
**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 20, 2022

Baudax Bio, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of
incorporation or organization)

001-39101
(Commission
File Number)

47-4639500
(I.R.S. Employer
Identification No.)

490 Lapp Road, Malvern, Pennsylvania
(Address of principal executive offices)

19355
(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	BXXR	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 April 20, 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.	<u>Document</u>
99.1	Investor Presentation of Baudax Bio, Inc., dated April 20, 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: April 20, 2022

Baudax BIO™

**Baudax Bio
Noblecon18
Presentation**

April 20th, 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 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 the 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 advance its current product candidate pipeline through pre-clinical studies and clinical trials, 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, the accuracy of Baudax Bio's estimates of the potential market for ANJESO, Baudax Bio's ability to achieve its financial goals; Baudax Bio's ability to maintain its 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.

BAUDA[×] BIO[®]



ANJESO[®] (meloxicam) injection

Only once daily, 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 12/31/21:

Approximately \$16Million



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						U.S. approval 2/20/2020
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 patients¹

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

BAUDA[®] BIO

Please see Important Safety Information including BOXED WARNING at the end of presentation.
Full Prescribing Information at www.ANJESO.com

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ANJESO® (meloxicam) injection Overview



- Proprietary non-opioid, once daily IV injection
- Incorporates Alkermes' NanoCrystal® technology
- Once daily, long-acting, preferential COX-2 inhibitor for moderate to severe acute pain
- Commercial Launch ongoing - 2021 growth trend continues
 - Q4'21 reported metrics*:
 - Total number of vials sold to all end-users up approximately 32%
 - Vials sold to new ambulatory surgery centers up approximately 45%
 - Significant December rebound and overall Q4 growth, in spite of November/December CV-19 Omicron Impact
- Orange Book Listed patents run until 2030

* Quarter over quarter metrics based on fourth quarter of 2021 compared to third quarter 2021

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® (meloxicam) Injection: The First and Only Once-Daily IV 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

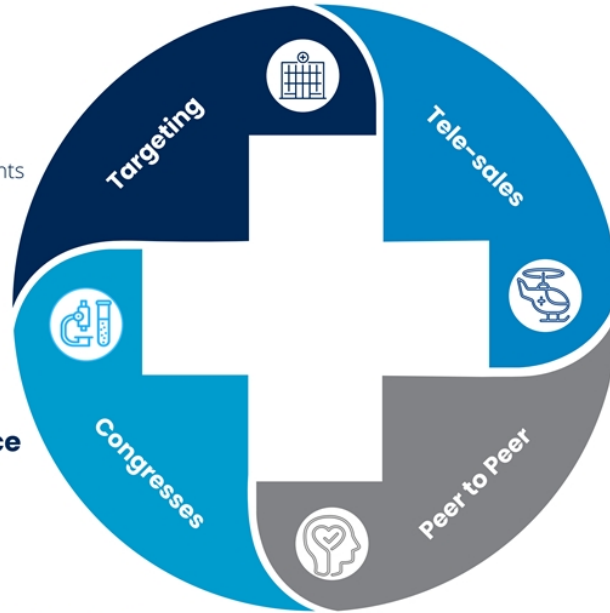
When initiating ANJESO, monitor patient analgesic response. Because the median time to meaningful pain relief was 2 and 3 hours after ANJESO administration in two clinical studies, a non-NSAID analgesic with a rapid onset of effect may be needed, for example, upon anesthetic emergence or resolution of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

Closed 2021 with Impactful Commercial Metrics

Field Sales Targeting

90% Hyper Target Reach
70% Reach on Formulary Target Accounts



Tele-sales

Driving awareness and adoption
Expanded reach to over 400 new ASCS
5 accounts "On Formulary"

