 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): June 18, 2019**

# 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)** |

**3280 Bayshore Blvd, Suite 100**
**Brisbane, CA 94005**
**(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** | **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 8.01 Other Events**

On June 18, 2019, Unity Biotechnology, Inc., a Delaware corporation ("UNITY" or the "Company") announced top-line results from its Phase 1 clinical study of UBX0101 in patients with moderate to severe osteoarthritis ("OA") of the knee. In the study, UBX0101 was well-tolerated and demonstrated improvement in several clinical measures, including pain and function. In addition, modulation of certain senescence-associated secretory phenotype ("SASP") factors and disease-related biomarkers was observed after a single dose of UBX0101. The Company expects to present additional data from its Phase 1 clinical study of UBX0101 at an upcoming scientific meeting.

The Phase 1 clinical study of UBX0101 in patients with moderate to severe OA is a randomized, double-blind, placebo-controlled study evaluating the safety, tolerability and pharmacokinetics of a single intra-articular injection of UBX0101 in patients diagnosed with moderate to severe painful OA of the knee. UBX0101 is a p53/MDM2 interaction inhibitor that targets selective elimination of senescent cells.

In Part A of the study, 48 patients were randomly assigned to receive one of six dose levels of UBX0101 (between 0.1 mg to 4.0 mg) or placebo in a 3-to-1 randomization by dose level cohort. Primary endpoints were safety and tolerability. Secondary and exploratory endpoints included plasma pharmacokinetics, synovitis as measured by MRI, pain, and measurement of SASP factors and disease-related biomarkers present in synovial fluid and plasma. Patients randomized had a mean age of 62 years and 67% were female, with a modest imbalance with respect to race and ethnicity.

In Part B of the study, 30 patients were randomized to receive UBX0101 (4.0 mg dose) or placebo in a 2-to-1 randomization by dose level cohort. Primary endpoints were safety and tolerability. Secondary and exploratory endpoints included changes in the levels of SASP factors and disease-related biomarkers present in synovial fluid and plasma, and pain. Synovial fluid samples were obtained at baseline and four weeks post-treatment. Patients randomized had a mean age of 61 years and 50% were female, with a modest imbalance with respect to race and ethnicity.

*Safety, Tolerability and Pharmacokinetics*

In Part A of the study, UBX0101 was well-tolerated up to the maximum administered dose of 4.0 mg. Approximately 58% of patients reported treatment-emergent adverse events, there were no serious adverse events and no patients discontinued because of an adverse event. There were no dose-dependent adverse events or relevant clinical laboratory findings. The majority (66%) of adverse events were mild, with the most common adverse events being nasopharyngitis (a cold), procedural pain, arthralgia (joint pain) and headache.

In Part B of the study, UBX0101 was well-tolerated at the 4.0 mg dose. Approximately 26.7% of patients reported treatment-emergent adverse events, there were no serious adverse events and no patients discontinued because of an adverse event. The majority (75%) of adverse events were mild and there were no relevant clinical laboratory findings, with the most common adverse events being procedural pain and arthralgia (joint pain).

UBX0101 demonstrated dose-proportional plasma pharmacokinetics. Model-based predictions of concentrations within the knee suggested that doses at or above 1 mg may be pharmacologically active. This informed the prospectively defined low dose (0.1, 0.2, and 0.4 mg) and high dose (1.0, 2.0, and 4.0 mg) groupings for analyses.

*Secondary Endpoints – Pain Measurements*

During the Phase 1 clinical study of UBX0101, evaluation of pain was measured using the Numeric Rating Scale ("NRS") and the Western Ontario and McMaster Universities Arthritis Index ("WOMAC") A (pain). To report pain severity on the NRS, patients select an integer ranging from 0 to 10 corresponding to the degree of severity of their pain, where 0 represents no pain and 10 represents the worst pain imaginable. NRS scores were measured at baseline and once each week for a period of 12 weeks. To report pain severity on WOMAC-A, patients provide responses to a standardized questionnaire and the responses are then scored ranging from 0 to 4 corresponding to the degree of severity of their pain, where 0 represents no pain and 4 represents severe pain. WOMAC-A scores were measured at baseline and at one, two, four, eight and 12 weeks from initial treatment.

