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): December 5, 2019

Baudax Bio, Inc.
(Exact name of registrant as specified in its charter)

Pennsylvania	001-39101	47-4639500
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

490 Lapp Road, Malvern, Pennsylvania	19355
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (484) 395-2470

Not Applicable
(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.01	BXRX	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:

None

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure

On December 5, 2019, the Company updated information reflected in a slide presentation, including certain financial information, which is attached as Exhibit 99.1 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.

The information furnished pursuant to this Item 7.01, including exhibit 99.1, 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 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 exhibits are being filed herewith:

Exhibit No.	Document
99.1	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: December 5, 2019

Exhibit 99.1

BAUDAX BIO

Corporate Overview

December 2019

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. These statements, among other things, the Company's ability to complete the spin out from Recro Pharma, Inc., uncertainty of whether the anticipated benefits of the spin-off can be achieved, risks of unexpected costs or delays in the Company's ability to complete the spin-off, the Company's ability to continue the development and commercialization of ANJESO™ (IV meloxicam), the Company's ability to execute its strategic initiatives, the Company's ability to adequately resolve the outstanding labeling issues with the FDA for IV meloxicam, and the time frame associated with any such resolution; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to manage costs and execute on its operational and budget plans, the Company's ability to achieve its financial goals; and the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. 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 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.

Non-Promotion:
This presentation is intended to be non-promotional and for investor discussion purposes only. The information provided herein contains references to ANJESO™ (IV meloxicam), an investigational product. Use of IV meloxicam has not been approved by the FDA. The safety and efficacy of the investigational use of IV meloxicam has not been determined. There is no guarantee that IV meloxicam will be approved for marketing by any regulatory agency.

Company Highlights

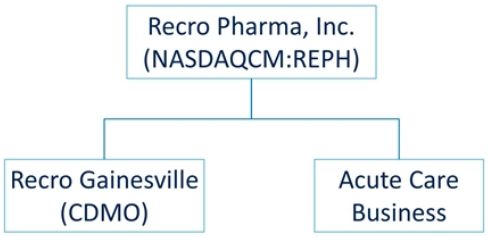
- Pharmaceutical company focused on developing and commercializing innovative products for acute care settings with late stage investigational product, ANJESO™ (IV meloxicam), targeting management of moderate to severe pain
- **ANJESO™ (IV meloxicam)**
  - October 2019 – Appeal granted for the New Drug Application (NDA)
  - Significant Potential Commercial Opportunity
- Multiple therapeutics in clinical development for acute care settings
- Baudax Cash position – $19 million as of Separation Date; no debt
- Experienced management team with significant development, regulatory and commercial experience

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

Spin-Off of Acute Care Business: Recro Pharma and Baudax Bio

The spin-off is expected to be completed by the end of November

Pre-spin-off structure



Post-spin-off structure

Recro (CDMO)
(NASDAQCM:REPH)

Baudax Bio (Acute Care)
(NASDAQCM:BXRX)

Spin-Off Details

- Gerri Henwood (current CEO) and Ryan Lake (current CFO) will continue as executives of both businesses
- 2.5 REPH Common Shares : 1 BXRX Common Share
- Record date – November 15th
- Distribution date – November 21st
- Taxable Spin-Off

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

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

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

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™ (IV meloxicam) Update & Clinical Highlights

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

ANJESO™ (IV meloxicam) Overview

- Oral product FDA approved, preferential COX-2 inhibitor; used in a number of indications
- 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
- Regulatory Status
  - October 2019 – Appeal granted for New Drug Application (NDA)
  - ANJESO™ tradename received tentative approval, pending final product approval
  - Company expects to resubmit NDA including labeling and updated safety data in Q4
- Formulation IP (Orange Book Listable) issued through 2022 and additional IP (also Orange Book Listable) issued through May 2030

NanoCrystal® is a registered trademark of APIL

A Non-Opioid Alternative: ANJESO™ (IV meloxicam)

Dosed once-daily, IV, for the management of moderate to severe pain

Administered as a 30 mg IV push[1]

Significant reduction in pain

Across hard and soft tissue surgeries[1]

Well tolerated safety profile

Evaluated in more than 1400 patients[1]

COX-2 selective IV NSAID*

That can be incorporated into MMA protocols

*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. 1. Data on file. Recro Pharma, Inc.

