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): January 22, 2020

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**

Securities registered pursuant to Section 12(g) of the Act:

None

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 January 22, 2020, Baudax Bio, Inc. issued a press release announcing that the U.S. Food and Drug Administration has set a Prescription Drug User Fee Act goal date of February 20, 2020 for its decision on the New Drug Application for intravenous meloxicam for the management of moderate to severe pain. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is 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 January 22, 2020.

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: Chief Executive Officer

Date: January 22, 2020

Baudax Bio Announces PDUFA Date for Intravenous Meloxicam

PDUFA Goal Date Set for February 20, 2020

MALVERN, Pa., January 22, 2020 – Baudax Bio, Inc. (NASDAQ:BXRX), a specialty pharmaceutical company focused on therapeutics for acute care settings, today announced that the U.S. Food and Drug Administration (FDA) has set a PDUFA goal date of February 20, 2020 for its decision on the New Drug Application (NDA) for intravenous (IV) meloxicam for the management of moderate to severe pain. The assignment of this PDUFA goal date follows the FDA's acceptance of Baudax's latest complete response package relating to its 2019 complete response letter (CRL) and appeal filing, seeking approval for IV meloxicam.

"We are pleased by the FDA's acceptance of our latest response package, which we believe addresses their concerns and which includes proposed labeling for IV meloxicam for the management of moderate to severe pain, alone or in combination with other analgesics," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "We will be working closely with the FDA as they complete their review of the IV meloxicam NDA and work toward the PDUFA goal date."

In October 2019, Baudax (through its former parent, Recro Pharma, Inc.) received a written decision from the FDA granting the appeal of the CRL the Company had previously received (in March of 2019) relating to its IV meloxicam NDA.

About Intravenous Meloxicam

Baudax holds exclusive global rights to Intravenous (IV) meloxicam, an NDA-pending non-opioid analgesic developed for the treatment of moderate to severe pain. If approved, IV meloxicam will be a novel IV non-opioid option for patients with moderate to severe pain. IV meloxicam successfully completed three Phase III clinical studies, including two Phase III efficacy studies and one Phase III safety study, four Phase II clinical studies, as well as other safety studies. The active ingredient meloxicam is a long-acting, preferential COX-2 inhibitor that exhibits analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase (COX) and subsequent reduction in prostaglandin biosynthesis. IV meloxicam was designed using the NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

About Baudax Bio

Baudax Bio is a specialty pharmaceutical company focused on therapeutics for acute care settings. The Company's lead product candidate is a proprietary intravenous (IV) form of meloxicam, a non-opioid, long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled

Phase III safety trial, four Phase II clinical efficacy trials, as well as other safety studies. Upon IV meloxicam approval, ANJESO™, will be a novel non-opioid option for the management of moderate to severe pain. As anon-opioid, IV meloxicam has the potential to overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential while maintaining meaningful analgesic effects for relief of pain. For more information please visit www.baudaxbio.com.

Cautionary Statement Regarding 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," "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 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. Baudax Bio assumes no obligation to update any such forward-looking statements. Factors that could cause Baudax Bio's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: the Company's ability to execute its strategy for further development and commercialization of IV meloxicam, the Company's ability to execute its strategic initiatives, the Company's ability to adequately resolve the outstanding labeling issues with the FDA for IV meloxicam, and ,the time frame associated with any such resolution as well as the timeframe of any FDA action related to the IV meloxicam NDA; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to manage costs and execute on its operational and budget plans; the Company's ability to achieve its financial goals; the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the Company's lack of operating history as a standalone business; risks relating to the separation from Recro, including, among others, failure to achieve the anticipated benefits from the separation, reliance on Recro and other third parties to provide certain services post-separation, and the Company's ability to satisfy liabilities and potential indemnification obligations in connection with the separation. The forward-looking statements in this press release 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.

CONTACT:

Investor Relations Contact: Argot Partners
Sam Martin / Claudia Styslinger
(212) 600-1902
sam@argotpartners.com
claudia@argotpartners.com

Baudax Bio
Ryan D. Lake
(484) 395-2436
rlake@baudaxbio.com

Media Contact:
Argot Partners
David Rosen
(212) 600-1902
david.rosen@argotpartners.com