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): October 19, 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)

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))

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**

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 1.01 Entry Into Material Definitive Agreement.

On October 19, 2020, Baudax Bio, Inc. (the "Company") entered into Warrant Exchange Agreements (each, an "Exchange Agreement") with certain holders (each, a "Holder") of the Company's outstanding Series A Warrants (the "Series A Warrants") to purchase common stock of the Company, par value $0.01 per share ("Common Stock") and Series B Warrants to purchase Common Stock (the "Series B Warrants," and together with the Series A Warrants, the "Warrants"). Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their Series A Warrants or Series B Warrants, in each case for 0.2 shares of Common Stock per Warrant (rounded up to the nearest whole share) (the "Exchange"). No Holder will exchange both series of Warrants in the Exchange. The closings of the exchanges contemplated by the Exchange Agreements are expected to occur on October 21, 2020.

As a result of the Exchange, pursuant to certain price adjustment provisions in the Warrants, the exercise price of each of the Series A Warrants or Series B Warrants (including Warrants held by Holders not participating in the Exchange) that were not exchanged shall be adjusted to par value, or $0.01, for each share of Common Stock underlying such Warrant. Pursuant to the Exchange Agreements, any outstanding Warrant held by a Holder participating in the Exchange (i) shall be amended to remove certain anti-dilution and variable pricing protections and (ii) in the case of Series A Warrants not exchanged by a participating Holder, shall be amended to adjust the expiration date of such Series A Warrants to April 26, 2021 (which is the expiration date of the Series B Warrants).

The Company expects to issue 1,186,774 shares of Common Stock to the participating Holders as a result of the Exchange. Series A Warrants and Series B Warrants to purchase 8,646,154 shares of Common Stock will be outstanding immediately after the Exchange.

A form of Exchange Agreement is filed as Exhibit 10.1 to this Current Report on Form8-K, and is incorporated herein by reference. The foregoing description of the Exchange Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the document.

Item 3.02 Unregistered Sales of Equity Securities.

The information set forth under Item 1.01 of this Current Report on Form8-K is incorporated by reference into this Item 3.02. The Company offered the Common Stock in exchange for such Series A Warrants and Series B Warrants in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended.

This report does not constitute an offer to sell, or a solicitation of an offer to buy, any security and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offering would be unlawful.

Item 3.03 Material Modification to Rights of Security Holders.

The information set forth under Item 1.01 of this Current Report on Form8-K is incorporated by reference into this Item 3.03.

Item 8.01 Other Events.

On October 20, 2020, the Company issued a press release regarding the Exchange, as well as certain commercial updates. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
10.1	Form of Warrant Exchange Agreement
99.1	Press Release of Baudax Bio, Inc.
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 hereunto duly authorized.

Baudax Bio, Inc.

By: /s/ Gerri A. Henwood
Name: Gerri A. Henwood
Title: Chief Executive Officer

Date: October 20, 2020

Exhibit 10.1

October 19, 2020

Holder of Series A and Series B Warrants to Purchase Common Stock

Re: Exchange Offer of Warrants to Purchase Common Stock

Dear Holder:

Baudax Bio, Inc., a Pennsylvania corporation (the "Company"), is pleased to offer to you the opportunity to exchange all of either (a) the Series A Warrants to Purchase Common Stock or (b) Series B Warrants to Purchase Common Stock (collectively, the "Warrants") currently held by you (the "Holder") for shares of common stock of the Company, par value $0.01 ("Common Stock"). The Holder shall elect which series of Warrants it so elects to exchange hereunder on the Holder's signature page hereto (the series of Warrants elected for exchange hereunder as indicated on the Holder's signature page hereto, the "Exchange Warrants" and the series of Warrants not exchanged, the "Outstanding Warrants").

