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): September 28, 2023

Baudax Bio, Inc.
(Exact name of registrant as specified in its charter)

Pennsylvania	**001-39101**	**47-4639500**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (484) 395-2470

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**	**Name of Exchange on Which Registered**
Common Stock, par value $0.01	BXRX	Nasdaq Capital Market

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 28, 2023, Baudax Bio, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has granted orphan drug designation to its lead clinical candidate, TI-168, for the treatment of Hemophilia A with inhibitors. A copy of this press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
99.1	Press release of Baudax Bio, Inc., dated September 28, 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.

Baudax Bio, Inc.

By: /s/ Gerri A. Henwood
Name: Gerri A. Henwood
Title: President and Chief Executive Officer

Date: September 29, 2023

Baudax Bio Announces Orphan Drug Designation Granted by U.S. FDA for TI-168 for the Treatment of Hemophilia A with Inhibitors

MALVERN, Pa., Sept. 28, 2023 (GLOBE NEWSWIRE) — Baudax Bio, Inc. (the "Company" or "Baudax Bio") (NASDAQ: BXRX), a biotechnology company focused on developing T cell receptor ("TCR") therapies utilizing human regulatory T cells ("Tregs"), as well as a portfolio of clinical stage Neuromuscular Blocking Agents ("NMBs") and an associated reversal agent, today announced that U.S. Food and Drug Administration (FDA) has granted orphan drug designation to its lead clinical candidate TI-168 for the treatment of Hemophilia A with inhibitors.TI-168 is the Company's next-generation, FVIII specific Treg therapy designed to reliably and effectively address Hemophilia A patients with FVIII inhibitors.

"We are very pleased with the FDA's decision to grant orphan drug designation toTI-168, which we believe highlights the urgent need for innovation and new therapeutic options for Hemophilia A patients," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "We believe this is an important therapeutic area, with established preclinical proof of concept in TI-168 through successes observed in Hemophilia A with inhibitors in animal models. With an Investigational New Drug (IND) application already FDA-cleared, we believe we can activate the Phase 1/2a Clinical Trial ofTI-168 for Treatment of hemophilia A with inhibitors with a modest initial budget, and advance this therapy to further clinical investigation in early 2024."

The FDA's Office of Orphan Products Development grants orphan status to drugs being developed to treat, diagnose, or prevent a rare disease or condition affecting fewer than 200,000 people in the United States. Orphan Drug Designation is designed to provide drug developers with various benefits to support the development of novel drugs, including the potential for market exclusivity for seven years upon FDA approval, eligibility for tax credits for qualified clinical trials, waiver of application fees, reduced annual product fees, clinical protocol assistance and potential qualification for expedited development programs.

About Baudax Bio

Baudax Bio is a biotech company focused on innovative products for certain auto-immune conditions, of which many, but not all, are orphan drug conditions as well as acute care and related settings. The combined company will further the development of Treg therapy specific to HA (pipeline candidate TI-168). TI-168 is a next-generation, FVIII specific Treg therapy designed to reliably and effectively address Hemophilia A patients with FVIII inhibitor. By combining the patented Treg culture method and TeraImmune designed FVIII-specific TCR, the Company has successfully demonstrated the therapeutic concept of FVIII TCR-Treg therapy in controlling of FVIII ADA in a hemophilic animal model. The lead programTI-168 has shown encouraging pre-clinical data, and the FDA has cleared an IND to commence a Phase 1/2a clinical trial for the treatment of Hemophilia A with inhibitors.

In addition, over time, the combined company will advance the development of TeraImmune's innovative immune-cell therapies, leveraging a dual Treg manufacturing platform consisting of both natural regulatory Tregs isolated from patients and induced Tregs converted from a patient's T-effector ("Teff") cells. This Treg platform technology is designed for conditions that suppress unwanted immune reactions and includes the allogenic, or off-the-shelf, Tregs obtained from Umbilical Cord Blood for the treatment of skin diseases such as Atopic Dermatitis. For more information, please visit www.baudaxbio.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect Baudax Bio's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "goal," "intend," and "expect," and similar expressions, as they relate to Baudax Bio, are intended to identify such forward-

looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Baudax Bio's current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, clinical results and other future conditions. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Baudax Bio's most recent Annual Report on Form 10-K filed with the SEC and its subsequent filings with the SEC. Any forward looking statement speaks only as of the date on which it was made. Neither Baudax Bio, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Baudax Bio's views as of any date subsequent to the date hereof.

Investor Relations Contact:

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com