



Atara Biotherapeutics Announces Second Quarter 2019 Financial Results and Recent Operational Progress

August 8, 2019

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today reported financial results for the second quarter of 2019 and recent operational highlights.

"I am confident we are now in a strong position to execute and create value across our tab-cel[®], multiple sclerosis and next-generation CAR T programs," said Pascal Touchon, President and Chief Executive Officer of Atara Biotherapeutics. "We believe our updated tab-cel[®] development strategy, focusing on initiating an EBV+ PTLD regulatory submission first in the United States, prioritizes the most attractive market for such an ultra-rare disease and advances our mission to bring transformative T-cell immunotherapies to patients in critical need. In addition, we are encouraged by the initial safety results from our ongoing ATA188 Phase 1 study for patients with progressive MS and look forward to presenting the initial efficacy results from this study in September. We also strengthened our financial position, funding planned operations into 2021 and through key milestones next year including initiating the tab-cel[®] BLA submission and next-generation mesothelin CAR T IND."

Recent Highlights and Anticipated Upcoming Milestones

Tab-cel[®] (tabelecleucel)

- Atara continues to progress tab-cel[®] Phase 3 development for patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease (EBV+ PTLD).
 - Based on discussions with the U.S. Food & Drug Administration (FDA), Atara plans to initiate a tab-cel[®] biologics license application (BLA) submission for patients with EBV+ PTLD in the second half of 2020.
 - In the United States and Australia, 34 sites are available for enrollment and the company is preparing to open additional sites in the United States, Europe and Canada.
- We continue to see strong tab-cel[®] investigator, physician and patient interest and, in cases where we are not able to enroll patients in our EBV+ PTLD Phase 3 clinical studies, we are providing tab-cel[®] to patients in need under our early access and single patient use programs.
- Atara is in discussions with the European Medicines Agency (EMA) and the outcome of these discussions will determine the timing of the tab-cel[®] EU conditional marketing authorization (CMA) application for patients with EBV+ PTLD.
- Studies supporting potential additional tab-cel[®] indications are also advancing.
 - A Phase 1/2 clinical study of tab-cel[®] in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA[®] (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated nasopharyngeal carcinoma (NPC) is currently enrolling.
 - Atara expects to initiate a Phase 2 multi-cohort study including patients with other EBV+ cancers in the second half of 2020.

ATA188 & ATA190 for Multiple Sclerosis (MS)

- A Phase 1 clinical study of off-the-shelf, allogeneic ATA188 in patients with progressive MS is ongoing across clinical sites in the United States and Australia.
 - Initial ATA188 Phase 1 safety results for patients with progressive MS were presented at the 5th Congress of the European Academy of Neurology (EAN). The first three ATA188 dose cohorts were well tolerated with no dose-limiting toxicities and no ≥ 3 grade treatment-related, treatment-emergent adverse events.
 - Atara plans to present initial efficacy and additional safety results from this study at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) to be held September 11-13 in Stockholm, Sweden.
 - A randomized, double-blind, placebo-controlled Phase 1b part of this study using the recommended Phase 2 dose (RP2D) is now planned following completion of the open-label, dose-escalation period.
- Atara expects to initiate a randomized study of autologous ATA190 in progressive MS patients during the second half of 2019.

Next-Generation CAR T

- Positive Phase 1 clinical results for a mesothelin-targeted CAR T immunotherapy in patients with advanced mesothelioma were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2019.
 - Memorial Sloan Kettering Cancer Center (MSK) collaborators presented results demonstrating that their regionally delivered mesothelin-targeted, autologous CAR T cells were well tolerated and showed encouraging anti-tumor activity in combination with pembrolizumab, a PD-1 checkpoint inhibitor.
 - In a subset of 16 malignant pleural mesothelioma patients with minimum follow-up time of 3 months who also received pembrolizumab and lymphodepleting chemotherapy, 12-month overall survival was 80% and best overall response rate was 63%, including 3 investigator-assessed complete responses.
- Atara prioritized the mesothelin-targeted next-generation CAR T program, with an IND planned for autologous ATA2271 in advanced mesothelioma in 2020.

Corporate

- Pascal Touchon was appointed President, Chief Executive Officer and member of the Board of Directors. Prior to joining Atara in June, Dr. Touchon served as Novartis Oncology Global Head, Cell & Gene and member of the Oncology Executive Committee.
- Atara completed facility commissioning and qualification activities to support clinical operations at ATOM (Atara T-cell Operations and Manufacturing).
 - Commercial production qualification activities are nearing completion and, together with our contracted manufacturing partner, are aligned with our planned commercial strategy.

