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

August 10, 2021

UBX1325 demonstrates favorable tolerability in Phase 1 safety study and improvement in visual acuity and central subfield thickness in majority of patients with diabetic macular edema (DME) and wet age-related macular degeneration (AMD)

Results from Phase 1 study of UBX1325 in additional patients with wet AMD expected by end of year

UBX1325 Phase 2a proof-of-concept study enrolling patients with DME; data expected first half of 2022

SOUTH SAN FRANCISCO, Calif., Aug. 10, 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 second quarter ended June 30, 2021.

“This quarter has been exciting and productive, marked by the compelling data from the Phase 1 study of UBX1325. In addition to the reassuring safety profile, we observed initial signs of efficacy in both vision and corresponding ocular structures in patients suffering from advanced DME and wet AMD for whom anti-VEGF therapy was no longer considered beneficial – and who in fact hadn’t received any anti-VEGF therapy for at least three months. This initial data has generated strong enthusiasm and support from the physician community, and we have both completed the enrollment of additional wet AMD patients in our Phase 1 study and are rapidly recruiting in our international Phase 2a study in DME,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “There’s a large unmet need for treatment options beyond anti-VEGF therapy, and UBX1325 may fill that void as a senolytic option working through an entirely novel and potentially disease-modifying mechanism. We look forward to sharing additional data from the Phase 1 study in the coming months, and the results of the Phase 2a study in the first half of 2022.”

Key Business Highlights

Ophthalmology – UBX1325 Phase 1 Results

In July, UNITY announced positive data from its Phase 1 safety study of UBX1325 in patients with advanced disease from DME or wet AMD for whom anti-VEGF therapy was no longer considered effective. In addition to a favorable safety and tolerability profile, UBX1325, a small molecule inhibitor of Bcl-xL, showed rapid improvements in these advanced patients. Specifically, the majority of patients from this study showed a positive gain in key clinical measures of disease progression, including in best-corrected visual acuity (BCVA), central subfield thickness (CST), and sub- and intra-retinal fluid (SRF, IRF).

The following improvements in vision and retinal structure were observed as summarized below:

Treatment of patients with UBX1325 resulted in the following clinical changes as of June 30, 2021:

Gain in ETDRS Letters from Baseline in Best-Corrected Visual Acuity (BCVA)

- Overall (across all doses): 10 of 12 patients showed a gain in ETDRS letters from baseline in BCVA at 2 weeks; 9 of 12 patients showed a gain at 4 weeks
- In high dose groups (5, 10 mcg): 6 of 6 patients showed a gain in ETDRS letters from baseline in BCVA at 2 weeks; 5 of 6 patients showed a gain at 4 weeks

Decrease in Central Subfield Thickness (CST)

- Overall (across all doses): 6 of 12 patients had a decrease (improvement) in CST at 2 weeks; 5 of 12 patients showed reductions at 4 weeks
- In high dose groups (5, 10 mcg): 4 of 6 patients showed decrease in CST at 2 weeks; 3 of 6 patients showed reductions at 4 weeks

Reduction in Subretinal / Intraretinal Fluid

- 3 of 4 patients with wet AMD had a reduction in subretinal / intraretinal fluid (SRF / IRF), and improvement in disease-relevant pathology

Based on these data, the Company has, as of August 5, 2021, completed the enrollment of additional patients with advanced wet AMD in the Phase 1 study to inform a potential Phase 2a study in wet AMD to start this fall. A parallel Phase 2a proof-of-concept study in DME is actively recruiting

patients, with information about that trial available here.

Second Quarter Financial Results

Cash, cash equivalents, and marketable securities totaled $97.5 million as of June 30, 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 through the third quarter of 2022.

Operating loss for the three months ended June 30, 2021 was $17.0 million compared to $23.3 million for the three months ended June 30, 2020. Cash used in operations during the first and second quarters of 2021 was $28.5 million compared to $44.4 million for the first and second quarters of 2020.

Research and development expenses decreased by $5.1 million, to $11.0 million for the three months ended June 30, 2021 from $16.1 million for the three months ended June 30, 2020. The decrease was primarily due to decreases of $3.2 million in personnel costs due to reduction in force, $0.6 million in laboratory supplies, $0.8 million in facilities-related costs, $0.1 million in consultant expenses, and $0.4 million in net direct research and development expenses mainly due to termination of UBX0101 offset by increase of $2.0 million in license expense from Ascentage International reaching a milestone, which was a non-cash expense.

General and administrative expenses decreased by $0.3 million, to $6.0 million for the three months ended June 30, 2021 from $6.3 million for the three months ended June 30, 2020. The decrease was primarily due to a decrease of $0.6 million in personnel costs due to reduction in force, offset by increases of $0.1 million in facilities-related costs, $0.1 million in professional fees and $0.1 million in insurance-related expense.

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. In its Phase 1 safety trial in patients with advanced DME or wet AMD who were no longer expected to benefit from anti-VEGF therapies, UBX1325 showed a favorable safety and tolerability profile as well as initial evidence of relevant biological efficacy. UNITY's goal with UBX1325 is to transformationally improve real-world outcomes for patients with DME, AMD, and DR.

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, 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 June 30, 2021, filed with the Securities and Exchange Commission on August 10, 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)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 11,016	$ 16,123	$ 19,733	$ 35,388
General and administrative	5,980	6,320	12,206	12,273
Change in fair value of contingent consideration	—	906	—	685

Impairment of long-lived assets	—	—	—	2,159
Total operating expenses	16,996	23,349	31,939	50,505
Loss from operations	(16,996)	(23,349)	(31,939)	(50,505)
Interest income	26	340	62	867
Interest expense	(784)	—	(1,559)	—
Other income (expense), net	(72)	4,342	(146)	2,933
Net loss	(17,826)	(18,667)	(33,582)	(46,705)
Other comprehensive gain (loss)				
Unrealized gain (loss) on marketable debt securities	(10)	(141)	—	142
Comprehensive loss	$ (17,836)	$ (18,808)	$ (33,582)	$ (46,563)
Net loss per share, basic and diluted	$ (0.32)	$ (0.38)	$ (0.62)	$ (0.96)
Weighted-average number of shares used in computing net loss per share, basic and diluted	54,859,727	49,659,153	54,516,445	48,606,768

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

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,498	$ 17,807
Short-term marketable securities	70,445	79,892
Prepaid expenses and other current assets	3,665	3,167
Total current assets	87,608	100,866
Property and equipment, net	11,251	12,627
Operating lease right-of-use assets	22,416	23,509
Long-term marketable securities	13,542	17,871
Restricted cash	1,446	1,446
Total assets	$ 136,263	$ 156,319
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,898	$ 2,558
Accrued compensation	2,613	5,355
Accrued and other current liabilities	8,884	6,550
Total current liabilities	13,395	14,463
Operating lease liability, net of current portion	32,036	34,468
Long-term debt, net	24,892	24,508
Other long-term liabilities	23	—
Total liabilities	70,346	73,439
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	438,788	422,379
Related party promissory notes for purchase of common stock	—	(210)
Accumulated other comprehensive gain	5	5
Accumulated deficit	(372,881)	(339,299)
Total stockholders' equity	65,917	82,880
Total liabilities and stockholders' equity	$ 136,263	$ 156,319

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Source: Unity Biotechnology, Inc.