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 10, 2020

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 2.02 Results of Operations and Financial Condition.

On August 10, 2020, Baudax Bio, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company has scheduled a conference call and webcast for 9:00 a.m. Eastern time on August 10, 2020 to discuss these financial results and business updates.

The information disclosed under Item 2.02, 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 8.01 Other Events.

On August 10, 2020, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

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 August 10, 2020.
99.2	Investor Presentation of Baudax Bio, Inc.

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: August 10, 2020

Baudax Bio Reports Second Quarter 2020 Financial Results

Commenced Commercial Launch of ANJESO® in the U.S.

Awarded J-Code from CMS

Executed Contract with a top National GPO for hospital purchases, Vizient, and one of the top 3 IDNs Nationally

Secured $50 Million Credit Facility

MALVERN, Pa., August 10, 2020 — Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today reported financial results for the three and six months ended June 30, 2020.

"The second quarter of 2020 was most important because of the full commercial launch of ANJESO," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "We believe that with our experienced acute care sales force, receipt of our J-code from the Centers for Medicare and Medicaid Services (CMS) (effective in October 2020), entry into an agreement with the Group Purchasing Organization (GPO) Vizient Inc., and other strategic initiatives underway, we are well positioned to continue to target the acute care space. We look forward to continuing to raise awareness and educate acute care providers about ANJESO as an advantageous option for the management of moderate to severe pain."

Second Quarter 2020 and Recent Business Highlights

- **Commenced Full Commercial Launch of ANJESO.** In June 2020, the Company commenced the commercial launch of ANJESO, following its approval by the U.S. Food and Drug Administration (FDA) in February 2020. ANJESO is the only approved 24-hour, intravenous COX-2 preferential NSAID that offers once-daily dosing. Baudax has hired, trained, and now deployed 50 acute care sales representatives to match key territories identified in the U.S.
- **Receipt of J-Code from CMS.** In early August 2020, CMS established a new permanent J-code for ANJESO, facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. The code, J1738 (Injection, meloxicam, 1 mg), will take effect on October 1, 2020 and it is expected to replace the previously issued C-code (C9059).
- **Company Secures Pharmacy Supplier Agreement with Vizient Inc.** In July 2020, Baudax entered into an agreement with the GPO Vizient Inc., the largest member-driven healthcare performance improvement company in the U.S., to offer ANJESO with enhanced savings to Vizient's diverse membership, which includes more than 50% of the nation's acute care providers, 95% of the nation's academic medical centers, and more than 20% of ambulatory care providers. Vizient represents more than $100 billion in annual purchasing volume.

- **Company signed agreement with top IDN.** In July 2020, the Company signed an agreement with one of the top 3 Integrated Delivery Networks (IDNs) for terms for availability of ANJESO to their member institutions and the company has begun the regional formulary processes associated with this central review and approval.
- **Presented New Phase IIIb ANJESO Data at American Society of Colon and Rectal Surgeons (ASCRS) Meeting.** In July 2020, Baudax presented a virtual poster highlighting new Phase IIIb ANJESO (meloxicam) injection clinical data as part of the ASCRS 2020 Annual Scientific Meeting. The published data supports the use of ANJESO administered preoperatively to patients prior to undergoing colorectal surgery. The key findings from this study include statistically significant reductions in opioid use, as well as time to bowel function recovery and hospital discharge, resulting in cost savings for ANJESO-treated patients.
- **Secured $50 Million Credit Facility.** In June 2020, the company announced the close of a credit facility of up to $50 million from funds managed by Marathon Asset Management, a global credit solutions partner. Proceeds from the facility will generally be used to support the commercial launch of ANJESO (meloxicam) injection, and for working capital purposes. JMP Securities LLC acted as exclusive financial advisor and sole placement agent to Baudax on this transaction.

