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): April 25, 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 April 25, 2023, Baudax Bio, Inc. (the "Company") issued a press release announcing positivetop-line results from its Phase 2 clinical trial of BX1000 for neuromuscular blockade in patients undergoing elective surgery. A copy of this press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

On April 25, 2023, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company will use the updated presentation in various meetings with investors from time to time.

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 April 25, 2023.
99.2	Investor Presentation of Baudax Bio, Inc., dated April 25, 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: April 25, 2023

Exhibit 99.1

Baudax Bio Announces Positive Top-Line Final Results

From Phase 2 Randomized Clinical Trial of BX1000

All Patients in Three BX1000 Treatment Cohorts Met Criteria for Good or Excellent Intubation Conditions at 60 Seconds

Results to be Discussed in Key Opinion Leader Webinar Today at 10:00am Eastern Time

MALVERN, Pa., April 25, 2022 (GLOBE NEWSWIRE) — Baudax Bio, Inc. (Nasdaq:BXRX) (the "Company"), a pharmaceutical company focused on innovative products for hospital and related settings, today 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.

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 clinical trial of 80 adult patients undergoing elective surgery utilizing total intravenous anesthesia. A total of 81 patients were randomized to the four treatment groups. One patient discontinued early and did not receive a study drug. A total of 80 patients were treated. Each BX1000 dose cohort had 20 evaluable patients and the rocuronium cohort had 19 evaluable patients (one subject in this arm experienced a delay in intubating condition assessment.) The primary efficacy endpoint of the study was the proportion of patients that met criteria for Good or Excellent intubating conditions using a standardized scale. Additionally, the clinical trial evaluated the safety and tolerability profile of BX1000 and rocuronium in this patient population.

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.

There will be further patient safety follow up at 28 days after surgery as well as additional analyses of neuromuscular blockade data in the coming weeks. The Company will be continuing the development program for BX 1000 with a target of submitting a New Drug Application ("NDA") by approximately year-end 2025. The Company also remains committed to working and collaborating with regulators to advance development of its NMB product candidates, including BX1000, and its reversal agent product candidate.

"We believe these results demonstrate that BX1000 at the highest dose compares favorably to rocuronium, and when combined with our reversal agent BX3000, may provide improved control of neuromuscular paralysis for surgical patients," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "These very encouraging data indicate that BX1000 may represent the first innovation in NMBs in decades. We look forward to discussing the results in greater detail with our Key Opinion Leaders today, and to advancing BX1000 and our NMB program to the next phase of development."

Key Opinion Leader Webinar Today at 10:00am ET

The Company will host a virtual key opinion leader event *Innovation in Anesthesia: BX1000 for Neuromuscular Blockade (NMB)* featuring Dr. Todd M. Bertoch, Chief Executive Officer of JBR Clinical Research, and Dr. Harold S. Minkowitz, Associate Director for Clinical Research at The University of Texas MD Anderson Cancer Center Department of Anesthesiology and Perioperative Medicine to discuss in greater detail results from its Phase 2 trial of BX1000 for neuromuscular blockade (NMB) in patients undergoing elective surgery.

To register for the event, click here.

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 investigational new drug (IND) submission in 2023. BX3000 is a specific reversal agent that may rapidly reverse 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, including statements relating to the clinical development of Baudax Bio's product candidates, 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 clinical trials, that earlier-stage trials may not be indicative of later-stage trials, the approvability of product candidates, 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:

Investor Relations Contact:

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Exhibit 99.2

BAUDAX BIO®

Study BDX-22-006 Top Line Results

25 April 2023

Forward-Looking Statements

This presentation contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements, including statements relating to the clinical development of Baudax Bio's product candidates, 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 presentation 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 clinical trials, that earlier-stage trials may not be indicative of later-stage trials, the approvability of product candidates, 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.

