

August 5, 2020



# Atara Biotherapeutics Announces Second Quarter 2020 Financial Results and Operational Progress

– Company to host conference call 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 severe diseases including solid tumors, hematologic cancers and autoimmune disease, today reported financial results for the second quarter ended June 30, 2020 and recent business highlights.

“I am proud of the continued tremendous progress made by Atara’s team in delivering on our strategic priorities and on our mission to bring transformative therapies to patients with severe diseases,” said Pascal Touchon, President and Chief Executive Officer of Atara. “We remain on track to initiate a BLA submission for tab-cel<sup>®</sup> for patients with EBV+ PTLD by the end of 2020, despite the COVID-19 outbreak. During the quarter we also reported positive ATA188 clinical data in progressive multiple sclerosis at EAN, successfully completed a follow-on financing, made key executive and board hires, and progressed our CAR T programs closer to the clinic.”

## Recent Highlights and Anticipated Upcoming Milestones

### *Tab-cel<sup>®</sup> (tabelecleucel)*

#### ***Post-transplant lymphoproliferative disease (PTLD)***

- Atara remains on track to initiate a biologics license application (BLA) submission for patients with EBV+ PTLD by the end of 2020.
- The Company continues to advance development of tab-cel<sup>®</sup> in Phase 3 for patients with EBV+ PTLD, for which the Company has obtained Breakthrough Therapy Designation (BTD) in the United States (U.S.) and PRiority MEdicines (PRIME) designation in the European Union (EU).
- The Company plans to conduct an interim analysis of the tab-cel<sup>®</sup> Phase 3 study in the third quarter of 2020 and then discuss the totality of tab-cel<sup>®</sup> data with the U.S. Food and Drug Administration (FDA) in a pre-BLA meeting prior to initiating the BLA submission.
- Atara is in active discussions with the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) regarding a Pediatric Investigation Plan (PIP). Following discussion with the PRIME team and after EMA approval of the PIP, Atara plans to submit an EU marketing authorization application (MAA) for patients with EBV+ PTLD in 2021.
- In the U.S., Europe and Australia, more than 40 clinical study sites are available for

enrollment, with new sites in Spain, Austria and Belgium.

- Given the severity of previously treated PTLD, time sensitivity for treatment and promising clinical results to date with tab-cel<sup>®</sup>, Atara continues to provide tab-cel<sup>®</sup> to patients in need under its expanded access protocol (EAP) and single patient use (SPU) programs.

### ***Tab-cel Potential Additional Indications***

- Atara remains on track to initiate enrollment in the second half of 2020 in a tab-cel<sup>®</sup> Phase 2 multi-cohort study, enriching the evidence base with the goal of expanding the potential label in PTLD and closely related diseases.
- Atara will focus on extending further into IA-LPDs (immunodeficiency-associated lymphoproliferative diseases) as the next step in the tab-cel<sup>®</sup> potential label expansion 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>.
- The multi-cohort study will evaluate both treatment-naïve and previously treated patients in six patient populations, including within IA-LPDs, two cohorts addressing front-line EBV+ PTLD patients with significant unmet need as well as two cohorts addressing EBV+ LPDs arising out of primary or acquired immune deficiencies including AID-LPD and PID-LPD (EBV+ acquired immunodeficiency-associated lymphoproliferative disease and EBV+ primary immunodeficiency-associated lymphoproliferative disease).
- Altogether these populations represent an additional few thousand patients with addressable EBV-driven diseases in the U.S. alone.
- Previously reported clinical data from ASH (2018) and ESMO (2018) suggest that tab-cel<sup>®</sup> may provide benefit for patients with other EBV-driven diseases. Atara will publish tab-cel<sup>®</sup> efficacy and safety data in AID-LPD and PID-LPD in an e-poster accepted at ESMO 2020.
- Based on a strategic prioritization to expand tab-cel<sup>®</sup> business potential through the significant opportunity in IA-LPDs, the Company will now focus its tab-cel<sup>®</sup> efforts on the initiation of the multi-cohort Phase 2 study and the planned BLA initiation in EBV+ PTLD.
- The Company's Phase 1b study of tab-cel<sup>®</sup> in combination with anti-PD-1 therapy, KEYTRUDA<sup>®</sup> (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated nasopharyngeal carcinoma (NPC) achieved its safety endpoints and stable disease in a subset of patients. These data will be presented at an appropriate forum in the future.
- At this time, Atara will not initiate the Phase 2 portion of the NPC study in combination with pembrolizumab but will generate additional translational data in NPC to further inform the Company's strategy for this patient population.

