
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 4, 2021

Atara Biotherapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36548
(Commission
File Number)

46-0920988
(IRS Employer
Identification No.)

611 Gateway Boulevard, Suite 900 South San Francisco, CA
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's telephone number, including area code: (650) 278-8930

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions *see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities pursuant to Section 12 (b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.0001 per share	ATRA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 4, 2021, Atara Biotherapeutics, Inc. (“Atara”) announced certain financial results for the third quarter ended September 30, 2021. A copy of Atara’s press release, titled “Atara Biotherapeutics Announces Third Quarter 2021 Financial Results and Operational Progress” is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 4, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The information in this report, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this report and the attached Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ATARA BIOTHERAPEUTICS, INC.

Date: November 4, 2021

By: /s/ Utpal Koppikar

Utpal Koppikar

Chief Financial Officer

Atara Biotherapeutics Announces Third Quarter 2021 Financial Results and Operational Progress

Positive Pivotal Phase 3 ALLELE Data Reinforcing the Transformative Potential of Tab-cel® to be Highlighted as Oral Presentation at Upcoming American Society of Hematology Meeting

Significant Tab-cel® Regulatory Progress with Imminent EU MAA Submission and Additional Clarity on FDA Requirements for BLA Submission Planned for Q2 2022

ATA188 Data Demonstrates Durable, Clinically Meaningful Disability Improvement and Possible Remyelination in Patients with Progressive Multiple Sclerosis

Company to Host Live Conference Call and Webcast Today at 8:30 a.m. EDT

SOUTH SAN FRANCISCO, Calif., November 4 -- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today reported financial results for the third quarter 2021, recent business highlights and key catalysts over the next several months.

“Atara continues to make meaningful progress across our strategic priorities and with positive data from our pivotal Phase 3 ALLELE study and imminent EU regulatory submission, we are now at an inflection point as we work to deliver tab-cel®, a potentially transformative first-in-kind therapy, to patients in need,” said Pascal Touchon, President and Chief Executive Officer of Atara. “We are equally encouraged by new data confirming our conviction for ATA188 as the first investigational therapy to reverse disability in progressive multiple sclerosis, and upcoming milestones related to our potentially best-in-class CAR T portfolio that does not require TCR or HLA gene editing.”

Tablecleucel (tab-cel®) for Post-Transplant Lymphoproliferative Disease (PTLD)

- First presentation of new positive data from the pivotal Phase 3 ALLELE study, reinforcing the transformative potential of tab-cel, has been accepted as an oral session at the 63rd American Society of Hematology (ASH) Annual Meeting in December 2021
 - Top-line data with additional patients and extended follow up confirm a strong objective response rate (ORR) and a safety profile in line with prior results, demonstrate durability of response, and will support the imminent EU Marketing Authorization Application (MAA) submission
 - An ORR, as measured by independent oncologic response adjudication (IORA) assessment, of 50% (19/38, 95% CI: 33.4, 66.6) was observed, with an ORR of 50% (12/24, 95% CI: 29.1, 70.9) in PTLT following SOT and 50% (7/14, CI: 23.0, 77.0) in PTLT following HCT, with a best overall response of Complete Response (CR; n=5, SOT; n=5, HCT) or Partial Response (PR; n=7, SOT; n=2, HCT)
 - Overall, the median time to response (TTR) was 1.1 months (0.7-4.7). Of 19 responders, 11 had a duration of response (DOR) lasting more than six months and median DOR has not been reached yet
 - The one-year survival rate was 61.1% overall (57.4% for SOT, and 66.8% for HCT). Those who responded had a longer survival compared to the non-responders, with a median
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- overall survival (OS) not evaluable (NE) (95% CI: 16.4, NE) and 1-year survival rate of 89.2% (95% CI: 63.1, 97.2)
- Safety findings were consistent with previously published data, with no new signals. There were no reports of tumor flare reaction, and no confirmed evidence of graft versus host disease (GvHD), organ rejection, infusion reactions, or cytokine release syndrome (CRS) related to tab-cel
- At ASH, Atara will present additional data on tab-cel through several abstracts, including a second oral presentation on long term OS from Phase 2 and multi-center Expanded Access Protocol (EAP) studies in relapsed/refractory EBV+ PTLD showing median OS of 54.6 months in all patients and OS at two years reaching over 86% in responders whether patients experienced CR or PR
- Following successful interactions with the European Medicines Agency (EMA), and their recent granting of accelerated assessment to tab-cel, Atara will imminently submit a MAA for tab-cel, with an EU approval decision anticipated in H2 2022
- The previously announced exclusive agreement with Pierre Fabre for the commercialization of tab-cel in Europe, the Middle East, Africa, and other select emerging markets for EBV-positive cancers has started strongly. Atara will retain full rights to tab-cel in other major markets, including North America, Asia Pacific, and Latin America
- Atara has continued to make good progress through Type B meetings with the U.S. Food and Drug Administration (FDA)
 - After gaining clarity, alignment on key comparability methodology has been reached
 - Based on the requests from FDA following recent interactions, Atara will provide the Agency with additional analyses of CMC data already generated
 - FDA has not requested additional studies or manufacturing lots
 - Atara subsequently plans to have further interactions with the FDA in Q1 2022 and complete the Biologics License Application (BLA) submission for tab-cel in Q2 2022