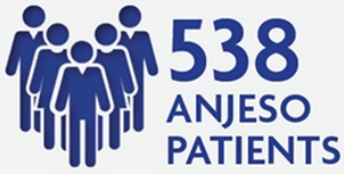
ANJESO™ Was Studied in More Than 1400 Surgical Patients[1]

- Phase 2 efficacy and safety studies: bunionectomy, gynecologic, and molar extraction[3]
- Phase 3 efficacy and safety studies: bunionectomy and abdominoplasty[1,4]
- Phase 3 safety study: abdominoplasty, bunionectomy, complex foot, gastrointestinal, gynecologic, other soft tissue surgeries, and total hip and total knee replacements[3]

1. Pollak RA et al. *Clin J Pain*. 2018;34(10):918-926. 2. Berkowitz RD et al. 2017 PAINWeek Conference; September 5-9, 2017. Poster 77. 3. Data on file. Recro Pharma, Inc. 4. Singla N et al. *Plast Reconstr Surg Glob Open*. 2018;6:e1846.

ANJESO™ Was Evaluated in the Largest Placebo-Controlled Safety Trial* Involving the Study of an IV NSAID to Date

Procedures in a phase 3 safety study of 711 patients having major surgery



Hard Tissue		Soft Tissue	
Total knee replacement	117	Other soft tissue	128
Complex foot	52	Gynecologic	68
Total hip replacement	50	Abdominoplasty	32
Bunionectomy	40	GI	26

Subjects were randomly assigned to treatment with ANJESO (538) or placebo (183) in a 3:1 assignment ratio according to the randomization scheme.

Excluded procedures included cranial surgeries, open heart procedures, CABG, organ transplant, and/or any procedure in which NSAIDs are contraindicated.

*As of November 2019. Study date: May 2017. CABG, coronary artery bypass graft.

ANJESO™ Demonstrated Low Overall Rates of Adverse Events Across All Phase 3 Studies

