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): March 27, 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 March 27, 2023, Baudax Bio, Inc. (the "Company") issued a press release announcing the positive results from the second interim analysis of Phase II randomized trial for BX1000. 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 March 27, 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: March 27, 2023

Exhibit 99.1

March 27, 2023

Baudax Bio Announces Positive Results from 2nd Interim Analysis of Phase 2 Randomized Trial for BX1000

41 Subjects Meet Criteria for Good or Excellent Intubation Conditions at 60 Seconds

Top Line Results Expected Late April/Early May

MALVERN, Pa., March 27, 2023 (GLOBE NEWSWIRE) — Baudax Bio, Inc. (Nasdaq:BXRX) (the "Company"), a pharmaceutical company focused on innovative products for hospital and related settings, today announced positive results from the second preplanned interim analysis of its Phase 2 trial of BX1000 for neuromuscular blockade (NMB) in patients undergoing elective surgery.

The BX1000 Phase 2 surgery trial is a randomized, double-blind, active-controlled clinical trial comparing three different doses of BX1000 to a standard dose of 0.6mg/kg rocuronium in a planned trial of 80 adult patients undergoing elective surgery utilizing total intravenous anesthesia. The primary efficacy endpoint is the proportion of patients meeting criteria for Good or Excellent intubating conditions using a standardized scale. Additionally, the clinical trial is evaluating the safety and tolerability profile of BX1000 and rocuronium in this patient population.

The second preplanned interim analysis evaluated the intubating conditions in 41 patients in four cohorts, with each cohort having a minimum of 10 evaluable patients. Results showed that all 41 subjects were observed to have met the criteria for Good or Excellent intubating conditions at 60 seconds. Actual intubation of 40 of the subjects occurred at 60 seconds and 1 subject at 90 seconds. Study treatments were generally well tolerated, with no occurrence of severe or serious adverse events, and one patient experienced a treatment-emergent adverse event that was determined to be possibly related to study treatment. This blinded interim analysis did not result in the decision to drop any of the four study groups nor any decision to adjust planned study enrollment number**.**

"With data from 50% of the planned total enrollment for this trial, these results provide us with confidence that BX1000, combined with our reversal agent BX3000, may provide more precise control of neuromuscular paralysis for surgical patients and have the potential to improve on total time of blockade and reversal compared to available agents," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "Importantly, this data set includes subjects from a recently activated second clinical site, and provides an early indication that these results can be replicated in broader clinical use. We anticipate completing enrollment in this trial soon, and announcing top line results in late April or early May."

About Baudax Bio's Neuromuscular Blocking Agents (NMBs)

Baudax Bio holds exclusive global rights to two novel NMBs, BX1000, an intermediate

duration, clinical stage blocking agent, and BX2000, an ultra-short duration, clinical stage blocking agent, as well as a proprietary chemical reversal agent, BX3000, undergoing nonclinical studies intended to support an IND filing in 2023. BX3000 is a specific reversal agent that rapidly reverses BX1000 and BX2000. All three agents are licensed from Cornell University. We believe these agents will allow for a very rapid induction of neuromuscular blockade for surgical settings, a predictable offset of blockade after administration, enhanced by rapid reversal of the neuromuscular blockade when BX 3000 is used with the NMB agent. These novel agents have the potential to meaningfully reduce the time to onset of blocking and of reversal of blockade, reducing overall time in operating rooms or post-acute care settings, resulting in potential clinical and cost advantages, as well as time-related valuable cost savings for hospitals and ambulatory surgical centers.

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on innovative products for hospital and related settings. The Company has a pipeline of innovative pharmaceutical assets including two clinical-stage, novel neuromuscular blocking (NMBs) agents, one undergoing a Phase II clinical trial and an additional unique NMB undergoing a dose escalation Phase I clinical trial, as well as a proprietary chemical reversal agent specific to these NMBs, which is currently undergoing nonclinical and manufacturing studies to prepare for an expected IND filing in the summer of 2023. For more information, please visit www.baudaxbio.com.

Forward Looking Statements

This press release contains forward-looking statements 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, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Baudax Bio as of the date of publication of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Baudax Bio's performance to differ materially from those expressed in, or implied by, these forward-looking statements. These risks and uncertainties include, among other things, risks related to market, economic and other conditions, the ongoing economic and social consequences of the COVID-19 pandemic, Baudax Bio's ability to advance its current product candidate pipeline through pre-clinical studies and clinical trials, that interim results may not be indicative of final results in later clinical trials, Baudax Bio's ability to raise future financing for continued development of its product candidates such as BX1000, BX2000 and BX3000, Baudax Bio's ability to pay its debt and satisfy conditions necessary to access future tranches of debt, Baudax Bio's ability to comply with the financial and other covenants under its credit facility, Baudax Bio's ability to manage costs and execute on its operational and budget plans, Baudax Bio's ability to achieve its financial goals; Baudax Bio's ability to maintain listing on the Nasdaq Capital Market; and Baudax Bio's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. These forward-looking statements should be considered together with the risks and uncertainties that may affect Baudax Bio's business and future results included in Baudax Bio's filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to Baudax Bio, and Baudax Bio assumes no obligation to update any forward-looking statements except as required by applicable law.

CONTACTS:

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Source: Baudax Bio, Inc.