COVID-19 Impact

The Company's efforts to commercialize ANJESO have been, and may continue to be, impacted by theCOVID-19 pandemic. Hospitals have reduced and diverted staffing, diverted resources to patients suffering from COVID-19 and limited hospital access for nonpatients, including our sales professionals, which the Company believes may impact their marketing and commercialization efforts. The Company believes that the reduction in elective surgeries during the COVID-19 pandemic has and may continue to result in decreased demand for ANJESO. The Company anticipates that many hospitals and health care providers will continue to suffer negative financial consequences due to an increase in unexpected costs, including for additional staff, personal protective equipment and ventilators, along with a reduction in revenue due to fewer elective procedures being performed, which may result in a decreased demand for ANJESO. While access restrictions have eased in some locations, spikes of COVID-19 cases in certain states or regions may further impact the Company's sales force as access to hospitals may be restricted and elective surgeries may be limited in those areas. Due to the rapidly evolving environment, continued uncertainties from the impact of the COVID-19 global pandemic, and recent regional outbreaks that are impacting the recovery, the Company cannot estimate the full extent to which the Company's commercialization of ANJESO and financial results may be adversely impacted.

Second Quarter 2020 Financial Results

As of June 30, 2020, Baudax had cash and cash equivalents of $39.4 million.

For the three months ended June 30, 2020, net product revenue was $350,000, related to sales of ANJESO in the U.S. There was no product revenue recognized during the three months ended June 30, 2019.

For the three months ended June 30, 2020, cost of sales was $0.7 million and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Certain product costs of ANJESO units recognized as revenue during the three months ended June 30, 2020 were incurred prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect cost of sales to increase as we build new inventory not expensed during the pre-approval period, validate a larger manufacturing suite and deplete our initial inventory levels. No cost of sales were recorded for the three months ended June 30, 2019.

For the three months ended June 30, 2020, research and development expenses were $1.4 million, compared to $7.2 million for the three months ended June 30, 2019, a decrease of $5.8 million. Excluding $2.6 million of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, our research and development expenses decreased $3.2 million primarily resulting from a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of $2.3 million and a decrease in personnel costs and overhead expenses of $0.9 million as we allocated or recategorized certain expenses related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO.

For the three months ended June 30, 2020, selling, general and administrative expenses were $11.2 million, compared to $7.4 million for the same prior year period, an increase of $3.8 million. Excluding $3.4 million of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, our selling, general and administrative expenses increased $7.2 million primarily due to selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of $5.6 million for the three months ended June 30, 2020 increased $5.0 million due to increased personnel costs of $3.1 million and increased commercial costs of $1.9 million. General and administrative expenses of $5.6 million for the three months ended June 30, 2020 increased $2.2 million primarily due to increased personnel costs, including over half of which was attributed to medical affairs and regulatory support functions which had previously been recorded within research and development expense in the prior year period.

For the three months ended June 30, 2020, Baudax reported a net loss (includingnon-cash charges of $19.8 million) of $30.4 million, or $1.72 per share. The non-cash charges of $19.8 million were associated with stock-based compensation,non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration. This compares to a net loss of $10.6 million, or $1.13 per share, for the comparable period in 2019. For the three months ended June 30, 2020, there was $10.6 million in cash based expenses and an additional $0.7 million use of cash associated with working capital adjustments primarily related to the build of inventory for ANJESO.

Six months ended June 30, 2020 Financial Results

For the six months ended June 30, 2020, net product revenue was $350,000, related to sales of ANJESO in the U.S. There was no product revenue recognized during the six months ended June 30, 2019.

For the six months ended June 30, 2020, cost of sales was $0.7 million and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Certain product costs of ANJESO units recognized as revenue during the six months ended June 30, 2020 were incurred prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect cost of sales to increase as we build new inventory not expensed during the pre-approval period, validate a larger manufacturing suite and deplete our initial inventory levels. No cost of sales were recorded for the six months ended June 30, 2019.

For the six months ended June 30, 2020, research and development expenses were $4.4 million, compared to $16.7 million for the six months ended June 30, 2019, a decrease of $12.3 million. Excluding $2.8 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, our research and development expenses decreased $9.5 million primarily resulting from a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of $6.2 million, a decrease in development costs for other pipeline products of $2.1 million and a decrease in personnel and overhead expenses of $1.2 million as we re-allocated costs related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO.