ANJESO™ (n)= 748

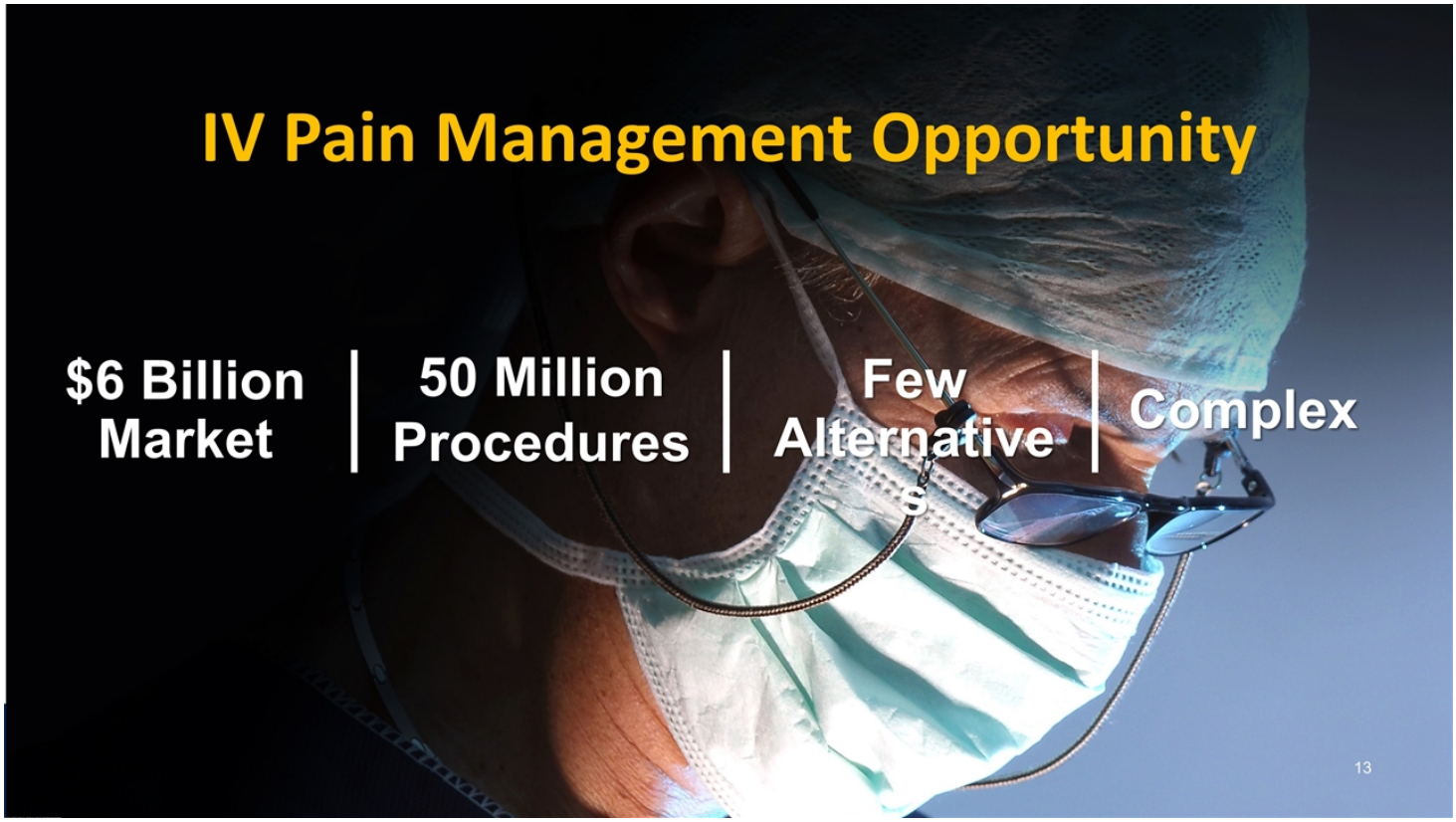
Adverse Reactions Occurring in ≥3% of Patients	ANJESO™ 30 mg + Rescue (n=748)	Placebo + Rescue (n=393)
	% (n)	% (n)
Any adverse reaction	**441 (59.0%)**	**253 (64.4%)**
Nausea	173 (23.1%)	118 (30.0%)
Headache	41 (5.5%)	42 (10.7%)
Constipation	57 (7.6%)	24 (6.1%)
Vomiting	35 (4.7%)	33 (8.4%)
Pruritus	29 (3.9%)	15 (3.8%)

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

BAUDAX BIO

Commercial Opportunity

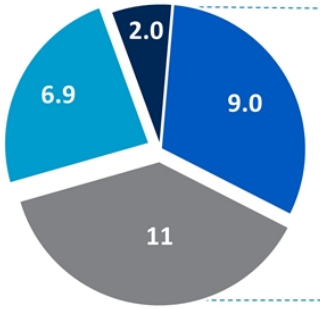
ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.


IV Pain Management Opportunity
$6 Billion Market
50 Million Procedures
Few Alternatives
Complex
13

