

Atara Bio Announces Third Quarter 2016 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2016 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, today reported financial results for the third quarter ended September 30, 2016 and recent operational highlights.

“We are pleased to report that for our lead product candidate, EBV-CTL, we have received feedback from FDA on our approach to comparing material manufactured by our CMO with material previously produced at MSK and have commenced manufacturing to support our Phase 3 trials,” said Isaac Ciechanover, Chief Executive Officer and President of Atara Bio. “We have also submitted our Phase 3 trial protocols to FDA, and we look forward to the initiation of these trials by year end.”

Recent Highlights and Anticipated Upcoming Milestones

EBV-CTL

- Submitted Phase 3 protocols to the U.S. Food and Drug Administration (FDA) incorporating its feedback on two trials of allogeneic Epstein-Barr virus (EBV)-specific cytotoxic T lymphocytes (EBV-CTL) in patients with rituximab refractory EBV-post transplant lymphoproliferative disorder (PTLD) following hematopoietic cell transplant (HCT) and solid organ transplant (SOT).
 - Phase 3 trials are expected to initiate by year end.
- Completed manufacturing process transfer for EBV-CTL to our contract manufacturing organization (CMO).
 - Developed end-to-end supply chain and logistics to support manufacturing and distribution of EBV-CTL.
- Received feedback from FDA regarding our comparability protocol designed to compare EBV-CTL material manufactured by our CMO with material previously produced at Memorial Sloan Kettering (MSK).
 - Commenced production of full scale EBV-CTL lots for the expanded access protocol (EAP) and the Phase 3 trials.
- Granted access to priority medicines (PRIME) regulatory support by the European Medicines Agency (EMA) for allogeneic EBV-CTL for the treatment of EBV-PTLD after HCT.
- Scientific Advice meeting with the EMA and health technology assessment groups (HTAs) scheduled in the 4th quarter of 2016 to discuss potential pathways for

submission of a marketing authorization application (MAA) for EBV-CTL in the treatment of rituximab refractory EBV-PTLD after HCT.

- First patient dosed in multi-center EAP trial of EBV-CTL in patients with rituximab refractory EBV-PTLD.
 - We plan to broaden our EAP trial to include enrollment of patients with other EBV-associated hematologic malignancies and solid tumors.

CMV-CTL

- Conducted an end of Phase 2 meeting with the FDA to discuss late-stage development of allogeneic cytomegalovirus (CMV)-specific CTL (CMV-CTL) for the treatment of anti-viral refractory or resistant CMV infection following either HCT or SOT.
 - We expect to initiate a Phase 3 trial in 2017, once we have completed discussions with the FDA on trial design.
- Received positive opinion from the EMA on orphan drug designation for the treatment of CMV infection in patients with impaired immune systems.

CTL Platform Expansion

- Expanded our relationship with the Queensland Institute of Medical Research (QIMR Berghofer) including the development of allogeneic CTLs targeting human papilloma virus (HPV) and BK virus (BKV).
 - HPV is associated with a number of solid tumors including head and neck cancer, cervical cancer, and anal cancer.
 - BKV is a challenging clinical problem in kidney transplant patients and is a potential cause of organ loss.

Third Quarter 2016 Financial Results

- Cash and investments as of September 30, 2016 totaled \$278.1 million, which the Company believes will be sufficient to fund its planned operations through 2018.
- The Company reported a net loss of \$25.4 million, or \$0.88 per share, for the third quarter of 2016, as compared to a net loss of \$11.9 million, or \$0.43 per share, for the third quarter of 2015.
- Total research and development expenses were \$18.8 million for the third quarter of 2016, compared to \$8.1 million for the third quarter of 2015, including \$2.6 million and \$0.9 million of non-cash stock-based compensation expenses, respectively. The increase was primarily due to an increase in our clinical trial, research, regulatory and manufacturing expenses associated with our T-cell programs of \$10.9 million and increased headcount related costs to support these activities of \$4.4 million, offset by a decrease in costs associated with our other molecular programs of \$4.6 million.
- General and administrative expenses were \$7.1 million for the third quarter of 2016, compared to \$4.1 million for the third quarter of 2015, including \$2.7 million and \$1.3 million of non-cash stock-based compensation expenses, respectively. The increase was primarily due to a \$1.4 million increase in non-cash stock-based compensation driven by new award grants, a \$0.9 million increase in compensation-related expenses driven by increased headcount, and to a lesser extent, higher consulting and outside services costs.

