

Atara Bio Announces Second Quarter 2016 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2016 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases, today reported financial results for the second quarter ended June 30, 2016 and recent operational highlights.

“We are pleased with the continued progress of our lead program and the recent initiation of our multi-center expanded access protocol trial for our investigational allogeneic product candidate, Epstein-Barr Virus Cytotoxic T-Lymphocyte (EBV-CTL), to treat EBV-associated Post-Transplant Lymphoproliferative Disorders (PTLDs),” said Isaac Ciechanover, Chief Executive Officer and President of Atara Bio. “The commencement of the expanded access protocol trial was an important step towards initiation of our two pivotal trials in patients with rituximab-refractory EBV-PTLD after solid organ transplant (SOT) and hematopoietic cell transplant (HCT) by the end of this year. In addition, our collaborating investigators at Memorial Sloan Kettering Cancer Center (MSK) presented encouraging results at the American Society of Clinical Oncology (ASCO) annual meeting on the use of our allogeneic EBV-CTLs for the treatment of EBV-associated nasopharyngeal carcinoma (NPC), which unlike HCT and SOT, is a solid tumor setting with patients who are not immunocompromised. We look forward to developing this product candidate as both a single agent and in combination with other therapies in hematologic malignancies and solid tumors.”

Recent Highlights and Upcoming Milestones

- Initiated a multi-center expanded access protocol to study the Company’s EBV-CTL product candidate in EBV-associated lymphomas and lymphoproliferative disorders
 - Planning to commence two pivotal clinical trials of EBV-CTL for rituximab-refractory EBV-PTLD following HCT and SOT by the end of 2016.
- Received Advanced Therapy Medicinal Product (ATMP) classification in June for EBV-CTL from the European Medicines Agency (EMA)
 - Therapies classified as ATMP are deemed to have the potential to reshape the treatment of a wide range of conditions, particularly in disease areas where conventional approaches are inadequate.
 - ATMP classification can provide developers with scientific regulatory guidance, help clarify the applicable regulatory framework and development path, provide access to all relevant services and incentives offered by the EMA, and can also be advantageous when submitting clinical trial dossiers to national EU regulatory authorities.
- Collaborating investigators at MSK reported positive clinical data from an ongoing Phase 2 clinical trial of Atara's allogeneic EBV-CTL product candidate for the treatment of EBV-associated metastatic NPC at the ASCO 2016 Annual Meeting

- Data showed a 21% objective response rate in NPC patients, including one complete response and two partial responses. The report also highlighted that 11 of the 14 NPC patients were alive with median 18-month follow-up.
- Of the 126 patients enrolled across all indications, there were two grade 4 and seven grade 3 possibly related serious adverse events.
- Planning to discuss clinical trial design for the product candidate, cytomegalovirus, or CMV-CTL, with the FDA in the fourth quarter of this year.
- Presented initial safety data during the ASCO 2016 Annual Meeting from the open-label dose escalation portion of Atara's Phase 1 trial of its Activin A inhibitor, STM 434, in advanced solid tumors
 - Plan to begin the monotherapy dose expansion component of the trial by the end of this year in patients with advanced granulosa cell or clear cell ovarian cancer.

Second Quarter 2016 Financial Results

- Cash and investments as of June 30, 2016 totaled \$294.6 million, which the Company believes will be sufficient to fund its planned operations through 2018.
- The Company reported a net loss of \$18.9 million, or \$0.66 per share, for the second quarter of 2016, as compared to a net loss of \$14.9 million, or \$0.62 per share, for the second quarter of 2015.
- Total research and development expenses were \$13.0 million for the second quarter of 2016, compared to \$11.5 million for the second quarter of 2015, including \$2.4 million and \$1.3 million of non-cash stock-based compensation expenses, respectively. The increase was primarily due to higher clinical trial, manufacturing and headcount-related expenses associated with the EBV-CTL program as a result of expanded clinical development activities.
- General and administrative expenses were \$6.5 million for the second quarter of 2016, compared to \$3.6 million for the second 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 an increase in compensation-related expenses driven by increased headcount.

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. is a biopharmaceutical company focused on 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 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

commencement of two pivotal clinical trials of EBV-CTLs for rituximab-refractory EBV-PTLD following HCT as well as SOT by the end of 2016, plans to develop EBV-CTL as both a single agent and in combination with other therapies for NPC, plans to discuss with the FDA clinical trial design for CMV-CTL in the fourth quarter of this year, plans to begin the monotherapy dose expansion component of the STM 434 Phase 1 trial by the end of this year in patients with advanced granulosa cell or clear cell ovarian cancer and the belief that cash and investments as of June 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 annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 4, 2016 and its quarterly report on Form 10-Q filed with the SEC on May 6, 2016, including the documents incorporated by reference therein, and subsequent filings with the 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.
Consolidated Balance Sheets
(Unaudited)
(In thousands)

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,356	\$ 23,746
Short-term investments	268,201	296,736
Restricted cash	194	194
Prepaid expenses and other current assets	4,132	3,921
Total current assets	<u>298,883</u>	<u>324,597</u>
Property and equipment, net	1,830	270
Other assets	101	108
Total assets	<u>\$ 300,814</u>	<u>\$ 324,975</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,235	\$ 1,445
Accrued compensation	2,135	2,624
Accrued research and development expenses	3,799	5,112
Other accrued liabilities	837	528
Total current liabilities	<u>10,006</u>	<u>9,709</u>
Long-term liabilities	563	166
Total liabilities	<u>10,569</u>	<u>9,875</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	423,600	413,725
Accumulated other comprehensive income (loss)	193	(518)
Accumulated deficit	<u>(133,551)</u>	<u>(98,110)</u>
Total stockholders' equity	<u>290,245</u>	<u>315,100</u>
Total liabilities and stockholders' equity	<u>\$ 300,814</u>	<u>\$ 324,975</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 12,991	\$ 11,507	\$ 24,238	\$ 17,274
General and administrative	6,494	3,601	12,308	7,145
Total operating expenses	<u>19,485</u>	<u>15,108</u>	<u>36,546</u>	<u>24,419</u>
Loss from operations	(19,485)	(15,108)	(36,546)	(24,419)
Interest and other income, net	605	163	1,108	316
Loss before provision for income taxes	(18,880)	(14,945)	(35,438)	(24,103)
Provision for income taxes	-	-	3	2
Net loss	<u>\$ (18,880)</u>	<u>\$ (14,945)</u>	<u>\$ (35,441)</u>	<u>\$ (24,105)</u>
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	142	(48)	711	34
Comprehensive loss	<u>\$ (18,738)</u>	<u>\$ (14,993)</u>	<u>\$ (34,730)</u>	<u>\$ (24,071)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (0.66)</u>	<u>\$ (0.62)</u>	<u>\$ (1.24)</u>	<u>\$ (1.04)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>28,665</u>	<u>24,224</u>	<u>28,603</u>	<u>23,079</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.