For the six months ended June 30, 2020, selling, general and administrative expenses were $19.3 million, compared to $17.3 million for the same prior year period, an increase of $2.0 million. Excluding $4.4 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, our selling, general and administrative expenses increased $6.4 million primarily due to increased selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of $8.9 million for the six months ended June 30, 2020 increased $3.5 million primarily due to increased personnel costs of $1.9 million and increased commercial costs of $1.6 million. General and administrative expenses of $10.4 million for the six months ended June 30, 2020 increased $2.9 million primarily due to increased personnel costs of $2.4 million, including over half of which was attributed to medical affairs and regulatory support functions which had previously been recorded within research and development expense in the prior year period and increased public company costs of approximately $0.5 million as the prior year costs represent an allocated portion of the costs in the historical combined financial statements prior to our separation from Recro Pharma, Inc.

For the six months ended June 30, 2020, Baudax reported a net loss (including non-cash charges of $51.8 million) of $70.7 million, or $5.11 per share. The non-cash charges of $51.8 million were associated with stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration. This compares to a net loss of $14.9 million, or $1.60 per share, for the comparable period in 2019.

About ANJESO®

ANJESO (meloxicam) injection is a proprietary, long-acting, preferential COX-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 approved by the U.S. Food and Drug Administration in February 2020 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. The ANJESO product approval was 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 specialty pharmaceutical company focused on therapeutics for acute care settings. The Company's first commercial product, ANJESO®, had its New Drug Application approved by FDA on February 20, 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. 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. As a non-opioid, IV meloxicam 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. For more information please visit www.baudaxbio.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 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 our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

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BAUDAX BIO, INC.
Consolidated Balance Sheets
(Unaudited)

(amounts in thousands, except share and per share data)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 39,410	$ 17,740
Accounts receivable	382	—
Inventory	753	—
Prepaid expenses and other current assets	2,122	2,395
Total current assets	$ 42,667	$ 20,135
Property, plant and equipment, net	4,610	4,821
Right of Use asset	542	730
Intangible assets, net	25,541	26,400
Goodwill	2,127	2,127
Total assets	$ 75,487	$ 54,213
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	2,190	271
Accrued expenses & other current liabilities	3,972	3,532
Current portion of long-term debt, net	598	—
Current portion of operating lease liability	258	318
Current portion of contingent consideration	13,135	3,592
Total current liabilities	20,153	7,713
Long-term debt, net	8,097	—
Long-term operating lease liability	329	455
Warrant liability	21,410	—
Long-term portion of contingent consideration	84,902	62,766
Total liabilities	134,891	70,934
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding.	—	—
Common stock, $0.01 par value. Authorized, 100,000,000 shares; issued and outstanding, 18,374,604 shares at June 30, 2020 and 9,350,709 shares at December 31, 2019	184	94
Additional paid in-capital	47,375	19,405
Accumulated deficit	(106,963)	(36,220)
Total shareholders' equity	(59,404)	(16,721)
Total liabilities and shareholders' equity	$ 75,487	$ 54,213

BAUDAX BIO, INC.
Consolidated and Combined Statements of Operations
(Unaudited)

(amounts in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue, net	$ 349	$ —	$ 349	$ —
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	650	—	650	—
Research and development	1,350	7,180	4,420	16,734
Selling, general and administrative	11,217	7,449	19,263	17,284
Amortization of intangible assets	644	—	859	—
Change in warrant valuation	12,667	—	14,045	—
Change in contingent consideration valuation	4,053	(4,059)	31,679	(19,150)
Total operating expenses	30,581	10,570	70,916	14,868
Operating income / (loss)	(30,232)	(10,570)	(70,567)	(14,868)
Other income (expense):				
Interest income (expense)	(213)	(12)	(176)	(49)
Net loss before income taxes	$ (30,445)	$ (10,582)	$ (70,743)	$ (14,917)
Income tax benefit	—	—	—	—
Net loss	$ (30,445)	$ (10,582)	$ (70,743)	$ (14,917)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.72)	$ (1.13)	$ (5.11)	$ (1.60)
Weighted average common shares outstanding, basic and diluted	17,691,700	9,350,709	13,846,464	9,350,709

Exhibit 99.2

BAUDAX BIO

Corporate Overview

August 10, 2020

Forward Looking Statements

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "anticipate", "believe", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "will" and similar terms and phrases may be used to identify forward-looking statements in this presentation. Our operations involve risks and uncertainties, many of which are outside our control, and any one of which, or a combination of which, could materially affect our results of operations and whether the forward-looking statements ultimately prove to be correct.