### ***ATA188 for Progressive Multiple Sclerosis (MS)***

- Atara's Phase 1a clinical study of off-the-shelf, allogeneic ATA188 in patients with progressive forms of MS is ongoing across clinical sites in the U.S. and Australia.
  - Safety and sustained disability improvement (SDI) 12-month data for cohorts 1-3, and six-month data for cohort 4, were presented at the 2020 European Academy

of Neurology Virtual Congress (EAN) held in May 2020.

- All patients in cohorts 1-3 showing SDI at six months maintained improvement at 12 months and there was a higher proportion of patients showing SDI with increasing dose. SDI is defined as clinically significant improvement in Expanded Disability Status Scale (EDSS) or timed 25-foot walk (T25FW) observed at two consecutive time points. While these data will need to be confirmed in a double-blind, placebo-controlled, randomized study, they indicate the potential for the first treatment option in progressive MS to halt or reverse the progression of disease. These results align with the body of evidence supporting the important role of EBV-infected B cells in the chronic autoimmune pathology of MS.
- ATA188 was well-tolerated in patients with progressive forms of MS and no dose-limiting toxicities and no fatal adverse events (AEs) have been reported. ATA188 treatment showed no clinically meaningful effect on cytokine levels and no dose-related safety trends were identified. Rhinorrhea (runny nose) is the only treatment-related event that occurred in more than one subject.
- Atara expects to present 12-month clinical results for cohort 4 at an appropriate forum in the second half of 2020.
- Atara is re-treating patients in the open-label extension (OLE) of the Phase 1a study and expects to present preliminary OLE data, at an appropriate forum in the second half of 2020.
- Based on the promising data presented at EAN, the cohort 3 dose from the Phase 1a study was selected for the double-blind, randomized placebo-controlled study evaluating the efficacy and safety of ATA188 in patients with progressive forms of MS. The study design allows for addition of the cohort 4 dose, if desired, based on the 12-month data for cohort 4 that will be available in the third quarter of 2020.
  - The study enrolled its first patient in June 2020. In addition to measuring change in disability measures compared to baseline, especially sustained disability improvement over time, the study will also include multiple measures of patients' function as well as various biomarkers.

## ***CAR T Programs***

### ***ATA2271/ATA3271 (Solid tumors)***

- Atara's next generation CAR T immunotherapy programs include autologous ATA2271 targeting mesothelin--a tumor antigen expressed on a number of solid tumors including mesothelioma, ovarian cancer, pancreatic cancer, non-small cell lung cancer, and other tumors over-expressing mesothelin.
  - ATA2271 is designed to improve efficacy, persistence, and durability of response versus CD28/CD3z-based CARs in using a novel 1XX CAR co-stimulatory signaling domain and cell intrinsic checkpoint inhibition technology with a PD-1 dominant negative receptor (DNR).
  - Data from IND-enabling studies for ATA2271 were presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting II in June 2020. These data support the first application of the combination of 1XX CAR co-stimulatory domain and cell intrinsic checkpoint inhibition technology with a PD-1 DNR, that are associated with less cell exhaustion, improvements in functional

persistence, serial cell killing, and in vivo efficacy which was maintained through multiple tumor re-challenges when compared with first-generation CD28/CD3z-based mesothelin CAR.

- ATA2271 collaborators at Memorial Sloan Kettering Cancer Center (MSK) recently submitted an Investigational New Drug (IND) application to the FDA for patients with advanced mesothelioma.
- Atara is also developing and has initiated IND-enabling studies for ATA3271, an off-the-shelf, allogeneic CAR T immunotherapy targeting mesothelin using its novel combination of 1XX CAR co-stimulatory signaling domain and cell intrinsic checkpoint inhibition technology with a PD-1 DNR through its EBV T-cell platform.

