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): April 26, 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) 395-2440

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 8.01 Other Events.

On April 26, 2021, Baudax Bio, Inc. issued a press release announcing the online publication of Phase IIIb data highlighting the safety and efficacy of preoperative ANJESO® (meloxicam) injection in patients undergoing unilateral total knee arthroplasty when used within a multimodal analgesic regimen, in the peer-reviewed medical journal, *Pain Medicine*. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is being filed herewith:

Exhibit No.	Document
99.1	Press Release of Baudax Bio, Inc., dated April 26, 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 hereunto duly authorized.

Baudax Bio, Inc.

By: /s/ Gerri A. Henwood
Name: Gerri A. Henwood
Title: President and Chief Executive Officer

Date: April 26, 2021

Baudax Bio Announces Publication of Phase IIIb Data on Preoperative Administration of ANJESO® in Patients Undergoing Total Knee Arthroplasty (TKA) in *Pain Medicine*

Patients Administered ANJESO Prior to the Start of Surgery had Significantly Lower Summed Pain Intensity Scores on the First Postsurgical Day and Throughout Their Inpatient Course

ANJESO Treated TKA Patients Demonstrated Decreased Opioid Consumption Following Surgery, Particularly in the First 24 hours Post-Surgery.

Total Mean Hospital Charges for Hospital Stay and Total Overall Charges Were Lower in the ANJESO Group Compared to Placebo

MALVERN, Pa., April 26, 2021 — Baudax Bio, Inc. (Nasdaq: BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced the online publication of data highlighting the safety and efficacy of preoperative ANJESO® (meloxicam) injection in patients undergoing unilateral total knee arthroplasty (TKA) when used within a multimodal analgesic regimen, in the peer-reviewed medical journal *Pain Medicine.* ANJESO is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics.

Preemptive administration allows providers to better control pain at the outset of surgery, rather than waiting until inflammation and pain have already set in. Preoperative use of NSAIDs is recommended by the American Society for Enhanced Recovery (ASER) and the Perioperative Quality Initiative (POQI). Further multimodal analgesia involves the administration of 2 or more drugs that act by different mechanism for providing analgesia, the aim of which is to improve pain relief while reducing opioid requirements and opioid-related adverse effects.

“Patients typically report high levels of pain after orthopedic surgery and managing this pain can be challenging. In this study we administered ANJESO prior to the start of the surgery helping us to stay ahead of the pain. Which is a critical component of patient care,” said Richard Berkowitz, M.D., University Orthopedic and Joint Replacement Center, Tamarac, Florida. “In the past there has been a tendency to resort to opioids for pain control, given the risks associated with opioids such as addiction, gastrointestinal adverse events, pruritus, and respiratory depression, among others, there has been an increased need for alternative medications for patients undergoing elective or nonelective surgical procedures and it is encouraging to see these results.”

“The data published by Pain Medicine continues to support ANJESO as an advantageous option for the management of moderate to severe pain. The data not only highlight the efficacy and tolerability of ANJESO when administered preoperatively within a multimodal analgesic regimen to patients undergoing TKA, but also conveys a decreased need for opioids following surgery,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Baudax Bio. “The findings are especially compelling because they suggest select measures of health care resource utilization (HRU) also tended to be lower in the ANJESO treated group, including 10% lower mean total hospital charges. These data suggest ANJESO has a promising role in multimodal analgesic regimens in this clinical setting.”

Efficacy and Safety Results Following Administration of Preoperative ANJESO Compared to Placebo

During the 1st 24 hours, ANJESO patients used ~32% less opioids and reported ~22% greater pain reduction relative to placebo treated patients. ANJESO-treated patients had a significantly lower Summed Pain Intensity score on the first postsurgical day and throughout their inpatient course (p£0.0001). Additionally, ANJESO-treated patients had significantly lower opioid consumption during the first postsurgical day, with a 31.7% reduction compared to placebo (mean 19mg vs. 28mg; p<0.0001). Significant reductions in opioid use were observed on subsequent days and throughout treatment. ANJESO-treated patients had a significantly longer time to first opioid rescue after surgery compared to placebo treated patients. ANJESO-treated subjects had lower incidences of all cause hospital readmissions, fewer patients admitted to skilled nursing facilities upon discharge, and fewer emergency room visits, and doctor calls related to pain during the follow-up period.

