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): August 23, 2022

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 7.01 Regulation FD Disclosure.

On August 23, 2022, Baudax Bio, Inc. (the "Company") updated information reflected in a slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company will use the updated presentation in various meetings with investors from time to time.

The information disclosed under Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is being furnished herewith:

Exhibit No.	Document
99.1	Investor Presentation of Baudax Bio, Inc., dated August 23, 2022.
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: August 23, 2022

Exhibit 99.1

Baudax Bio Corporate Presentation

August 2022

Forward Looking Statements

This presentation 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 risks and uncertainties include, among other things, risks related to market and other conditions, the ongoing economic and social consequences of the COVID-19 pandemic, including on Baudax Bio's supply chain and labor force, 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 BX1000, BX2000 and BX3000, 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; Baudax Bio's ability to maintain listing on the Nasdaq Capital Market, 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.

BAUDAX BIO®

ANJESO® (meloxicam) injection

Only once daily, IV non-opioid, analgesic

Approved for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics

Significant potential commercial opportunity

Acute Care Clinical-Stage Pipeline

Neuromuscular blocking agents (NMBs) and proprietary reversal agent

Financial Position

Cash and cash equivalents as of 6/30/22:

Approximately $5.2 Million

Experienced leadership team

Significant commercial, development, and regulatory experience

Clinical Development Status

Product / Compound	Pre-Clinical	Phase I	Phase 2	Phase 3	Marketed	Rights
ANJESO® (MELOXICAM) INJECTION						WW
ANJESO® (meloxicam) injection						
NEUROMUSCULAR BLOCKING AGENTS (NMBs)						WW
IV Intermediate-action (BX1000)						
IV Ultra-short action (BX2000)						
NMB REVERSAL (ANESTHESIA)						WW
BX3000						

BAUDAX BIO

Commercial Update

ANJESO® (meloxicam) Injection: The First and Only Once-Daily, Non-Opioid, IV Analgesic

Up to 24-hour pain relief

Efficacy in orthopedic & soft tissue procedures

Demonstrated Safety & Tolerability

Evaluated in more than 1500 patients[1]

COX-2 Preferential IV NSAID*

That can be incorporated into MMA protocols

Once-daily IV push

Ready-to-use, no reconstitution or refrigeration

1. Data on file. Baudax Bio, Inc. *The mechanism of action of IV meloxicam, like other NSAIDs, is not completely understood, but involves inhibition of both COX-1 and COX-2 pathways.
COX-1 = cyclooxygenase 1; COX-2 = cyclooxygenase 2; IV = intravenous; NSAID = nonsteroidal anti-inflammatory drug; MMA = multimodal analgesia

ANJESO® (meloxicam) Injection: The First and Only Once-Daily IV Non-Opioid Analgesic

Source: ANJESO Prescribing Information.
*Vial size approximately 16 X 34.5 mm

Dosing and Administration Highlights

- **Once-daily, IV bolus injection over 15 seconds**
  - Administered as a 30-mg (1 mL) dose
  - Available in a small* single dose vial
- **Ready-to-use**
  - No reconstitution required
  - Room temperature storage – no need to refrigerate

When initiating ANJESO, monitor patient analgesic response. Because the median time to meaningful pain relief was 2 and 3 hours after ANJESO administration in two clinical studies, a non-NSAID analgesic with a rapid onset of effect may be needed, for example, upon anesthetic emergence or resolution of local or regional anesthetic blocks.

Some patients may not experience adequate analgesia for the entire 24-hour dosing interval and may require administration of a short-acting, non-NSAID, immediate-release analgesic.

Two Phase 3b Health Economic Studies Completed with Preoperative Administration of ANJESO®

Study Population[1]	ANJESO® 30 mg	Placebo	Primary Endpoint	Selection of Secondary Endpoints	Selection of Results[2]
 Total Knee Arthroplasty (TKA)	n=93	n=88	Evaluate efficacy of preoperative* administration measured by total opioid consumption	Evaluate impact on pain control and healthcare resource utilization	Preoperative administration of ANJESO as part of a MMA regimen was associated with lower total mean hospital costs >$2,500 during the hospital stay than patients in the placebo group
 Bowel Resection Surgery	n=27	n=28	Evaluate safety and tolerability of preoperative* administration	Evaluate impact on hospital LOS, opioid consumption and healthcare resource utilization	Preoperative administration of ANJESO as part of a MMA regimen was well tolerated and decreased mean LOS by 1.1 days (3.6 vs 4.7 days)

