
**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 9, 2020

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 9, 2020, Atara Biotherapeutics, Inc. (“Atara”) announced certain financial results for the third quarter ended September 30, 2020. A copy of Atara’s press release, titled “Atara Biotherapeutics Announces Third Quarter 2020 Financial Results and Operational Progress” is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits.*

Exhibit No.	Description
99.1	Press Release, dated November 9, 2020
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 9, 2020

By: /s/ Utpal Koppikar

Utpal Koppikar

Chief Financial Officer

Atara Biotherapeutics Announces Third Quarter 2020 Financial Results and Operational Progress

Interim Analysis of the pivotal 302 study (ALLELE) showed tab-cel[®] in EBV+ PTLD achieved a 50 percent objective response rate and safety consistent with historical data

Discussions with FDA confirmed Atara can complete BLA filing with the ALLELE study's currently enrolled patients with at least six-months follow-up for duration of response

Atara plans to initiate the rolling BLA submission of tab-cel[®] for EBV+ PTLD by the end of 2020 and finalize BLA the submission in Q3 2021

Initiated the tab-cel[®] Phase 2 multi-cohort study in Q3 2020

Conference call to discuss results and operational highlights today at 4:30 p.m. EST

SOUTH SAN FRANCISCO, Calif.-- [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 serious diseases including solid tumors, hematologic cancers and autoimmune disease, today reported financial results for the third quarter ended September 30, 2020 and recent business highlights.

“Atara is on track to finish the year strong, meeting each milestone set to date,” said Pascal Touchon, President and Chief Executive Officer of Atara. “Following an encouraging interim analysis of the pivotal Phase 3 data for tab-cel[®] in relapsed-refractory EBV+ PTLD and very productive interactions with regulatory authorities, we are preparing for tab-cel[®] submissions, and then approval and launch. We are committed to bringing this potentially life-saving therapy to the patients who acutely need it as they have no other therapeutic solution and face a very limited median life expectancy of only two to three months.”

Tab-cel[®] for Post-transplant Lymphoproliferative Disease (PTLD)

- An Interim Analysis of the tab-cel[®] ALLELE study showed a 50 percent objective response rate (ORR) to tab-cel[®] with independent oncologic and radiographic assessment (IORA) in patients with relapsed-refractory EBV+ PTLD following hematopoietic cell transplants (HCT) or solid organ transplants (SOT) that had reached at least six months follow-up after achieving a response. This ORR is consistent with previously published data. The tab-cel[®] safety profile is also consistent with previously published investigator assessed data, with no new safety signals.
 - In October, working under the Breakthrough Therapy Designation (BTD) for tab-cel[®], Atara presented a comprehensive data package to the FDA. The Company aligned with FDA on several key topics related to the regulatory package, including:
 - a rolling submission is acceptable for the biologics license application (BLA);
 - the Company can complete the BLA submission with the ALLELE study's currently enrolled patients with at least six months follow-up for duration of response; and
 - the FDA will consider the following as supportive data to the pivotal study in the BLA clinical module: the Phase 2 trials conducted at Memorial Sloan Kettering (MSK); Atara's Phase 2 multicenter expanded access protocol (201 EAP study); and the Single Patient Use (SPU) program.
 - Atara remains on track to initiate a BLA submission for patients with EBV+ PTLD by the end of 2020. The Company will continue engaging with the FDA as part of its rolling BLA and BTD status and expects to finalize the BLA submission in Q3 2021.
 - Following discussion with the PRiority MEdicines (PRIME) team and after EMA approval of the Pediatric Investigation Plan (PIP) expected in December 2020, Atara is on track to submit an EU marketing authorization application (MAA) for patients with EBV+ PTLD in the second half of 2021.
 - Data from the ALLELE study will be presented at an appropriate congress in 2021.
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Tab-cel for Potential Additional Indications

- Atara initiated a tab-cel® Phase 2 multi-cohort study in the third quarter of 2020 and expects to enroll the first patient in the fourth quarter of 2020. This study is being initiated concurrently in the U.S. and the EU.
- The multi-cohort study is intended to enrich the evidence base with the goal of expanding the potential label for tab-cel® in both treatment-naïve and previously treated patients (in six populations, including four within Immunodeficiency-Associated Lymphoproliferative Diseases (IA-LPDs) and two in other EBV-associated diseases).
- Data demonstrating tab-cel® was well-tolerated and showed encouraging clinical activity in patients with EBV+ AID-LPD and PID-LPD (Acquired and Primary Immunodeficiency LPDs) were featured in an e-poster at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress held in September 2020. Specifically, in patients where previous treatments have failed, the objective response rates, including complete responses, were 33.3 percent (three out of nine patients) in AID-LPD and 37.5 percent (three out of eight patients) in PID-LPD groups. Tab-cel® was generally well-tolerated with a favorable safety profile consistent with previously published clinical studies.
- Data on tab-cel® in patients with life-threatening complications stemming from persistent EBV viremia was accepted for presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition being held virtually December 5-8, 2020. These clinical data demonstrate that tab-cel® was well-tolerated and showed encouraging clinical activity in this patient population with objective response rates ranging from 50 to 80 percent, warranting further investigation in the Phase 2 multi-cohort study.

