

August 9, 2021



# Atara Biotherapeutics Announces Second Quarter 2021 Financial Results and Operational Progress

*Progress with FDA on evaluating tab-cel<sup>®</sup> product comparability and new robust Phase 3 ALLELE study data*

*Recent positive milestones with EMA provide clear path for EU Marketing Authorization Application submission in November 2021*

*Important new ATA188 magnetization transfer ratio (MTR) imaging biomarker data and updated clinical data to be presented at ECTRIMS in October*

*Company to Host Live Conference Call and Webcast Today at 4:30 p.m. EDT*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA), a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today reported financial results for the second quarter 2021, recent business highlights and key catalysts over the next several months.

“We are very pleased with the progress achieved across all of our programs and important clinical updates across our full pipeline, which will enable us to deliver on key value drivers through the rest of this year and into 2022,” said Pascal Touchon, President and Chief Executive Officer of Atara. “Recent tab-cel<sup>®</sup> regulatory progress and alignment with both FDA and EMA allow us to continue anticipating approvals in 2022, while exciting new ATA188 imaging data reinforces our belief in this potentially transformative therapy for patients with multiple sclerosis.”

## ***Tablecleucel (tab-cel<sup>®</sup>) for Post-Transplant Lymphoproliferative Disease (PTLD)***

- Atara conducted productive meetings with the U.S. Food and Drug Administration (FDA), gaining clarity on specific next steps required for submission of the Biologics License Application (BLA)
  - Alignment on key methodologies for evaluating comparability between Atara product used in the pivotal ALLELE study and the intended commercial product. Atara will provide data on substantially all lots made to date through a Type B CMC meeting to enable FDA to make a final determination on the data package to support comparability
  - FDA decided it cannot make a determination of comparability between material used in non-pivotal and pivotal studies because analytical data is not available and cannot be generated for all lots manufactured at Memorial Sloan Kettering Cancer Center (MSK) and used in non-pivotal studies. Consequently, Atara plans to submit clinical data from the pivotal ALLELE study and the non-pivotal studies

- as separate, non-pooled analyses in the anticipated BLA submission
  - FDA has not requested additional assays or manufacturing lots
- Atara completed a new data analysis from its Phase 3 ALLELE study, as previously discussed with FDA. Top-line data with additional patients confirm a strong objective response rate (ORR) in line with prior results while demonstrating durability. There were no new safety signals, consistent with previously published findings
- These data will be discussed with the FDA through a Type B meeting and are planned to be presented at an appropriate congress in Q4 2021
- Based on the outcome of the recent and anticipated interactions with the FDA, Atara expects to complete the BLA submission for tab-cel<sup>®</sup> in Q1 2022. Atara is adapting investment in U.S. commercial readiness toward anticipated approval in H2 2022
- Following recent successful Rapporteur/Co-Rapporteur and pre-submission meetings with the European Medicines Agency (EMA), Atara has completed the necessary regulatory and compliance steps needed to submit an EU Marketing Authorization Application (MAA) for tab-cel<sup>®</sup> in patients with EBV<sup>+</sup> PTLD, which is on track for November 2021. The Company anticipates a decision regarding approval in H2 2022
- Discussions with potential partners for the commercialization of tab-cel<sup>®</sup> in Europe are advancing well and are in line with our expectation to secure a partner by Q4 2021
- Atara presented data at the American Transplant Congress (ATC) in June 2021 from a combined long-term overall survival (OS) analysis from three clinical studies of tab-cel<sup>®</sup> demonstrating that patients with EBV<sup>+</sup> PTLD following solid organ transplant (SOT) that is relapsed or refractory to initial treatment, derived similar OS benefit of greater than 80 percent at two years whether they achieved complete or partial response with tab-cel<sup>®</sup>