Tab-cel for Potential Additional Indications

- Atara is committed to pursuing the development of tab-cel in additional EBV-positive patient populations, with a primary focus on immunodeficiency-associated lymphoproliferative diseases (IA-LPDs)
- Enrollment is continuing at sites in the Phase 2 multi-cohort study, which is evaluating six patient populations, including four within IA-LPDs and two in other EBV-driven diseases, in the U.S. and EU. Phase 2 study data is expected in 2023

ATA188 for Progressive Multiple Sclerosis

- Positive momentum around the ATA188 program continues to build, with increasing awareness of and excitement for the transformative potential of ATA188 in multiple sclerosis (MS) among the medical community and industry
 - At the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting in October, Atara presented translational data based on magnetization transfer ratio (MTR), an imaging biomarker of myelin density, and updated Phase 1 open-label extension (OLE) clinical data in patients with progressive MS treated with ATA188 for up to 39 months
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- Findings continue to demonstrate that patients may achieve sustained disability improvement (SDI) at a higher rate and longer duration than would be expected based on the natural history of progressive MS; the majority of SDI is driven by improvement in the expanded disability status scale (EDSS)
- In seven of eight patients, SDI was maintained at all subsequent timepoints up to 33 months, with multiple patients regaining enough function that they no longer needed a walking aid and were able to walk a few hundred meters unassisted. Most patients in the OLE were progression free, which could be another significant measure of clinical benefit in people with progressive MS
- Magnetic Resonance Imaging (MRI) results showed increases in MTR suggestive of remyelination. In patients treated with ATA188 who achieved sustained EDSS improvement versus those who did not, MTR for non-enhancing T2 chronic brain lesions increased at six months and this increase achieved statistical significance at 12 months; A similar trend of MTR increase was also seen in normal-appearing brain tissue
- These MTR data, where the time course for increase in MTR parallels the EDSS improvements observed, provides evidence that remyelination may be the driver for clinical improvement, and supports a potential biological basis for clinical EDSS improvements observed with ATA188
- Updated results from the ongoing OLE demonstrate continued safety and tolerability of ATA188 with up to three annual treatments. As of August 2021, no fatal adverse events, grade >3 events, dose-limiting toxicities, CRS, or GvHD were observed
- Atara is continuing to make good progress with enrollment of the Phase 2 randomized, double-blind, placebo-controlled dose-expansion EMBOLD study evaluating the efficacy and safety of ATA188 in patients with progressive MS, across clinical sites in North America and Australia
 - An interim analysis to assess efficacy and safety is planned for H1 2022. The Company plans to communicate its decision on next steps for the program, including rationale, while still maintaining the integrity of the study
 - Atara expects to complete enrollment for EMBOLD in H1 2022
- Atara will present encore data at the 29th Annual Meeting of the European Charcot Foundation in November 2021. The Company will present an overview of the methodology planned to determine the potential pharmacodynamic effect of ATA188, by quantifying a decrease of EBV infected cells following treatment with ATA188

CAR T Programs

ATA2271/ATA3271 (Solid Tumors Over-Expressing Mesothelin)

- The global strategic collaboration for ATA2271 and ATA3271 with Bayer continues to progress, with work advancing across both mesothelin-partnered CAR-T immunotherapy programs
 - The first presentation of preclinical, clinical, and translational data from the lowest dose cohorts of 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, will take place during a Mini Oral session at the ESMO Immuno-Oncology Congress on December 9, 2021 (presentation #46MO)
 - 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
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receptor (DNR) and 1XX CAR co-stimulatory signaling domain technologies and expects an IND filing in H2 2022

- Preclinical data for ATA3271 will be presented at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting, taking place November 10-14, 2021 (poster #136)

ATA3219 (B-cell Malignancies)

- Atara is making good progress and expects to submit an IND for ATA3219, an off-the-shelf, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies, in Q1 2022
- Leveraging our next-generation 1XX CAR co-stimulatory signaling domain and allogeneic EBV T-cell platform, ATA3219 is a potential best-in-class therapy that does not require T-cell receptor (TCR) or human leukocyte antigen (HLA) gene editing

Allogeneic T Cell Platform Development

- To date, the safety and tolerability of Atara's allogeneic EBV T-cell therapies and platform has been validated by clinical studies and experience in approximately 400 patients in various disease areas
- We have established a new Atara Research Center (ARC) to house the Company's Translational and Pre-Clinical Sciences, Process Sciences, and Analytical Development teams. New capabilities will support our product pipeline and further drive innovation by leveraging our unique and differentiated allogeneic cell therapy platform