In consideration for exchanging in full all of the Exchange Warrants held by you (the "Warrant Exchange" and this agreement, this "Agreement")), the Company hereby offers you in exchange therefor 0.2 shares of Common Stock ("Exchange Shares") for each share of Common Stock issuable upon exercise of the Exchange Warrants being exchanged (rounded up to the nearest whole share). Notwithstanding anything herein to the contrary, in the event that the Warrant Exchange would cause the Holder to exceed the Maximum Percentage (as defined in the Exchange Warrant) in the Exchange Warrant, the Company shall only issue such number of shares of Common Stock to the Holder that would not cause the Holder to exceed the Maximum Percentage with the balance to be held in abeyance until written notice from the Holder that the balance (or portion thereof) may be issued in compliance with the Maximum Percentage. The Company agrees that the Warrant Exchange shall in no event result in the Holder beneficially owning more than the Maximum Percentage. Within two Trading Days of the date hereof, the Company shall deliver the Exchange Shares to the DTC account of the Holder via the DWAC system in accordance with the DTC Instructions provided by the Holder on the signature page hereto. The terms of the Warrant Exchange, including but not limited to the obligations to deliver the Exchange Shares, shall remain in effect as if the acceptance of this offer was a formal Notice of Exercise. The Holder hereby acknowledges that upon receipt of the Exchange Shares, such Holder's Exchange Warrants exchanged for such Exchange Shares shall be deemed to be cancelled without further action required by either the Company or the Holder.

The Exchange Warrants were issued in a public offering by the Company pursuant to a registration statement on Form S-3, File No. 333-235408 ("Registration Statement"). The Warrant Exchange is being undertaken as a cashless exchange and as such the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Exchange Shares shall take on the registered characteristics of the Exchange Warrants being exchanged hereunder. The Company agrees not to take any position contrary to this covenant.

Expressly subject to the paragraph immediately following this paragraph below, Holder may accept this offer by signing this letter below, with such acceptance constituting Holder's exchange in full of the Exchange Warrant for Exchange Shares, subject to the Maximum Percentage on or before 5:00 p.m. (New York City time) on October 19, 2020.

Additionally, the Company agrees to the representations, warranties and covenants set forth on Annex A attached hereto.

Other than an Exempt Issuance (as defined below), from the date hereof until 30 days following the date hereof, (i) the Company shall not issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or any securities convertible or exchangeable into Common Stock, (ii) other than pursuant to any Other Warrant Exchange Agreement, the Company shall not enter into any agreement to amend, exchange or otherwise provide any incentive to exercise any of the warrants originally issued pursuant to the Registration Statement, and (iii) the Company shall not file any registration statement or any amendment or supplement thereto. "Exempt Issuance" means the issuance of (a) shares of Common Stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the board of directors of the Company or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company or to new employees of the Company under NASDAQ Rule 5635(c)(4), (b) securities upon the exercise or exchange of securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities, other than any such automatic increase, decrease or extension in accordance with the terms of such securities and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144 under the Securities Act of 1933, as amended) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the prohibition period set forth hereunder, and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

On or before 9:00 a.m. (New York City time) on October 20, 2020, the Company shall file a Current Report on Form 8-K with the Securities and Exchange Commission disclosing all material terms of the transactions contemplated hereunder, including a form of this agreement as an exhibit thereto ("8-K Filing"). From and after the issuance of the 8-K Filing, the Company represents to the Holder that it shall not be in possession of any material, nonpublic information received from the Company, any of its Subsidiaries or any of their respective officers, directors, employees or agents, that is not disclosed in the 8-K Filing. In addition, effective upon the filing of the 8-K Filing, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, employees or agents, on the one hand, and the Holder or any of its affiliates, on the other hand, shall terminate. The Company shall not, and shall cause each of its Subsidiaries and its and each of their respective officers, directors, employees and agents, not to, provide the Holder with any material, nonpublic information regarding the Company or any of its Subsidiaries from and after the date hereof without the express prior

written consent of the Holder. To the extent that the Company, any of its Subsidiaries or any of their respective officers, directors, employees or agents, delivers any material, non-public information to the Holder without the Holder's consent, the Company hereby covenants and agrees that the Holder shall not have any duty of confidentiality with respect to, or a duty not to trade on the basis of, such material, non-public information.

