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): August 16, 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 2.02 Results of Operations and Financial Condition.

On August 16, 2023, Baudax Bio, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information disclosed under Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being furnished herewith:

Exhibit No.	Document
99.1	Press Release of Baudax Bio, Inc., dated August 16, 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, thereunto duly authorized.

Baudax Bio, Inc.

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

Date: August 16, 2023

Exhibit 99.1

Baudax Bio Reports Second Quarter 2023 Financial Results and Provides Business Update

Transformative Period Led by Acquisition of TeraImmune

Company to Prioritize Development of New TI-168 Treg Asset for Hemophilia A

Continuing to Advance Neuromuscular Blockade (NMB) Portfolio at Modest Pace

Announcement of Positive Top-Line Results from Phase 2 BX1000 Trial

MALVERN, Pa., August 16, 2023 (GLOBE NEWSWIRE) — Baudax Bio, Inc. (Nasdaq:BXRX) ("Baudax Bio" or the "Company"), is 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 results for the three and six months ended June 30, 2023 and provided a business update.

"Our second quarter was a transformative period for Baudax Bio, during which we announced positivetop-line results from our Phase 2 BX1000 trial and capped off with our acquisition of TeraImmune," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "The transaction with TeraImmune adds the promising TI-168 clinical stage asset to our portfolio. TI-168 is a next-generation, autologous FVIII TCR-Treg cell therapy candidate to eliminate clotting factor VIII (FVIII) inhibitors in Hemophilia A patients — a rare genetic bleeding disorder that is caused by a lack of FVIII. We believe this is an attractive therapeutic area, with established preclinical proof of concept in TI-168 through successes observed in Hemophilia A with inhibitors, animal models, and with an Investigational New Drug (IND) application already FDA-cleared. We believe we can, with a modest initial budget, activate the Phase 1/2a Clinical Trial of TI-168 for Treatment of hemophilia A with inhibitors. More broadly, we believe that this platform has potential for clinical applications, alone and in combination of, multiple other autoimmune disorders and therapeutic areas. By combining TeraImmune's world class scientific team with Baudax Bio's proven ability to execute clinical development programs, we believe we are well positioned to pursue development of TI-168 and realize its clinical potential, for one-time treatment, and further providing proof of concept for this TCR Treg approach.

"As noted above, we announced positivetop-line data from our Phase 2 trial of BX1000 showing all patients in three BX1000 study cohorts were observed to have met the criteria for Good or Excellent intubating conditions at 60 seconds, and that study treatments were generally well tolerated with no occurrence of severe or serious adverse events," continued Ms. Henwood. "Based on the strength of data from this program, which were highlighted in the Key Opinion Webinar we hosted, we continue to believe that when combined with our reversal agent BX3000, our NMB regimen may provide improved control of neuromuscular paralysis for surgical patients and deliver the first innovation in NMB in decades."

"We believe the actions we've taken during our second quarter and recent weeks are a win for shareholders of both TeraImmune and Baudax Bio, and we look forward to working with our new colleagues to develop these assets to their full potential," concluded Ms. Henwood.

Second Quarter 2023 and Recent Business Highlights

Acquisition of TeraImmune

- The acquisition of TeraImmune was structured as a stock-for-stock transaction whereby all TeraImmune outstanding equity interests were exchanged for a combination of shares of Baudax common stock and shares of newly designated convertible Series X Non-Voting Convertible Preferred Stock. Subject to shareholder approval of the conversion, each share of Series X Non-Voting Convertible Preferred Stock will automatically convert into 1,000 shares of common stock, subject to certain beneficial ownership limitations set by each holder. On a pro forma basis and based upon the number of shares of Baudax Bio common stock and preferred stock issued in the acquisition, Baudax Bio equity holders immediately prior to the acquisition will own approximately 18% of the combined Company (on an as-converted, fully-diluted basis and excluding certain out-of-the-money warrants held by Baudax Bio's equity holders) immediately after these transactions. The acquisition was unanimously approved by the Board of Directors of Baudax Bio and the Board of Directors of TeraImmune. The closing of the transaction was not subject to the approval of Baudax Bio shareholders.
- Gerri Henwood, President and Chief Executive Officer of Baudax Bio, will continue as CEO of the combined entity. In conjunction with the transaction, Yong Chan Kim, PhD, former Chief Executive Officer of TeraImmune, was appointed to the Board of Directors of Baudax Bio in July.
- Nobel Capital provided a fairness opinion to the Baudax Bio Board of Directors.

