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): May 17, 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**

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 May 17, 2021, Baudax Bio, Inc. issued a press release announcing that the results of its Phase IIIb study evaluating ANJESO® (meloxicam) injection administered preoperatively prior to colorectal surgery were published online in the journal *Pain Management.* 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 May 17, 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: May 17, 2021

Baudax Bio Announces Publication of Phase IIIb ANJESO® Data in the Journal *Pain Management*

Preoperative Administration of ANJESO was Well Tolerated, Significantly Reduced Opioid Use and Decreased Hospital Length of Stay by Over 1 Day (28 hours) Versus Placebo

MALVERN, Pa., May 17, 2021 — Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced that the results of the Phase IIIb study evaluating ANJESO (meloxicam) injection administered preoperatively prior to colorectal surgery were published online in the journal *Pain Management*. ANJESO is the Company's marketed, non-opioid, once daily, intravenous (IV) non-steroidal anti-inflammatory (NSAID) agent for use in adults for the management of moderate to severe pain that is indicated for use alone or in combination with other non-NSAID analgesics.

"Adequate pain relief is an important component of ERAS (enhanced recovery after surgery) protocols and is associated with various beneficial effects, including shorter length of stay (LOS), enhanced recovery, faster mobilization and better patient satisfaction," said Jennifer Silinsky, MD, Colorectal Surgeon, Tulane University School of Medicine, and lead author of the manuscript. "Opioids have historically been a mainstay of perioperative pain control, however, an important goal of ERAS protocols is to reduce opioid consumption, which in turn may lead to decreased known opioid-related risks and adverse events. In this study, both groups received a standardized ERAS protocol that included pain control and the results demonstrated that ANJESO was superior to placebo when added to the ERAS regimen. In addition, ANJESO was generally well tolerated, with over 92% of patients reporting satisfaction with their post-operative pain medication. ANJESO-treated patients also experienced statistically significant reductions in opioid consumption, time to first bowel sounds, time to first bowel movement and time to hospital discharge, all compared to placebo. These data support 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."

"We are honored to have these data published by such a well-regarded medical journal to be shared with the anesthesia, pain management and surgical community," said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Baudax Bio. "We believe the successful outcome of this study represents an important advancement for colorectal surgery physicians and their patients and we are sincerely grateful to all of the patients and investigators who participated in the study. The ANJESO launch is progressing well and these positive results will continue to inform our ongoing physician education initiatives as we work to drive adoption of ANJESO."

The full manuscript can be accessed here.

Summary of the Phase IIIb Results

This multi-center, randomized, double-blind, placebo-controlled Phase IIIb study evaluated 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 assessed in this study, including various pain outcomes (e.g., patient global assessment [PGA], brief pain inventory [BPI], etc.), opioid consumption, return of bowel function, healthcare resource utilization and hospital length of stay.

Safety

For safety, the incidence of individual adverse events (AEs) was comparable between groups and was numerically lower in the ANJESO group. ANJESO was generally well tolerated. The most common treatment-emergent AEs (TEAEs) in both study groups were nausea and vomiting and the majority of these were mild or moderate in intensity. The incidence of serious AEs was also comparable between groups and numerically lower in the ANJESO group. None of the SAEs was considered related to study medication and all resolved. For AEs commonly associated with opioid use (e.g., nausea, vomiting and ileus) the incidence rate was either comparable to the placebo group or lower in the ANJESO group.

Opioid Consumption

Opioid consumption was lower in the ANJESO-treated group at all time intervals, and the differences versus placebo were statistically significant at some time points. Total opioid consumption was 35% lower in the ANJESO group ($p=0.03$). The largest difference in opioid consumption occurred on post-surgery Day 2 (hour 24-48), when ANJESO was associated with 49% lower opioid consumption ($p=0.01$). Overall, patients treated with ANJESO received 16.9mg fewer opioids, compared to placebo-treated patients, (49.25mg vs 66.14mg, $p=0.04$).

Efficacy

While patients in the placebo group had higher opioid use, ANJESO-treated patients had similar or better pain scores and similar patient satisfaction. BPI was significantly lower for the ANJESO group on postoperative Day 1 ($p=0.03$). For other BPI time intervals, there were no meaningful differences between the study groups. Most subjects in both the ANJESO (92.3%) and placebo (92.6%) groups were satisfied with their postoperative pain medication. There were no significant differences in PGA of pain control between the groups.

Healthcare Resource Utilization

The mean time from end of surgery to actual hospital discharge and mean total LOS were significantly shorter (28 hours) for the ANJESO group. There was no significant difference in total cost of hospital stay between the study groups, although costs in the ANJESO group, but not the placebo group, were driven by outliers. Regression analysis demonstrated that increased opioid consumption was associated with increased LOS, with every 1mg increase in opioid consumption from hour zero to discharge was associated with a 0.58-hour increase in LOS ($p=0.0005$). Surgery type (bowel resection vs other) was significantly associated with total costs and LOS, with the highest costs linked to bowel resection.

Functional Outcomes

The mean times to first bowel sound, first flatus and first bowel movement were significantly shorter in the ANJESO group (p=0.02, p=0.03 and p=0.02, respectively). Mean times to first ambulation were similar between the ANJESO and placebo groups.

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).

INDICATION AND USAGE

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 Enzymes (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.

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.

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.

CONTACT:

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

Media Contact:

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