The Company acknowledges and agrees that the obligations of the Holder under this letter agreement are several and not joint with the obligations of any other holder of Common Stock purchase warrants of the Company (each, an "Other Holder") under any other agreement related to the exercise of such warrants (each, an "Other Warrant Exchange Agreement"), and the Holder shall not be responsible in any way for the performance of the obligations of any Other Holder or under any such Other Warrant Exchange Agreement. Nothing contained in this letter agreement, and no action taken by the Holder pursuant hereto, shall be deemed to constitute the Holder and the Other Holders as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Holder and the Other Holders are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by this letter agreement and the Company acknowledges that the Holder and the Other Holders are not acting in concert or as a group with respect to such obligations or the transactions contemplated by this letter agreement or any Other Warrant Exchange Agreement. The Company and the Holder confirm that the Holder has independently participated in the negotiation of the transactions contemplated hereby with the advice of its own counsel and advisors. The Holder shall be entitled to independently protect and enforce its rights, including, without limitation, the rights arising out of this letter agreement, and it shall not be necessary for any Other Holder to be joined as an additional party in any proceeding for such purpose.

The Company hereby represents and warrants as of the date hereof and covenants and agrees from and after the date hereof until 30 days following the date of this Agreement that none of the terms offered to any Other Holder with respect to any Other Warrant Exchange Agreement (or any amendment, modification or waiver thereof, which, for the avoidance of doubt, does not include changes to the exercise price of the warrants pursuant to the terms of thereof), is or will be more favorable to such Other Holder than those of the Holder and this letter agreement. If and whenever on or after the date hereof, the Company enters into an Other Warrant Exchange Agreement, then (i) the Company shall provide notice thereof to the Holder promptly following the occurrence thereof and (ii) the terms and conditions of this letter agreement shall be, without any further action by the Holder or the Company, automatically amended and modified in an economically and legally equivalent manner such that the Holder shall receive the benefit of the more favorable terms and/or conditions (as the case may be) set forth in such Other Warrant Exchange Agreement (including the issuance of additional Exchange Shares or the issuance of new Common Stock purchase warrants to the Other Holder), including, without limitation, the same price discount and the same issuance of new warrants as in the Other Warrant Exchange Agreement, provided that upon written notice to the Company at any time the Holder may elect not to accept the benefit of any such amended or modified term or condition, in which event the term or condition contained in this letter agreement shall apply to the Holder as it was in effect immediately prior to such amendment or modification as if such amendment or modification never occurred with respect to the Holder. The provisions of this paragraph shall apply similarly and equally to each Other Warrant Exchange Agreement.

Each of the Company and the Holder hereby acknowledges and agrees that the Warrant Exchange shall have the effect of causing an adjustment to the Outstanding Warrants (including Warrants issued to other holders whether or not a holder thereof executed an Other Warrant Exchange Agreement) issued pursuant to the Registration Statement and pursuant to Section 2(a) thereunder the New Issuance Price (as defined thereunder) is reduced to the lowest price per share which, in respect to the Warrant Exchange, is the par value of the Common Stock, or $0.01. The adjustment hereunder shall be effective immediately at the time that this Agreement becomes effective and the Holder may rely on this representation in undertaking an exercise of its Outstanding Warrants. Additionally, the Company and the Holder hereby agree that, immediately following the consummation of the Warrant Exchange, (i) Sections 2(a), 4(c) and 11 of the Outstanding Warrant held by the Holder is hereby deleted and, following the aforementioned adjustment, is no longer of any force or effect and (ii), to the extent the Outstanding Warrant is a Series A Warrant to Purchase Common Stock, the Expiration Date (as defined in the Outstanding Warrant) of the Outstanding Warrant held by the Holder shall be adjusted to April 26, 2021. Each of the Company and the Holder hereby agree that notwithstanding anything in this Agreement to the contrary, the total number of shares of Common Stock that may be issued by the Company pursuant to this Agreement and any other agreement entered into by the Company on the date hereof with any other Warrant holder relating to an exchange of such holder's Warrants, shall not, in the aggregate, exceed 19.99% of the Company's outstanding shares of Common Stock as of the date hereof.

