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): September 19, 2023

Atara Biotherapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36548**	**46-0920988**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2380 Conejo Spectrum Street	
Suite 200	
Thousand Oaks, California	**91320**
(Address of Principal Executive Offices)	**(Zip Code)**

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

(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 8.01 Other Events.

On September 19, 2023, Atara Biotherapeutics, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") and the Company are now aligned on analytical comparability between manufacturing process versions of tabelecleucel ("Tab-cel"), an allogenic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells in an HLA-restricted manner. This alignment supports the Company's ability to pool the pivotal clinical trial data from different process versions in its Tab-Cel Biologics License Application submission. A copy of the Company's press release, titled "Atara Biotherapeutics Announces Plans to Submit Tab-cel® BLA in Q2 2024 Following FDA Agreement on Comparability" is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release, dated September 19, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: September 19, 2023

By: /s/ Eric Hyllengren
Eric Hyllengren
Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Exhibit 99.1

Atara Biotherapeutics Announces Plans to Submit Tab-cel® BLA in Q2 2024 Following FDA Agreement on Comparability

THOUSAND OAKS, Calif.—September 19, 2023—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 important progress related to the regulatory pathway for tabelecleucel (tab-cel®) in the U.S.

Following productive discussions between Atara and the U.S. Food and Drug Administration (FDA), the FDA and Atara are now aligned on analytical comparability between manufacturing process versions. This alignment supports Atara's ability to pool the pivotal clinical trial data from different process versions in the Biologics License Application (BLA) submission.

Atara expects to submit the tab-cel BLA in Q2 2024, which will enable Atara to incorporate the latest tab-cel pivotal trial data from the Phase 3 ALLELE study into the BLA filing package.

"We are pleased with the FDA's positive assessment and conclusion of comparability, and we look forward to progressing to the next stage of preparing our BLA submission for tab-cel," said Pascal Touchon, President and Chief Executive Officer of Atara. "Following this clarity, we can also continue to advance our U.S. partnership discussions with several parties, selecting the best possible partner to bring this potentially life-saving treatment to patients."

Tabelecleucel is an allogeneic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells in an HLA-restricted manner. Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV+ PTLD) is a rare, acute, and potentially deadly hematologic malignancy that occurs after transplantation when patient T-cell immune responses are compromised by immunosuppression. It can impact patients who have undergone solid organ transplant (SOT) or allogeneic hematopoietic cell transplant (HCT). Poor median survival of 0.7 months and 4.1 months for HCT and SOT, respectively, is reported in EBV+ PTLD patients for whom standard of care failed, underscoring the significant need for new therapeutic options.

Tabelecleucel is commercialized by Pierre Fabre in Europe as EBVALLO™ following European Commission marketing authorization in December 2022. In Europe, EBVALLO™ is indicated as a monotherapy for the treatment of adult and pediatric patients two years of age and older with relapsed or refractory EBV+ PTLD who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy, unless chemotherapy is inappropriate.

About Atara Biotherapeutics, Inc.

Atara is harnessing the natural power of the immune system to develop off-the-shelf cell therapies for difficult-to-treat cancers and autoimmune conditions, including multiple sclerosis, that can be rapidly delivered to patients within days. With cutting-edge science and differentiated approach, Atara is the first company in the world to receive regulatory approval of an allogeneic T-cell immunotherapy. Our advanced and versatile Epstein-Barr virus (EBV) T-cell platform does not require T-cell receptor or HLA gene editing and forms the basis of a diverse portfolio of investigational therapies that target EBV, the root cause of certain diseases, in addition to next-generation AlloCAR-Ts designed for best-in-class opportunities across a broad range of non-EBV-associated liquid and solid tumors. Atara is headquartered in Southern California. For more information, visit atarabio.com and follow @Atarabio on X (formerly known as 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) dialogue with the FDA regarding a potential BLA submission for tab-cel; (2) 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, including the pooling of pivotal clinical trial data from different process versions in a BLA submission; (3) the potential submission of a BLA for tab-cel; and (4) the timing and progress of Atara's discussions with potential commercial partners for tab-cel in the U.S. 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 , 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.

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