UNITY Biotechnology, Inc. Reports Second Quarter 2019 Financial Results and Program Updates

August 7, 2019

SAN FRANCISCO, Aug. 07, 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 second quarter ended June 30, 2019.

"During the second quarter, we announced promising results from our Phase 1 study of UBX0101 in patients with OA of the knee. We believe these results provide strong support for the broad potential of our therapies directed against senescent cells," said Keith Leonard, chairman and chief executive officer of UNITY. “We look forward to initiating a Phase 2 study later this year with results expected in the second half of 2020. We also made excellent progress in advancing our development candidates in the ophthalmology pipeline towards IND filing in early 2020.”

Recent Highlights and Program Updates

Osteoarthritis – UBX0101

In June 2019, UNITY announced results from its first-in-human Phase 1 study of UBX0101 (NCT03513016) in patients with moderate-to-severe osteoarthritis (OA) of the knee. The study demonstrated that UBX0101 was well-tolerated with no dose-dependent adverse events or relevant clinical laboratory findings. Improvement in several clinical measures, including pain, function, as well as modulation of certain senescence-associated secretory phenotype (SASP) factors and disease-related biomarkers was observed after a single dose of UBX0101.

UNITY recently announced plans to initiate a Phase 2 study of UBX0101 in patients with moderate-to-severe OA of the knee. The trial is expected to enroll approximately 180 patients with initiation expected in the fourth quarter of 2019 and initial 12-week results expected in the second half of 2020. UNITY also announced plans to study the safety, tolerability and initial effectiveness of both a new higher dose and repeat doses in a parallel Phase 1B study. Details of that study will be forthcoming.

Ophthalmology

In January 2019, UNITY announced it selected UBX1967 as a development candidate in the ophthalmology pipeline for advancement into Investigational New Drug (IND) enabling studies. During the second quarter, UNITY also advanced an additional senolytic molecule, UBX1325 into IND enabling studies. UBX1325 is an inhibitor of particular members of the Bcl-2 family of apoptosis regulatory proteins with a pharmacokinetic profile that is distinct from UBX1967. UNITY intends to pursue multiple age-related diseases of the eye in the clinic, such as age-related macular degeneration, proliferative diabetic retinopathy and diabetic macular edema.

Alpha-Klotho
In May 2019, UNITY and UC San Francisco (UCSF) announced that UNITY executed an exclusive, worldwide license to UCSF intellectual property relating to the alpha-Klotho protein, a circulating protein associated with improved cognitive performance. UNITY is exploring the utility of alpha-Klotho in collaboration with UCSF, with a goal to identify a potential drug candidate to treat particular diseases of aging, including cognitive decline.

Second Quarter 2019 Financial Results
Cash, cash equivalents and investments totaled $132.0 million as of June 30, 2019 compared with $171.1 million as of December 31, 2018.

Operating loss for the three months ended June 30, 2019 was $24.5 million compared with $20.8 million for the same period in 2018. The second quarter of 2019 operating loss includes $1.9 million in non-cash stock based compensation expense, $1.0 million in non-cash expense related to the upfront stock issuance for the UCSF Klotho license agreement, $1.0 million in non-cash change in fair value of contingent consideration and $0.6 million of non-cash rent expense related to the new South San Francisco lease agreement. Cash used for operations during the second quarter of 2019 was $19.3 million.

Research and development expenses were $18.5 million during the second quarter of 2019 compared with $15.2 million for the second quarter of 2018. The increase was primarily attributable to an increase of $3.1 million for IND enabling study costs associated with our ophthalmology pipeline and $0.5 million for facilities-related costs. The increase was partially offset by a $0.4 million decrease in consulting expenses.

General and administrative expenses were $5.0 million during the second quarter of 2019 compared with $3.8 million for the second quarter of 2018. The increase was predominantly due to $0.7 million in personnel-related expenses, $0.2 million in insurance expense and $0.2 million in professional services.

The change in estimated fair value of contingent consideration expense was $1.0 million during the second quarter of 2019 compared with $1.7 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 design of UNITY's planned Phase 2 OA trial; and timing of initiation of and data read out from UNITY's Phase 2 OA trial; and 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. 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 quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 7, 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	18,468	15,198	34,973	28,223
General and administrative	4,970	3,842	9,447	7,299
Change in fair value of contingent consideration	1,032	1,758	(213)	1,758
Total operating expenses	24,470	20,798	44,207	37,280
Loss from operations	(24,470)	(20,798)	(44,207)	(37,280)
Interest income (expense), net	900	826	1,906	1,178
Other expense, net	(103)	(30)	(139)	(33)
Net loss	(23,673)	(20,002)	(42,440)	(36,135)
Other comprehensive loss				
Unrealized gain (loss) on marketable securities, net of tax	94	61	208	27
Comprehensive loss	$ (23,579)	$ (19,941)	$ (42,232)	$ (36,108)
Net loss per share, basic and diluted	$ (0.56)	$ (0.76)	$ (1.00)	$ (2.41)
Weighted-average number of shares used in computing net loss per share, basic and diluted	42,442,886	26,298,666	42,311,040	15,003,493

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

	June 30, 2019 (Unaudited)	**December 31, 2018**
Assets		
Current Assets:		
Cash and cash equivalents	$ 23,113	$ 15,399
Short-term marketable securities	104,889	155,736
Prepaid expenses and other current assets	2,775	1,830
Tenant improvement receivable	10,650	—
Total current assets	141,427	172,965
Property and equipment, net	5,658	6,238
Long-term marketable securities	4,040	—
Restricted cash	1,446	550
Other long-term assets	1,639	1,622
Total assets	$ 154,210	$ 181,375

Liabilities, convertible preferred stock, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,381	$ 4,847
Accrued compensation	2,741	3,791
Accrued and other current liabilities	4,840	4,990
Settlement liability	—	2,059
Contingent consideration liability	2,270	895
Total current liabilities	15,232	16,582
Deferred rent, net of current portion	11,921	2,467
Contingent consideration liability, net of current portion	-	1,588
Other non-current liabilities	7	45
Total liabilities	27,160	20,682
Stockholders' equity:		
Common stock	4	4
Additional paid-in capital	333,252	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	113	(95)
Accumulated deficit	(205,718)	(163,278)
Total stockholders' equity	127,050	160,693
Total liabilities, convertible preferred stock, and stockholders' equity	$ 154,210	$ 181,375

Investors
Endurance Advisors
Peter Rahmer
prahmer@enduranceadvisors.com

Media
Canale Communications
Jason Spark
jason@canalecomm.com

Source: Unity Biotechnology, Inc.