Except as expressly set forth herein, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this letter agreement. The Company shall pay all transfer agent fees, stamp taxes and other taxes and duties levied in connection with the delivery of any Exchange Shares. This letter agreement shall be governed by the laws of the State of New York without regard to the principles of conflicts of law thereof.

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To accept this offer, Holder must counter execute this letter agreement and return the fully executed agreement to the Company at e-mail: ***, attention: Chief Financial Officer, on or before 5:00 pm (New York City time) on October 19, 2020.

Please do not hesitate to call me if you have any questions.

Sincerely yours,

BAUDAX BIO, INC.

By: _____
Name:
Title:

Accepted and Agreed to:

Name of Holder: _____

Signature of Authorized Signatory of Holder: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Circle Warrants to be Exchanged: Series A/Series B

Exchange Warrant Shares: _____

Exchange Shares (0.2 of Exchange Warrant Shares): _____

DTC Instructions:

Annex A

Representations, Warranties and Covenants of the Company. The Company hereby makes the following representations and warranties to the Holder:

(a) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this letter agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement by the Company and the consummation by the Company of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, its board of directors or its stockholders in connection therewith. This letter agreement has been duly executed by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) No Conflicts. The execution, delivery and performance of this letter agreement by the Company and the consummation by the Company of the transactions contemplated hereby do not and will not: (i) conflict with or violate any provision of the Company's certificate or articles of incorporation, bylaws or other organizational or charter documents; or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company in connection with, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any material agreement, credit facility, debt or other material instrument (evidencing Company debt or otherwise) or other material understanding to which such Company is a party or by which any property or asset of the Company is bound or affected; or (iii) conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company is bound or affected.

(c) Nasdaq Corporate Governance. The transactions contemplated under this letter agreement, comply with all rules of the Nasdaq Stock Market.

Baudax Bio Provides Commercial and Corporate Update

ANJESO® Launch Underway; Over 50 Institutions have Added ANJESO to Their Formularies

ANJESO Users Giving Highly Positive Feedback; Average Order Size Has Increased 75% Since Launch, Despite Ongoing COVID-related Impact to Access

Company Executes Strategic Transaction to Simplify Capital Structure and Exchange Warrants

MALVERN, Pa., October 20, 2020 — Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today provided an update regarding the initial commercial launch of ANJESO and provided an overview of other corporate initiatives and achievements.

"During the first half of 2020, we saw the approval and commercial launch of ANJESO, the first and onlynon-opioid, once daily, intravenous (IV) non-steroidal anti-inflammatory (NSAID) agent for the management of moderate to severe pain," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "Overall, the ANJESO launch is progressing well and we are pleased with the early commercial uptake and feedback from physicians. Although we are seeing more customers placing orders and the order size is increasing, the commercial rollout continues to be impacted by the ongoing COVID-19 pandemic and we believe the revenue ramp will likely take more time than originally anticipated. Looking ahead to the remainder of 2020 and beyond, we are focused on securing hospital formulary adoption and incorporation into standard pain management protocols. We are also working with the surgical and anesthesia community to increase awareness of ANJESO and help ensure physicians and patients have access to this important product."

ANJESO Launch and Commercial Rollout

The U.S. commercial rollout of ANJESO, Baudax's lead asset indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics, is progressing well. ANJESO became broadly available through wholesalers in the U.S in June 2020. As of today, over 50 institutions have added ANJESO to their formulary and the average order size has increased by nearly 75% since launch. The ANJESO re-order rate is a robust 50% with a deepening usage pattern. In just over 3 months on the market, ANJESO has been utilized across a wide variety of surgical and non-surgical procedures and is now beginning to be incorporated into surgical protocols and electronic health record (EHR) order sets, with demand increasing monthly. However, Baudax's ongoing commercial efforts continue to be impacted by COVID-19 pandemic related obstacles, including an absence of hospital formulary meetings where new drugs can be adopted, as well as access within hospitals. Many hospital formularies just recently resumed meetings after a 6-month absence. Despite there being a backlog of agents scheduled to be reviewed, the Company believes it will make steady progress getting ANJESO added to further hospital formularies in the months and quarters ahead.

