

February 28, 2022



# Atara Biotherapeutics Announces Fourth Quarter and Full Year 2021 Financial Results and Operational Progress

*Tab-cel U.S. BLA Submission Not Currently Expected for Q2 2022 as Further FDA Engagement and Alignment Required; Anticipated EU Approval On-Track for Q4 2022 Under Accelerated Assessment*

*ATA188 Granted FDA Fast Track Designation in Both Non-Active PPMS and Non-Active SPMS with Phase 2 EMBOLD Study Interim Analysis Planned for Q2 2022*

*Entered Long-Term Strategic Manufacturing Partnership with Fujifilm with Upfront Cash Payment of USD 100 Million*

*Conference Call and Webcast Today at 1:30 p.m. PST/ 4:30 p.m. EST*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA), a leader 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 fourth quarter and full year 2021, recent business highlights and key upcoming catalysts for 2022.

“With our EMA filing for tab-cel<sup>®</sup> and a strategic commercial collaboration with Pierre Fabre, ATA188’s FDA Fast Track designations and new data reinforcing its potential to reverse or halt disability in progressive multiple sclerosis, 2021 provided strong validation for Atara and our industry-leading allogeneic T-cell pipeline,” said Pascal Touchon, President and Chief Executive Officer of Atara. “2022, which has already delivered two landmark publications confirming EBV as the leading cause of MS in advance of our interim analysis from our ATA188 Phase 2 study, and a long-term strategic manufacturing partnership with Fujifilm, will be a critical year as we progress our strategic priorities. Although further engagement and alignment is required with FDA to determine the path forward for a BLA submission in the U.S., we anticipate a groundbreaking EU approval this year that will position tab-cel as the first ever allogeneic off-the-shelf T-cell therapy available for patients.”

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

- Atara has performed extensive studies demonstrating analytical comparability between the tab-cel manufacturing process versions used for the pivotal study and that intended for commercialization
  - Comprehensive comparability analyses included all 74 available product lots manufactured by Atara and covered 21 key attributes associated with potency, purity, and alloreactivity. Atara believes analytic comparability between tab-cel process versions has been demonstrated based on well-established statistical methodology and application of ICH<sup>1</sup> guidelines and is further supported by

significant and consistent clinical experience

- These comparability data analyses were submitted to the European Medicines Agency (EMA) through our MAA filing in November 2021 and the review, under Accelerated Assessment, is progressing as planned following receipt of EMA day 80 Critical Assessment report, with anticipated approval in Q4 2022
- A Type B CMC meeting was conducted in late February 2022 with the U.S. Food & Drug Administration (FDA) review team to discuss and potentially align on comparability between commercial and pivotal clinical trial products
- Preliminary meeting responses and discussion did not result in alignment on comparability and the FDA has initially recommended Atara conduct a clinical study with commercial product as they do not agree that comparability has been demonstrated
  - Atara has responded with additional questions to clarify the FDA's view and has suggested several alternative approaches to progress to a BLA submission given tab-cel is a BTB product that addresses an urgent medical need and has the potential to save the lives of patients with an ultra-rare, often fatal disease with no approved therapeutic options
- Additional interactions with the Agency are expected, including receipt of final Type B CMC meeting minutes. However, based on the preliminary feedback received from the FDA, Atara does not currently expect to file a BLA in Q2 2022
- Atara expects further engagement with FDA on potential pathways to a BLA submission for tab-cel and plans to provide a further update during its next quarterly call
- After entering an exclusive commercialization collaboration in Q4 2021, Atara is working with Pierre Fabre to prepare for the launch of tab-cel in Europe while adapting its U.S. commercialization preparation to account for possible delays in submission and potential approval of a BLA in the U.S.

