
**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): January 4, 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 January 4, 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:

<u>Exhibit No.</u>	<u>Document</u>
99.1	Investor Presentation of Baudax Bio, Inc., dated January 4, 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: *Chief Executive Officer*

Date: January 4, 2022

Baudax BIO

**Baudax Bio
Corporate
Presentation**

January 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 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.

Company Highlights

- 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
- Additional neuromuscular blocking agents (NMBs) and proprietary reversal agent pipeline candidates in clinical stage development for acute care settings
- Baudax financial position
 - Cash, cash equivalents and short-term investments as of 9/30/21 : \$25 Million
- Experienced management team with significant commercial, development, and regulatory experience

Experienced Commercial Management & Launch Leadership Team

Geri Henwood – President and CEO

Founded Recro Pharma (REPH), Auxilium Pharmaceuticals (AUXL – NASDAQ then Endo) and IBAH (NASDAQ then Omnicare); GSK

Richard Casten – Chief Financial Officer

25 years diversified financial experience – Lupin Pharmaceuticals (LUPIN - NSE), Endo International (ENDP - NASDAQ), Campbell Soup Company (CPB - NYSE), Ernst & Young LLP

Jyrki Mattila, MD, PhD –EVP, Business Development

Over 30 years of Pharma executive leadership and business development experience -Lipocine, iCeutica, Auxilium, Orion Pharma

Greg Gangemi – Chief Commercial Officer and Sr. Vice President

Over 25 years of industry, launch and operations experience – Recro, Sepracor/Sunovion, Cubist, Ferring and Ocular Therapeutix

Janeese Carter – Vice President, Marketing

Over 15 years of marketing, market research, new business strategy, and sales – Recro Pharma, CSL Behring, Pfizer/Wyeth

Baudax BIO™

**Commercial
Opportunity**

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

BAUDAX 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 - Q4 growth trend continues
 - Q3'21 reported metrics*:
 - Total number of vials sold to all customers up 16%
 - Vials sold to existing hospitals up 11%
 - Vials sold to new ambulatory surgery centers up 66%
 - Significant September rebound and overall Q3 growth, in spite of July/August CV-19 Delta Impact
- Orange Book Listed patents run until 2030

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

ANJESO® Evaluated in Three Phase 3 Studies

Study Population ^a	ANJESO 30 mg	Placebo	Primary Endpoint	Outcome
 Bunionectomy ¹	n=100	n=101	SPID48*	31% greater pain reduction vs placebo (p=0.0034)
 Abdominoplasty ²	n=110	n=109	SPID24*	17% greater pain reduction vs placebo (p=0.0145)
 Safety study; multiple hard & soft tissue procedures ³	n=538	n=183	Safety, including number of patients with adverse events up to 28 days after dosing	Adverse Events comparable to placebo

*SPID (Sum of Pain Intensity Differences) is calculated by the sum of the difference between current pain and baseline pain at each post-dose time point. SPID48 = summed pain intensity difference from 0-48 hours, SPID24 = summed pain intensity difference from 0-24 hours. ^aAll studies completed with efficacy, safety and opioid reduction data.

1. Pollak RA et al. Clin J Pain. 2018;34(10):918-926. 2. Singla N et al. Plast Reconstr Surg Glob Open. 2018;6:e1846. 3. Bergese SD et al. Clin Pharmacol Drug Dev. 2019;8(8) 1062-1072.

ANJESO® Adverse Events Across All Phase 3 Studies



**ANJESO
(n=748)**

Adverse Reactions in Placebo-Controlled Phase 3 Clinical Trials occurring in $\geq 2\%$ of Patients Treated with ANJESO® and at a greater frequency than Placebo	ANJESO 30 mg (n=748)	Placebo (n=393)
	% (n)	% (n)
Constipation	57 (7.6%)	24 (6.1%)
Gamma-Glutamyl Transferase Increased	21 (2.8%)	6 (1.5%)
Anemia	18 (2.4%)	4 (1.0%)

Source: ANJESO Prescribing Information

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

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. Abstracts and publications pending. 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.