“For the significant number of patients undergoing surgical procedures, there is an important need for newnon-opioid options to manage their pain post-surgically,” said Harold K. Humphries, M.D., Anesthesiologist and Operations Officer at Greater Sacramento Surgery Center. “At our center, we have noticed that ANJESO alone works as well as peripheral nerve blocks for controlling postoperative pain in total knee replacement cases. We’ve also found that with ANJESO the utilization of our 23-hour stay program is reduced, resulting in significant savings with overhead costs, which markedly offsets the cost of the product itself. ANJESO is an excellent addition to our patient care protocols.”

Effective October 1, 2020, ANJESO is reimbursed by the Centers for Medicare and Medicaid Services (CMS), under a unique J code, facilitating reimbursement for use in the hospital outpatient, ambulatory surgery center and physician office settings of care.

Strategic Transaction to Simplify Capital Structure and Exchange Warrants

Effective October 19, 2020, the Company entered into exchange agreements with holders of its short dated (13 months) Series B Warrants and long dated (5 year) Series A Warrants providing for the immediate exchange of 0.2 shares of common stock per warrant, for either all Series A Warrants or Series B Warrants held by each holder, at the holders election. As a result of the warrant exchange, the exercise price of the remaining outstanding warrants (whether Series A Warrants or Series B Warrants, including warrants held by holders not participating in the exchange) was adjusted to $0.01 per share. Holders participating in the exchange also agreed to amend their Warrants not so exchanged to remove certain anti-dilution and variable pricing protective provisions. Additionally, following the completion of the warrant exchange, for holders participating in the exchange, to the extent such holder’s outstanding warrant is a Series A Warrant, the expiration date for such warrant was amended to April 26, 2021.

As a result of the warrant exchange, the exercise and exchange of all of the Series A Warrants and Series B Warrants (approximately 15 million warrants outstanding prior to the exchange) is expected to result in the issuance of approximately 9.8 million shares of the Company’s common stock in the aggregate. This Warrant restructuring transaction was done to improve the Company’s capital structure and remove certain financial overhang, which the Company believes negatively impacted its expected valuation and ability to attract additional capital investments.

“By executing this strategic warrant restructuring, we have cleaned up the balance sheet and significantly improved the capital structure of the Company through elimination of certain provisions that would have contributed to a financial overhang for the remaining 4-year plus life of the Series A warrants, all while minimizing the anticipated dilution for our shareholders by over 25%,” said Ryan D. Lake, Chief Financial Officer of Baudax Bio. “As of today, holders of approximately 90% of the Warrants are participating in the exchange. We sincerely appreciate the ongoing support of all of our shareholders and their willingness to work constructively with the Company and our bankers to execute this important transaction.”

Other material terms related to the Series A Warrant and Series B Warrant exchange and amendments can be found in the Company’s current report on Form 8-K, which was filed with the Securities and Exchange Commission on October 20, 2020.

About ANJESO®

ANJESO (meloxicam) injection is a proprietary, long-acting, preferentialCOX-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 launched in the U.S. in June 2020 following its approval by the Food and Drug Administration in February 2020. ANJESO is indicated 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. ANJESO is 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).

INDICATION AND USAGE

ANJESO is indicated for use in adults for the management ofmoderate-to-severe pain, alone or in combination withnon-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.

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.

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.

DRUG INTERACTIONS

Drugs That Interfere With Hemostasis (e.g., 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 Enzymes (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 in³ 2% of patients treated with ANJESO and at a greater frequency than placebo include: 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.

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on therapeutics for acute care settings. The launch of Baudax Bio's first commercial product ANJESO® began in June 2020 following its approval by the U.S. Food and Drug Administration in February 2020. 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. In addition to ANJESO, Baudax has a pipeline of other pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs which is currently in preclinical studies, and intranasal dexmedetomidine which is being developed for possible uses in pain or sedation. 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 its 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; 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 its 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 assume no obligation to update any forward-looking statements except as required by applicable law.

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