### ***Tab-cel<sup>®</sup> for Potential Additional Indications***

- Atara continues to pursue development of tab-cel<sup>®</sup> in additional patient populations with an initial focus on immunodeficiency-associated lymphoproliferative diseases (IA-LPDs), given the commonality of their EBV-driven mechanism of disease in immunocompromised patients, high unmet medical need, and positive clinical data to date with tab-cel<sup>®</sup>
  - Actively enrolling at sites in the Phase 2 multi-cohort study, which is evaluating six patient populations, including four within IA-PLDs and two in other EBV-driven diseases, in the U.S. and EU
- Atara joined the [Rare Disease Company Coalition](#), an alliance of innovative life sciences companies engaging policymakers on the unique needs of the rare disease community, the urgency of and support for innovation to address significant unmet patient need and dialogue around policies that advocate for timely and appropriate access to safe and transformational treatments, including tab-cel<sup>®</sup>

### ***ATA188 for Progressive Forms of Multiple Sclerosis (PMS)***

- Long-term, two-year clinical data from the Phase 1 open-label extension (OLE) and translational data from the Phase 1 study of ATA188 in PMS has been accepted for presentation at the 37<sup>th</sup> Congress of the European Committee for Treatment and

## Research in Multiple Sclerosis (ECTRIMS) in October

- The presentation, titled “Updated open-label extension clinical data and new magnetization transfer ratio imaging data from a Phase I study of ATA188, an off-the-shelf, allogeneic Epstein-Barr virus-targeted T-cell immunotherapy for progressive multiple sclerosis” will feature updated clinical and new imaging biomarker data considered to reflect the state of myelination in the central nervous system, known as magnetization transfer ratio (MTR)
- MTR may provide important insights into the mechanism of expanded disability status scale (EDSS) improvement in our clinical assessment of ATA188
- Atara is making progress on enrolling the ATA188 Phase 2 randomized, double-blind, placebo-controlled trial (EMBOLD study) evaluating the efficacy and safety of ATA188 in patients with PMS
  - Planned interim analysis in H1 2022 to assess efficacy and safety
  - Based on current target, Atara expects to complete enrollment in H1 2022
- The Company will present a poster on PMS fatigue and an oral presentation on the ongoing EMBOLD study at the upcoming 2021 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) in October
- There is growing awareness of the transformative potential of ATA188 in MS among neurologists

## **CAR T Programs**

### **ATA2271/ATA3271 (Solid Tumors Over-Expressing Mesothelin)**

- The global strategic collaboration for ATA2271 and ATA3271 with Bayer continues to progress well with advancement of the mesothelin-partnered CAR T immunotherapy programs
- The Company anticipates presentation of the first update on clinical data from the open-label, single-arm Phase 1 clinical study of ATA2271, an autologous CAR T therapy targeting mesothelin, designed to improve efficacy, persistence, and durability of response for patients with advanced mesothelioma, in an appropriate forum in Q4 2021. Enrollment has been completed for the first cohort and is nearly complete for the second cohort of this study
- Atara is continuing to make progress on IND-enabling studies for ATA3271, an off-the-shelf, allogeneic CAR T therapy targeting mesothelin using next-generation PD-1 dominant negative receptor (DNR) and 1XX CAR co-stimulatory signaling domain technologies and expects an IND filing in H2 2022
- The Company plans to present preclinical data for ATA3271 at an appropriate forum in Q4 2021

### **ATA3219 (B-cell Malignancies)**

- Atara expects to submit an IND for ATA3219, an off-the-shelf, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies, as a potential best-in-class therapy without the need for T-cell receptor (TCR) gene editing, using our next-generation 1XX CAR co-stimulatory signaling domain and EBV T-cell platform in Q1 2022

## **Executive and Board Appointments**

- Cell therapy and oncology expert, Cokey Nguyen, Ph.D., recently joined Atara as Chief Scientific Officer to further our mission of developing transformative therapies for patients with severe diseases. Dr. Nguyen joined Atara from Fate Therapeutics, where, as Vice President, Innovation, Research and Development, he directed strategy for discovery and innovation efforts, and spearheaded the corporate collaboration program with ONO Pharma
- Cell therapy and oncology commercialization veteran, Ameet Mallik, was appointed to the Board of Directors. Mr. Mallik is CEO of Rafael Holdings, a late-stage cancer metabolism therapeutic company and has held several leadership roles at Novartis, most recently as EVP & Head of U.S. Oncology. He brings to Atara's Board a wealth of experience with U.S. payer, access and reimbursement strategies and launches of innovative oncology therapies, including CAR T