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Commercial Update

Executive Summary

Innovative Roles
are Driving Growth

Anticipated Fast
Start for 2022

Q4 Targeted Efforts Focused on Closing 2021

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"

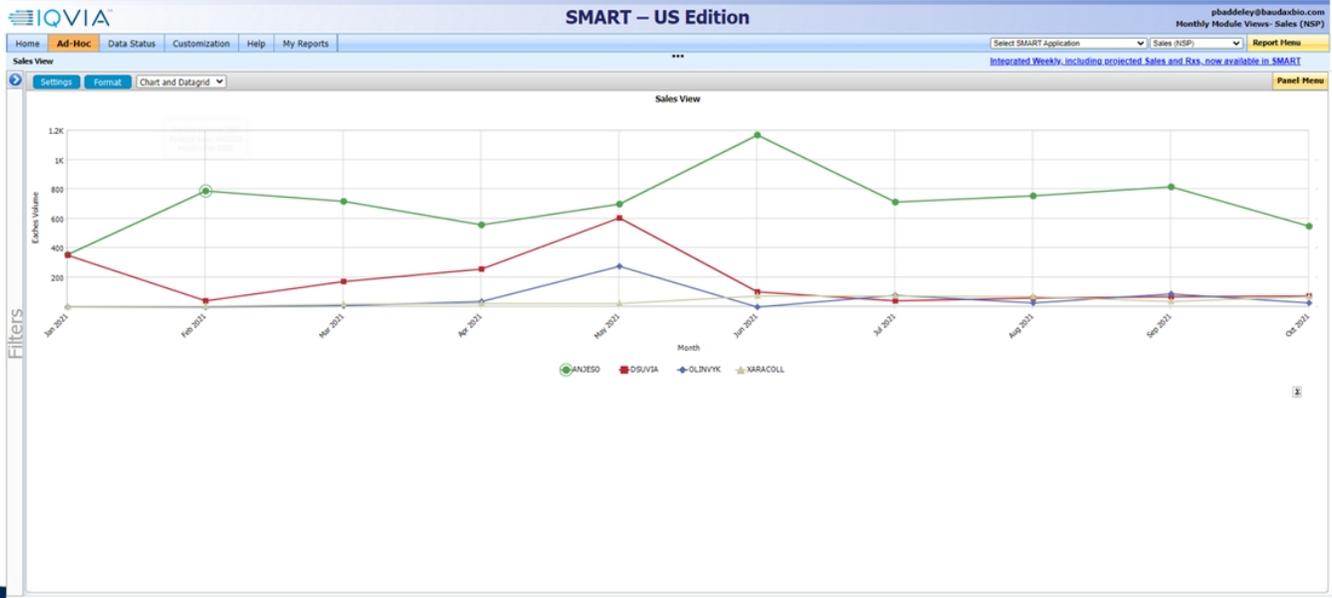
Strong Congress Presence

