

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 08, 2022

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.)

**2380 Conejo Spectrum Street
Suite 200
Thousand Oaks, California**
(Address of Principal Executive Offices)

91320
(Zip Code)

Registrant's Telephone Number, Including Area Code: (805) 623-4211

**611 Gateway Blvd., Suite 900
South San Francisco, California 94080**
(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:

- 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 registered 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 8, 2022, the Company announced certain financial results for the third quarter ended September 30, 2022. A copy of the Company's press release, titled "Atara Biotherapeutics Announces Third Quarter 2022 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 8, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The information (including Exhibit 99.1) is being furnished in this Item 2.02 "Results of Operations and Financial Condition" 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, and 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 thereunto duly authorized.

ATARA BIOTHERAPEUTICS, INC.

Date: November 8, 2022

By: /s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer

Atara Biotherapeutics Announces Third Quarter 2022 Financial Results and Operational Progress

Ebvallo™ Positioned to be the First Allogeneic T-Cell Therapy Ever Approved Following CHMP Positive Opinion

New ATA188 Biomarker Imaging Data Show Less Brain Atrophy and Possible Remyelination in Patients Achieving Confirmed Disability Improvement in Progressive MS

Phase 1 Study of ATA2271 Enrollment Resumed

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

THOUSAND OAKS, Calif.--November 8, 2022-- 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 third quarter 2022, recent business highlights, and key upcoming catalysts.

"Receiving the positive CHMP opinion for Ebvallo™ (tabelecleucel) positions our product to be the first-ever approved allogeneic off-the-shelf T-cell therapy and provides important validation for our EBV T-cell platform and portfolio," said Pascal Touchon, President and Chief Executive Officer of Atara. "We continue to generate positive forward momentum across our programs, punctuated by compelling new biomarker imaging and long-term clinical data that further reinforce our belief in the transformative potential of ATA188."

Tabelecleucel (tab-cel® or Ebvallo™) for EBV-Associated Ultra-Rare Cancers

- Atara received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) for Ebvallo™ as a monotherapy for treatment of adult and pediatric patients two years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD)

- With CHMP positive opinion, the European Commission's (EC) potential approval of the Ebvallo™ Marketing Authorization Application (MAA) is expected by the end of 2022

- Atara recently held a meeting with the U.S. Food and Drug Administration (FDA) that culminated in clear guidance and agreement on specific chemistry, manufacturing, and controls (CMC) Module 3 requirements for potential biologics license application (BLA) submission

- A new meeting is planned with the FDA to discuss and potentially align on clinical data package requirements to prepare for a pre-BLA meeting

- Atara will present updated interim analysis and safety results of the Phase 3 ALLELE study in relapsed/refractory (r/r) EBV+PTLD with additional patients and longer follow up at the 64th American Society of Hematology (ASH) Annual Meeting in December 2022

- Consistent with the transformative potential of tab-cel in EBV+ PTLD, overall ORR was 51.2% (22/43, 95% CI: 35.5, 66.7), 50% (7/14, 95% CI: 23.0, 77.0) in HCT, and 51.7% (15/29, 95% CI: 32.5, 70.6) in SOT with median TTR of 1.0 month and median duration of response (DOR) of 23 months

- Overall median OS was 18.4 months (95% CI: 6.9, NE), with patients who responded having longer survival versus non-responders

- Additionally, Atara will present updated efficacy and safety data from two single-center, open-label studies and a multicenter expanded access program in patients with EBV+ leiomyosarcomas (EBV+ LMS), who have received at least one therapy at the ASH Annual Meeting

oClinical benefit rate (CR, PR, SD) was 77.8% (95% CI: 56.6, 96.2), with objective response rate of 22.2% (95% CI: 6.4, 47.6); the estimated median OS (95% CI) was 77.4 months (18.0, NE)

•The safety profile of tab-cel remains consistent with previously reported data with no reports of tumor flare reaction, cytokine release syndrome, transmission of infectious diseases, graft-versus-host disease, or infusion reaction related to treatment

•Atara continues to seek a partner for potential U.S. commercialization

ATA188 for Progressive Multiple Sclerosis (MS)