### ***Second Quarter 2021 Financial Results***

- Cash, cash equivalents and short-term investments as of June 30, 2021 totaled \$373.4 million, as compared to \$435.2 million as of March 31, 2021
- Atara believes that its cash as of June 30, 2021 is sufficient to fund planned operations into 2023
- License and collaboration revenue was \$3.9 million for the second quarter 2021 and consisted of revenue from activities performed under the Bayer Collaboration Agreements. Atara did not recognize any license and collaboration revenue for the same period in 2020
- Net cash used in operating activities was \$61.6 million for the second quarter 2021, as compared to \$56.6 million for the same period in 2020
- Atara reported net losses of \$83.8 million, or \$0.91 per share, for the second quarter 2021, as compared to \$77.5 million, or \$1.14 per share, for the same period in 2020
- Total operating expenses include non-cash expenses of \$16.1 million for the second quarter 2021, as compared to \$15.9 million for the same period in 2020
- Research and development expenses were \$68.5 million for the second quarter 2021, as compared to \$61.6 million for the same period in 2020
  - The increase in the second quarter 2021 was primarily due to higher employee-related costs from increased headcount, increased spending on the Company's ATA188 and CAR T programs and increased facilities and information technology expenses allocated to research and development
- Research and development expenses include \$8.3 million of non-cash stock-based compensation expenses for the second quarter 2021, as compared to \$8.5 million for the same period in 2020
- General and administrative expenses were \$19.4 million for the second quarter 2021, as compared to \$16.4 million for the same period in 2020
- General and administrative expenses include \$5.5 million of non-cash stock-based compensation expenses for the second quarter 2021, as compared to \$5.4 million for the same period in 2020

### **Conference Call and Webcast Details**

Atara will host a live conference call and webcast today, Monday, August 9, 2021, at 4:30 p.m. EDT to discuss the Company's financial results and recent operational highlights. Analysts and investors can participate in the conference call by dialing 877-407-8291 for

domestic callers and 201-689-8345 for international callers, using the conference ID 13720150. A live audio webcast can be accessed by visiting the [Investors & Media – News & Events](#) section of [atarabio.com](#). An archived replay will be available on the Company's website for 30 days.

## **About Atara Biotherapeutics, Inc.**

[Atara Biotherapeutics, Inc. \(@Atarabio\)](#) is a pioneer in T-cell immunotherapy leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with serious diseases including solid tumors, hematologic cancers and autoimmune disease. With our lead program in Phase 3 clinical development, Atara is the most advanced allogeneic T-cell immunotherapy company and intends to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-associated diseases, or other serious diseases through incorporation of engineered CARs (chimeric antigen receptors) or TCRs (T-cell receptors). Atara is applying this one platform to create a robust pipeline including: tab-cel<sup>®</sup> in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV<sup>+</sup> PTLD) and other EBV-driven diseases; ATA188, a T-cell immunotherapy targeting EBV antigens as a potential treatment for multiple sclerosis; and multiple next-generation chimeric antigen receptor T-cell (CAR T) immunotherapies for both solid tumors and hematologic malignancies. Improving patients' lives is our mission and we will never stop working to bring transformative therapies to those in need. Atara is headquartered in South San Francisco and our leading-edge research, development and manufacturing facility is based in Thousand Oaks, California. For additional information about the company, please visit [atarabio.com](#) and follow us on [Twitter](#) and [LinkedIn](#).