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

- The multi-cohort Phase 2 study evaluating tab-cel in six additional patient populations for EBV+ immunodeficiency-associated lymphoproliferative diseases (IA-LPDs) and other EBV-driven diseases is currently enrolling in the U.S. and EU
- First data from the multi-cohort study is on track for presentation in 2023

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

- Recent landmark [studies](#) further validate Atara's approach and EBV-targeted platform. Publications in *Science* and *Nature* provide compelling new epidemiological evidence that EBV is the leading cause of MS and mechanistic evidence showing how EBV infection can initiate and propagate the autoimmune attack on the brain in MS
- The FDA granted Fast Track designation to ATA188 for non-active primary progressive multiple sclerosis (PPMS) and non-active secondary progressive multiple sclerosis (SPMS), two populations with high unmet medical need and limited treatment options
- Encouraging data presented at ECTRIMS 2021 from the ongoing Phase 1 open-label extension study of ATA188 with up to 39 months follow-up demonstrated that 20 out of 24 patients had sustained disability improvement or stabilization of disease on expanded disability status scale (EDSS)
  - Patients who achieved sustained EDSS improvement at any time showed

- significant increase in Magnetization Transfer Ratio (MTR) in non-enhancing T2 lesions at 12 months compared to baseline, suggestive of remyelination
- Atara continues to advance enrollment in the Phase 2 EMBOLD study, with target enrollment of 80 patients expected soon after a planned formal interim analysis (IA) in Q2 2022
    - The IA will include efficacy, safety, and biomarker data to inform adjustments to sample size, if needed, to optimize likelihood of Phase 2 success, and confirm the Company's current development strategy moving forward
    - A key data point at the time of the IA will be EDSS improvement at six months for applicable patients. In the Phase 1 study, EDSS improvement at six months was >85 percent predictive of achieving sustained EDSS improvement at 12 months, the primary endpoint of EMBOLD
  - Following the IA, Atara plans to communicate next steps for the program, including rationale, while still maintaining the integrity of the study. Atara also plans to interact with the FDA following the IA to discuss potential development pathways for ATA188
  - Prior to conducting the IA in Q2 2022, the Company will host a public webcast, Atara MS Day, for the investor community on March 22<sup>nd</sup> to review the key drivers generating excitement around our potentially transformative ATA188 MS program. The Company will also communicate new areas of development, including exploratory work on a differentiated EBV vaccine with encouraging pre-clinical data

### ***CAR T Programs***

- Atara is building an innovative next-generation CAR T platform, which includes key features needed for efficacy and persistence, such as the use of PD-1 dominant negative receptor (DNR) and 1XX CAR co-stimulatory signaling domain technologies
- The CAR T platform retains the endogenous T-cell receptor (TCR), shown to be essential for T-cell persistence and survival

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

- The global strategic collaboration for autologous ATA2271 and allogeneic ATA3271 with Bayer continues to progress
- Encouraging early safety and persistence of ATA2271 from lower dose cohorts of the ongoing Phase 1 dose-escalation trial in patients with advanced mesothelioma was presented at the ESMO Immuno-Oncology Congress in December 2021
- Memorial Sloan Kettering Cancer Center (MSK) notified the FDA of a fatal serious adverse event (SAE) associated with a patient treated in the third, higher dose cohort in the ongoing Phase 1, MSK-conducted dose-escalation clinical study of autologous mesothelin CAR T, ATA2271
- MSK has voluntarily paused enrollment of new patients in the ATA2271 study on a temporary basis while additional information regarding the case is gathered and reviewed. The FDA notified MSK of its agreement with this approach
  - Subject to the outcome of this review and resumption of enrollment of new patients in this study we expect to provide a data update from this Phase 1 study in 2022
  - The single case involved a patient with a history of multiple malignancies and other comorbidities undergoing treatment for advanced recurrent mesothelioma
- The temporary pause in ATA2271 study enrollment does not impact the IND-enabling

work currently underway to advance ATA3271, a separate off-the-shelf, allogeneic CAR-T therapy targeting mesothelin using next-generation PD-1 DNR and 1XX CAR technologies for patients with advanced mesothelioma, with an expected IND filing in Q4 2022

- Atara's pipeline programs, including ATA3271, ATA3219, tab-cel, and ATA188 all utilize the Company's allogeneic EBV T-cell platform, the safety and tolerability of which has been demonstrated by clinical studies and experience in approximately 400 patients in various disease areas with no SAEs, including cytokine release syndrome (CRS), observed to date

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

- Atara is progressing ATA3219, our potential best-in-class, allogeneic CAR T for B cell malignancies expressing CD19, and expects to submit an IND in Q4 2022
- ATA3219 is an optimized approach to address high unmet medical need, leveraging our next-generation 1XX CAR co-stimulatory signaling domain and allogeneic EBV T-cell platform and does not require TCR or human leukocyte antigen (HLA) gene editing