ATA188 for Progressive Forms of Multiple Sclerosis (MS)

- Atara's Phase 1 clinical study of off-the-shelf, allogeneic ATA188 in patients with progressive forms of MS is ongoing, with encouraging data recently reported and more data from the Open Label Extension (OLE) to be periodically presented over the next 12 months including at the European Charcot Foundation (ECF) 28th Annual Meeting November 15-19, 2020.
 - Twelve-month data from all four cohorts in the Phase 1a portion of the study were presented at the MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting held in September 2020.
 - These data demonstrated that ATA188 was well-tolerated across all four dose cohorts; patients who demonstrated sustained disability improvements (SDI) at any timepoint maintained it at all future timepoints; and a higher proportion of patients showed SDI with increasing dose (42 percent in Cohorts 3 and 4 (higher doses) vs 17 percent in Cohorts 1 and 2 (lower doses)).
 - No dose-limiting toxicities and no fatal adverse events (AEs) have been reported. The safety profile has remained consistent with previously reported data.
 - Data from the OLE with redosing at 12 months show that of the three patients enrolled in the OLE at that time that had SDI at 12 months, all maintained SDI at 15 months, including one patient evaluated at both 15 and 18 months who maintained SDI at both time points. A fourth patient demonstrated SDI during the OLE at 24 months.
 - Atara also presented preclinical translational data at ACTRIMS-ECTRIMS that further support the proposed mechanism of action of ATA188 targeting EBV-infected B cells. These combined analyses of T cells comprising ATA188 are consistent with its proposed mechanism of targeting EBV-infected B cells by recognizing MS-relevant EBV antigens on these cells via defined T cell receptors (TCRs).
 - The double-blind randomized placebo-controlled trial (RCT), which enrolled its first patient in June 2020 continues active recruitment.
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- Given encouraging clinical results to date in ATA188 studies and the significant unmet medical need in progressive forms of MS, the Company is increasing its investment in the ATA188 program. Atara is expanding the size of the RCT to at least 64 patients, changing the primary endpoint of the study to disability improvement, and maintaining biological and functional endpoints; the design allows for the addition of the cohort 4 dose if desired.
- Atara plans to discuss the Phase 1a data with the FDA by the end of this year, as well as the updated RCT study design, and potential opportunities for accelerated development of ATA188 for MS patients.

CAR T Programs

ATA2271/ATA3271 (Solid Tumors Over-Expressing Mesothelin)

- The open-label, single-arm Phase 1 clinical study of ATA2271, the Company's second-generation autologous CAR T therapy targeting mesothelin (MSLN) that incorporates for the first time both a PD-1 DNR (dominant-negative programmed death-1 receptor) for intrinsic check-point inhibition and novel 1XX co-stimulatory domain, has been initiated for the treatment of advanced mesothelioma. Recently presented preclinical data have shown improved functional persistence and enhanced anti-tumor efficacy superior to first-generation MSLN CAR T. MSK is on track to enroll the first patient in the Phase 1 study in Q4 2020.
- ATA3271 is an off-the-shelf, allogeneic CAR T therapy targeting MSLN using a PD-1 DNR and 1XX CAR co-stimulatory signaling domain through Atara's EBV T-cell platform. In new preclinical data, ATA3271 demonstrates potent anti-tumor activity, functional persistence and significant survival benefit with no evidence of allocytotoxicity in vivo, suggesting that allogeneic MSLN-CAR-engineered EBV T cells are a promising approach for the treatment of MSLN-positive cancers. These data will be presented at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting November 11-14, 2020.

ATA3219 (B-cell Malignancies)

- A collaborative and successful pre-IND meeting with the FDA in October 2020 provided feedback to guide the IND filing in 2021.
- IND-enabling studies are progressing with a package ready to be filed in 2021 for ATA3219, a potent next-generation off-the-shelf allogeneic CD19 CAR T utilizing the 1XX technology without the need for TCR gene editing through Atara's EBV T-cell platform.
- The first-abstract to be presented on ATA3219 was accepted for presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition being held virtually December 5-8, 2020. These preclinical data for ATA3219 demonstrate persistence, polyfunctional phenotype and efficient targeting of CD19-expressing tumor cells with no evidence of allocytotoxicity in vivo.

