UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): **June 15, 2023**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36306**	**20-8179278**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315 **Woodcliff Lake, NJ** (Address of principal executive offices)	**07677** (Zip Code)

Registrant's telephone number, including area code: **(201) 326-5300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ 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 each exchange on which registered**
Common Stock (par value $0.001 per share)	EGRX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 June 15, 2023, Eagle Pharmaceuticals, Inc., or the Company, issued a press release providing updates on its business, products and product candidates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under 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, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated June 15, 2023.
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.

Dated: June 15, 2023

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer

Exhibit 99.1

Eagle Pharmaceuticals Provides Business Update and Reiterates 2023 Guidance

WOODCLIFF LAKE, N.J. — June 15, 2023 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today provided a business update and reiterated its 2023 financial guidance.

"As we approach midyear 2023, our business remains strong, and we are pleased with the positive growth trajectory in our key commercial products. Through our well-trained and experienced sales force -- made up of 50 reps on the hospital side of the business and 25 focused on oncology -- for the quarter to date, Barhemsys® and Byfavo® have already topped the sales number posted in the first quarter of 2023, and PEMFEXY® has achieved an 18% market share in early Q2. We are pleased to see these two assets gaining uptake in the hospital and reflecting the value we saw when we originally decided to make the acquisition," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"The team is executing well on our plans to drive adoption of our products, and as we look to future growth beyond our current marketed offerings, we anticipate expanding the portfolio through pipeline success and potential acquisition," concluded Tarriff.

Company Highlights and Commercial Update

Balance sheet: Eagle's balance sheet remains strong in the second quarter of 2023. A substantial number of receivables have been collected, and the Company paid down a significant portion of debt.

PEMFEXY: Market share of commercial (non-340B) pemetrexed usage in community oncology in the U.S. has grown from 6% to 18% early in the second quarter of 2023. Eagle anticipates continued growth in net sales of PEMFEXY in the remainder of 2023 as compared to 2022. Eagle does not believe that the recently approved pemetrexed product will have an impact on its expectations of the market or its anticipated share.

Barhemsys[1] and Byfavo[2]: Barhemsys and Byfavo, together, are beginning to reflect the pace of growth anticipated when Eagle purchased Acacia in mid-2022. In the first quarter of 2023 -- the first full quarter with a fully staffed and trained sales team in place -- net sales of the two products were just below $1 million on a combined basis. Thus far in the second quarter of 2023, sales have exceeded this figure, and the Company expects the products to show strong year-over-year and sequential growth throughout the back half of 2023. Barhemsys is the first and only antiemetic approved by the U.S. Food and Drug Administration (FDA) for rescue treatment of postoperative nausea and vomiting (PONV) despite prophylaxis. It is also indicated for the treatment of PONV in patients who have not received prophylaxis and for the prevention of PONV, either alone or in combination with an antiemetic of a different class. Byfavo is indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. Based on current positive feedback from physicians and nurses, Eagle expects this momentum to continue for the foreseeable future.

Bendamustine franchise: The revenue and royalty produced across the bendamustine markets has also been strong for the year to date. The Company continues to expect that it will maintain approximately 75% of the gross profit for the year as compared to 2022.

Pipeline Progress and Future Growth Opportunities:

EA-114 Product Candidate (for the treatment of HR+/HER- advanced breast cancer, **is** intended to be an improved version of Faslodex**):** The Company had positive results from its EA-114 study and intends to conduct a type C meeting with FDA in August. Additional updates are anticipated in the event FDA and Eagle agree on next steps.

CAL02: The Company's Phase 2 study is underway. It is a multi-center adaptive, randomized, double-blind, placebo-controlled study designed to assess the efficacy and safety of CAL02, a novel first-in-class anti-toxin drug candidate, being developed to treat severe community-acquired bacterial pneumonia (SCABP) as an adjunctive therapy to standard of care. The study plans to enroll approximately 276 patients with SCABP at more than 100 sites in over 20 countries worldwide.

- On June 14, 2023, FDA granted Qualified Infectious Disease Product (QIDP) Designation under the Generating Antibiotic Incentives Now (GAIN) Act and Fast Track Designation for CAL02. QIDP designation entitles Eagle to an additional five years of marketing exclusivity upon approval. Moreover, Eagle believes CAL02 is a new chemical entity (NCE), which would result in five years of marketing exclusivity upon approval or three years without NCE designation. In total, CAL02 may be eligible for a total of eight or ten years of exclusivity upon approval.

[1] https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf

[2] https://bynder.acaciapharma.com/m/403e8c343b2922de/original/Byfavo-PI.pdf

- Eagle has approved patents for CAL02 running until September 2035, with filed patent applications that would extend into 2037 or later, and may qualify for up to five additional years of patent term exclusivity, up to 2040.