Defining Our Market

Large Addressable Patient Opportunity

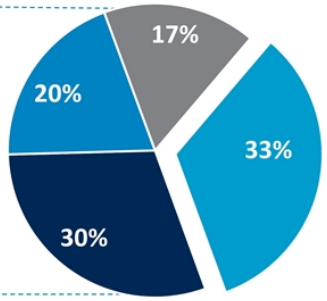
29 Million Patients*



■ ASCs ■ HOPD ■ Hospital IP ■ ED

Core Procedures: Belly, Bowel & Bones

% by Specialty

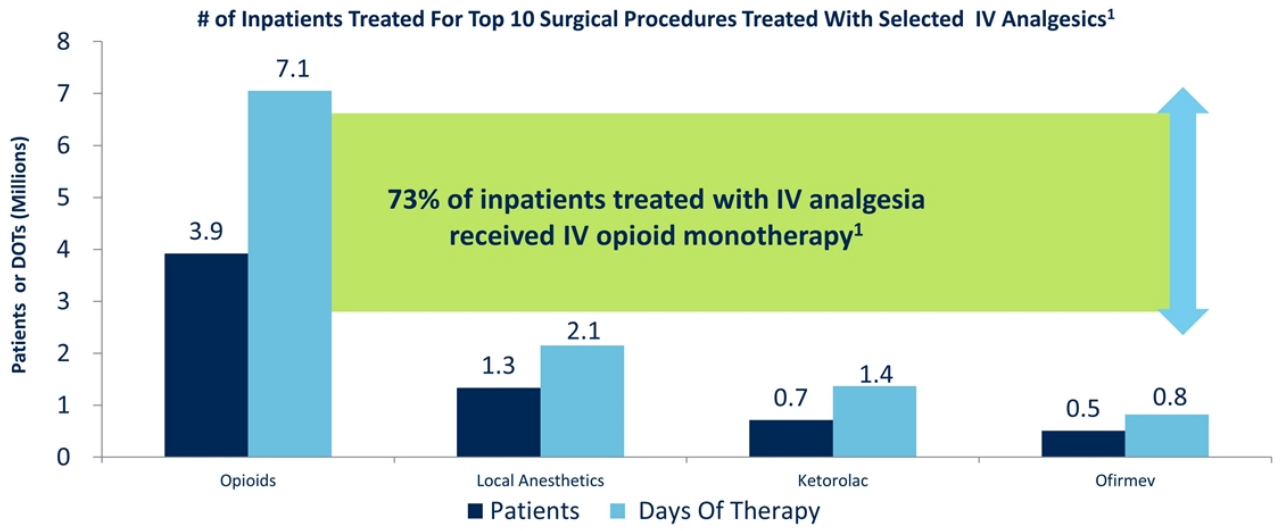


■ Ortho ■ GenSurg ■ GI / CRS ■ Inpatient Other

Source: Definitive, LexisNexis and Company Estimates. *Includes addressable procedures where ANJESO™ use is anticipated.
ASCs = Ambulatory Surgical Centers, HOPD = Hospital Outpatient Department, IP = Inpatient, ED = Emergency Department, GI / CRS = Gastrointestinal / Colorectal Surgeons

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

Opioids Dominate the IV Pain Market



Sources: Truven Health Analytics 2014. 1. Shaffer EE, et al. *Adv Ther*. 2016;33:2211–2228.

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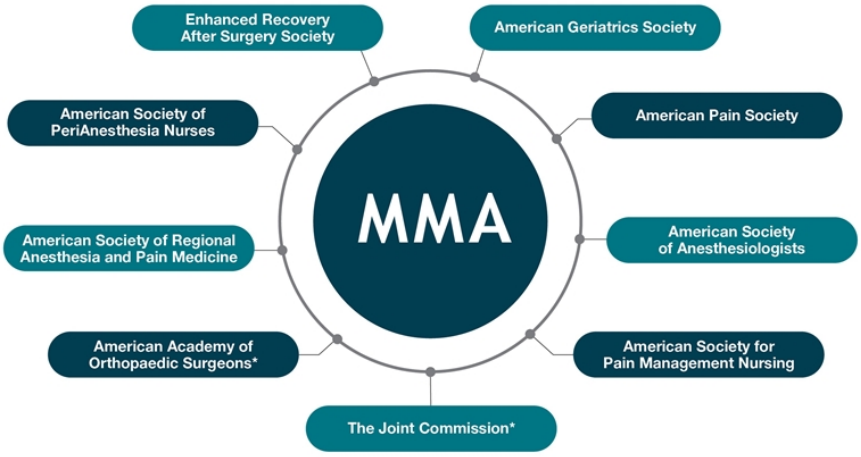
Limited Acute Pain Relief Options for Patients

