UNITY Biotechnology, Inc. Reports Second Quarter 2022 Financial Results and Business Updates

August 12, 2022

- Announced Positive Data in Phase 2 BEHOLD Study of UBX1325 in Patients with Diabetic Macular Edema; single injection in subjects led to statistically significant and clinically meaningful improvement in BCVA and CST with favorable safety profile at 12 and 18 weeks -

- Near-Term Milestones include 24-week Data in BEHOLD and 16-week Data in Phase 2 ENVISION Study of UBX1325 in Patients with Wet Age-Related Macular Degeneration by Year-End -

- Tie2/VEGF Bispecific Program Achieved Advanced Candidate Nomination -

- As of June 30, 2022, UNITY had approximately $64.5 million in cash, cash equivalents and marketable securities, providing runway through Q1 2023 -

SOUTH SAN FRANCISCO, Calif., Aug. 12, 2022 (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 second quarter ended June 30, 2022.

“We are thrilled with the recent data announced in our BEHOLD Study in patients with DME and are grateful for the support and enthusiasm from our physician community and other stakeholders,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “The sustained and significant improvement in visual acuity after a single injection of UBX1325 is very impressive, and , if approved, could provide an attractive treatment option for patients who currently can only hope to maintain their vision at the cost of frequent injections with current standard of care. We look forward to sharing our 24-week data in BEHOLD as we continue to investigate UBX1325, along with 16-week data in ENVISION, our study in wet age-related macular degeneration.”

As reported on August 12, 2022, the Company announced positive 12- and 18-week data in its Phase 2 BEHOLD Study of UBX1325 in Patients with Diabetic Macular Edema:

Evidence of favorable safety, vision improvement, and structural stability in a difficult-to-treat patient population:

Overall Safety
UBX1325 demonstrated a favorable safety and tolerability profile with no cases of intraocular inflammation, retinal vein occlusion, endophthalmitis, or vasculitis.

At 12 weeks (primary analysis set of 65 patients)

- Patients enrolled in BEHOLD were receiving regular anti-VEGF treatment prior to enrollment into the study with the last anti-VEGF injection occurring 3 – 6 weeks prior to randomization
- Patients treated with UBX1325 had a mean improvement in BCVA of +4.7 ETDRS letters compared to +1.3 ETDRS letters in sham-treated patients (p=0.1148)
- Patients treated with UBX1325 had a mean change in CST of -1.4 microns from baseline compared to +40.3 microns in sham-treated patients (p=0.0747)

At 18 weeks (primary analysis set of 54 patients)

- Patients treated with UBX1325 had a mean improvement in BCVA of +6.1 ETDRS letters compared to +1.1 EDTRS letters in sham-treated patients (p=0.0368)
- Patients treated with UBX1325 had a mean change from baseline in CST of +3.2 microns compared to +53.5 microns in sham-treated patients (p=0.0719)

Based on pre-defined proof-of-concept criteria of alpha=0.15, the study demonstrated a statistically significant treatment effect for both BCVA and CST at both timepoints.

In addition, the Company’s Tie2/VEGF bispecific drug development candidate obtained the preclinical data to support its selection as an advanced candidate. Tie2 is a receptor tyrosine kinase that is implicated in regulating barrier function in blood vessels of the eye, which are affected in several prevalent eye diseases. The Tie2/VEGF preclinical program targeting both Tie2 and VEGF is designed to neutralize VEGF and activate Tie2, two major pathways involved in retinal disease.

Upcoming Milestones

- UBX1325 24-week safety and efficacy data from BEHOLD, the Phase 2 DME clinical trial (UBX1325-02 Study) before year-end 2022
- UBX1325 16-week safety and efficacy data from ENVISION, the Phase 2 wAMD clinical trial (UBX1325-03 Study) expected before year-end 2022
- Tie2/VEGF bispecific preclinical data to support selection of development candidate by year-end 2022

Second Quarter Financial Results

Cash, cash equivalents and marketable securities totaled $64.5 million as of June 30, 2022, compared with $79.2 million as of March 31, 2022. UNITY believes that current cash, cash equivalents, and marketable securities are sufficient to fund operations through the first quarter of 2023.

Operating loss for the three months ended June 30, 2022, was $12.3 million compared to $17.0 million for the three months ended June 30, 2021. Cash used in operations during the first and second quarters of 2022 was $29.8 million compared to $28.5 million for the first and second quarters of 2021.

Research and development expenses decreased by $3.5 million, to $7.5 million for the three months ended June 30, 2022 from $11.0 million for the three months ended June 30, 2021. The decrease was primarily due to decreases of $1.4 million in direct research and development expenses mainly due to the $2.0 million milestone payment to Ascentage Pharma during the three months ended June 30, 2021, $0.7 million in personnel costs due to reduction in force, $0.5 million in laboratory supplies and $0.9 million in facilities-related and other operating costs due to allocation to general and administrative expenses of net expenses on Brisbane and East Grand facilities which have been subleased.

General and administrative expenses decreased by $1.0 million, to $5.0 million for the three months ended June 30, 2022 from $6.0 million for the three months ended June 30, 2021. The decrease was primarily due to decreases of $0.7 million in personnel costs mainly due to reduction in force, $0.2 million in professional fees and $0.1 million in facilities-related and other operating costs.

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 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 June 30, 2022, filed with the Securities and Exchange Commission on August 12, 2022, 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
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Licensing revenue - related party	236	—	$ 236	—
Operating expenses:				
Research and development	7,553	11,016	$ 20,014	$ 19,733
General and administrative	4,941	5,980	10,747	12,206
Total operating expenses	12,494	16,996	30,761	31,939
Loss from operations	(12,258)	(16,996)	(30,525)	(31,939)

Interest income	58	26	87	62
Interest expense	(894)	(784)	(1,702)	(1,559)
Other income (expense), net	(43)	(72)	88	(146)
Net loss	(13,137)	(17,826)	(32,052)	(33,582)
Other comprehensive (loss) gain				
Unrealized loss on marketable debt securities	(11)	(10)	(143)	—
Comprehensive loss	$ (13,148)	$ (17,836)	$ (32,195)	$ (33,582)
Net loss per share, basic and diluted	$ (0.19)	$ (0.32)	$ (0.47)	$ (0.62)
Weighted-average number of shares used in computing net loss per share, basic and diluted	69,247,818	54,859,727	68,392,934	54,516,445

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 19,442	$ 32,905
Short-term marketable securities	45,065	55,170
Prepaid expenses and other current assets	2,765	1,879
Restricted cash	550	550
Total current assets	67,822	90,504
Property and equipment, net	8,697	9,942
Operating lease right-of-use assets	20,116	21,286
Long-term marketable securities	—	1,993
Long-term restricted cash	896	896
Other long-term assets	62	91
Total assets	$ 97,593	$ 124,712
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,437	$ 1,985
Accrued compensation	3,291	4,028
Accrued and other current liabilities	4,604	6,370
Deferred revenue	—	216
Derivative liability related to debt	—	963
Current portion of long-term debt	7,087	3,055
Total current liabilities	16,419	16,617
Operating lease liability, net of current portion	28,573	30,094
Long-term debt, net	12,670	18,409
Other long-term liabilities	—	23
Total liabilities	57,662	65,143
Commitments and contingencies		
Stockholders' equity:		
Common stock	7	6
Additional paid-in capital	472,187	459,631
Accumulated other comprehensive loss	(187)	(44)
Accumulated deficit	(432,076)	(400,024)
Total stockholders' equity	39,931	59,569
Total liabilities and stockholders' equity	$ 97,593	$ 124,712

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