

UNITY Biotechnology, Inc. Reports Third Quarter 2019 Financial Results and Business Updates

November 6, 2019

SAN FRANCISCO, Nov. 06, 2019 (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 third quarter ended September 30, 2019.

"During the third quarter, we announced the design of 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 recently initiated this study and expect initial 12-week results in the second half of next year. I am proud of the execution by our team to get this study initiated so that we can continue to explore the promise of UBX0101."

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 in patients with moderate-to-severe osteoarthritis (OA) of the knee. The study is expected to enroll approximately 180 patients with initial 12-week results expected in the second half of 2020.

UNITY also plans to study the safety, tolerability and initial effectiveness of both a new higher dose and repeat doses in a Phase 1b study. The study is expected to enroll approximately 36 patients with initiation expected in the first half of 2020 with initial 12-week results expected in the second half of 2020. The Phase 1b study will be a randomized, double-blind, placebo-controlled study evaluating an 8mg dose of UBX0101 administered via a single intra-articular injection as well as two 4mg doses of UBX0101 administered via intra-articular injection one month apart. The primary measure will be safety and tolerability. Secondary measures will include pain (using the WOMAC-A and the Numerical Rating Scale, or NRS instruments) and function (by WOMAC-C) at 12 weeks, as well as similar measures at 24 weeks.

Ophthalmology

UNITY is advancing UBX1967 and UBX1325 through Investigational New Drug (IND) enabling studies. Both senolytic molecules are inhibitors of particular members of the Bcl-2 family of apoptosis regulatory proteins and have distinct pharmacokinetic profiles. UNITY remains on track to file an IND in early 2020 and intends to pursue multiple age-related diseases of the eye in the clinic, such as age-related macular degeneration, diabetic retinopathy and diabetic macular edema.

Financial Outlook

UNITY announced that it expects year-end cash, cash equivalents and investments to exceed \$110 million. UNITY believes that current cash, cash equivalents and investments are sufficient to fund operations into the second half of 2021.

Third Quarter 2019 Financial Results

Cash, cash equivalents and investments totaled \$120.3 million as of September 30, 2019 compared with \$171.1 million as of December 31, 2018.

Operating loss for the three months ended September 30, 2019 was \$22.4 million compared with \$19.4 million for the same period in 2018. The third quarter of 2019 operating loss includes \$3.8 million in non-cash stock based compensation expense and \$1.1 million of non-cash rent expense related to the new South San Francisco lease agreement. Cash used for operations during the third quarter of 2019 was \$16.8 million.

Research and development expenses were \$17.8 million during the third quarter of 2019 compared with \$14.4 million for the third quarter of 2018. The increase was primarily due to increases of \$2.3 million in direct research and development costs, \$0.9 million in facilities-related costs and \$0.8 million in personnel-related costs. The increase was partially offset by a \$0.6 million decrease in consulting expenses.

General and administrative expenses were \$5.7 million during the third quarter of 2019 compared with \$4.4 million for the third quarter of 2018. The increase was predominantly due to \$1.1 million in personnel-related costs and \$0.2 million in facilities-related costs.

The change in estimated fair value of contingent consideration expense was a decrease of \$1.1 million during the third quarter of 2019 compared with an increase of \$0.6 million for the same period in 2018. The change in contingent consideration expense was due to a change in the estimated fair value of the liability under our license agreements.

About UNITY

UNITY is developing therapeutics to extend healthspan by slowing, halting or reversing diseases of aging. UNITY's initial focus is on creating senolytic medicines to selectively eliminate senescent cells and thereby treat age-related diseases, such as osteoarthritis, eye diseases and pulmonary 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 diseases of aging; UBX101's potential to selectively eliminate senescent cells in patients with OA of the knee; the potential benefits, activity, effectiveness and safety of UBX0101; the timing of initiation of and data read out from the Phase 2 OA study; the design of

UNITY's planned Phase 1b OA study and timing of initiation of and data read out from that Phase 1b OA study; UNITY's ability to successfully complete ongoing pre-clinical studies of UBX1967 and UBX1325 and the potential timing of any future filings of any IND applications; and UNITY's expectations regarding its year-end cash, cash equivalents and investments and its 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 guarter 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2019		2018		2019		2018	
Operating expenses:								
Research and development	\$ 17,777		\$ 14,353		\$52,750		\$ 42,577	
General and administrative	5,692		4,389		15,139		11,688	
Change in fair value of contingent consideration	(1,115)	635		(1,327)	2,393	
Total operating expenses	22,354		19,377		66,562		56,658	
Loss from operations	(22,354)	(19,377)	(66,562)	(56,658)
Interest income (expense), net	756		1,068		2,663		2,246	
Other expense, net	(112)	(37)	(251)	(70)
Net loss	(21,710)	(18,346)	(64,150)	(54,482)
Other comprehensive loss								
Unrealized gain (loss) on marketable securities, net of tax	(18)	(42)	190		(15)
Comprehensive loss	\$ (21,728)	\$ (18,388)	\$ (63,960)	\$ (54,497)
Net loss per share, basic and diluted	\$ (0.51)	\$ (0.45)	\$ (1.51)	\$ (2.29)
Weighted-average number of shares used in								
computing net loss per share, basic and diluted	42,965,945		41,057,861		42,584,835		23,762,450	

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

	September 30,	December 31, 2018		
	2019			
	(Unaudited)			
Assets				
Current Assets:				
Cash and cash equivalents	\$ 36,768	\$ 15,399		
Short-term marketable securities	76,206	155,736		
Prepaid expenses and other current assets	2,249	1,830		
Tenant improvement receivable	10,650	_		
Total current assets	125,873	172,965		
Property and equipment, net	5,359	6,238		
Long-term marketable securities	7,353	_		
Restricted cash	1,446	550		
Other long-term assets	1,647	1,622		
Total assets	\$ 141,678	\$ 181,375		

Liabilities, convertible preferred stock, and stockholders' equity

Current liabilities:

Accounts payable	\$ 4,578		\$4,847	
Accrued compensation	3,672		3,791	
Accrued and other current liabilities	4,912		4,990	
Settlement liability	_		2,059	
Contingent consideration liability	1,156		895	
Total current liabilities	14,318		16,582	
Deferred rent, net of current portion	12,643		2,467	
Contingent consideration liability, net of current portion	_		1,588	
Other non-current liabilities	_		45	
Total liabilities	26,961	20,682		
Stockholders' equity:				
Common stock	4		4	
Additional paid-in capital	342,647		324,663	
Related party promissory notes for purchase of common stock	(201)	(201)
Employee promissory notes for purchase of common stock	(400)	(400)
Accumulated other comprehensive loss	95		(95)
Accumulated deficit	(227,428)	(163,278)
Total stockholders' equity	114,717		160,693	
Total liabilities, convertible preferred stock, and stockholders' equity	\$ 141,678		\$ 181,375	

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Source: Unity Biotechnology, Inc.