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 3, 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)

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

Securities registered pursuant to Section 12(g) of the Act:
None

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))

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 3, 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. Representatives of 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 exhibit is being filed herewith:

Exhibit No.	Document
99.1	Investor Presentation of Baudax Bio, Inc., dated March 3, 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 3, 2023

Exhibit 99.1

BAUDAX BIO

Corporate Presentation

March 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

BX-1000 key data readouts anticipated 1H 2023

- Second pre-planned interim analysis expected March 2023
- Top line phase 2 data readout anticipated by mid Q2 2023

BX-3000 key events

- IND filing for NMB reversal agent anticipated 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 AbbVie)

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

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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

BX1000 Phase 2 Study – Interim Analysis

Interim Analysis (n=20) Reported January 2023

- 5 patients/group received one of study medications
- 20 patients met criteria for Good or Excellent intubating conditions at 60 seconds
- 19 subjects successfully intubated following assessment at 60 seconds
- 1 subject successfully intubated following assessment at 90 seconds
- Study treatments generally well tolerated, no occurrence of severe or serious adverse events
- Blinded interim analysis did not result in the decision to drop any of the four study groups, adjustment to planned study enrollment

Second preplanned interim analysis anticipated March 2023, Topline Results Expected Q2 2023

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

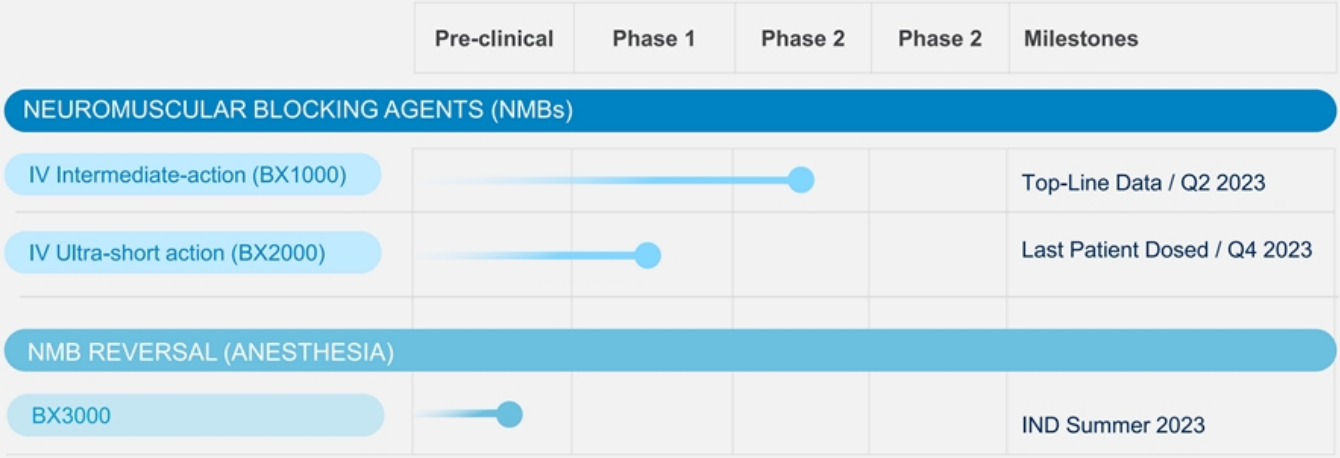
- Evaluate the safety and tolerability of single ascending doses of BX2000
- Characterize the pharmacokinetics
- Evaluate the neuromuscular blocking profile
- Each cohort's data reviewed by a safety committee

BX3000 IND Enabling Studies

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

Pipeline

2023 Catalysts to inform development priorities

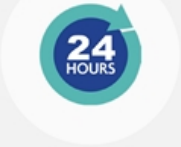


BAUDAX BIO®

Commercial Update

ANJESO® (meloxicam) Injection: DISCONTINUED
The First and Only Once-Daily, Non-Opioid, IV Analgesic

Evaluating alternative approaches for monetizing asset in U.S., ex-U.S. markets



Up to 24-hour pain relief

Efficacy in orthopedic & soft tissue procedures

Demonstrated Safety & Tolerability

Evaluated in more than 1500 patients[1]

COX-2 Preferential IV NSAID*

That can be incorporated into MMA protocols

Once-daily IV push

Ready-to-use, no reconstitution or refrigeration

Data on file. Baudax Bio, Inc. *The mechanism of action of IV meloxicam, like other NSAIDs, is not completely understood, but involves inhibition of both COX-1 and COX-2 pathways. COX-1 = cyclooxygenase 1; COX-2 = cyclooxygenase 2; IV = intravenous; NSAID = nonsteroidal anti-inflammatory drug; MMA = multimodal analgesia

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 January 2023 through warrant exercise

THANK YOU!
BAUDAX BIO