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

Peer to Peer Programs

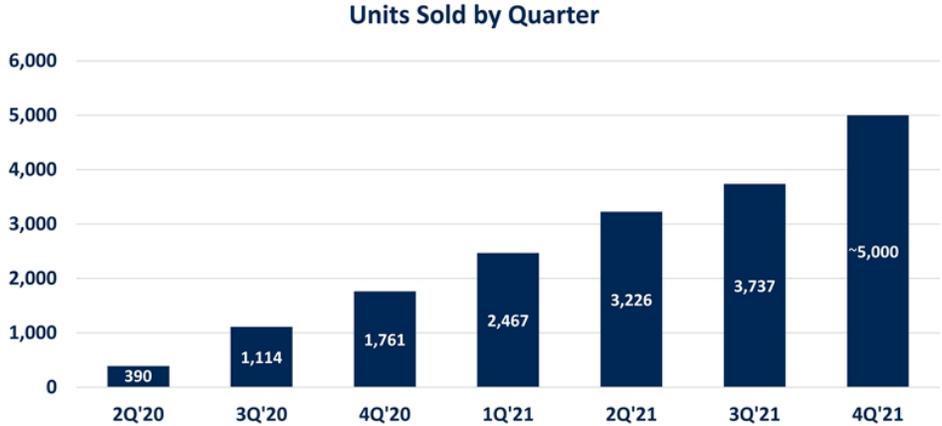
> 100 in completed in 2021

IQVIA NSP – Acute Care Launch Products



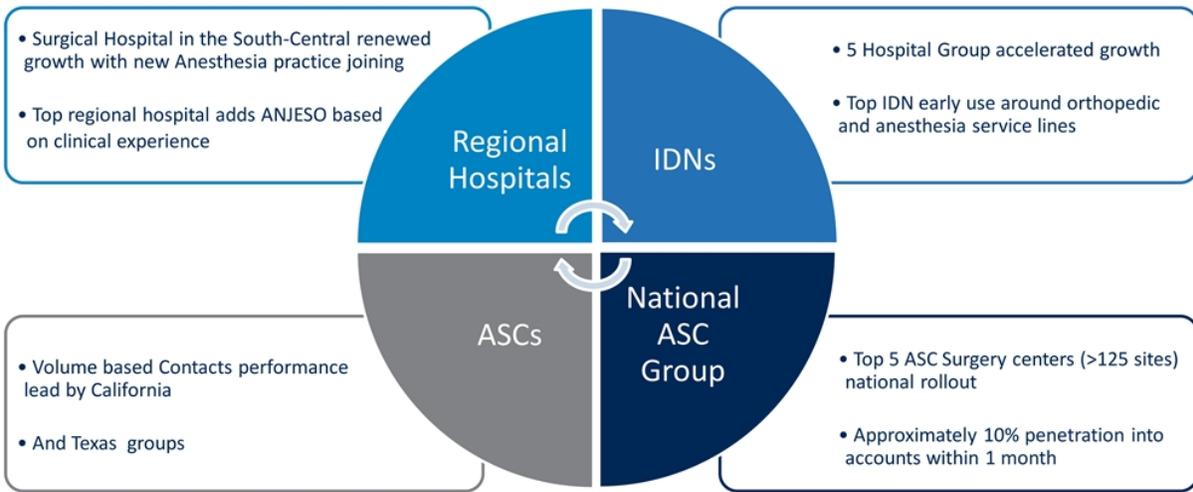
Sales continue to show quarter over quarter growth

Estimated* Q4 Unit Sales growth has continued!