Study BDX-22-006

A Phase 2, Randomized, Double-Blind, Active-Controlled, Evaluation of Intubation Conditions Following Administration of BX1000 or Rocuronium in Patients Undergoing Surgery

Study BDX-22-006 – Objectives

- To evaluate the intubating conditions at 60, 90 and 120 seconds after administration of BX1000 or Rocuronium
- To evaluate the safety and tolerability of BX1000
- To evaluate the neuromuscular blocking (NMB) profile of BX1000

Study BDX-22-006 – Design

- Phase 2 randomized, double blinded, active-controlled study
- 4 Treatment groups (n=20/group)
  - Single bolus dose of BX1000:
    - 0.15 mg/kg
    - 0.25 mg/kg
    - 0.35 mg/kg
  - Single bolus dose of Rocuronium: 0.6 mg/kg
- Patients undergoing hernia repair & other elective surgeries
- Efficacy evaluation at 60, 90 and 120 seconds

FDA Required Primary Efficacy Endpoint

- Proportion of subjects with Excellent or Good intubating conditions at 60 seconds after NMBA administration

Criteria	*Acceptable*		*Unacceptable*
	Excellent	**Good**	**Poor**
Vocal cord position	Abducted	Intermediate	Closed/Adducted
Vocal cord movement	None	Moving	Closing
Ease of laryngoscopy*	Easy	Fair	Difficult
Airway reaction	None	Diaphragm	Sustained >10s
Limb movement	None	Slight	Vigorous

Viby-Mogensen 1996
Scoring Intubation conditions
Excellent: All qualities are excellent
Good: All qualities are either excellent or good
Poor: The presence of a single quality listed under "poor"

*Ease of Laryngoscopy
- Easy: Jaw relaxed, no resistance to blade in the course of laryngoscopy
- Fair: Jaw not fully relaxed, slight resistance to blade
- Difficult: Poor jaw relaxation, active resistance of the patient to laryngoscopy

Study BDX-22-006
Demographics

	Rocuronium	BX1000			
	0.6 mg/kg (N=20)	0.15 mg/kg (N=20)	0.25 mg/kg (N=20)	0.35 mg/kg (N=20)	Total (N=80)
Subjects dosed n (%)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	80 (100.0)
Subjects in Efficacy Evaluation n (%)	19 (95.0)*	20 (100.0)	20 (100.0)	20 (100.0)	79 (97.5)
Mean Age (yrs)	37	38.2	40.5	39.5	38.8
n (%) Female	18 (90.0)	13 (65.0)	13 (65.0)	15 (75.0)	59 (73.8)
Race, n (%)					
White	19 (95.0)	19 (95.0)	20 (100.0)	19 (95.0)	19 (95.0)
Black or African American	1 (5.0)	--	--	1 (5.0)	2 (2.5)
Multiple	--	1 (5.0)	--	--	1 (1.3)
Mean Baseline BMI (kg/m^2)	26.1	28.2	26.2	25.9	26.6

*1 Subject experienced a delay in intubating condition assessments due to issues with the endotracheal tube

Study BDX-22-006 – Primary Endpoint
Intubating Conditions at 60 seconds

	n (%) of Subjects				
	Rocuronium	BX1000			
	0.6 mg/kg (N=19)	0.15 mg/kg (N=20)	0.25 mg/kg (N=20)	0.35 mg/kg (N=20)	Total (N=79)
Excellent or Good	19 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	79 (100.0)
Poor	--	--	--	--	--
Not Done	1*	--	--	--	--

*1 Subject experienced a delay in intubating condition assessments at 60, 90, and 120 seconds after NMBA administration due to issues with the endotracheal tube, and therefore not included in the efficacy analyses

Study BDX-22-006

Adverse Events - ≥5% of Total Population

	n (%) of Subjects				
	Rocuronium	BX1000			
Preferred Term	0.6 mg/kg (N=20)	0.15 mg/kg (N=20)	0.25 mg/kg (N=20)	0.35 mg/kg (N=20)	Total (N=80)
Subjects with >=1 TEAE	12 (60.0)	11 (55.0)	9 (45.0)	9 (45.0)	41 (51.3)
Nausea	5 (25.0)	5 (25.0)	2 (10.0)	2 (10.0)	14 (17.5)
Hypotension	2 (10.0)	2 (10.0)	2 (10.0)	3 (15.0)	9 (11.3)
Constipation	1 (5.0)	1 (5.0)	2 (10.0)	2 (10.0)	6 (7.5)
Hypoxia	1 (5.0)	1 (5.0)	2 (10.0)	1 (5.0)	5 (6.3)
Vomiting	1 (5.0)	2 (10.0)	1 (5.0)	--	4 (5.0)
Rash	3 (15.0)	--	1 (5.0)	--	4 (5.0)

No SAEs have been reported for any treatment group at this time