About Atara Biotherapeutics' Allogeneic Cellular Therapy Platform

Atara Bio's cellular therapy platform provides healthy immune capability to a patient and arms the immune system to precisely target and combat disease. Cells derived from healthy donors are manufactured in advance and stored as inventory so that a customized unit of cells can be chosen for each patient. The cells are ready to infuse in patients in approximately 3 to 5 days. Once administered, the cells home to their target, expand in-vivo to eliminate diseased cells, and eventually recede. This versatile platform can be directed towards a broad array of disease causing targets and has demonstrated clinical proof of concept across both viral and non-viral targets in conditions ranging from liquid and solid tumors to infectious and autoimmune diseases. The Company's lead product candidate derived from this platform is expected to enter Phase 3 trials in 2016. The Company has pursued prospective feedback from health authorities on both manufacturing and clinical trial design. Its lead product candidate has the potential to be the first commercial allogeneic T-cell therapy for a viral target implicated in cancer.

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. is a biopharmaceutical company developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, with an initial focus on immunotherapy and oncology. Atara Bio's programs include T-cell product candidates and molecularly targeted product candidates. The T-cell product candidates include EBV-CTL, CMV-CTL, and Wilms Tumor 1 targeted Cytotoxic T-cells (WT1-CTL) and harness the power of the immune system to recognize and attack cancer cells and cells infected with certain viruses. The molecularly targeted product candidates include STM 434. These product candidates target activin and myostatin, members of the TGF-beta family of proteins, and have demonstrated the potential to have therapeutic benefit in a number of clinical indications.

Forward-Looking Statements

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding the initiation of the Phase 3 trials for EBV-CTLs for EBV-PTLD by year end, the Scientific Advice meeting with EMA and health technology assessment groups scheduled in the 4th quarter of 2016, expectation to broaden our EAP trial to include enrollment of patients with other EBV-associated hematologic malignancies and solid tumors, expectation to initiate a pivotal trial with CMV-CTL in 2017, and the belief that cash and investments, as of September 30, 2016, will be sufficient to fund the Company's planned operations through 2018. Because such statements deal with future events and are based on Atara Bio's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Bio could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those discussed under the heading "Risk Factors" in Atara Bio's quarterly report in Form 10-Q filed with the SEC on August 8, 2016, including the documents incorporated by reference therein, and subsequent filings with the Securities and Exchange Commission (SEC). Except as otherwise required by law, Atara Bio disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or

otherwise.

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,013	\$ 23,746
Short-term investments	232,134	296,736
Restricted cash	194	194
Prepaid expenses and other current assets	3,889	3,921
Total current assets	282,230	324,597
Property and equipment, net	2,085	270
Other assets	102	108
Total assets	<u>\$ 284,417</u>	<u>\$ 324,975</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,463	\$ 1,445
Accrued compensation	3,156	2,624
Accrued research and development expenses	5,109	5,112
Other accrued liabilities	960	528
Total current liabilities	13,688	9,709
Long-term liabilities	527	166
Total liabilities	14,215	9,875
Commitments and contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	429,088	413,725
Accumulated other comprehensive income (loss)	35	(518)
Accumulated deficit	(158,924)	(98,110)
Total stockholders' equity	270,202	315,100
Total liabilities and stockholders' equity	<u>\$ 284,417</u>	<u>\$ 324,975</u>

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 18,802	\$ 8,113	\$ 43,040	\$ 25,387
General and administrative	7,140	4,146	19,448	11,291
Total operating expenses	<u>25,942</u>	<u>12,259</u>	<u>62,488</u>	<u>36,678</u>
Loss from operations	(25,942)	(12,259)	(62,488)	(36,678)
Interest and other income, net	576	380	1,684	696
Loss before provision (benefit) for income taxes	(25,366)	(11,879)	(60,804)	(35,982)
Provision (benefit) for income taxes	7	(11)	10	(9)
Net loss	<u>\$ (25,373)</u>	<u>\$ (11,868)</u>	<u>\$ (60,814)</u>	<u>\$ (35,973)</u>
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(158)	117	553	151
Comprehensive loss	<u>\$ (25,531)</u>	<u>\$ (11,751)</u>	<u>\$ (60,261)</u>	<u>\$ (35,822)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (0.88)</u>	<u>\$ (0.43)</u>	<u>\$ (2.12)</u>	<u>\$ (1.46)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>28,801</u>	<u>27,675</u>	<u>28,670</u>	<u>24,628</u>

INVESTOR & MEDIA CONTACT:

Investors:
Steve Klass
212-213-0006 x331
sklass@burnsmc.com

Media:
Justin Jackson
212-213-0006 x327
jjackson@burnsmc.com

[Primary Logo](#)

Source: Atara Biotherapeutics, Inc.