TI-168 and other Potential Product Candidates

The most advanced of the TeraImmune TCR Tregs is TI-168, intended for one time treatment of Hemophilia A with inhibitors. An IND for a Phase 1/2a study of TI-168 in patients with Hemophilia A with inhibitors has been cleared by FDA. The Company is now in the process of speaking with prospective investigators and assessing the readiness of potential study site staff and logistics for support of the clinical trial. The Company intends to select study sites and file for IRB (Investigational Review Board) approval at those study institutions. Hemophilia A with inhibitors is an Orphan Condition (in terms of numbers of patients) and the Company estimates that the trial would be ready to open one or more initial study sites and begin to enroll patients in approximately Q1 of 2024.

In addition to the TI-168 clinical stage product candidate, the Company has begun research work on other potential candidates for the TCR Treg platform in conditions such as Myasthenia Gravis, which it believes can be advanced to IND stage by approximately the end of 2024/early 2025, as well as other earlier stage potential product candidates.

NMB Portfolio

- **BX1000 Top-Line Data** - The Company announced positive top-line results from its Phase 2 clinical trial of BX1000 for neuromuscular blockade (NMB) in patients undergoing elective surgery. Results of the study showed that BX1000 met the primary endpoint of readiness for intubation (evaluated as "Good" or "Excellent") at all dose levels assessed. No severe adverse events were observed in any dose regimen.
- Results showed that all patients in three BX1000 study cohorts were observed to have met the criteria for Good or Excellent intubating conditions at 60 seconds. There was evidence of a dose-response across the three doses of BX1000, and the degree of blockade for the highest dose group appears comparable to that of the "standard" dose of rocuronium (0.6 mg/kg) employed in the study. Study treatments were generally well tolerated, with no occurrence of severe or serious adverse events. The frequency and severity of adverse events was similar across all four dose groups, and no notable events were aggregated in any one dose group.
- A further patient safety follow-up at 28 days after surgery, as well as additional analyses of EMG neuromuscular blockade data, showed a clear dose response for BX1000 on maximum T1 suppression with comparable results for the 1.5x ED95 dose of BX1000 and the 2X ED95 dose of rocuronium. An equivalent "time to 80% NMB" was also observed between the highest dose level for BX1000 (0.35 mg/kg) and rocuronium (0.66 mg/kg). Recovery measures showed equivalent time for "full recovery" for the highest dose of BX1000 (0.35 mg/kg) and rocuronium (0.60 mg/kg), but with tighter, thus more predictable, margins for BX1000.

- The Company intends to continue development of its NMB portfolio at a prudent pace while prioritizing development ofTI-168.

Financial Results for the Three Months Ended June 30, 2023

As of June 30, 2023, Baudax Bio had cash and cash equivalents of $1.4 million.

Research and development expenses from continuing operations for the three months ended June 30, 2023 were $1.8 million compared to $0.9 million for the three months ended June 30, 2022. The increase of $0.9 million was primarily the result of an increase in clinical and preclinical trials costs associated with our NMB program.

General and administrative expenses from continuing operations for the three months ended June 30, 2023 were $2.3 million compared to $2.9 million for the same prior year period. The decrease of $0.6 million was primarily a result of a reduction in personnel costs of $0.6 million and a decrease in consulting expenses of $0.3 million, partially offset by an increase in public company costs of $0.3 million.

