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): July 30, 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)

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 July 30, 2020, Baudax Bio, Inc. issued a press release announcing a virtual poster presentation highlighting new Phase IIIb ANJESO® (meloxicam) injection clinical data at the American Society of Colon and Rectal Surgeons 2020 Annual Scientific Meeting. 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 July 30, 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: July 31, 2020

Exhibit 99.1

Baudax Bio Announces Presentation of New Phase IIIb ANJESO® Data at the American Society of Colon and Rectal Surgeons 2020 Annual Scientific Meeting

Virtual Presentation Highlights New ANJESO Clinical Results, Including Safety, Reductions in Opioid Use and Time to Bowel Function Recovery Data When Administered Preoperatively Prior to Colorectal Surgery

MALVERN, Pa., July 30, 2020 — Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced a virtual poster presentation highlighting new Phase IIIb ANJESO® (meloxicam) injection clinical data at the American Society of Colon and Rectal Surgeons (ASCRS) 2020 Annual Scientific Meeting.

"The data published virtually this year by the ASCRS supports the use of ANJESO® administered preoperatively as part of an Enhanced Recovery After Surgery (ERAS) protocol to patients prior to undergoing colorectal surgery," said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Baudax Bio. "The key findings from this study include statistically significant reductions in opioid use, as well as faster time to bowel function recovery and earlier hospital discharge. These positive results will inform our future physician education initiatives as we support the ongoing commercial launch of ANJESO."

The virtual presentation describes clinical outcomes from a randomized, placebo-controlled Phase IIIb study evaluating preoperative doses of ANJESO in 55 patients undergoing bowel resection and/or anastomosis. Patients were randomized 1:1 to receive ANJESO or placebo with the first dose administered 30 minutes prior to the start of surgery, then every 24 hours on top of a Standardized ERAS protocol that included a multimodal pain management plan in addition to study treatment all patients received gabapentin 300mg once prior to surgery, and acetaminophen 650mg starting prior to surgery and continuing every 8 hours until 24 hours after the last dose of study medication. Following surgery, opioid rescue was available upon request. The primary objective of the study was to assess the safety of ANJESO when administered pre-operatively, with a key measure being the incidence and severity of adverse events. Numerous additional efficacy parameters were also explored in this study including opioid consumption, return of bowel function, and hospital length of stay.

The incidence of individual adverse events (AEs) were comparable between groups or numerically lower in the meloxicam IV group. The majority of AEs were mild or moderate in severity. The incidence of serious AEs was also higher in the placebo group. ANJESO-treated patients experienced statistically significant reductions in opioid consumption (35%; $p<0.05$), in time to first bowel sounds (59%; $p<0.05$), time to first bowel movement (18%; $p<0.05$), and time to hospital discharge (27%; $p<0.05$), all compared to placebo. This study supports the efficacy and safety of ANJESO administered once daily, with administration beginning prior to start of surgery, as part of a standardized multimodal regimen in patients undergoing colorectal procedures.

Title: Safety and Efficacy of Preoperative Meloxicam IV in Colorectal Surgery
Lead Author: Conor Delaney
Presentation #: MED.0320-136.a

About ANJESO®

ANJESO (meloxicam) injection is a proprietary, long-acting, preferentialCOX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase type 2 pathway (COX-2) and subsequent reduction in prostaglandin biosynthesis. ANJESO was approved by the U.S. Food and Drug Administration in February 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. Because of the delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required. The ANJESO product approval was supported by two pivotal Phase III clinical efficacy trials, a large double-blind, placebo-controlled Phase III safety trial and four Phase II clinical efficacy trials, as well as other safety studies. As a non-opioid, Baudax Bio believes ANJESO 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. ANJESO 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 first commercial product, ANJESO®, had its New Drug Application approved by FDA on February 20, 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. ANJESO is a once daily IV NSAID with preferential Cox-2 activity, which has successfully completed three Phase III clinical trials, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other studies for the management of moderate to severe pain. As a non-opioid, ANJESO 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," "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 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, including, among other things, the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the commercial launch of ANJESO® or disruption in supply chain, Baudax Bio's ability to maintain regulatory approval for ANJESO, Baudax Bio's ability to successfully commercialize ANJESO; the acceptance of ANJESO by the medical community, including physicians, patients, health care providers and hospital formularies; Baudax Bio's ability and that of Baudax Bio's third party manufacturers to successfully scale-up our commercial manufacturing

process for ANJESO, Baudax Bio's ability to produce commercial supply in quantities and quality sufficient to satisfy market demand for ANJESO, Baudax Bio's ability to raise future financing for continued product development, payment of milestones and ANJESO commercialization, 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 our operational and budget plans, the accuracy of Baudax Bio's estimates of the potential market for ANJESO, 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 other risks and uncertainties that may affect our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

CONTACT:

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

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

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