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

- Atara is developing ATA3219, an off-the-shelf, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies as a potential best-in-class therapy using the next-generation 1XX CAR co-stimulatory domain and EBV T-cell platform. Atara intends to leverage the differentiation of 1XX and allogeneic EBV T cell to address remaining unmet need despite currently approved autologous CD19 CAR T and other allogeneic CD19 cell therapies in development.
- Findings from an academic, off-the-shelf, allogeneic CD19 CAR T clinical study using an allogeneic EBV T-cell construct and CD28/CD3z co-stimulatory domain for patients with relapsed/refractory B-cell malignancies provided initial clinical proof-of-principle that an EBV T-cell platform has the potential to generate off-the-shelf, allogeneic CAR T immunotherapies with high response rates, durable responses, and low risk of toxicity. These results were presented in February at the 2020 Transplantation and Cellular Therapy Meetings.
- The Company has initiated IND-enabling studies for ATA3219 and anticipates filing an IND in 2021.

### **Operations**

- Atara continues to advance key elements of its off-the-shelf, allogeneic T-cell immunotherapy platform.
  - Atara is completing the manufacturing process validation activities for tab-cel<sup>®</sup> while building inventory according to its commercial product supply strategy.
  - Atara continues to scale its EBV T-cell manufacturing platform to improve product yields from a single donor leukapheresis. The Company has generated data confirming the use of stirred-tank perfusion bioreactors to improve yield and cell growth productivity.
    - These data confirm that ATA188 can be manufactured in stirred-tank perfusion bioreactors, with the potential to produce up to 40,000 doses per donor leukapheresis.
    - Atara's scale-up technology is a key enabler to deliver biologic-like cost of goods manufactured and will be leveraged across its portfolio, including the Company's CAR T programs.
  - Despite the challenges of the COVID-19 environment, Atara continues to consistently deliver product from inventory to clinical sites on time.

## ***Executive and Board Appointments***

- Two scientific leaders in the field of cell and gene therapy recently joined Atara in its mission to leverage its novel, allogeneic EBV T-cell platform to develop transformative therapies for patients with severe diseases:
  - Jakob Dupont, M.D. was named Executive Vice President, Global Head of R&D. He possesses deep and diverse expertise from cell therapy research to oncology clinical development and global regulatory approvals. Dr. Dupont joined Atara from Gossamer Bio where he served as Chief Medical Officer, and held previous roles at Genentech/Roche and OncoMed. At Memorial Sloan Kettering Cancer Center (MSK), Dr. Dupont served on faculty and worked in the laboratories of Richard O'Reilly, M.D., the scientific inventor of tab-cel<sup>®</sup>, and Michel Sadelain, M.D., Ph.D, Atara's collaborator on multiple next generation CAR T programs.
  - Maria Grazia Roncarolo, M.D. was appointed to the Board of Directors. Dr. Roncarolo holds several professorships and director roles at Stanford University, and in 2014 established the Stanford Center for Definitive and Curative Medicine. The center is dedicated to the development of innovative stem cell and gene therapies for patients with currently incurable diseases. Dr. Roncarolo is one of the world's leading experts in immunology and T cells and has a record of translating scientific discoveries in cell and gene therapy into novel treatments.

## ***Second Quarter 2020 Financial Results***

- Cash, cash equivalents and short-term investments as of June 30, 2020 totaled \$347.7 million, as compared to \$214.6 million as of March 31, 2020.
  - June 30, 2020 cash balance of \$347.7 million included aggregate net proceeds of \$189.3 million from the sale of 14,958,039 shares of common stock and pre-funded warrants to purchase 2,866,961 shares of common stock in May and June of 2020 in an underwritten public offering, including the full exercise of the option to purchase additional shares by the underwriters.
  - Atara believes that its cash, cash equivalents and short-term investments as of June 30, 2020 are sufficient to fund planned operations into 2022.
- Net cash used in operating activities was \$56.6 million for the second quarter of 2020, as compared to \$54.6 million for the same period in 2019.
- The number of outstanding shares of common stock and pre-funded common stock warrants as of June 30, 2020 was 74,307,894 shares and warrants to purchase 5,755,487 shares, respectively.
- Atara reported net losses of \$77.5 million, or \$1.14 per share, for the second quarter of 2020, as compared to \$74.3 million, or \$1.60 per share, for the same period in 2019.
- Total operating expenses include non-cash expenses of \$15.9 million for the second quarter 2020, as compared to \$16.9 million for the same period in 2019.
- Research and development expenses were \$61.6 million for the second quarter of 2020, as compared to \$52.3 million for the same period in 2019. The increase in the 2020 period was due to costs associated with the Company's continuing expansion of research and development activities, including:
  - Clinical study, manufacturing and process performance qualification activities related to tab-cel<sup>®</sup>.
  - Higher employee-related costs from increased headcount.
- Research and development expenses include \$8.5 million of non-cash stock-based

compensation expenses for the second quarter of 2020, as compared to \$6.7 million for the same period in 2019.