Guidance: The Company reaffirms previously provided 2023 full-year guidance.

- Adjusted EBITDA of $74.0-$80.0 million
- Adjusted non-GAAP earnings per share of $4.20-$4.53
- Adjusted non-GAAP R&D expense of $41.0-$45.0 million
- Adjusted non-GAAP SG&A expense of $86.0-$90.0 million

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include PEMFEXY®, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM® (Japan), and BYFAVO® and BARHEMSYS® through its wholly owned subsidiary Acacia Pharma Inc. Eagle's oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipate,” “forward,” “will,” “would,” ‘could,” “should,” “may,” “remain,” “maintain,” “opportunity,” “potential,” “prepare,” “expect,” “believe,” “plan,” “future,” “belief,” “guidance,” “estimate,” “project,” “forecast” “continue,” “further” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements with respect to: Eagle Pharmaceuticals, Inc.’s (“Eagle” or the “Company”) ability to achieve earnings growth and support research and development, and its capability for further expansion and improve margin and contribution of key products; expectations with respect to the Company’s financial results, including projected estimated financial information, including projected adjusted EBITDA, adjusted non-GAAP earnings per share, adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense for fiscal year 2023 and expectations with respect anticipated future product revenue and profits for fiscal year 2023, including projected estimated mix of product revenue and profits; expectations with respect to potential exit run rates, potential revenues, potential market share, potential commercial opportunity, expected pricing of drugs and future royalties; the Company’s development programs, products and pipeline; the potential for the Company to transition into a diversified pharmaceutical company with a portfolio of branded, first-in-class assets and to utilize legacy products; the Company's clinical development plan for its product candidates, including the number and timing of development initiatives or new indications for the Company’s product candidates; the development of, potential therapeutic and economic benefits of and expected regulatory activities and matters with respect to the product candidates of the Company; potential commercial opportunities, addressable markets, patient populations and settings for the Company’s products and product candidates; CAL02’s ability to neutralize virulence factors produced by bacteria that are commonly associated severe pneumonia; the potential of CAL02 to be a first-in-class broad-spectrum anti-virulence agent for the treatment of severe community-acquired bacterial pneumonia; the Company’s expectations for the design and timing of the CAL02 Phase 2 study, including with respect to enrollment and the timing thereof; the Company’s marketing, product development, partnering and growth strategy, including relating to the commercialization of Barhemsys and Byfavo and its other products; expectations with respect to the Company’s ability to potentially acquire additional assets; the timing, scope or likelihood and timing of regulatory filings and approvals, and the outcome of meetings with the U.S. Food and Drug Administration (“FDA”) for product candidates and the ability to maintain regulatory approval of products and product candidates; clinical development plans for product candidates; the success of the Company's collaborations with its strategic partners and the timing and results of these partners’ preclinical studies and clinical trials, and the Company’s potential earnings potential through such collaborations; the Company's plans and ability to advance the product candidate in its pipeline; potential opportunities for, and the Company’s ability to complete, acquisitions or business development transactions, in a timely manner, on favorable terms to the Company, or at all; the sufficiency of the Company’s cash flows and capital resources and expectations with respect to deployment of cash resources; and the Company’s ability to achieve expected future financial performance and results. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company’s control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the risk that the anticipated benefits of the Company’s acquisition of Acacia are not realized; the impacts of the continuing effects of the COVID-19 pandemic and geopolitical events such as the conflict in Ukraine, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and disruption of the global economy or other events on the Company's business, financial condition and results of operations; macroeconomic conditions, including rising inflation and interest rates, uncertain credit and financial markets and recent and potential disruptions in banking systems; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners’ product candidates; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its products or that may have an impact on any of our products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic and geopolitical events, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; any unanticipated factors in addition to the foregoing that may impact the Company’s financial and business projections and guidance that may cause the Company’s actual results and outcomes to materially differ from its projections and guidance; and those risks and uncertainties identified in the “Risk Factors” sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (the “SEC”) on March 23, 2023, and its other subsequent filings with the SEC, including the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on May 9, 2023. Readers are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. This press release includes statistical and other industry and market data that the Company obtained from industry publications and research, surveys and studies conducted by third parties or us. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. All of the market data used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While the Company believes these industry publications and third-party research, surveys and studies are reliable, the Company has not independently verified such data. The industry in which the Company operates is subject to a high degree of uncertainty, change and risk due to a variety of factors, which could cause results to differ materially from those expressed in the estimates made by the independent parties and by the Company.

