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): July 17, 2024

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

Not Applicable
(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 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 July 17, 2024, Atara Biotherapeutics, Inc. (the "***Company***") announced that the U.S. Food and Drug Administration ("***FDA***") has accepted for priority review the Company's Biologics License Application ("***BLA***") for tabelecleucel (tab-cel®), an allogeneic, Epstein-Barr virus (EBV) specific T-cell immunotherapy designed to target and eliminate EBV-infected cells. The application has a Prescription Drug User Fee Act target action date of January 15, 2025. A copy of the Company's press release, titled "Atara Biotherapeutics Announces U.S. FDA Acceptance and Priority Review of the Biologics License Application for Tabelecleucel (Tab-cel®) for the Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease" 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 July 17, 2024
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: July 17, 2024

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

Exhibit 99.1

Atara Biotherapeutics Announces U.S. FDA Acceptance and Priority Review of the Biologics License Application for Tabelecleucel (Tab-cel®) for the Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease

Prescription Drug User Fee Act (PDUFA) Target Action Date of January 15, 2025

If Approved, Tab-cel Would Be First Approved Therapy in U.S. for EBV+ PTLD

BLA Acceptance Triggers $20 Million Milestone Payment from Pierre Fabre Laboratories, with Additional $60 Million Milestone if Approved by FDA

THOUSAND OAKS, Calif. — July 17, 2024 Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leader inT-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 announced that the U.S. Food and Drug Administration (FDA) has accepted the filing of its Biologics License Application (BLA) for tabelecleucel (tab-cel®) indicated as monotherapy for treatment of adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate. There are no FDA approved therapies in this treatment setting.

The BLA has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) target action date of January 15, 2025.

“The acceptance of the tab-cel BLA is a significant milestone towards making this first-of-its-kind treatment available to patients in the U.S.,” said Pascal Touchon, President and Chief Executive Officer of Atara. “The FDA’s granting of priority review highlights the high unmet need in EBV+ PTLD, which is a devastating disease with limited treatment options and a poor overall survival rate. We continue to work closely with the Pierre Fabre Laboratories team to help prepare for the potential launch in the U.S. in early 2025, along with the potential label expansion multicohort Phase 2 EBVision trial.”

Tab-cel is an allogeneic, EBV-specific T-cell immunotherapy designed to target and eliminate EBV-infected cells. The BLA is supported by pivotal and supportive data covering more than 430 patients treated with tab-cel across multiple life-threatening diseases including the latest pivotal ALLELE study data that demonstrated a statistically significant 48.8% Objective Response Rate (ORR) ($p<0.0001$) and favorable safety profile consistent with previous analyses.

Tab-cel has been granted Breakthrough Therapy Designation for the treatment of rituximab-refractoryEBV-associated lymphoproliferative disease by the U.S. FDA and has orphan drug designation.

In December 2023, Atara announced the closing of the expanded global partnership with Pierre Fabre Laboratories for the U.S. and remaining global commercial markets for tab-cel, building on an initial partnership covering Europe, Middle East, Africa, and other select emerging markets. With the acceptance of the tab-cel BLA, Atara will receive a $20 million milestone payment from Pierre Fabre, with the potential to receive a $60 million milestone payment from Pierre Fabre contingent upon FDA approval of the tab-cel BLA. In addition, Pierre Fabre is reimbursing Atara for expected tab-cel global development costs through the BLA transfer and purchasing tab-cel inventory through the manufacturing transfer date. Atara is also eligible to receive sales milestones and double-digit tiered royalties on net sales of tab-cel in the U.S. and remaining global commercial markets referenced above.

Tab-cel was granted marketing authorization under the brand name Ebvallo™ in December 2022 by the European Commission. Marketing authorization was also granted by the Medicines and Healthcare Products Regulatory Agency in the United Kingdom in May 2023 and by Swissmedic in Switzerland in May 2024. In all three territories, Ebvallo is indicated as 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. Ebvallo was awarded the 2024 Prix Galien International Award for “Best Product for Orphan/Rare Diseases.”

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 that can be rapidly delivered to patients from inventory. 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 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 hematological malignancies and B-cell driven autoimmune diseases. Atara is headquartered in Southern California. For more information, visit atarabio.com and follow @Atarabio on X 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: (i) the development, timing and progress of tab-cel®, including the BLA filed for tab-cel®; (ii) the potential characteristics and benefits of tab-cel®, the indication(s) for which tab-cel could potentially obtain FDA approval for; (iii) the global partnership with Pierre Fabre Laboratories involving tab-cel®; and (iv) Atara's planned transition of substantially all activities relating to tab-cel at the time of the BLA transfer to Pierre Fabre and the timing thereof. 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 COVID-19 pandemic and the wars in Ukraine and the Middle East, 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 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.

Investor and Media Relations

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