In Part A of the study, evaluation of pain by NRS measured at 12 weeks demonstrated a dose-dependent and clinically meaningful reduction. The range of mean baseline values was between 5.90 to 6.76.

| | Part A: NRS | |
|---|---|---|
| | CFBL | Pbo-Adj |
| Placebo (n = 14) | -1.96 | NA |
| Low doses (n = 16) | -2.66 | -0.65 (p = 0.42) |
| High doses (n = 18) | -3.95 | -1.98 (p < 0.01) |

*CFBL = change from baseline; Pbo-Adj = placebo adjusted; low doses = 0.1, 0.2, and 0.4 mg; high doses = 1.0, 2.0, and 4.0 mg*

In Part A of the study, evaluation of pain by WOMAC-A mean item score measured at 12 weeks demonstrated a dose-dependent and clinically meaningful reduction. The range of mean baseline values was between 1.80 to 2.36.

| | Part A: WOMAC-A | |
|---|---|---|
| | CFBL | Pbo-Adj |
| Placebo (n = 14) | -0.74 | NA |
| Low doses (n = 16) | -0.49 | +0.23 (p = 0.43) |
| High doses (n = 18) | -1.09 | -0.41 (p = 0.07) |

*CFBL = change from baseline; Pbo-Adj = placebo adjusted; low doses = 0.1, 0.2, and 0.4 mg; high doses = 1.0, 2.0, and 4.0 mg*

In addition, 100% of patients receiving the 4.0 mg dose reached a clinically meaningful reduction of mean item score of 0.5 and 50% of such patients achieved a reduction of mean item score of greater than 1.5.

In Part B of the study, pain evaluation using WOMAC-A, measured at four weeks, showed a numerical reduction that was not significantly different from placebo.

*Secondary Endpoints – Function*

In Part A of the study, evaluation of function by WOMAC-C mean item score (0-4 point scale) demonstrated a dose-dependent and clinically meaningful improvement. The range of mean baseline values was between 1.40 to 2.47.

| | PART A: WOMAC-C | |
|---|---|---|
| | CFBL | Pbo-Adj |
| Placebo (n = 14) | -0.72 | NA |
| Low doses (n = 16) | -0.49 | +0.22 (p = 0.43) |
| High doses (n = 18) | -1.05 | -0.35 (p = 0.13) |

*CFBL = change from baseline; Pbo-Adj = placebo adjusted; low doses = 0.1, 0.2, and 0.4 mg; high doses = 1.0, 2.0, and 4.0 mg*

In Part B of the study, evaluation of function by WOMAC-C, measured at four weeks, showed a numerical reduction that was not significantly different from placebo.

*Secondary Endpoints – Other*

Evaluation of stiffness by WOMAC-B mean item score (0-4 point scale) resulted in no significant differences between UBX0101 and placebo in changes in stiffness in either Part A or Part B of the study.

In Part A of the study, patients were also evaluated using a patient global impression of change measurement. Patient global impression of change is a summary measure of treatment benefit from the perspective of the patient measuring their perception of improvement or worsening of their condition. In Part A of the study, a higher proportion of patients reported being “much improved” or “very much improved” versus placebo (placebo = 42.9%, low doses = 50.0%, high doses = 61.1%).

*Exploratory Measures*

In Parts A and B of the study, patients underwent knee MRI imaging with contrast enhancement and arthroscopy in order to evaluate synovial inflammation using an 11-region semi-quantitative scoring system, where inflammation in each region was scored 0 to 2 for a possible range of 0 to 22. No statistically significant change at any dose level was demonstrated as compared to placebo.

In Part A of the study, an insufficient number of matched samples were collected due to a lack of adequate levels of synovial fluid in patients for sampling. Therefore, an analysis of change in biomarkers from baseline to 12 weeks was not performed.

In Part B of the study, 19 biomarkers were analyzed across 20 matched pair patient samples. In approximately half the biomarkers measured in synovial fluid (treatment versus placebo) modulation of SASP factors was observed in a manner we believe to be consistent with elimination of senescent cells and potential improvement in the tissue environment. Changes were observed in MMPs, tissue remodeling factors, and inflammatory cytokines, including: MMP-3, MMP-10, MMP-12, MMP-13, IL-6, IL-10, CCL20 (MIP-3alpha), A2M, ICAM-1 and VEGF-C.

**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 the Company's understanding of cellular senescence and the role cellular senescence plays in diseases of aging, the Company's expectations regarding the potential benefits, activity, effectiveness and safety of UBX0101, and the Company's expectations with regard to the timing, availability and implications of the results of its clinical studies. 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 March 31, 2019, filed with the SEC on May 8, 2019, 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: July 3, 2019

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