Baudax Bio reported net loss from continuing operations of $(7.3) million, or $(1.49) per share, for the three months ended June 30, 2023. Net loss from continuing operations for the three months ended June 30, 2022 was $(4.3) million, or $(24.20) per share.

Financial Results for the Six Months Ended June 30, 2023

Research and development expenses from continuing operations for the six months ended June 30, 2023 were $4.7 million compared to $1.6 million for the six months ended June 30, 2022. The increase of $3.1 million was primarily due to an increase in operational expenses associated with our NMB program, including clinical and preclinical trials costs, of $2.8 million and an increase in general expenses, including consulting and other outside service expenses, of $0.3 million.

General and administrative expenses from continuing operations for the six months ended June 30, 2023 were $4.0 million compared to $9.8 million for the same prior year period. The decrease of $5.8 million was primarily a result of a reduction in personnel costs of $4.1 million, a decrease in consulting expenses of $0.9 million, a decrease in public company costs of $0.4 million, a decrease of $0.2 million in patent legal expenses and a decrease of $0.2 million in other costs.

Baudax Bio reported net loss from continuing operations of $(14.7) million, or $(4.08) per share, for the six months ended June 30, 2023. Net loss from continuing operations for the six months ended June 30, 2022 was $(12.5) million, or $(89.40) per share.

About Baudax Bio

Baudax Bio/TeraImmune 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 program TI-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 inhibition.

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 T cells (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, including, but not limited to, statements regarding: uses of proceeds; projected cash runways; future product development plans; and stockholder approval of the conversion rights of the Series X Preferred Stock, in each case, that involve risks and uncertainties. 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 or its management, and TeraImmune or its management, 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. There are a number of important factors that could cause Baudax Bio's actual results to differ materially from those indicated or implied by such forward-looking statements including, without limitation: whether Baudax Bio will be able to successfully integrate the TeraImmune operations and realize the anticipated benefits of the acquisition of TeraImmune; whether BaudaxBio's shareholders approve the conversion of the Series X Preferred Stock and the required cash payment of the then-current fair value of the Series X Preferred Stock if such approval is not provided; whether Baudax Bio's cash resources will be sufficient to fund Baudax Bio's continuing operations and the newly acquired TeraImmune operations, including the liabilities of TeraImmune incurred in connection with the completion of the Merger; whether Baudax Bio's collaborations will be successful; whether Baudax Bio will be able to advance its current product candidate pipeline through preclinical studies and clinical trials, that interim results may not be indicative of final results in clinical trials, that earlier-stage trials may not be indicative of later-stage trials, the approvability of product candidates; whether Baudax Bio will be able to comply with the financial and other covenants under its credit facility; and whether Baudax Bio will be able to maintain its listing on the Nasdaq Capital Market. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks anduncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Baudax Bio may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. 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, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forwardlooking 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.

Important Additional Information and Where to Find It

Baudax Bio, Inc., its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Baudax Bio's shareholders in connection with the matters to be considered at Baudax Bio's 2023 Special Meeting of Shareholders. Information regarding the names of Baudax Bio's directors and executive officers and their respective interests in Baudax Bio by security holdings or otherwise can be found in Baudax Bio's proxy statement for its 2022 Annual Meeting of Shareholders, filed with the SEC on April 28, 2023. To the extent holdings of Baudax Bio's securities have changed since the amounts set forth in Baudax Bio's proxy statement for the 2023 Annual Meeting of Stockholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents are available free of charge at the SEC's website at www.sec.gov. Baudax Bio intends to file a proxy statement and accompanying proxy card with the SEC in connection with the solicitation of proxies from Baudax Bio shareholders in connection with the matters to be considered at Baudax Bio's 2023 Special Meeting of Shareholders. Additional information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in Baudax Bio's proxy statement for its 2023 Special Meeting, including the schedules and appendices thereto. INVESTORS AND SHAREHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND THE ACCOMPANYING PROXY CARD AND ANY AMENDMENTS AND SUPPLEMENTS THERETO AS WELL AS ANY OTHER DOCUMENTS FILED BY BAUDAX BIO WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION. Shareholders will be able to obtain copies of the proxy statement, any amendments or supplements to the proxy statement, the accompanying proxy card, and other documents filed by Baudax Bio with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of Baudax Bio's corporate website at https://www.baudaxbio.com/news-and-investors.com or by contacting Baudax Bio's Investor Relations at Baudax Bio, Inc., 490 Lapp Road, Malvern, PA 19355 or by calling Baudax Bio's Investor Relations at (484) 395-2440.