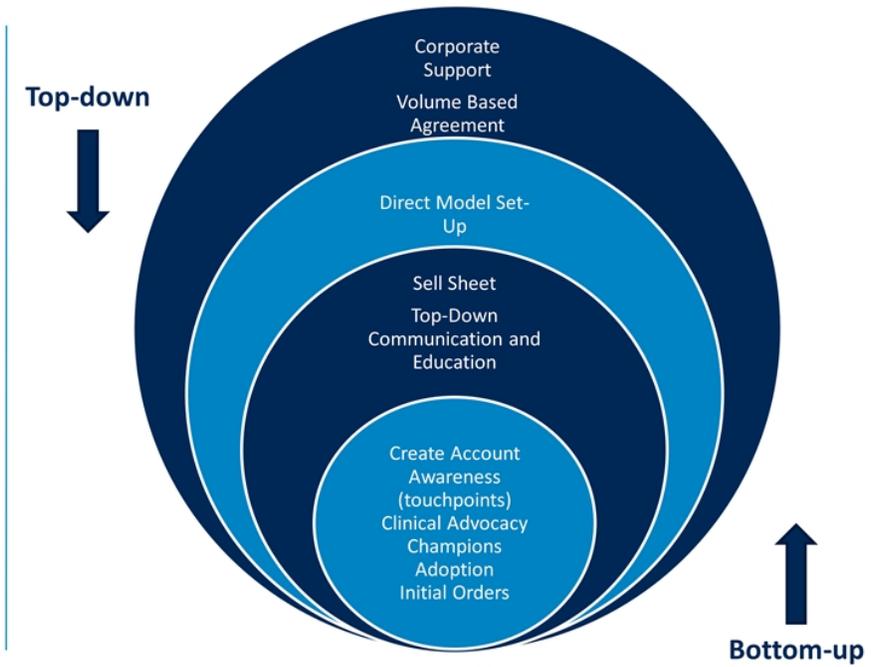


* Final reconciliation pending YE close analysis

Q4 Highlights Demonstrated Success Across Arenas



Our Strategic Approach To Large Accounts



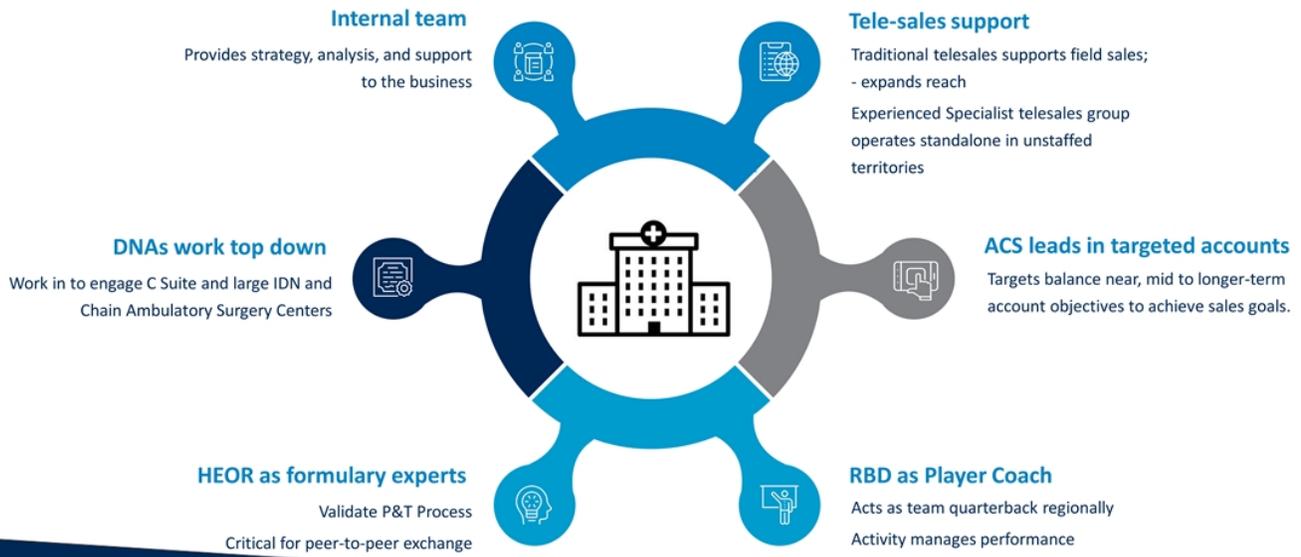
Baudax BIO™

Preparing For 2022

Commercial Roles Work Closely Together

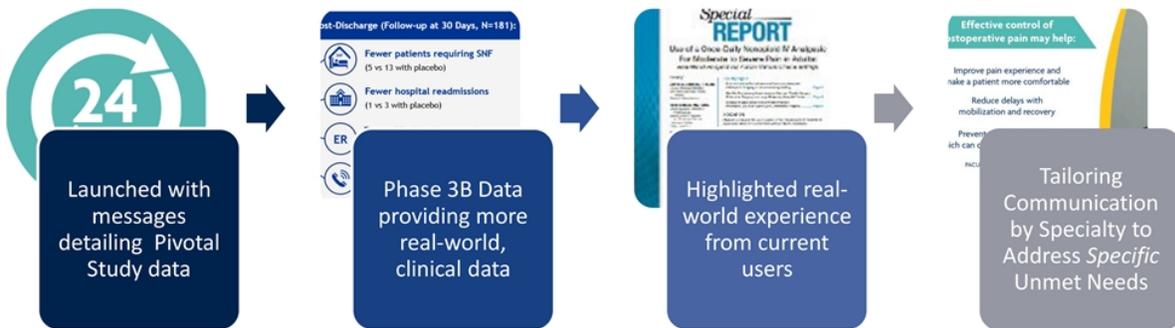
Field Role Integration is Critical

Field Leadership Meeting 9/27

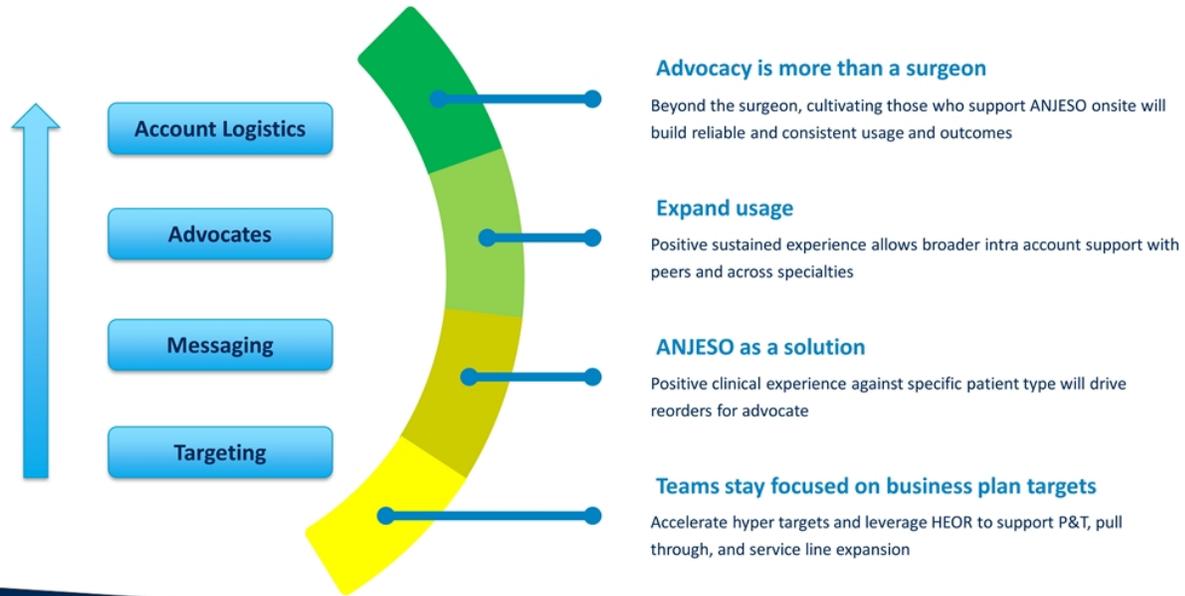


Tailored Communication By Specialty Is Key To Increasing Likelihood To Trial Usage

Evolving the Sophistication of our Messages



Early Trial Accounts Are Opportunity To Expand Usage



Investments in Execution Excellence in 2022

Fast Start Regional POA Meetings



Ongoing Training Investments

- Integrity Selling Follow-Up & Coaching
- Micro-Learning Platform to Reinforce Key Messaging/Content
- Surgical Profile Backgrounders
- Phase II Training to bring tenured Reps into Home Office for continued reinforcement

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Thank you!

Important 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 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.baudaxbio.com.

Baudax BIO™

**APPENDIX:
Additional information for
ANJESO®**

Surgical Setting Coding and Reimbursement

Hospital Inpatient

Medicare

- Use J3490
- Reimbursement bundled into DRG payment

Commercial

- Use J3490
- Bundled and part of a case rate

Hospital Outpatient

Medicare

- Unique Code, C9059 (Injection, Meloxicam 1mg)
- Reimbursed at 80% of 95% of AWP

Commercial

- Permanent J-code J1738 effective 10/1/2020
- May be bundled with procedure or separately reimbursed based on the facility contract

Ambulatory Surgery Centers

Medicare

- Unique Code, C9059 (Injection, Meloxicam 1mg)
- Reimbursed at 80% of 95% of AWP

Commercial

- Permanent J-code J1738 effective 10/1/2020
- May be bundled with procedure or separately reimbursed based on the facility contract

AWP=average wholesale price; DRG=diagnosis related group.

Permanent J-code J1738 "Injection, meloxicam, 1 mg" effective 10/1/2020 and replaced all other codes