•MS is a debilitating disease affecting millions, with limited treatment options and high unmet medical need in progressive forms

•Atara presented new magnetic resonance imaging (MRI) biomarker imaging and open-label extension (OLE) clinical data from the Phase 1 study of ATA188 in progressive MS at the 2022 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) conference

oNew MRI biomarker imaging data suggest patients who achieved confirmed disability improvement (CDI) demonstrated significantly less brain atrophy over time and increased nMTR in unenhancing lesions. These data support that brain structural changes, including potential remyelination, may underlie durable CDI associated with ATA188

oUpdated results from the ongoing OLE with up to 46 months total follow up in patients achieving CDI demonstrate durability of improvement once achieved. Patients with stable disease, meaning no decline in EDSS, have maintained stability for up to four years

•Based on enrollment in the Phase 2 EMBOLD study at the end of July, approximately 90 patients are planned to be included in the read out of the study primary endpoint of confirmed disability improvement of EDSS at 12 months. Communication of these data is planned to occur in October 2023

CAR T Programs

ATA2271 (Solid Tumors Over-Expressing Mesothelin)

•The ongoing Phase 1, Memorial Sloan Kettering Cancer Center (MSK)-conducted, and investigator led clinical study of autologous mesothelin chimeric antigen receptor (CAR) T-cell therapy, ATA2271, has resumed after a voluntary pause of enrollment earlier this year

•Details on the latest findings, including clinical and safety observations, will be presented at a session titled, "Building on CAR-T Experience in Mesothelioma" at ESMO Immuno-Oncology on December 7, 2022

ATA3219 (B-cell Malignancies)

•ATA3219 is a potential best in class off-the-shelf allogeneic CD19 program using 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, ATA3219 does not require TCR or human leukocyte antigen (HLA) gene editing

•The ATA3219 manufacturing process optimization is progressing to ensure appropriate scale-up. Atara anticipates filing an IND in Q2 2023 following completion of process optimization and manufacturing runs in the GMP manufacturing suites of our strategic manufacturing partner, FUJIFILM Diosynth Biotechnologies

Third Quarter 2022 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2022 totaled \$265.4 million, as compared to \$331.3 million as of June 30, 2022
- In September 2022, Atara announced an additional near-term milestone payment under an updated tabelecleucel commercialization agreement with Pierre Fabre. Under this agreement, Atara will receive an additional \$30 million upon EC approval and subsequent filing of the MAA transfer to Pierre Fabre
- Atara believes that its cash and investments as of September 30, 2022, together with potential cash inflows from Pierre Fabre and the expected reductions in operating cash burn, will be sufficient to fund the Company's planned operations into Q1 2024
- Net cash used in operating activities was \$65.1 million for the third quarter 2022, as compared to \$59.0 million for the same period in 2021
- Atara reported a net loss of \$84.1 million, or \$0.82 per share, for the third quarter 2022, as compared to a net loss of \$84.7 million, or \$0.90 per share, for the same period in 2021
- License and collaboration revenue was \$4.5 million for the third quarter 2022, primarily consisting of revenue recognized due to the termination of the Bayer agreements, as compared to \$5.4 million for the same period in 2021.
- Total operating expenses include non-cash expenses of \$15.4 million for the third quarter 2022, as compared to \$16.0 million for the same period in 2021
- Research and development expenses were \$70.2 million for the third quarter 2022, as compared to \$70.3 million for the same period in 2021
 - Research and development expenses include \$8.0 million of non-cash stock-based compensation expenses for the third quarter 2022 as compared to \$7.8 million for the same period in 2021
- General and administrative expenses were \$18.9 million for the third quarter 2022, as compared to \$19.8 million for the same period in 2021
 - General and administrative expenses include \$6.0 million of non-cash stock-based compensation expenses for the third quarter 2022, as compared to \$5.9 million for the same period in 2021