These forward-looking statements are subject to risks and uncertainties including, among other things, 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, our ability to maintain regulatory approval for ANJESO®, our ability to successfully commercialize ANJESO®; the acceptance of ANJESO® by the medical community, including physicians, patients, health care providers and hospital formularies; our ability and that of our third party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO®, our ability to produce commercial supply in quantities and quality sufficient to satisfy market demand for ANJESO®, our ability to raise future financing for continued product development and ANJESO® commercialization, our ability to manage costs and execute on our operational and budget plans, the accuracy of our estimates of the potential market for ANJESO®, our ability to achieve our financial goals; and our 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 our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

This presentation is intended to be non-promotional and for investor discussion purposes only.

Company Highlights

- ANJESO® (meloxicam) injection*
  - Approved February 20, 2020 for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics
  - Significant Potential Commercial Opportunity
  - Commercial launch June 2020
- Additional pipeline candidates in clinical stage development for acute care settings
- Baudax Cash position – $39.4 million as of June 30, 2020
  - $50 million credit facility secured in May 2020; $10 million drawn
  - Short dated Cash Exercisable Series B Warrants expected to provide additional $25 million in gross proceeds before or by April 2021, assuming full exercise. As of June 30, 2020, warrant exercises have provided $2.5 million in net proceeds.
- Experienced management team with significant commercial, development, and regulatory experience

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

Experienced Management & Launch Leadership Team

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

Ryan Lake – Chief Financial Officer
20 years of senior financial and life sciences leadership experience – Recro Pharma (REPH), Aspire Bariatrics, DSM (DSM.AS) - DSM Biomedical, Kensey Nash (KNSY), Deloitte

Stewart McCallum, MD – Chief Medical Officer
Board certified Urologist (Stanford & Weill Cornell) with 13 years of industry experience at Recro Pharma and GSK

Jyrki Mattila, M.D., Ph.D – EVP, Business Development
Over 30 years of BD and general management experience – Recro, Lipocine, iCeutica, LZ Therapeutics, Auxilium & Orion

John Harlow – EVP and Chief Commercial Officer
Over 20 years commercial launch and leadership experience – Recro, Novartis, Alpharma/King/Pfizer, Endo, Shionogi, Janssen

Greg Gangemi – Vice President, Sales, Trade & Market Access
Over 25 years of industry, launch and operations experience – Recro, Sepracor/Sunovion, Cubist, Ferring and Ocular Therapeutix

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

Paul Baddeley – Senior Director, Commercial Operations
20 years of industry and consulting experience in commercial operations & analytics – Recro, Collegium, IMS Health, Endo

BAUDAX BIO

Anjeso™ (meloxicam) injection

Highlights

ANJESO® (meloxicam) injection Overview

- Proprietary non-opioid, long-acting IV form
  - Incorporates Alkermes' NanoCrystal® technology
- Once daily, long-acting, preferential COX-2 inhibitor for moderate to severe acute pain
- Commercial Launch Underway
  - Receipt of permanent J-code effective October 1, 2020 and it is expected to replace the previously issued C-code that became effective July 1, 2020
  - Signed contract with a top 3 IDN and GPO; others in-process
- Orange Book Listed patents run until 2030

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

Up to 24-hour pain relief

Efficacy in orthopedic & soft tissue procedures

Demonstrated Safety & Tolerability

Evaluated in more than 1400 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® 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. [a]All 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 ≥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

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 push over 15 seconds**
  - Administered as a 30-mg (1 mL)
  - Available as a small* (2 mL) 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 Opportunity

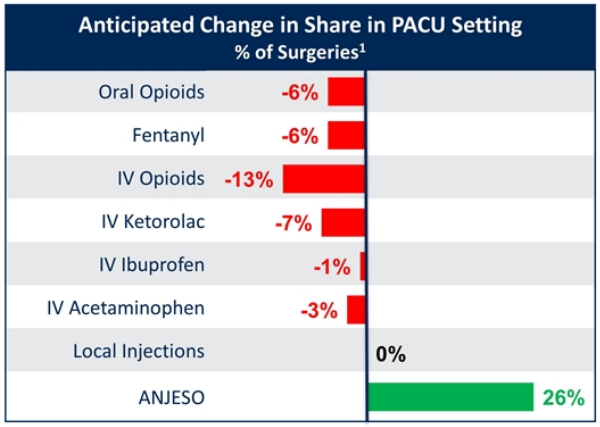
Large Opportunity Waiting For Non-Opioid Solutions: Market Can Be Targeted Efficiently & Effectively