Second Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments as of June 30, 2019 totaled \$190.1 million. In July 2019 we sold approximately 6.9 million shares of common stock and pre-funded warrants to purchase approximately 2.9 million shares of common stock for net proceeds of \$140.6 million in an underwritten public offering.
- The Company believes the net proceeds from the offering, together with existing cash, cash equivalents and short-term investments, are sufficient to fund planned operations into 2021.
- The Company reported net losses of \$74.3 million, or \$1.60 per share, for the second quarter of 2019 as compared to \$50.9 million, or \$1.15 per share, for the same period in 2018.
- Total operating expenses include total non-cash expenses of \$16.9 million for the second quarter of 2019 as compared to \$8.7 million for the same period in 2018.
- Research and development expenses were \$52.3 million for the second quarter of 2019 as compared to \$33.4 million for the same period in 2018. The increase in the second quarter of 2019 was due to costs associated with the Company's continuing expansion of research and development activities, including:

- clinical study, manufacturing and outside service costs related to our tab-cel[®], ATA188 and ATA190 programs, including strategic spending to build inventory for clinical studies and potential commercialization;
 - higher employee-related and overhead costs from increased headcount and operations, and
 - an increase in facilities and information technology expenses that are attributed to our research and development function.
- Research and development expenses include \$6.7 million of non-cash stock-based compensation expense for the second quarter of 2019 as compared to \$3.4 million for the same period in 2018.
 - General and administrative expenses were \$23.3 million for the second quarter of 2019 as compared to \$19.2 million for the same period in 2018. The increase in the second quarter of 2019 was primarily due to increases in professional services costs and employee-related costs driven by increased headcount to support the Company's expanding operations.
 - General and administrative expenses include \$8.5 million of non-cash stock-based compensation expense for the second quarter of 2019 as compared to \$4.6 million for the same period in 2018.

Conference Call and Webcast Information

Atara will host a live conference call and webcast today at 8:00 a.m. EDT to discuss the Company's financial results and recent operational highlights. Analysts and investors can participate in the conference call by dialing (888) 540-6216 for domestic callers and (734) 385-2715 for international callers, using the conference ID 4179789. A live audio webcast can be accessed by visiting the Investor Events and Presentations section of atarabio.com. An archived replay will be available on the Company's website for approximately 14 days following the live webcast.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](http://Atarabio) is a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. Atara's technology platform leverages research collaborations with leading academic institutions with the Company's scientific, clinical, regulatory and manufacturing expertise. Atara's pipeline includes tab-cel[®] (tabelecleucel), which is in Phase 3 development for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disorder (EBV+ PTLD) as well as in earlier stage development for other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma (NPC); T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis; and next-generation chimeric antigen receptor T-cell (CAR T) immunotherapies. The company was founded in 2012 and is co-located in South San Francisco and Southern California. Our Southern California hub is anchored by the state-of-the-art Atara T-cell Operations and Manufacturing (ATOM) facility in Thousand Oaks, California. For additional information about the company, please visit atarabio.com.

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 timing of and the Company's ability to achieve clinical and regulatory milestones in 2019 and 2020, including submission of a tab-cel[®] BLA for patients with EBV+ PTLD, initiation of a Phase 2 study including patients with EBV+ cancers, expansion of the Company's ATA188 study using the RP2D, initiation of an ATA190 study and submission of an IND for ATA2271; discussions with regulators, including with the EMA regarding its tab-cel[®] CMA application; enrollment and results of the Company's clinical studies, including its ability to open additional clinical sites; the Company's planned presentation of clinical results; and commercial production qualification activities; and the sufficiency of the Company's cash, cash equivalents and short-term investments to fund operations into 2021. Because such statements deal with future events and are based on Atara Biotherapeutics' current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Biotherapeutics 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 in Atara Biotherapeutics' filings with the Securities and Exchange Commission (SEC), including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. Except as otherwise required by law, Atara Biotherapeutics 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)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,159	\$ 60,698
Short-term investments	130,976	248,933
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	10,810	11,664
Total current assets	201,139	321,489

Property and equipment, net	57,090	68,576
Operating lease assets	14,396	—
Restricted cash - long-term	1,200	1,200
Other assets	319	574
Total assets	\$ 274,144	\$ 391,839

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 6,420	\$ 3,719
Accrued compensation	7,822	10,636
Accrued research and development expenses	5,139	19,210
Other current liabilities	6,422	6,414
Total current liabilities	25,803	39,979
Operating lease liabilities - long-term	14,919	—
Other long-term liabilities	1,143	13,003
Total liabilities	41,865	52,982

Commitments and contingencies

Stockholders' equity:

Common stock	5	5
Additional paid-in capital	899,671	866,541
Accumulated other comprehensive income (loss)	173	(340)
Accumulated deficit	(667,570)	(527,349)
Total stockholders' equity	232,279	338,857
Total liabilities and stockholders' equity	\$ 274,144	\$ 391,839

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 52,251	\$ 33,387	\$ 100,919	\$ 61,847
General and administrative	23,284	19,236	42,507	33,228
Total operating expenses	75,535	52,623	143,426	95,075
Loss from operations	(75,535)	(52,623)	(143,426)	(95,075)
Interest and other income, net	1,207	1,743	2,841	2,752
Loss before provision for income taxes	(74,328)	(50,880)	(140,585)	(92,323)
Provision for income taxes	—	3	-	3
Net loss	\$ (74,328)	\$ (50,883)	\$ (140,585)	\$ (92,326)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	135	19	513	(354)
Comprehensive loss	\$ (74,193)	\$ (50,864)	\$ (140,072)	\$ (92,680)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (1.60)	\$ (1.15)	\$ (3.04)	\$ (2.20)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	46,426	44,379	46,276	42,001

INVESTOR & MEDIA CONTACTS:

Investors:

John Craighead, Atara Biotherapeutics
650-410-3012
jcraighead@atarabio.com

John Grimaldi, Burns McClellan
212-213-0006 x362
jgrimaldi@burnsmc.com

Media:

Robert Flamm, Burns McClellan
212-213-0006 x364
rflamm@burnsmc.com



Source: Atara Biotherapeutics, Inc.