## **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: (1) the potential benefits, safety and efficacy of tab-cel<sup>®</sup>; the timing and progress of tab-cel<sup>®</sup>, including (i) tab-cel<sup>®</sup> clinical trials, and the timing and outcome of Atara's discussions with the FDA regarding a BLA submission for tab-cel<sup>®</sup>, (ii) the timing and outcome of Atara's discussions with EMA regarding an MAA for tab-cel<sup>®</sup>, (iii) the timing of the initiation or submission of the BLA and MAA for tab-cel<sup>®</sup>, (iv) Atara's ability to successfully advance the development of tab-cel<sup>®</sup>, (v) Atara's activities in anticipation of potential tab-cel<sup>®</sup> approval and commercial launch in the U.S., and (vi) Atara's efforts to seek a commercialization partner for tab-cel<sup>®</sup> in Europe; (2) the potential benefits, safety and efficacy of ATA188; the timing and progress of ATA188, including (i) ATA188 clinical trials, (ii) Atara's ability to successfully advance the development of ATA188, and (iii) partnering options for ATA188; (3) the timing and progress of its CAR T programs, including (i) ATA2271 clinical trial, (ii) ATA3271 and ATA3219 preclinical development, (iii) progress of the strategic collaboration with Bayer for ATA2271 and 3271, and (iv) Atara's ability to successfully advance the development of its CAR T programs; and (4) Atara's ability to advance development of its programs. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results,

performance or achievements of Atara 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, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; the ongoing COVID-19 pandemic, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in South San Francisco and Southern California and at our clinical trial sites, as well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of Atara's cash resources and need for additional capital; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara's 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 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.

## Financials

**ATARA BIOTHERAPEUTICS, INC.**  
**Consolidated Balance Sheets**  
**(Unaudited)**  
**(In thousands)**

	<b>June 30, 2021</b>	<b>December 31, 2020</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 123,856	\$ 200,404
Short-term investments	249,524	300,255
Restricted cash - short-term	194	194
Accounts receivable	—	1,250
Prepaid expenses and other current assets	18,751	21,170
Total current assets	392,325	523,273
Property and equipment, net	51,029	50,517
Operating lease assets	11,548	12,303
Restricted cash - long-term	1,200	1,200
Other assets	689	827
Total assets	<u>\$ 456,791</u>	<u>\$ 588,120</u>

## Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 12,301	\$ 7,118
Accrued compensation	15,323	20,458
Accrued research and development expenses	12,871	15,813
Deferred revenue	40,968	33,455
Other current liabilities	7,367	6,057
Total current liabilities	88,830	82,901
Deferred revenue - long-term	22,470	27,795
Operating lease liabilities - long-term	12,182	13,041
Other long-term liabilities	1,771	2,044
Total liabilities	125,253	125,781

Commitments and contingencies

Stockholders' equity:

Common stock	8	8
Additional paid-in capital	1,618,177	1,586,616
Accumulated other comprehensive income	62	296
Accumulated deficit	(1,286,709)	(1,124,581)
Total stockholders' equity	331,538	462,339
Total liabilities and stockholders' equity	\$ 456,791	\$ 588,120

**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,	
	2021	2020	2021	2020
License and collaboration revenue	\$ 3,870	\$ —	\$ 7,422	\$ —
Operating expenses:				
Research and development	68,475	61,560	132,534	119,219
General and administrative	19,397	16,392	37,135	33,430
Total operating expenses	87,872	77,952	169,669	152,649
Loss from operations	(84,002)	(77,952)	(162,247)	(152,649)
Interest and other income, net	225	497	135	1,685
Loss before provision for income taxes	(83,777)	(77,455)	(162,112)	(150,964)
Provision for income taxes	16	1	16	1
Net loss	\$(83,793)	\$(77,456)	\$(162,128)	\$(150,965)
Other comprehensive gain (loss):				

Unrealized gain (loss) on available-for-sale securities	(99)	606	(234)	590
Comprehensive loss	<u>\$(83,892)</u>	<u>\$(76,850)</u>	<u>\$(162,362)</u>	<u>\$(150,375)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (0.91)</u>	<u>\$ (1.14)</u>	<u>\$ (1.77)</u>	<u>\$ (2.34)</u>
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	<u>92,152</u>	<u>67,975</u>	<u>91,806</u>	<u>64,592</u>

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20210809005755/en/>

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Source: Atara Biotherapeutics, Inc.