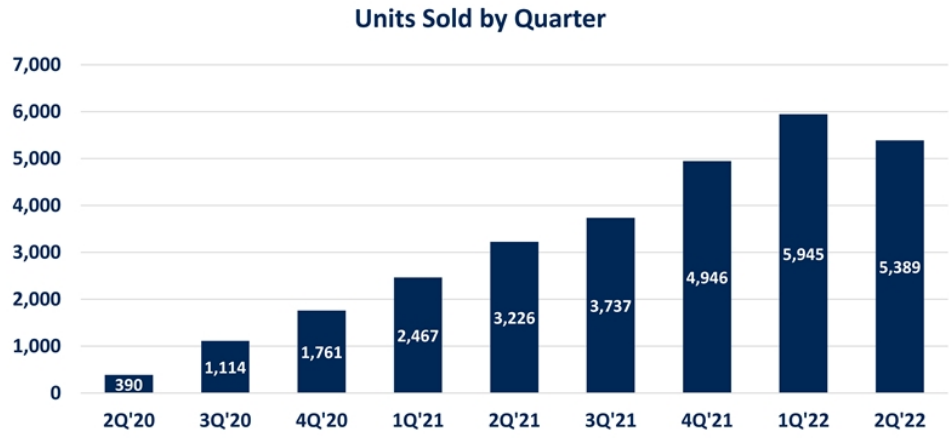
*Preoperative dosing = ANJESO 30mg was administered prior to surgical incision (TKA) or 30 minutes prior to the start of surgery (bowel resection), then once-daily while in hospital until discharge or IV analgesic was no longer appropriate. 1. Studies completed with efficacy, safety, opioid reduction and healthcare resource utilization measures. 2. Data on file. Baudax Bio, Inc. MMA = multimodal analgesia; LOS = length of stay

ANJESO® Highlights:

Source: ANJESO Prescribing Information.
*Vial size approximately 16 X 34.5 mm

- Achieved net product revenue of $0.3 million, up 49% YoY.
- Q2 was the second-best quarter since launch, in which vials sold to end-users during the quarter increased 67% YoY, in spite of a reduction in force during Q1 of approximately 80%.
- ANJESO sales reflect deepening usage at existing accounts, as Q2 sales in the hospital setting grew by 12% in vials sold to hospitals, compared to Q1 2022.
- Seven Orange Book Listed patents; with one additional patent expected to be issued in the coming months, with an expected expiry date of March 2039.

Q2’22 sales were 5,389 units: 67% increase YoY



Adjusted ANJESO® Field Coverage

Significantly Reduced Burn Rate and Operating Expenses

- Given current market conditions, in spite of promising trajectory for ANJESO® sales, in late Q1 forced to cut expenses and commercial team size reduced by approximately 80% to a total of 7 professionals
  - Finance, medical and other areas also trimmed
- After RIF expenses, burn rate was reduced by approximately 65% going forward
- Continue to focus on key accounts and contracts; Key staff continue to work with existing, ordering accounts as well as newly added institutions.
- Evaluating possible partnering options for ANJESO® portfolio

BAUDAX BIO

Neuromuscular Blockers and Reversal Agent

Neuromuscular Blockers & Reversal Agent Overview

400 million people receive neuromuscular blocking (NMB) agents annually[1]

- Used to induce rapid total paralysis to permit intubation and muscle relaxation during surgery or in ventilated patients
- Used either in the operating room or ASC to optimize surgical conditions; additional use in ICU to facilitate mechanical ventilation
- Numbers increasing with laparoscopic abdominal procedures

Two novel NMBs & a novel reversal agent in development

- Neuromuscular blocking agents
  - BX1000: Intermediate acting agent duration of action (~45 mins*)
    - Rapid onset
    - Completed one Dose escalation clinical trial; Phase 2 surgical trial expected to commence in 2022
  - BX2000: Ultra-short acting agent duration of action (10-15 mins*)
    - Rapid onset
    - Dosing completed for the second cohort of Phase 1 clinical study evaluating the safety, tolerability and pharmacokinetics in healthy volunteers
- Novel reversal agent
  - Specific for BX1000 and BX2000; provides complete chemical reversal of neuromuscular blockade from any depth of block within 2-5 minutes*
    - In pre-clinical development; expect to file IND in the first half of 2023.

1. IMS, MIDAS 2010

BAUDAX BIO | NMB = Neuromuscular blocking agents * Based on extrapolations from pre-clinical pharmacology data in animals

BAUDAX BIO

Thank you!

Important Anjeso® Safety Information

Indication and Boxed Warning

INDICATION

ANJESO is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-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.**

Important Safety Information (cont)

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.

Important Safety Information (cont)

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.

Important Safety Information (cont)

DRUG INTERACTIONS

Drugs That Interfere With Hemostasis (eg, 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 in ≥2% of patients treated with ANJESO and at a greater frequency than placebo included: constipation, gamma-glutamyl transferase increased and anemia.

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NSAIDs, including ANJESO, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of ANJESO use between about 20 and 30 weeks of gestation and avoid ANJESO use at about 30 weeks of gestation and later in pregnancy

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.baudaxbio.com.