CONTACTS:

Investor Relations Contact:

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Consolidated Balance Sheets

(Unaudited)

(amounts in thousands, except share and per share data)	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,416	$ 5,259
Prepaid expenses and other current assets	444	303
Current assets of discontinued operation	—	785
Total current assets	1,860	6,347
Property and equipment, net	3,781	9
Right-of-use asset, net	2,939	854
Intangible asset, net	3,500	—
Goodwill	9,236	2,127
Non-current assets of discontinued operation	—	695
Total assets	$ 21,316	$ 10,032
Liabilities, Non-Voting Convertible Preferred Stock and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,828	$ 3,198
Accrued expenses and other current liabilities	2,648	2,133
Current portion of long-term debt, net	4,861	5,600
Current portion of operating lease liability	614	231
Current portion of contingent consideration	260	—
Convertible bond payable	1,000	—
Derivative instrument	5,246	—
Current liabilities of discontinued operation	—	10,298
Total current liabilities	20,457	21,460
Long-term debt, net	—	1,519
Long-term operating lease liability	2,296	585
Deferred tax liability	202	—
Other long term liabilities	—	13
Non-current liabilities of discontinued operation	—	10,697
Total liabilities	22,955	34,274
Mezzanine equity:		
Series X non-voting convertible preferred stock, $0.01 par value, Authorized, 27,090 shares; issued and outstanding 20,066 shares at June 30, 2023	9,040	—
Shareholders' deficit:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 0 shares at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 6,961,867 shares at June 30, 2023 and 1,623,913 shares at December 31, 2022	70	16
Additional paid-in capital	176,126	166,646
Accumulated deficit	(186,875)	(190,904)
Total shareholders' deficit	(10,679)	(24,242)
Total liabilities, non-voting convertible preferred stock and shareholders' equity	$ 21,316	$ 10,032

Consolidated Statements of Operations
(Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended June 30, 2023	For the Three Months Ended June 30, 2022	For the Six Months Ended June 30, 2023	For the Six Months Ended June 30, 2022
Operating expenses:				
Research and development	$ 1,779	$ 879	$ 4,696	$ 1,573
General and administrative	2,254	2,898	4,025	9,832
Change in fair value of warrants and derivatives	2,870	(1)	2,870	(6)
Change in contingent consideration valuation	142	—	142	—
Total operating expenses	7,045	3,776	11,733	11,399
Operating loss from continuing operations	(7,045)	(3,776)	(11,733)	(11,399)
Other expense:				
Other expense, net	(256)	(569)	(2,954)	(1,140)
Net loss from continuing operations	$ (7,301)	$ (4,345)	$ (14,687)	$ (12,539)
Income (loss) on discontinued operation	(74)	(3,186)	18,716	(7,801)
Net income (loss)	$ (7,375)	$ (7,531)	$ 4,029	$ (20,340)
Per share information:				
Net loss per share from continuing operations, basic and diluted	$ (1.49)	$ (24.20)	$ (4.08)	$ (89.40)
Net income (loss) per share from discontinued operation, basic and diluted	$ (0.02)	$ (17.75)	$ 5.20	$ (55.62)
Net income (loss) per share, basic and diluted	$ (1.51)	$ (41.95)	$ 1.12	$ (145.03)
Weighted average common shares outstanding, basic and diluted	4,885,215	179,541	3,601,877	140,251