Strong Congress Presence

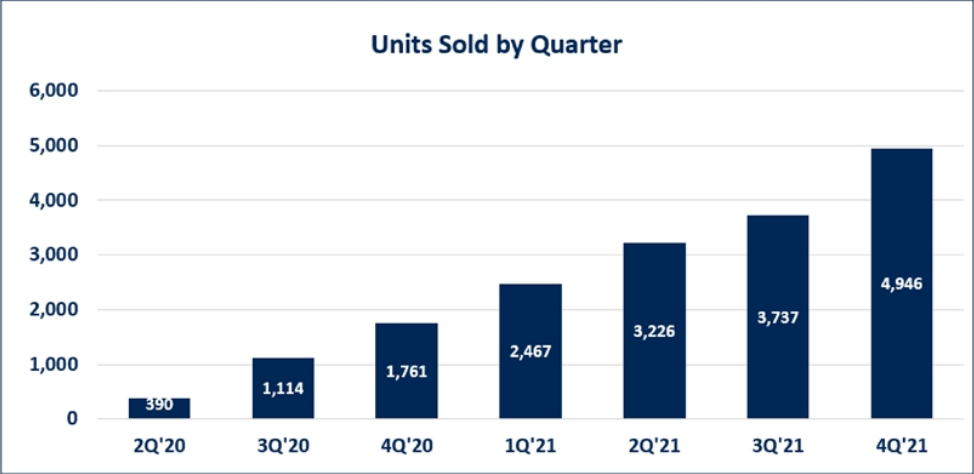
AAHKS, ASA, PAINweek, ERAS,
PGA, other local meetings

Peer to Peer Programs

> 100 completed in 2021

Sales continue to show quarter over quarter growth

Q4 Unit Sales growth has continued!

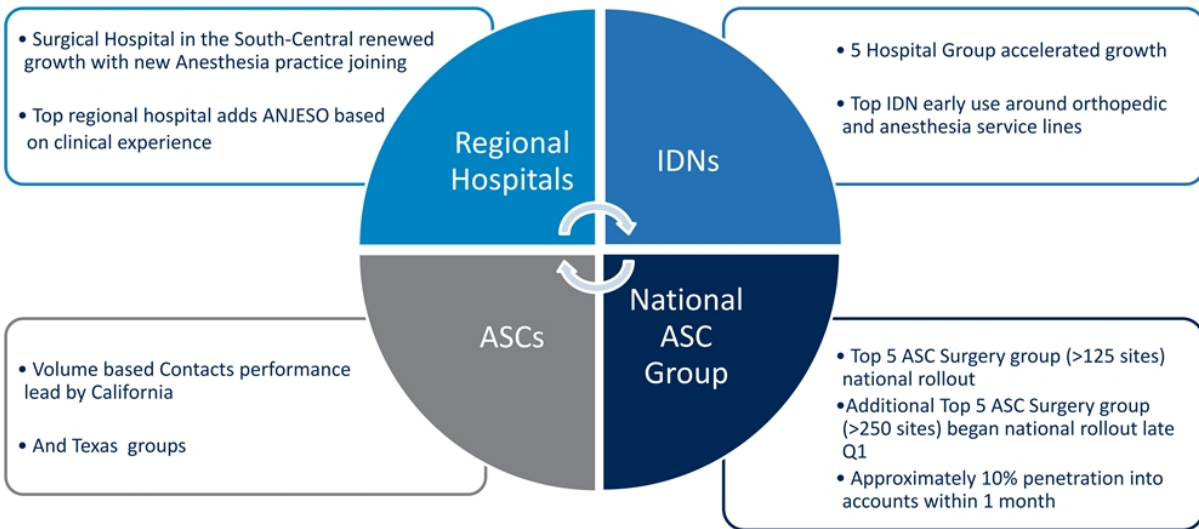


Adjusting Anjeso® field coverage

Significantly Reduced Burn Rate

- Given current market conditions, in spite of promising trajectory for Anjeso® sales, in late Q1 forced to cut expenses and commercial team size cut to a total of 7 professionals. Finance, Medical and other areas trimmed as well.
- After RIF expenses, burn rate 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

Q4 Highlights Demonstrated Success Across Arenas



Baudax BIO™

**Neuromuscular
Blockers and
Reversal Agent**

Neuromuscular Blockers & Reversal Agent Overview

400 million people receive neuromuscular blocking (NMB) agents annually¹

- 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 1H 2022
 - BX2000: Ultra-short acting agent duration of action (10-15 mins*)
 - Rapid onset
 - Preclinical development complete; IND filed and open ; Clinical dose-escalation study in healthy volunteers to commence in 1H 2022
- Novel reversal agent
 - Specific for BX1000 and BX2000; provides complete chemical reversal of neuromuscular blockade from any depth of block within 2-5 mins*
 - In pre-clinical development; expect to initiate clinical program in healthy volunteers by YE 22 or early 2023.

1. IMS, MIDAS 2010

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 $\geq 2\%$ 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.