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): May 10, 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 7.01 Regulation FD Disclosure.

On May 10, 2023, Baudax Bio, Inc. (the "Company") updated information reflected in a slide presentation, which is attached as Exhibit 99.1 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.

The information disclosed under Item 7.01, 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 exhibit is being furnished herewith:

Exhibit No.	Document
99.1	Investor Presentation of Baudax Bio, Inc., dated May 10, 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: May 10, 2023

Exhibit 99.1

BAUDAX BIO

Corporate Presentation

May 2023

BAUDAX BIO®

Forward Looking Statements

This presentation 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 on this internet site 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 and other conditions, the ongoing economic and social consequences of the COVID-19 pandemic, including on Baudax Bio's supply chain and labor force, Baudax Bio's ability to advance its current product candidate pipeline through pre-clinical studies and 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.

Investor Highlights

- Addressing an estimated $4 billion global opportunity in growing acute care neuromuscular blocking agents (NMBs) segment
- Clinical stage NMB assets offer potential for improved patient management, cost reduction for procedures requiring NMBs
  - BX1000 key data readouts reported in 1H 2023
    - Top Line, unblinded positive study results for Phase 2
  - BX2000 Update
    - Dose escalation study in healthy volunteers continues through cohort 3
  - BX3000 key events
    - IND filing for NMB reversal agent anticipated late summer 2023
- Global Commercial rights to NMBs and proprietary reversal agent.
- Experienced leadership with history of successful approvals and commercialization

Our Team

Significant drug development and commercial assessment expertise

Gerri Henwood

President & CEO

Founder, President, CEO Recro

President of Malvern Consulting Group

Founder, Pres., CEO Auxilium

Founder, CEO IBAH (NASDAQ listed CRO)

>10 years at SK&F (now GSK)

Randall Mack

EVP, Development & Operations

EVP Development, Recro

VP Development & Operations, Adolor

VP Development, Auxilium

Director Venture Development, Abbott Labs (now Abbie)

Stewart Mc Callum, MD

EVP, Medical Affairs

EVP Medical Affairs, Recro

Medical Director, GSK

Assistant Professor of Urology Stanford University

Staff Surgeon, Stanford University & Palo Alto VA Medical Center

Mike Choi

Finance

VP Finance, Recro

VP Finance, Auxilium

VP Finance, IBAH

Jillian Dilmore

Corporate Controller

Director of Accounting, Recro

Assistant Controller, Royal DSM

Senior Auditor, Deloitte & Touche

Diane Myers

SVP Regulatory & Quality

SVP Regulatory & Quality, Recro

SVP Regulatory Affairs & Quality Assurance, MCG

VP Regulatory Affairs & Quality, Auxilium

>15 years at GSK

BAUDAX BIO®

Neuromuscular Blockers and Reversal Agent

NMB Overview

~400 million patients receive NMB agents annually[1]

- Used to induce rapid total paralysis to permit intubation and muscle relaxation during surgery or in ventilated patients
- Used in the operating room/ASC to optimize surgical conditions
- Additional use in ICU to facilitate mechanical ventilation
- Procedural use increasing with growth of laparoscopic abdominal procedures

1. IMS, MIDAS 2010. NMB = Neuromuscular blocking agents * Based on extrapolations from dose escalation study in volunteers and on pre-clinical pharmacology data in animals

Limitations of Current Standard of Care

Agent Type	Characteristics	Products	Limitations
Depolarizing	Open receptor channels similar to acetylcholine	Succinylcholine	Malignant hyperthermia Fasciculations – micro contractions Hyperkalemia – high potassium levels Anaphylaxis - Residual neuromuscular blockade
Non-Depolarizing	Create neuromuscular blockade by competing with acetylcholine at neuromuscular junction	Rocuronium (largest usage) Vecuronium (and similar substituents)	Anaphylaxis Residual neuromuscular blockade Not ideally suited to Rapid Sequence Intubation

Limitations of Current Standard of Care (continued)

Agent Type	Characteristics	Products	Limitations
Reversal Agents	– Cyclodextrin which chelates the NMB – The only selective relaxant binding agent in routine clinical use	Sugammadex (Bridion® - Merck, $1.6B)	– Dose will vary by time of administration relative to time of NMB administration to dose of NMB given – Faster recovery than neostigmine as evidenced by numerous studies – Anaphylaxis, hypersensitivity reactions seen in some Sugammadex patient and healthy volunteers
Current Standard	– Blocks pseudocholinesterase – A type of "nerve agent"	Neostigmine (generic)	– Indirect, not direct, so not as quick – Anticholinesterases act indirectly by increasing acetylcholine in neuromuscular junctions – Requires an antimuscarinic product (atropine, scopolamine) to be administered to prevent excessive secretions

Portfolio offers potential to improve patient management

Rapid onset/offset may increase procedure capacity, reduce costs

AGENT	DURATION OF ACTION	TARGET PROFILE
BX1000	Intermediate duration of action (est. 30-45 mins)	Rapid onset Predictable offset without reversal
BX2000	Ultra short acting (est. 10-15 mins)	Rapid onset Predictable offset without reversal
BX3000	Rapid offset (2-5 min)	Specific for BX1000 and BX2000. Rapid Chemical reversal of neuromuscular blockade from any depth. Predictable dosing for rapid reversal

BX1000 Phase 2 Study

BDX-22-006 A Phase 2, Randomized, Double-Blind, Active-Controlled, Evaluation of Intubation Conditions Following BX1000 or Rocuronium in Subjects Undergoing Surgery

Single Center
N=80
Subjects undergoing hernia repair & other surgeries
4 Treatment groups (n=20/group)
BX1000 0.15mg/kg
BX1000 0.25 mg/kg
BX1000 0.35 mg/kg
Rocuronium: 0.6 mg/kg

Primary Outcomes

Assessment of Intubation

- Time Frame within 2 minutes after administration
- Conditions (Poor, Good, Excellent) Following Administration

Secondary Outcomes

- Safety, tolerability, onset/recovery of NM blockade

Study BDX-22-006 - Objectives

- To evaluate the intubating conditions at 60, 90 or 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 and 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 NMB administration

Criteria	Acceptable		Unacceptable
	Excellent	Good	Poor
Vocal cord position	Adducted	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 NMB 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

BX2000 Phase 1 Trial

Phase 1, double-blind, placebo-controlled, single dose escalation

BDX-20-004

- First in human use
- N=~80
- Active to placebo ratio (6:2)

Dose Range

- 10 cohorts
- 0.02 mg/kg to 0.64 mg/kg
- Anticipate enrollment ~7 cohorts

Objectives

- Evaluate the safety and tolerability of single ascending doses of BX2000
- Characterize the pharmacokinetics
- Evaluate the neuromuscular blocking profile
- Each cohort's data reviewed by a safety committee (to confirm the decision to dose escalate to next highest dose)

BX3000 IND Enabling Studies

GLP formulation production completed	Non-clinical Studies initiated December 2022	IND Filing
Available December 2022	Dose finding studies Q1 GLP Studies initiate dosing in Q1 (US, Canada, UK & China)	Anticipated late Summer 2023

Pipeline

2023 Catalysts to inform development priorities

Recent Financing

Cash & Cash Equivalent
as of 12/31/22: $5.3 million

$5 Million

Gross Proceeds from December 2022 Public Offering

Proceeds to be used for working capital, pipeline development, general corporate purposes

$4.3 Million

Raised in early January 2023 through warrant exercise

$4 Million

Gross Proceeds from May 2023 Public Offering

BAUDAX BIO®