



UNITY Biotechnology, Inc. Reports First Quarter 2020 Financial Results and Business Updates

May 7, 2020

SOUTH SAN FRANCISCO, Calif., May 07, 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 reported financial results for the first quarter ended March 31, 2020.

"During the first quarter, we sustained strong momentum on our UBX0101 development program," said Anirvan Ghosh, chief executive officer of UNITY. "We completed enrollment of both our Phase 2 and Phase 1b studies in patients with osteoarthritis (OA) of the knee. This progress is particularly noteworthy given the impact of the COVID-19 pandemic on the clinical trial landscape."

Recent Highlights and Business Updates

Osteoarthritis – UBX0101

In February 2020, UNITY announced completion of enrollment of a Phase 2 study of UBX0101 in patients with moderate-to-severe OA of the knee. 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. Consistent with prior guidance, both 12- and 24-week results are expected in the second half of 2020.

In March 2020, UNITY announced completion of enrollment of a Phase 1b study of UBX0101 in patients with moderate-to-severe OA of the knee. The study is randomized, double-blind, and placebo-controlled and will explore the safety, tolerability and initial efficacy of a single 8.0 mg dose or multiple doses (two 4.0 mg doses separated by one month) of UBX0101. Consistent with prior guidance, both 12- and 24-week results are expected in the second half of 2020.

Ophthalmology

UNITY is advancing its lead ophthalmology candidates, UBX1967 and UBX1325, through the final stages of Investigational New Drug (IND) -enabling 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. Consistent with prior guidance, UNITY continues to expect to file an IND for a Phase 1 safety study for this program in the second half of 2020 and, assuming clinical sites are able to recruit and retain investigators and study staff and screen and enroll patients, to initiate a Phase 1 study in the second half of 2020 and receive initial results from the study in 2021. However the impact of the COVID-19 pandemic is hard to assess due the rapidly evolving nature of the situation and it is possible that the study start could be delayed. 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.

Impact of COVID-19 Pandemic

UNITY's first priority during the COVID-19 pandemic has been to ensure the health and safety of employees and patients in its clinical programs as well as the integrity of the studies in which they participate. UNITY's clinical and regulatory teams remain active and are working closely with its investigators in its ongoing clinical studies of UBX0101 to adapt to the current environment and ensure the studies remain on-track. UNITY is also following FDA guidance on clinical trial conduct during the COVID-19 pandemic, including with respect to the remote monitoring of clinical data. Further, UNITY has sufficient supply of UBX0101 for all ongoing clinical studies.

In late February 2020, UNITY created a cross-functional COVID-19 Response Team to closely monitor the evolving situation and advise on UNITY's response. In mid-March 2020, in alignment with public health guidance designed to slow the spread of COVID-19, UNITY implemented a reduced onsite staffing model and transitioned to a remote work plan for all employees other than those providing essential services, such as laboratory staff. For its onsite employees, UNITY implemented heightened safety measures designed to comply with applicable federal, state and local guidelines in response to the COVID-19 pandemic. All other employees continue to perform business activities from remote locations.

Financial Outlook

UNITY believes that current cash, cash equivalents and investments are sufficient to fund operations into the second half of 2021.

First Quarter Financial Results

Cash, cash equivalents and marketable securities totaled \$109.2 million as of March 31, 2020 compared with \$125.0 million as of December 31, 2019.

Operating loss for the three months ended March 31, 2020 was \$27.2 million compared to \$19.7 million for the three months ended March 31, 2019. Cash used in operations during the first quarter of 2020 was \$25.1 million compared to \$20.6 million for the first quarter of 2019.

Research and development expenses increased by \$2.8 million, to \$19.3 million for the three months ended March 31, 2020 from \$16.5 million for the three months ended March 31, 2019. The increase was primarily due to increases of \$1.5 million in clinical study costs driven by development costs associated with UBX0101, \$1.4 million in facilities-related costs, and \$0.6 million in personnel-related costs, of which \$0.5 million was related to non-cash stock compensation expense, partially offset by a decrease of \$0.6 million in laboratory supplies.

General and administrative expenses increased by \$1.5 million, to \$6.0 million for the three months ended March 31, 2020 from \$4.5 million for the three months ended March 31, 2019. The increase was primarily due to increases of \$0.9 million in personnel-related costs, of which \$0.8 million was related to non-cash stock compensation expense, \$0.3 million in facilities-related costs and \$0.2 million in professional fees.

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 its 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 the potential for UNITY to develop therapeutics to extend healthspan, statements related to the timing of certain regulatory filings and the release of clinical trial data and the extent to which COVID-19 may impact UNITY's operations. 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. 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 recent Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the Securities and Exchange Commission on May 7, 2020, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission.

Unity Biotechnology, Inc.
Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended	
	March 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 19,265	\$ 16,505
General and administrative	5,953	4,477
Change in fair value of contingent consideration	(221)	(1,245)
Impairment of long-lived assets	2,159	—
Total operating expenses	27,156	19,737
Loss from operations	(27,156)	(19,737)
Interest income	527	1,006
Other expense, net	(1,409)	(36)
Net loss	(28,038)	(18,767)
Other comprehensive loss		
Unrealized gain on marketable securities, net of tax	283	114
Comprehensive loss	\$ (27,755)	\$ (18,653)
Net loss per share, basic and diluted	\$ (0.59)	\$ (0.44)
Weighted-average number of shares used in computing net loss per share, basic and diluted	47,544,401	42,190,457

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

	March 31,	December 31,
	2020	2019
	(Unaudited)	
Assets		

Current Assets:		
Cash and cash equivalents	\$ 25,059	\$ 37,473
Short-term marketable securities	84,179	84,508
Strategic investment	4,120	5,507
Prepaid expenses and other current assets	1,875	1,999
Total current assets	115,233	129,487
Property and equipment, net	15,067	16,636
Operating lease right of use asset	25,443	—
Long-term marketable securities	—	3,025
Restricted cash	1,446	1,446
Other long-term assets	598	627
Total assets	\$ 157,787	\$ 151,221
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,015	\$ 5,185
Accrued compensation	2,222	5,905
Accrued and other current liabilities	7,422	4,995
Contingent consideration liability	910	1,131
Total current liabilities	14,569	17,216
Operating lease liability, net of current portion	37,889	—
Deferred rent, net of current portion	—	13,298
Total liabilities	52,458	30,514
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	379,072	366,695
Related party promissory notes for purchase of common stock	(210) (210
Employee promissory notes for purchase of common stock	(418) (418
Accumulated other comprehensive loss	373	90
Accumulated deficit	(273,493) (245,455
Total stockholders' equity	105,329	120,707
Total liabilities and stockholders' equity	\$ 157,787	\$ 151,221

Investors

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Source: Unity Biotechnology, Inc.