Non-GAAP Financial Performance Measures

This press release contains adjusted EBITDA, projected adjusted non-GAAP EBITDA, projected adjusted non-GAAP earnings per share, projected adjusted non-GAAP R&D expense and projected adjusted non-GAAP SG&A expense. The Company believes these measures provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

Investors should note that reconciliations of the forward-looking or projected non-GAAP financial measures included in this press release to their most comparable GAAP financial measures cannot be provided because the Company cannot do so without unreasonable efforts due to the unavailability of information needed to calculate the reconciling items and the variability, complexity, and limited visibility of comparable GAAP measures, and the reconciling items that would be excluded from the non-GAAP financial measures in the future. Likewise, the Company is unable to provide projected GAAP financial measures. GAAP projections and reconciliations of the components of projected adjusted EBITDA, adjusted non-GAAP R&D expenses, adjusted non-GAAP SG&A expense, and adjusted non-GAAP earning per share to their most comparable GAAP financial measures are not provided because the quantification of projected GAAP R&D expenses, adjusted non-GAAP SG&A expense, net income and earnings per share and the reconciling items between projected GAAP to adjusted EBITDA, adjusted non-GAAP R&D expenses, adjusted non-GAAP SG&A expense and adjusted non-GAAP earnings per share cannot be reasonably calculated or predicted at this time without unreasonable efforts. For example, with respect to GAAP net income, R&D expenses and SG&A expenses, the Company is not able to calculate the favorable or unfavorable expenses related to the fair value adjustments on equity investments and derivative instruments primarily due to nature of these items. Such unavailable information could be significant such that actual GAAP net income, R&D expenses, SG&A expenses and earnings per share would vary significantly from projected adjusted EBITDA, adjusted non-GAAP R&D expenses, adjusted non-GAAP SG&A expense and adjusted non-GAAP earnings per share.

Important Safety Information for BYFAVO™ (remimazolam) Injection

Indications

BYFAVO is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS AND OTHER SEDATIVE-HYPNOTICS

Personnel and Equipment for Monitoring and Resuscitation

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and during the recovery period.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO.**

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics Concomitant use of benzodiazepines, including BYFAVO, and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation.

Contraindication

BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Personnel and Equipment for Monitoring and Resuscitation

Clinically notable hypoxia, bradycardia, and hypotension were observed in Phase 3 studies of BYFAVO. Continuously monitor vital signs during sedation and through the recovery period. Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO. Consider the potential for worsened cardiorespiratory depression prior to using BYFAVO concomitantly with other drugs that have the same potential (e.g., opioid analgesics or other sedative-hypnotics). Administer supplemental oxygen to sedated patients through the recovery period. A benzodiazepine reversal agent (flumazenil) should be immediately available during administration of BYFAVO.

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of BYFAVO and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of IV BYFAVO can be accentuated when administered with other CNS depressant medications (eg, other benzodiazepines and propofol). Titrate the dose of BYFAVO when administered with opioid analgesics and sedative-hypnotics to the desired clinical response. Continuously monitor sedated patients for hypotension, airway obstruction, hypoventilation, apnea, and oxygen desaturation. These cardiorespiratory effects may be more likely to occur in patients with obstructive sleep apnea, the elderly, and ASA-PS class III or IV patients.

Hypersensitivity Reactions

BYFAVO contains dextran 40, which can cause hypersensitivity reactions, including rash, urticaria, pruritus, and anaphylaxis. BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Neonatal Sedation

Use of benzodiazepines during the later stages of pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) in the neonate. Observe newborns for signs of sedation and manage accordingly.

Pediatric Neurotoxicity

Published animal studies demonstrate that anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of this is not clear. However, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life but may extend out to approximately 3 years of age in humans.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Adverse Reactions

The most common adverse reactions reported in >10% of patients (N=630) receiving BYFAVO 5-30 mg (total dose) and undergoing colonoscopy (two studies) or bronchoscopy (one study) were: hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension.

Use in Specific Populations

Pregnancy

There are no data on the specific effects of BYFAVO on pregnancy. Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Monitor neonates exposed to benzodiazepines during pregnancy and labor for signs of sedation and respiratory depression.

Lactation

Monitor infants exposed to BYFAVO through breast milk for sedation, respiratory depression, and feeding problems. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 5 hours after BYFAVO administration.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. BYFAVO should not be used in patients less than 18 years of age.

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects. However, there is a potential for greater sensitivity (eg, faster onset, oversedation, confusion) in some older individuals. Administer supplemental doses of BYFAVO slowly to achieve the level of sedation required and monitor all patients closely for cardiorespiratory complications.

Hepatic Impairment

In patients with severe hepatic impairment, the dose of BYFAVO should be carefully titrated to effect. Depending on the overall status of the patient, lower frequency of supplemental doses may be needed to achieve the level of sedation required for the procedure. All patients should be monitored for sedation-related cardiorespiratory complications.

Abuse and Dependence

BYFAVO is a federally controlled substance (CIV) because it contains remimazolam which has the potential for abuse and physical dependence.

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