- General and administrative expenses were \$16.4 million for the second quarter of 2020, as compared to \$23.3 million for the same period in 2019. The decrease in the 2020 period was primarily due to a decrease in outside services costs and non-cash stock-based compensation expenses.
- General and administrative expenses include \$5.4 million of non-cash stock-based compensation expenses for the second quarter of 2020, as compared to \$8.5 million for the same period in 2019.

## **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 severe 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 severe 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> (tabelecleucel) in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLN); 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](#).

## **Conference Call and Webcast Information**

Atara will host a live conference call and webcast today 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 (888) 540-6216 for domestic callers and (734) 385-2715 for international callers, using the conference ID 9355679. 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 14 days following the live webcast.

## **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: Atara's ability to deliver on key milestones relating to tab-cel<sup>®</sup>, including (i) conducting an interim analysis of the tab-cel<sup>®</sup> Phase 3 study and discussing the totality of tab-cel<sup>®</sup> data with the FDA prior to initiating the BLA submission, (ii) discussions with the EMA regarding a PIP under the

PRIME mechanism for the EMA., (iii) the timing and plan of submitting an EU MAA, (iv) initiating enrollment in a Phase 2 multi-cohort study and potentially expanding tab-cel<sup>®</sup> into other indications, (v) the timing and results of additional clinical data, and (vi) the timing of BLA submissions for tab-cel<sup>®</sup> for patients with EBV+ PTLD; the potential benefits and efficacy of Atara's drug candidates; the timing, enrollment and results of additional data from Atara's clinical trials; and the sufficiency of our cash, cash equivalents and short-term investments for our operations into 2022. 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 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 manufacturers, 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 the sections titled "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)**

	June 30, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 74,511	\$ 74,317
Short-term investments	273,201	184,792
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	11,081	13,689
Total current assets	358,987	272,992
Property and equipment, net	53,587	54,176
Operating lease assets	13,321	14,007
Restricted cash - long-term	1,200	1,200
Other assets	1,016	567
Total assets	<u>\$ 428,111</u>	<u>\$ 342,942</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,106	\$ 7,963
Accrued compensation	12,657	14,706
Accrued research and development expenses	8,244	8,341
Other current liabilities	5,677	5,733
Total current liabilities	31,684	36,743
Operating lease liabilities - long-term	13,420	14,136
Other long-term liabilities	1,882	1,282
Total liabilities	46,986	52,161
Commitments and contingencies		
Stockholders' equity:		
Common stock	7	6
Additional paid-in capital	1,349,234	1,108,516
Accumulated other comprehensive income	810	220
Accumulated deficit	(968,926)	(817,961)
Total stockholders' equity	381,125	290,781
Total liabilities and stockholders' equity	<u>\$ 428,111</u>	<u>\$ 342,942</u>



**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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 61,560	\$ 52,251	\$ 119,219	\$ 100,919
General and administrative	16,392	23,284	33,430	42,507
Total operating expenses	<u>77,952</u>	<u>75,535</u>	<u>152,649</u>	<u>143,426</u>
Loss from operations	(77,952)	(75,535)	(152,649)	(143,426)
Interest and other income, net	497	1,207	1,685	2,841
Loss before provision for income taxes	(77,455)	(74,328)	(150,964)	(140,585)
Provision for income taxes	1	—	1	—
Net loss	<u>\$ (77,456)</u>	<u>\$ (74,328)</u>	<u>\$ (150,965)</u>	<u>\$ (140,585)</u>
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	606	135	590	513
Comprehensive loss	<u>\$ (76,850)</u>	<u>\$ (74,193)</u>	<u>\$ (150,375)</u>	<u>\$ (140,072)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (1.14)</u>	<u>\$ (1.60)</u>	<u>\$ (2.34)</u>	<u>\$ (3.04)</u>
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share				
	<u>67,975</u>	<u>46,426</u>	<u>64,592</u>	<u>46,276</u>

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Source: Atara Biotherapeutics, Inc.