### ***Allogeneic T-Cell Platform Development and Operations***

- Atara entered a strategic manufacturing partnership in January 2022 with FUJIFILM Diosynth Biotechnologies (FDB), a subsidiary of FUJIFILM Corporation (Fujifilm), under which Fujifilm will acquire Atara's T-cell Operations and Manufacturing (ATOM) facility for USD 100 million upfront, retaining current manufacturing and quality staff at the site. Closing of the transaction is expected to occur in April
- As part of the long-term supply agreement, which could extend to 10 years following anticipated completion of the transaction, FDB will also provide Atara with flexible capacity and specific capability needed to manufacture and support the Company's maturing and promising pipeline
- Atara continues to leverage its recently established and now fully operational Thousand Oaks-based Atara Research Center (ARC), which houses the Company's Pre-Clinical, Translational Sciences, Manufacturing Process Sciences, and Analytical Development Teams to further drive innovation

### ***Fourth Quarter and Full Year 2021 Financial Results***

- Cash, cash equivalents and short-term investments as of December 31, 2021 totaled \$371.1 million, as compared to \$500.7 million as of December 31, 2020
- The December 31, 2021 cash balance includes \$47.7 million of net proceeds from the sale of 2,836,062 shares of common stock through the Company's ATM facilities in the fourth quarter, and a \$45.0 million upfront payment received under the Pierre Fabre Commercialization Agreement, partially offset by operating cash outflows
- Atara believes that its cash as of December 31, 2021, together with the anticipated \$100.0 million payable to Atara upon closing of the strategic transaction with FDB, will be sufficient to fund the Company's planned operations into the fourth quarter of 2023
- Net cash used in operating activities was \$34.3 million and \$220.5 million for the fourth quarter and fiscal year 2021, respectively, as compared to \$4.1 million and \$180.8 million for the same periods in 2020; the increase in operating cash usage in 2021 was primarily due to a \$33.5 million increase in net loss and increased usage of net working capital, partially offset by \$45.0 million received under the Pierre Fabre

### Commercialization Agreement

- Atara reported net losses of \$93.3 million, or \$0.96 per share, and \$340.1 million, or \$3.63 per share, for the fourth quarter and fiscal year 2021, respectively, as compared to \$81.3 million, or \$0.95 per share, and \$306.6 million, or \$4.15 per share, for the same periods in 2020
- Total operating expenses include non-cash expenses of \$16.5 million and \$63.0 million for the fourth quarter and fiscal year 2021, respectively, as compared to \$13.6 million and \$59.4 million for the same periods in 2020
- Research and development expenses were \$79.1 million and \$282.0 million for the fourth quarter and fiscal year 2021, respectively, as compared to \$65.6 million and \$244.7 million for the same periods in 2020
  - The increases in the fourth quarter and fiscal year 2021 were primarily due to higher employee-related and overhead costs from increased headcount, higher facility-related costs in support of continuing expansion of research and development activities and increased spending on research, development, and clinical trial costs to further advance ATA188 and CAR T programs
  - Research and development expenses include \$8.4 million and \$32.1 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2021, respectively, as compared to \$7.2 million and \$31.5 million for the same periods in 2020
- General and administrative expenses were \$21.8 million and \$78.8 million for the fourth quarter and fiscal year 2021, respectively, as compared to \$16.1 million and \$64.4 million for the same periods in 2020
  - The increases in the fourth quarter and fiscal year 2021 were primarily due to higher compensation-related costs from increased headcount and activities to support an anticipated tab-cel launch
  - General and administrative expenses include \$5.6 million and \$21.8 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2021, respectively, as compared to \$4.3 million and \$19.8 million for the same periods in 2020

### Conference Call and Webcast Details

Atara will host a live conference call and webcast today, Monday, February 28, 2022, at 4:30 p.m. EST 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 13725930. A live audio webcast can be accessed by visiting the [Investors & Media – News & Events](#) section of [atarabio.com](http://atarabio.com). An archived replay will be available on the Company's website for 30 days following the live webcast.