Third Quarter 2020 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2020 totaled \$327.2 million, as compared to \$347.7 million as of June 30, 2020.
 - September 30, 2020 cash balance of \$327.2 million included \$34.1 million net proceeds from at-the-market (ATM) facilities during the third quarter of 2020. Third quarter 2020 cash burn was \$20.5 million, net of ATM proceeds.
 - Atara believes that its cash, cash equivalents and short-term investments as of September 30, 2020 are sufficient to fund planned operations into 2022.
 - Net cash used in operating activities was \$53.0 million for the third quarter of 2020, as compared to \$52.1 million for the same period in 2019.
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- The number of outstanding shares of common stock and pre-funded common stock warrants as of September 30, 2020 was 77,220,159 shares and warrants to purchase 5,755,487 shares, respectively.
- Atara reported net losses of \$74.3 million, or \$0.92 per share, for the third quarter of 2020, as compared to \$71.9 million, or \$1.31 per share, for the same period in 2019.
- Total operating expenses include non-cash expenses of \$15.4 million for the third quarter 2020, as compared to \$13.9 million for the same period in 2019.
- Research and development expenses were \$59.9 million for the third quarter of 2020, as compared to \$53.5 million for the same period in 2019. The increase in the 2020 period was primarily due to costs associated with the Company's continuing expansion of research and development activities, including:
 - Clinical trial, manufacturing and process performance qualification activities related to tab-cel®.
 - Higher employee-related costs from increased headcount.
- Research and development expenses include \$8.2 million of non-cash stock-based compensation expenses for the third quarter of 2020, as compared to \$7.0 million for the same period in 2019.
- General and administrative expenses were \$14.8 million for the third quarter of 2020, as compared to \$19.0 million for the same period in 2019. The decrease in the 2020 period was primarily due to decrease in outside services costs and employee-related costs.
- General and administrative expenses include \$5.1 million of non-cash stock-based compensation expenses for the third quarter of 2020, as compared to \$5.1 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 serious diseases including solid tumors, hematologic cancers and autoimmune disease. With our lead program in Phase 3 clinical development, Atara is the most advanced allogeneic T-cell immunotherapy company and intends to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-associated diseases, or other serious diseases through incorporation of engineered CARs (chimeric antigen receptors) or TCRs (T-cell receptors). Atara is applying this one platform to create a robust pipeline including: tab-cel® (tabelecleucel) in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTL); 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. EST 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 2053259. 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[®], including (i) discussions with the FDA, including regarding the totality of tab-cel[®] data, prior to initiating the BLA submission for patients with EBV+ PTLID, (ii) discussions with the EMA regarding a PIP under the PRIME mechanism for the EMA, (iii) the timing and plans for submitting an EU MAA, (iv) initiating enrollment in a Phase 2 multi-cohort study and potentially expanding tab-cel[®] into other indications, (v) the timing and results of additional clinical data, and (vi) the timing and plans for initiating and completing the BLA for tab-cel[®]; investment into the ATA188 program and the amendment and expansion of the RCT; 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.

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,620	\$ 74,317
Short-term investments	264,565	184,792
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	12,053	13,689
Total current assets	339,432	272,992
Property and equipment, net	51,954	54,176
Operating lease assets	12,069	14,007
Restricted cash - long-term	1,200	1,200
Other assets	877	567
Total assets	<u>\$ 405,532</u>	<u>\$ 342,942</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,190	\$ 7,963
Accrued compensation	16,710	14,706
Accrued research and development expenses	8,883	8,341
Other current liabilities	5,272	5,733
Total current liabilities	36,055	36,743
Operating lease liabilities - long-term	13,129	14,136
Other long-term liabilities	2,413	1,282
Total liabilities	51,597	52,161
Commitments and contingencies		
Stockholders' equity:		
Common stock	8	6
Additional paid-in capital	1,396,674	1,108,516
Accumulated other comprehensive income	527	220
Accumulated deficit	(1,043,274)	(817,961)
Total stockholders' equity	353,935	290,781
Total liabilities and stockholders' equity	<u>\$ 405,532</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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 59,877	\$ 53,538	\$ 179,096	\$ 154,457
General and administrative	14,829	19,018	48,259	61,525
Total operating expenses	74,706	72,556	227,355	215,982
Loss from operations	(74,706)	(72,556)	(227,355)	(215,982)
Interest and other income, net	364	661	2,049	3,502
Loss before provision for income taxes	(74,342)	(71,895)	(225,306)	(212,480)
Provision for income taxes	6	—	7	—
Net loss	\$ (74,348)	\$ (71,895)	\$ (225,313)	\$ (212,480)
Other comprehensive loss:				
Unrealized (loss) gain on available-for-sale securities	(283)	60	307	573
Comprehensive loss	\$ (74,631)	\$ (71,835)	\$ (225,006)	\$ (211,907)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (0.92)	\$ (1.31)	\$ (3.21)	\$ (4.32)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	81,176	54,920	70,170	49,176

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Investors

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