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): November 11, 2021

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 November 11, 2021, Baudax Bio, Inc. (the "Company") issued a press release announcing a clinical update for its neuromuscular blocking agents ("NMBs"), including completion of a dose-escalation study evaluating BX-1000, the Company's proprietary NMB, in healthy volunteers. 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 November 11, 2021.
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: November 12, 2021

Baudax Bio Announces Clinical Program Update for Neuromuscular Blocking Agents BX-1000, BX-2000 and BX-3000

BX-1000 Completes Dose-Escalation Study; Was Generally Well Tolerated and Rapidly Achieved Muscle Paralysis, Along with Complete Spontaneous Recovery

BX-2000 and BX-3000 to Advance Into Clinical Studies in 2022

MALVERN, Pa., November 11, 2021 – Baudax Bio, Inc. (NASDAQ:BXRX) a pharmaceutical company focused on commercializing and developing innovative products for acute care settings, today announced a clinical program update for its neuromuscular blocking agents (NMBs), including completion of a dose-escalation study evaluating BX-1000 in healthy volunteers.

Baudax's proprietary NMBs are BX-1000, an intermediate duration NMB, BX-2000, an ultra-short duration NMB, and BX-3000, a reversal agent that rapidly reverses the effects of BX-1000 and BX-2000. Used together, these agents to allow a very rapid induction of neuromuscular blockade for surgical settings, followed by a rapid reversal of the neuromuscular blockade. We believe these novel agents have the potential to meaningfully reduce procedure recovery time in operating room or post-acute care settings, resulting in valuable cost savings to hospitals and ambulatory surgical centers.

"The completion of this dose-escalation study is an important step for the overall NMB program, and we look forward to finalizing the clinical study report and sharing the data with the U.S. Food and Drug Administration (FDA)," said Stewart McCallum, Chief Medical Officer of Baudax Bio. "We believe that the combination of either BX-1000 or BX-2000 with the dedicated reversal agent, BX-3000, may permit precise control of the time patients are under neuromuscular paralysis. This could be significantly impactful for patients, surgeons, and anesthesiologists by enhancing safety and controlling costs related to delayed recovery from neuromuscular paralysis following surgical procedures. We look forward to advancing our NMB and related candidates during 2022."

BX-1000

A total of 58 subjects participated in a dose-escalation study evaluating,BX-1000. Per FDA guidance and feedback, the evaluation ofBX-1000 was conducted in healthy volunteers who had already undergone endotracheal intubation while under general anesthesia. After intubation, subjects received a single IV bolus dose of BX-1000 and were carefully monitored for neuromuscular blockade and for any changes in vital signs or the presence of adverse events.

BX-1000 dose-escalations were continued until prespecified effects were observed. OverallBX-1000 was generally well tolerated through the dosing range tested. Muscle paralysis was rapidly achieved along with complete spontaneous recovery. Baudax is preparing the clinical study report for this dose-escalation study and expects to submit it to FDA early in the New Year. Meanwhile Baudax is finalizing plans to proceed to the next study in surgical patients that is expected to commence by about mid-year 2022.

BX-2000

BX-2000, a unique, ultra-short acting NMB, which was previously studied in non-human primates and Baudax is currently conducting an additional toxicology study requested by FDA, which began dosing this month. Baudax expects to submit the report for this toxicology study for BX-2000 to the FDA during the first quarter of 2022. Once the data has been evaluated by FDA, the Company plans to follow with timely initiation of a dose-escalation study in healthy volunteers.

BX-3000

BX-3000 was designed to induce chemical cleaving of BX-1000 and BX-2000, resulting in the rapid inactivation of those molecules and thus quickly reversing neuromuscular blockade. Baudax expects to initiate the clinical program for BX-3000 during late 2022.

About Baudax Bio's Neuromuscular Blocking Agents (NMBAs)

Baudax holds exclusive global rights to two novel NMBAs, BX-1000, an intermediate duration, clinical stage agent, and BX-2000, an ultra-short duration, preclinical stage agent, and a proprietary chemical reversal agent, BX-3000, that is specific to, and rapidly reverses, BX-1000 and BX-2000. All three agents were licensed from Cornell University in 2017. Used together, these agents allow for a very rapid induction of neuromuscular blockade for surgical settings, followed by a rapid reversal of the neuromuscular blockade. These novel agents have the potential to meaningfully reduce procedure recovery time in operating room or post-acute care settings, resulting in valuable cost savings to hospitals and ambulatory surgical centers.

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on commercializing and developing innovative products for acute care settings. ANJESO is the first and only 24-hour, intravenous (IV) COX-2 preferential non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain. In addition to ANJESO, as described in this release, Baudax Bio has a pipeline of other innovative pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs. 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 on this internet site, including statements relating to the development of each of BX-1000, BX-2000 and BX-3000, 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 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, Baudax Bio's ability to raise future financing for continued development of its product candidates such as BX-1000, BX-2000 and BX-3000, 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; 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.

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