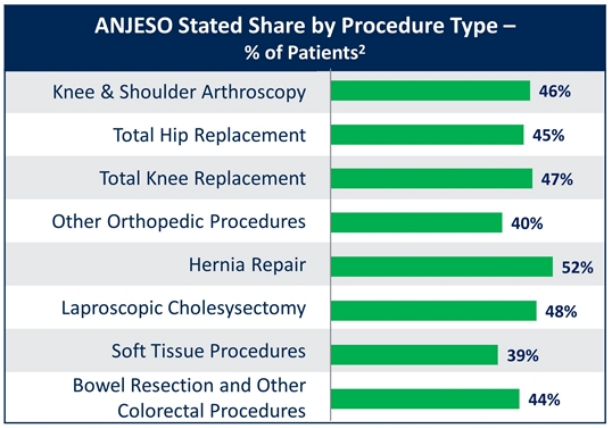

	HOSPITAL INPATIENT	HOPD	ASC	TOTAL
ADDRESSABLE PROCEDURES*	11m	9m	2.2m	~22m Procedures
CORE TARGET PROCEDURES	Orthopedic (Hip/Knee, Spine, other) General Surgery Colorectal			
TARGETED PROCEDURES	3.4m	6.9m	1.0m	~11.3m Procedures
TARGETED ACCOUNTS	~1,450 HOSPITALS		~550 ASCs	~2,000 Accounts

Source: Definitive, LexisNexis and Company Estimates. *Includes addressable procedures where ANJESO use is anticipated.

ANJESO® Stated Shares in Market Surveys Remain Consistently Positive

Approximately 65% of MDs surveyed believe they would likely use ANJESO with stated procedure shares ranging from 39-52%





*Product profile in surveys was fair balanced, based on clinical data and similar to final label. Stated shares do not account for possible access restrictions (i.e. special order, quantity limits, specific procedural prescribing, limitations by site of care, etc.) 1. December 2017 – Blinded, Third Party Market Research, n=462. 2. January 2020 – Blinded, Third Party Market Research, n=400. PACU = Post-Anesthesia Care Unit

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Commercial Launch

Early Progress Promising on Pull Through Opportunities

WHOLESALERS

ANJESO STOCKED IN MAJOR WHOLESALERS

- Wholesaler and Specialty Distributors agreements in place with sufficient launch inventory in forward distribution centers

GOVERNMENT FILINGS

SECURING ACCESS TO GOV'T PROGAMS

- Pass through status & C-code effective 7/1/2020
- CMS granted permanent J-code (HCPCS) to become effective 10/1/2020
- VHA Interim and FSS contracts in place providing access to VA/DOD, Tricare, Medicare, FSS and 340b

GPOs

95% OF HOSPITALS ARE GPO MEMBERS

- One GPO agreement signed and effective 7/1
- Additional GPO agreements under review and evaluation

STRATEGIC CUSTOMERS

KEY CUSTOMERS HAVE INTEREST

- Large national agreement went effective 7/1 and sales team focused on regional pull-through process
- Team focused on driving awareness and early usage at targeted accounts

Field Engaging Customers In-Person & Virtually with Comprehensive Resources

- Core Visual Aid
- Promotional Leave Behind
- Rep Inservice Deck
- Tabletop Panels
- Baudax Bio Brochure

Detail Aids & Collateral

Publication Resources

- Phase 3 Publication Flashcard
- Phase 3 Abdominoplasty Reprint
- Phase 3 Bunionectomy Reprint
- Phase 3 Safety Study Reprint
- Pharmacoeconomic Materials

- Site specific billing resources
- Comprehensive Billing Guides
- NDC Announcements
- HUB flashcard
- Coverage Announcements
- Commercial Claim Forms