With respect to safety, adverse events (AEs) were primarily mild or moderate in intensity and not related to study treatment, with a higher incidence of AEs reported in the placebo group. Additionally, the incidence of serious AEs was higher in the placebo group. All serious AEs in the ANJESO group were assessed by the primary investigators to be not related to study treatment. No subject discontinued due to an AE. The overall rate of AEs of special interest (AESI; events related to concerns associated with NSAIDS) were lower in the ANJESO-treated group at 9.7% than the placebo group at 21.6%. Rates of individual events in the ANJESO group occurred at similar or lower rates compared to the placebo group. Laboratory and surgical wound healing assessments were similar between treatment groups. 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 subjects undergoing primary unilateral TKA.

Healthcare Resource Utilization (HRU) Results Following Preoperative ANJESO Compared to Placebo

This study also evaluated HRU and costs, including total hospital costs, hospital length of stay (LOS), hospital readmissions, ER visits, physician office visits, and phone calls due to pain, associated with preoperative administration of ANJESO compared to placebo, through postoperative day 30. This study was not powered to show statistical differences in HRU endpoints.

The total mean charges for the hospital stay, and total overall charges were lower in the ANJESO group compared to the placebo group, ($56,424 vs $62,864), however, the differences were not statistically significant. Mean hospital LOS in days was lower in the ANJESO group compared to the placebo group (2.05 vs. 2.24 days), which was 8.6% lower compared to placebo, however, the difference was not statistically significant. There were fewer hospital readmissions (1 vs. 3), ER visits (0 vs. 4), and phone calls due to pain (4 vs. 9) for ANJESO versus placebo, respectively. There were no reports of unscheduled physician office visits due to pain in either group.

Mean total opioid use from hour 0-24, 0-48, and 0-72 hours was significantly lower among meloxicam IV compared to placebo (p<0.0001) and from hour 0 through hospital discharge (33.28mg vs. 44.87mg); (p<0.001). Time to the first oral opioid rescue medication was longer for the ANJESO group than placebo (7.31 vs. 5.22 hours; p=0.0226) and a similar trend was observed for mean time to first use of IV or oral opioid analgesia (4.75 vs. 3.09 hours; p=0.0126). While there was no significant association between opioid consumption and total hospital charges, every unit (1mg IV morphine equivalent) increase in opioid consumption was associated with a 0.5% increase in LOS in days (p=0.0001). The proportion of subjects with ³1 opioid related adverse drug effects were significantly higher for placebo than ANJESO (70.5% vs. 48.4%; p=0.003). Six ANJESO-treated patients (6.5%) had ³1 AESI in comparison to 12 placebo subjects (13.6%). Serious AEs were observed among 3 ANJESO-treated patients (3.2%) and 9 placebo subjects (10.2%).

The Overall Benefit of Analgesia Scores (OBAS) were also assessed. The OBAS is a simple, multi-dimensional quality assessment instrument to measure patients' benefit from postoperative pain therapy. Opioid symptom distress, pain relief, and patients' satisfaction are combined in a reliable and valid tool. A lower score indicates better pain management and lower opioid symptom distress. The OBAS score was significantly lower for meloxicam IV compared with placebo-treated subjects on the first postoperative day (LS mean [SE] 4.45 [0.360] vs 5.90 [0.375] for meloxicam and placebo, respectively; difference [95% CI], –1.45 [–2.39, –0.51]; P = 0.0027).

ANJESO® Phase IIIb Study Design

The study was designed to evaluate the effect of perioperative meloxicam IV on opioid consumption in primary TKA. This was a multicenter, randomized, double-blind, placebo-controlled trial and evaluated 181 adults undergoing elective primary TKA. Subjects received meloxicam 30 mg or placebo via IV bolus every 24 hours, with the first dose administered prior to surgery as part of a multimodal pain management protocol. The primary efficacy parameter was total opioid use over a 24-hour period following surgery. Findings from the study suggest perioperative meloxicam IV 30 mg as part of a multimodal analgesic regimen for elective primary TKA reduced opioid consumption in the 24-hour period following surgery versus placebo and was associated with a lower incidence of AEs typically associated with opioid use.