Pain Severity*	Class	Compounds	Advantages	Disadvantages
Mild	Acetaminophen		Antipyretic properties; Oral & IV; no opioid related AEs	Only effective for mild pain; short acting
	NSAIDs	Ketorolac, ibuprofen, aspirin	Mild to moderate analgesia; oral & IV; no opioid related AEs	Bleeding risk; GI and renal complications; short acting
Moderate	Sodium channel blockers	Bupivacaine, lidocaine	Use directly at pain site; mostly peri-operative	Limited duration of action; some are concerned about local tissue impact
	Alpha 2 agonists	Dexmedetomidine (Baudax Bio)	Target pain relief; anxiolytic properties; no respiratory depression, impaired GI or addictive properties	In development – potential to be approved for peri-procedural pain; blood pressure decrease
Moderate to Severe	Non-opioid, preferential COX-2	IV/IM meloxicam (Baudax Bio)	Once-daily dosing; Both Ph. 3 pivotal studies met primary endpoints; MOA with no impact on GI motility	Class effects: Bleeding risk; GI and renal complications.
	Opioids	Morphine, hydrocodone, oxycodone, fentanyl	Good pain relief	Respiratory depression, impaired GI motility after even one dose; frequent nausea and vomiting; abuse/addiction potential

*Pain severity based upon market research / physician feedback

Multiple Guidelines Recommend NSAIDs as Part of MMA

Numerous clinical practice guidelines recommend multimodal approaches to pain management—including NSAIDs—to provide better pain control while reducing opioids and related adverse events



*The American Academy of Orthopaedic Surgeons and The Joint Commission recommend MMA, but do not specifically recommend NSAIDs.

Market Research Indicators of Success: Need To Demonstrate Clinical & Economic Value

CLINICAL VALUE

- Effectively treats pain while reducing the need for rescue
- Avoid risks of analgesic-related AEs that lead to complications or prolong hospital stay
- Early patient mobilization so rehab begins within 24 hours
- Prevent avoidable readmissions due to surgical complications, adverse drug events or pain at the surgical site

ECONOMIC VALUE

- Allows ambulatory surgical centers to perform more complex procedures with higher reimbursements and discharge patients on the same day
- Allows hospitals to speed up patient discharge, reduce inpatient admission, and/or length of stay

Source: Blinded market research feedback on market dynamics.

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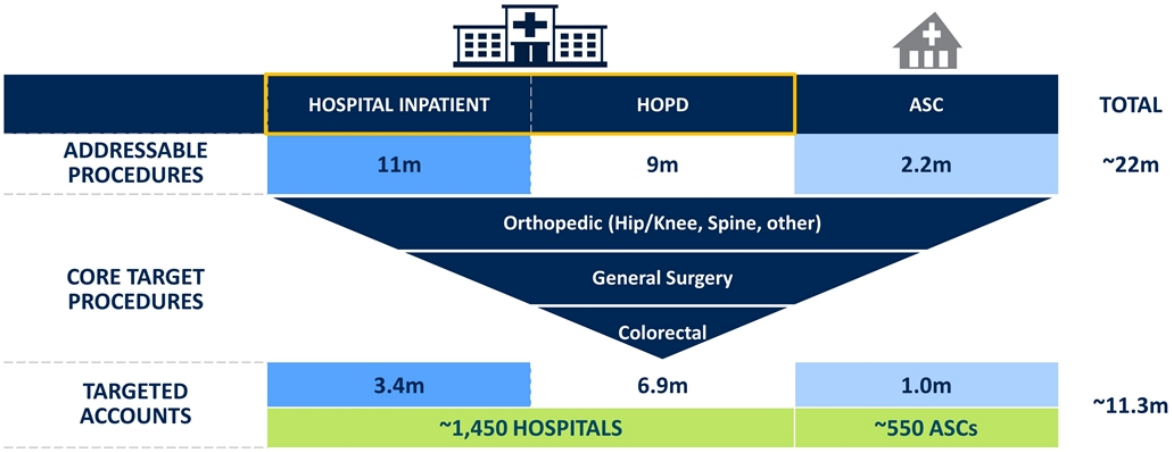
Commercial Launch

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

Target Opportunity Concentrated in ~2,000 Accounts



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

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ASCs Provide a Strategic Entry Point for Early Experience

GAIN EARLY EXPERIENCE WITH ANJESO™ (IV meloxicam):
Build market experience at settings of care that have lower barriers to adoption