Conference Call and Webcast Details

Atara will host a live conference call and webcast today, Tuesday, November 8, 2022, 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 13733805. 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 receiving a CHMP positive opinion for a marketing authorization 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 in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLN) 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 Southern 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 Company's corporate strategy, including seeking a commercial partner for tab-cel in the U.S; (2) the potential benefits, safety and efficacy of tab-cel[®]; the timing and progress of tab-cel[®], including (i) data and analyses relating to tab-cel[®], including from the ALLELE study; (ii) tab-cel[®] clinical trials, and the occurrence, timing and outcome of Atara's interactions and discussions with the FDA regarding a BLA submission for tab-cel[®], (iii) the potential submission of the BLA for tab-cel[®], and (iv) the potential approval of the MAA for Ebvallo[™] (tabelecleucel) by the EC and the timing thereof; (3) the potential benefits, safety and efficacy of ATA188; (4) the timing and progress of ATA188, including (i) data and analyses from ATA188 OLE study; (ii) ATA188 clinical trials, (iii) data and analyses from the EMBOLD study and the timing of when such data will be communicated; and (iv) Atara's ability to successfully advance the development of ATA188; (5) the timing and progress of Atara's CAR T programs, and the safety and efficacy of product candidates emerging from such programs, including ATA3219 and the ATA2271 clinical trial being conducted by MSK; and (6) Atara's cash runway. 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 and the war in Ukraine, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in Southern California and Denver 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.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 65,114	\$ 106,084
Short-term investments	200,290	264,984
Restricted cash	1,346	194
Accounts receivable	249	986
Prepaid expenses and other current assets	16,047	12,373
Total current assets	283,046	384,621
Property and equipment, net	7,270	53,780
Operating lease assets	70,834	26,159
Restricted cash - long-term	—	1,200
Other assets	7,166	2,367
Total assets	\$ 368,316	\$ 468,127
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 11,296	\$ 17,368
Accrued compensation	17,605	25,150
Accrued research and development expenses	17,868	13,451
Deferred revenue	2,662	40,760
Other current liabilities	22,813	9,057
Total current liabilities	72,244	105,786
Deferred revenue - long-term	42,338	55,708
Operating lease liabilities - long-term	61,072	25,518
Other long-term liabilities	5,549	1,501
Total liabilities	181,203	188,513
Stockholders' equity:		
Common stock—\$0.0001 par value, 500,000 shares authorized as of September 30, 2022 and December 31, 2021; 94,879 and 91,671 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	9	9
Additional paid-in capital	1,808,515	1,744,695
Accumulated other comprehensive (loss) income	(2,959)	(368)
Accumulated deficit	(1,618,452)	(1,464,722)
Total stockholders' equity	187,113	279,614
Total liabilities and stockholders' equity	\$ 368,316	\$ 468,127

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
License and collaboration revenue	\$ 4,459	\$ 5,370	\$ 63,352	\$ 12,792
Operating expenses:				
Research and development	70,157	70,333	210,018	202,867
General and administrative	18,924	19,849	58,308	56,984
Total operating expenses	89,081	90,182	268,326	259,851
Loss from operations	(84,622)	(84,812)	(204,974)	(247,059)
Other income (expense), net:				
Gain on sale of ATOM Facility	—	—	50,237	—
Interest and other income (expense), net	541	148	1,076	283
Total other income (expense), net	541	148	51,254	283
Loss before provision for income taxes	(84,081)	(84,664)	(153,720)	(246,776)
Provision for income taxes	10	—	10	16
Net income (loss)	\$ (84,091)	\$ (84,664)	\$ (153,730)	\$ (246,792)
Other comprehensive gain (loss):				
Net unrealized gain (loss) on available-for-sale securities	(341)	(38)	(2,591)	(272)
Comprehensive loss	<u>\$ (84,432)</u>	<u>\$ (83,702)</u>	<u>\$ (156,321)</u>	<u>\$ (247,064)</u>
Basic and diluted loss per common share	<u>\$ (0.82)</u>	<u>\$ (0.90)</u>	<u>\$ (1.51)</u>	<u>\$ (2.67)</u>
Basic and diluted weighted-average shares outstanding	<u>102,423</u>	<u>93,602</u>	<u>101,590</u>	<u>92,411</u>

INVESTORS & MEDIA:

Investors

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