Market Access/ Reimbursement

Speaker Program

- Virtual and In-Personal Speaker Programs

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

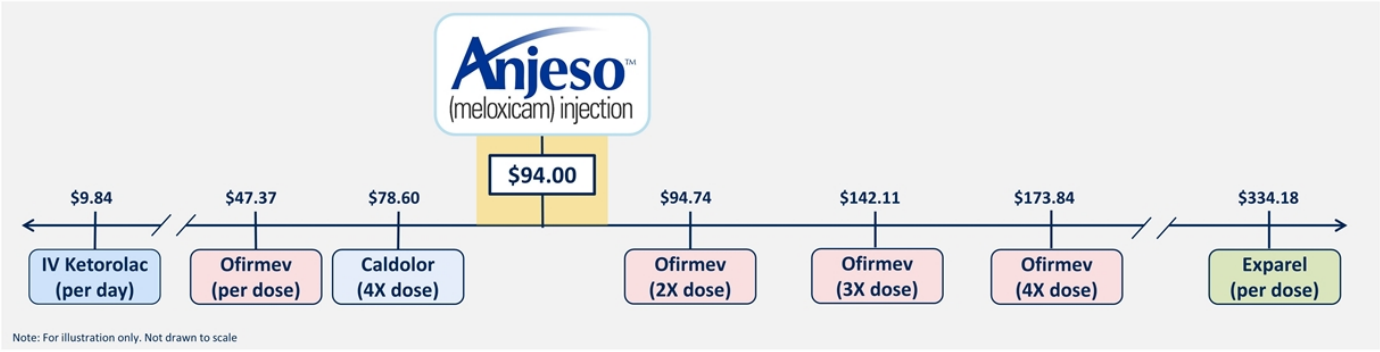
Prepared for an Efficient Launch

Solid Foundation → **Efficient Launch**

- **Surgical claims data identified ~2,000 accounts that cover 80% of the market**
- **Launching with ~50 Reps enables coverage of 800-1,000 accounts (~50% of market)**
- **Prior field team activity qualified and prioritized ~300 accounts**

Source: Definitive, LexisNexis and Company Estimates. *Includes addressable procedures where ANJESO use is anticipated.

Wholesale Acquisition Cost: ANJESO and Other Non-Opioids



Note: For illustration only. Not drawn to scale

Strong Economic Evidence Available at Launch	▪ **Economic Analysis** of two Phase 3b studies completed with positive data available ▪ **Budget Impact & Cost Effectiveness Models** to address ANJESO cost effectiveness vs. other IV analgesics ▪ **Retrospective Analyses** of claims database that models real-world AE rates and costs

Source: Wholesale Acquisition Cost Prices from Red Book accessed August 2020, which may not represent a customer's cost. Price per day equals dosing schedule times price per dose. Dosing schedule according to product prescribing information for 24-hour coverage. Generic ketorolac has multiple manufacturers, price reflects the lowest manufacturer WAC.

Surgical Setting Coding and Reimbursement as of July 1, 2020

Hospital Inpatient	Hospital Outpatient	Ambulatory Surgery Centers
Medicare • Use J3490 • Reimbursement bundled into DRG payment	**Medicare** • Unique Code, C9059 (Injection, Meloxicam 1mg) • Reimbursed at 80% of 95% of AWP	**Medicare** • Unique Code, C9059 (Injection, Meloxicam 1mg) • Reimbursed at 80% of 95% of AWP
Commercial • Use J3490 • Bundled and part of a case rate	**Commercial** • Use J3490 until 10/1/2020 • May be bundled with procedure or separately reimbursed based on the facility contract	**Commercial** • Use J3490 until 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 will replace all other codes

Pass-Through, Unique C-code & J-code All Granted by CMS

Unique C-Code Granted & Currently Effective

March 2020	July 1, 2020	Granted, 3 years of pass-through coverage until June 30, 2023
March 1, 2020 Apply for unique C-code	**Unique Code, C9059 (Injection, Meloxicam 1mg) Effective July 1, 2020**	

Permanent J-Code Granted

July/August 2020	October 1, 2020	Pass-through continues until June 30, 2023
July 2020 CMS posts final decision	**Level II HCPCS code J1738 "Injection, meloxicam, 1 mg" effective 10/1/2020** J-code replaces unique C-code when it becomes effective; Pass-through continues until June 30, 2023	

Source: Centers for Medicare & Medicaid Services (CMS) updated its Healthcare Common Procedural Coding System (HCPCS) Level II coding procedures in November 2019 to enable shorter and more frequent HCPCS code application cycles. More information can be found at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo