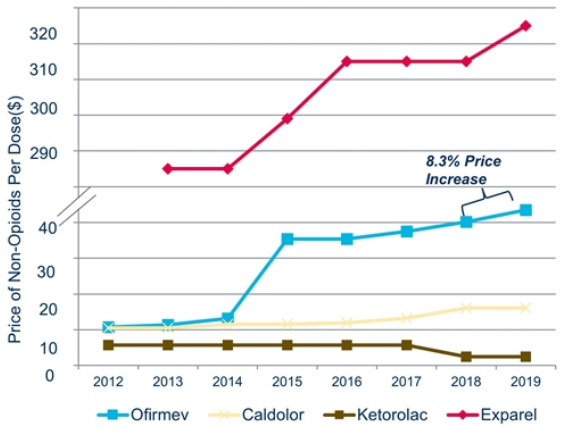
AMBULATORY SURGICAL CENTER SETTING	HOSPITAL OUTPATIENT SETTINGS	HOSPITAL INPATIENT SETTINGS

High Volume Surgeons That Practice at All Locations
Early usage may carry back and drive formulary reviews and adoption at hospitals

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

Acquisition Cost: WAC Prices of Other Non-Opioids

Price Per Dose



Price Per Day[1]

	Ketorolac[2]	Caldolor	ANJESO™	Ofirmev	Exparel
Price Per Dose	$2.46	$16.06		$43.46	$324.45
Dosing Schedule[3]	q6hrs	q6hrs	Once daily	q6hrs	1x at closure
Price Per Day	$9.84	$64.24		$173.84	$324.45

Source: Wholesale Acquisition Cost Prices from Red Book accessed November 2019

[1] Price per day equals dosing schedule times price per dose.

[2] Generic ketorolac has multiple manufacturers. Price reflects the lowest manufacturer WAC.

[3] Dosing schedule according to product prescribing information for 24-hour coverage.

Economic Evidence at Launch

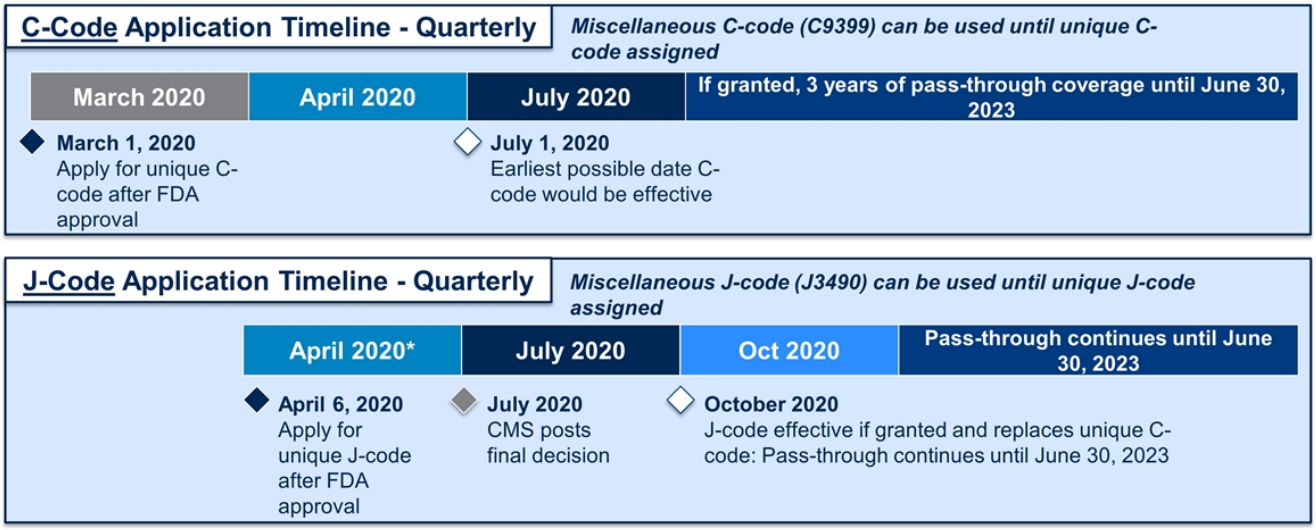
- **Budget Impact & Cost Effectiveness Models** to address ANJESO affordability and cost effectiveness vs. other IV analgesics
- **Retrospective Analyses** of claims database that models real-world AE rates and costs associated with existing therapies
- **Economic Analysis** of two Phase IIIb studies will be available at completion of studies