### 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 and currently under review to support registration in Europe, 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, which does not require TCR or HLA gene editing, 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](http://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) data and analyses from ALLELE study; (ii) tab-cel<sup>®</sup> clinical trials, and the occurrence, timing and outcome of Atara's interactions and discussions with the FDA regarding a BLA submission for tab-cel<sup>®</sup>, (iii) the timing and outcome of the MAA for tab-cel<sup>®</sup>, (iv) the timing of the initiation or submission of the BLA for tab-cel<sup>®</sup>, (v) the timing of the EMA's review of the MAA for tab-cel<sup>®</sup>, (vi) Atara's ability to successfully advance the development of tab-cel<sup>®</sup>, and (vii) Atara's collaboration with Pierre Fabre for commercializing tab-cel<sup>®</sup> in Europe, Middle East, Africa and other emerging markets; (2) the potential benefits, safety and efficacy of ATA188; the timing and progress of ATA188, including (i) regulatory designations for ATA188 granted by FDA and the impact thereof; (ii) the mechanistic link between EBV and multiple sclerosis and the ability of ATA188 to specifically target such link; (iii) data from ATA188 OLE study; (iv) ATA188 clinical trials, (v) Atara's ability to successfully advance the development of ATA188, and (vi) partnering options for ATA188; (3) the timing and progress of its CAR T programs, and the safety and efficacy of product candidates emerging from such 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; (4) Atara's research and development activities at ARC; (5) Atara's proposed sale of its ATOM manufacturing facility to FUJIFILM Diosynth Biotechnologies (FDB), including (i) the parties ability to consummate such transaction, including the timing thereof, (ii) the potential benefits of such transaction to Atara, including the potential financial benefits to Atara, (iii) the proposed supply agreement between the parties and the duration and benefits thereof, (iv) FDB's ability to perform under the proposed supply agreement and meet Atara's requirements, (v) FDB's potential plans for ATOM, and (vi) Atara's ability to retain its staff and capabilities, and (6) Atara's ability to advance development of its other 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)**

	December 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 106,084	\$ 200,404
Short-term investments	264,984	300,255
Restricted cash - short-term	194	194
Accounts receivable	986	1,250
Prepaid expenses and other current assets	12,373	21,170
Total current assets	384,621	523,273
Property and equipment, net	53,780	50,517
Operating lease assets	26,159	12,303
Restricted cash - long-term	1,200	1,200
Other assets	2,367	827
Total assets	\$ 468,127	\$ 588,120
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 17,368	\$ 7,118
Accrued compensation	25,150	20,458
Accrued research and development expenses	13,451	15,813
Deferred revenue	40,760	33,455
Other current liabilities	9,057	6,057
Total current liabilities	105,786	82,901
Deferred revenue - long-term	55,708	27,795
Operating lease liabilities - long-term	25,518	13,041
Other long-term liabilities	1,501	2,044
Total liabilities	188,513	125,781
Commitments and contingencies		
Stockholders' equity:		
Common stock	9	8
Additional paid-in capital	1,744,695	1,586,616
Accumulated other comprehensive (loss) income	(368)	296
Accumulated deficit	(1,464,722)	(1,124,581)
Total stockholders' equity	279,614	462,339
Total liabilities and stockholders' equity	\$ 468,127	\$ 588,120



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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
License and collaboration revenue	\$ 7,548	\$ —	\$ 20,340	\$ —
Operating expenses:				
Research and development	79,134	65,554	282,001	244,650
General and administrative	21,817	16,143	78,801	64,402
Total operating expenses	100,951	81,697	360,802	309,052
Loss from operations	(93,403)	(81,697)	(340,462)	(309,052)
Interest and other income, net	84	398	367	2,447
Loss before provision for income taxes	\$ (93,319)	\$ (81,299)	\$ (340,095)	\$ (306,605)
Provision for income taxes	30	8	46	15
Net loss	\$ (93,349)	\$ (81,307)	\$ (340,141)	\$ (306,620)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(392)	(231)	(664)	76
Comprehensive loss	\$ (93,741)	\$ (81,538)	\$ (340,805)	\$ (306,544)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (0.96)	\$ (0.95)	\$ (3.63)	\$ (4.15)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	97,407	85,301	93,670	73,973

<sup>1</sup> The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

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Source: Atara Biotherapeutics, Inc.