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 launched in the U.S. in June 2020 following its approval by the Food and Drug Administration in February 2020. ANJESO is indicated 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. ANJESO is 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 pharmaceutical company focused on therapeutics for acute care settings. The launch of Baudax Bio's first commercial product ANJESO® began in June 2020 following its approval by the U.S. Food and Drug Administration in February 2020. 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. In addition to ANJESO, Baudax Bio has

a pipeline of other pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs which is currently in preclinical studies, and intranasal dexmedetomidine which is being developed for possible uses in pain or sedation. For more information, please visit www.baudaxbio.com.

INDICATION

ANJESO is indicated for use in adults for the management ofmoderate-to-severe pain, alone or in combination withnon-NSAID analgesics.

Limitation of Use: Because of delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Risk

- Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- ANJESO is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

CONTRAINDICATIONS

ANJESO is contraindicated in patients with:

- Known hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to meloxicam or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.
- Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion.

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Elevations of ALT or AST have been reported in patients with NSAIDs. In addition, rare, sometimes fatal, cases of severe hepatic injury including fulminant hepatitis, liver necrosis, and hepatic failure have been reported. Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue ANJESO immediately if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypertension: NSAIDs including ANJESO can lead to new onset of hypertension or worsening of preexisting hypertension, which may contribute to the increased incidence of cardiovascular (CV) events. Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: NSAID use increased the risk of myocardial infarction (MI), hospitalization for heart failure, and death. Avoid use of ANJESO in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. If ANJESO is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Post MI Patients: Avoid the use of ANJESO in patients with recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ANJESO is used in these patients, monitor for signs of cardiac ischemia.

Renal Toxicity: Long-term administration of NSAIDs has resulted in renal papillary necrosis, renal insufficiency, acute renal failure, and other renal injury. ANJESO is not recommended in patients with moderate to severe renal insufficiency and is contraindicated in patients with moderate to severe renal insufficiency who are at risk for renal failure due to volume depletion. Correct volume status in dehydrated or hypovolemic patients prior to initiating ANJESO. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ANJESO in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. If ANJESO is used in patients with advanced renal disease, monitor patients for signs of worsening renal function.

Anaphylactic Reactions: Meloxicam has been associated with anaphylactic reactions in patients with and without known hypersensitivity to meloxicam and in patients with aspirin-sensitive asthma. Seek emergency help if an anaphylactic reaction occurs.

Exacerbation of Asthma Related to Aspirin Sensitivity: ANJESO is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Serious Skin Reactions: NSAIDs, including ANJESO, can cause serious skin reactions, including exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal and can occur without warning. Discontinue ANJESO at first appearance of skin rash or other signs of hypersensitivity.

Hematologic Toxicity: Anemia has occurred in NSAID-treated patients. Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia. NSAIDs, including ANJESO, may increase the risk of bleeding events. Monitor patients for signs of bleeding.

DRUG INTERACTIONS

Drugs That Interfere with Hemostasis (e.g., warfarin, aspirin, SSRIs/SNRIs): Monitor patients for bleeding who are concomitantly taking ANJESO with drugs that interfere with hemostasis. Concomitant use of ANJESO and analgesic doses of aspirin is not generally recommended.

Angiotensin Converting Enzyme (ACE) Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers: Concomitant use with ANJESO may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

ACE Inhibitors and ARBs: Concomitant use with ANJESO in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high risk patients, monitor for signs of worsening renal function.

Diuretics: NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to ensure diuretic efficacy including antihypertensive effects.

ADVERSE REACTIONS

The most common adverse reactions in controlled clinical trials occurring in³ 2% of patients treated with ANJESO and at a greater frequency than placebo include: constipation, gamma-glutamyl transferase increased, and anemia.

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation.

Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of ANJESO in women who have trouble conceiving.

Please see full Prescribing Information, including Boxed Warning at www.anjeso.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 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 forward-looking statements are subject to risks and uncertainties including, among other things, the completion of the registered direct offering and the intended use of proceeds from the registered direct offering, 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 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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