Surgical Setting Coding and Reimbursement at Launch

Hospital Inpatient	Hospital Outpatient	Ambulatory Surgery Centers
Medicare • Use J3490 • Reimbursed based on DRG	**Medicare** • Use C9399 • Reimbursed at 80% of 95% of AWP	**Medicare** • Use C9399 • Reimbursed at 80% of 95% of AWP
Commercial • Use J3490 • Bundled and part of a case rate	**Commercial** • Use J3490 • May be bundled with procedure or separately reimbursed based on the facility contract	**Commercial** • Use J3490 • May be bundled with procedure or separately reimbursed based on the facility contract

Miscellaneous reimbursement codes available day 1 of launch

2020 C-Code & J-Code Application Timelines



* J-Code timeline assumes FDA approval, if granted, occurs after the first quarter application deadline of January 6, 2020

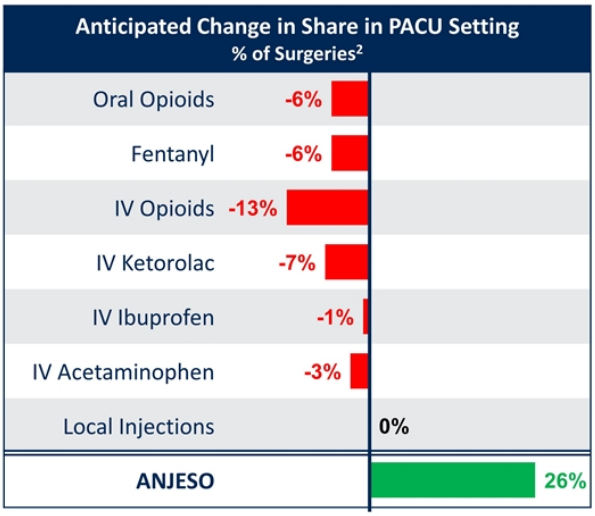
ANJESO™ Receptivity: Anticipated Usage

Current Use vs. Anticipated Usage After Reviewing Draft Clinical Profile*

In multiple market research surveys, the majority of HCPs surveyed said they would accept ANJESO™ as a valuable addition upon approval to multimodal pain-management protocols.

They estimated they would use the product in ~30% of their surgical cases[1].

**Clinical profile used in surveys was fair balanced and based on clinical data*



1. January 2018 – Blinded, Third Party Market Research, n=205.
2. December 2017 – Blinded, Third Party Market Research, n=462.

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Appendix

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Acute Care Clinical Stage Pipeline

Investigational Product	PC	I	II	III	Rights
Meloxicam					WW
IV formulation - Acute, post-operative pain					*Filed NDA/Appeal Granted Oct. 2019*
IM formulation - Acute pain					
Neuromuscular Blockade Agents (NMBA) (Anesthesia)					WW
IV Intermediate-action (RP1000)					
IV Ultra-short action (RP2000)					
NMBA Reversal (Anesthesia)					WW
RP3000					
Dexmedetomidine ("Dex")					WW, exc. Europe, Turkey, CIS
Dex-IN (intranasal) Peri-procedural pain					
Dex-IN (intranasal) Cancer breakthrough pain					

ANJESO™ (IV meloxicam) is an investigational drug that has not been evaluated as safe or effective by FDA.

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
  - RP1000: Intermediate acting agent duration of action (~45 mins*)
    - Rapid onset <90 secs* - completed one Phase 1 clinical trial; supplemental trials planned
  - RP2000: Ultra-short acting agent duration of action (10-20 mins*)
    - Rapid onset ~60 sec* - In pre-clinical development
- Novel reversal agent
  - Specific for RP1000 and RP2000; provides complete reversal of neuromuscular blockade from any depth of block within 2-5 mins*
  - In pre-clinical development

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

BAUDAX BIO

November 2019