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

Up to 24-hour pain relief

Efficacy in orthopedic & soft tissue procedures

Demonstrated Safety & Tolerability

Evaluated in more than 1400 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

Company Highlights

- ANJESO® (meloxicam) injection*
  - Approved February 20, 2020 for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics
  - Significant Potential Commercial Opportunity
  - Commercial launch June 2020
- Additional pipeline candidates in clinical stage development for acute care settings
- Baudax Cash position – $39.4 million as of June 30, 2020
  - $50 million credit facility secured in May 2020; $10 million drawn
  - Short dated Cash Exercisable Series B Warrants expected to provide additional $25 million in gross proceeds before or by April 2021, assuming full exercise. As of June 30, 2020, warrant exercises have provided $2.5 million in net proceeds.
- Experienced management team with significant commercial, development, and regulatory experience

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

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Appendix

Acute Care Clinical Stage Pipeline

Investigational Product	PC	I	II	III	MARKETED	Rights
Meloxicam						WW
IV formulation - Acute, post-operative pain						*Approved U.S. February 2020/ Pediatric Studies Planned*
IM formulation - Acute pain						
Neuromuscular Blockade Agents (NMBA) (Anesthesia)						WW
IV Intermediate-action (BX1000)						
IV Ultra-short action (BX2000)						
NMBA Reversal (Anesthesia)						WW
RP3000						
Dexmedetomidine ("Dex")						WW, exc. Europe, Turkey, CIS
Dex-IN (intranasal) Peri-procedural pain						
Dex-IN (intranasal) Cancer breakthrough pain						

Neuromuscular Blockers & Reversal Agent Overview

400 million people receive neuromuscular blocking agents annually [IMS, MIDAS 2010]

- Used to induce rapid total paralysis to permit intubation and muscle relaxation during surgery or in ventilated patients
  - 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 neuromuscular blocking agents & novel reversal agent in development

- Neuromuscular blocking agents
  - BX1000: Intermediate acting agent duration of action (~45 mins)
    - Rapid onset <90 secs - completed one Phase 1 clinical trial utilizing inhaled gas anesthesia
      - Phase 1 dose escalation trial with total IV anesthesia underway
  - BX2000: Ultra-short acting agent duration of action (10-20 mins*)
    - Rapid onset ~60 sec* - In pre-clinical development; planned IND/CTA submission Q42020
- Novel reversal agent
  - Specific for BX1000 and BX2000; provides complete reversal of neuromuscular blockade from any depth of block within 2-5 mins*
  - In pre-clinical development

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

Financing Activities

$25M in Proceeds through Structured Equity Raise (March 2020)

- Warrants:
  - Series A Five-year Warrants to purchase 7,692,308 at $4.59/share
  - Series B 13 month Warrants to purchase 7,692,308 at $3.25/share
- Short dated Cash Exercisable Series B Warrants expected to provide additional $25 million by April 2021, assuming full exercise
  - As of June 30, 2020, warrant exercises have provided $2.5 million in net proceeds.

$50 Million Credit Facility (May 2020)

- Five-year term loan, interest-only for 24 months at fixed rate of 13.5%; Issuance of 527,100 warrants at $4.59/share
- 5 Tranches:
  - Tranche 1 - $10M upon closing
  - Tranche 2 - $5M upon achieving $5M Trailing 3 Month Net Revenue (by 15 months from closing *)
  - Tranche 3 - $5M upon achieving $10M Trailing 3 Month Net Revenue (by 18 months from closing *)
  - Tranche 4 - $10M upon achieving $20M Trailing 3 Month Net Revenue (by 27 months from closing*)
  - Tranche 5 - $20M upon achieving $100M Trailing 12 Month Net Revenue (by 33 month from closing)

  * Provision in the agreement where if do not achieve a Tranche's Net Revenue target by the noted time period, can still pull down on the Tranche if achieve the subsequent Tranche's Net Revenue target by the noted time period
- Potential for Incremental amounts of up to an additional $50 million, at Marathon's discretion, to help support complementary and accretive acquisitions
- Financial flexibility to aid our transformation into a commercial-stage enterprise and leaves us well positioned to execute on the launch of ANJESO and to grow our acute care franchise

IV Meloxicam is an investigational drug that has not been evaluated as safe or effective by FDA.

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 ≥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
August 10, 2020