Third Quarter 2021 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2021 totaled \$357.2 million, as compared to \$373.4 million as of June 30, 2021
 - The September 30, 2021 cash balance includes \$46.4 million from the sale of 3,123,570 shares of common stock through the Company's at-the-market (ATM) facility
 - Atara believes that its cash as of September 30, 2021, together with the \$45.0 million upfront payment received as a result of our entry into the Pierre Fabre Commercialization Agreement, is sufficient to fund planned operations into the second quarter of 2023
 - License and collaboration revenue was \$5.4 million for the third 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 \$59.0 million for the third quarter 2021, as compared to \$53.0 million for the same period in 2020
 - Atara reported net losses of \$84.7 million, or \$0.90 per share, for the third quarter 2021, as compared to \$74.3 million, or \$0.92 per share, for the same period in 2020
 - Total operating expenses include non-cash expenses of \$16.0 million for the third quarter 2021, as compared to \$15.4 million for the same period in 2020
 - Research and development expenses were \$70.3 million for the third quarter 2021, as compared to \$59.9 million for the same period in 2020
 - The increase in the third quarter 2021 was primarily due increased research and clinical trial costs related to the Company's ATA188 and CAR T programs, and higher employee-related costs from increased headcount
 - Research and development expenses include \$7.8 million of non-cash stock-based compensation expenses for the third quarter 2021, as compared to \$8.2 million for the same period in 2020
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- General and administrative expenses were \$19.8 million for the third quarter 2021, as compared to \$14.8 million for the same period in 2020
 - The increase was primarily driven by higher compensation-related costs from increased headcount and activities to support our anticipated tab-cel launch
- General and administrative expenses include \$5.9 million of non-cash stock-based compensation expenses for the second quarter 2021, as compared to \$5.1 million for the same period in 2020

Conference Call and Webcast Details

Atara will host a live conference call and webcast today, Thursday, November 4, 2021, at 8:30 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 888-437-3179 for domestic callers and 862-298-0702 for international callers, using the conference ID 13723551. 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 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, 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[®] in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLTD) 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[®]; the timing and progress of tab-cel[®], including (i) data and analyses from ALLELE study; (ii) tab-cel[®] clinical trials, and the timing and outcome of Atara's discussions with the FDA regarding a BLA submission for tab-cel[®], (iii) the timing and outcome of Atara's discussions with EMA regarding an MAA for tab-cel[®], (iv) the timing of the initiation or submission of the BLA and MAA for tab-cel[®], (v) Atara's ability to successfully advance the development of tab-cel[®], (vi) Atara's activities in anticipation of potential tab-cel[®] approval and commercial launch in the U.S., and (vii) Atara's collaboration with Pierre Fabre for commercializing tab-cel[®] 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) translational and biomarker data for ATA188, including magnetization transfer ratio (MTR) data and MTR's potential link with remyelination; (ii) data from ATA188 OLE study; (iii) ATA188 clinical trials, (iv) Atara's ability to successfully advance the development of ATA188, and (v) 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 research and development activities at ARC; (5) 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 113,209	\$ 200,404
Short-term investments	244,036	300,255
Restricted cash - short-term	194	194
Accounts receivable	—	1,250
Prepaid expenses and other current assets	12,058	21,170
Total current assets	369,497	523,273
Property and equipment, net	53,485	50,517
Operating lease assets, net	25,071	12,303
Restricted cash - long-term	1,200	1,200
Other assets	670	827
Total assets	<u>\$ 449,923</u>	<u>\$ 588,120</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 16,543	\$ 7,118
Accrued compensation	19,140	20,458
Accrued research and development expenses	9,974	15,813
Deferred revenue	31,226	33,455
Other current liabilities	9,267	6,057
Total current liabilities	86,150	82,901
Deferred revenue - long-term	26,843	27,795
Operating lease liabilities - long-term	24,574	13,041
Other long-term liabilities	2,215	2,044
Total liabilities	139,782	125,781
Commitments and contingencies		
Stockholders' equity:		
Common stock	9	8
Additional paid-in capital	1,681,481	1,586,616
Accumulated other comprehensive income	24	296
Accumulated deficit	(1,371,373)	(1,124,581)
Total stockholders' equity	310,141	462,339
Total liabilities and stockholders' equity	<u>\$ 449,923</u>	<u>\$ 588,120</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
License and collaboration revenue	\$ 5,370	\$ —	\$ 12,792	\$ —
Operating expenses:				
Research and development	70,333	59,877	202,867	179,096
General and administrative	19,849	14,829	56,984	48,259
Total operating expenses	90,182	74,706	259,851	227,355
Loss from operations	(84,812)	(74,706)	(247,059)	(227,355)
Interest and other income, net	148	364	283	2,049
Loss before provision for income taxes	\$ (84,664)	\$ (74,342)	\$ (246,776)	\$ (225,306)
Provision for income taxes	—	6	16	7
Net loss	\$ (84,664)	\$ (74,348)	\$ (246,792)	\$ (225,313)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(38)	(283)	(272)	307
Comprehensive loss	\$ (84,702)	\$ (74,631)	\$ (247,064)	\$ (225,006)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (0.90)	\$ (0.92)	\$ (2.67)	\$ (3.21)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	93,602	81,176	92,411	70,170

INVESTORS & MEDIA:

Investors

Eric Hyllengren
805-395-9669
ehyllengren@atarabio.com

Media

Alex Chapman
805-456-4772
achapman@atarabio.com