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): **April 4, 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 1.01 Entry into a Definitive Material Agreement.

Settlement Agreement with Dr. Reddy's Laboratories

On April 4, 2023, or the Effective Date, Eagle Pharmaceuticals, Inc., or the Company, entered into a definitive settlement agreement, or the Settlement Agreement, with Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., or collectively, Dr. Reddy's, relating to the Company's product BENDEKA® (rapidly infused bendamustine hydrochloride), or the Company Product. This settlement resolves patent litigation (subject to U.S. Federal Trade Commission and U.S. Department of Justice review) brought by the Company, and its marketing partners Teva Pharmaceuticals International GmbH and Cephalon, LLC, or collectively, Teva, relating to the alleged infringement of Orange Book listed United States Patent Nos. 11,103,483 and 9,572,887, or the Patents-In-Suit, with respect to Dr. Reddy's 505(b)(2) New Drug Application, or NDA, No. 215668, submitted to the U.S. Food and Drug Administration, or FDA, seeking approval for the manufacture and sale in the United States of bendamustine hydrochloride injection solution in a 100 mg/4 mL (25 mg/mL) dosage strength for intravenous infusion over ten (10) minutes from a 50 ML infusion bag and used for the treatment of chronic lymphocytic leukemia and non-Hodgkin's lymphoma, or the Dr. Reddy's Product. The Settlement Agreement includes customary representations, warranties and agreements by the parties and the following terms:

Settlement of Patent Infringement and Antitrust Lawsuits and Antitrust Review

Within five days after the Effective Date, the parties to the litigation, or the Parties, will file a joint motion to dismiss all claims, defenses and counterclaims with prejudice in relation to litigation, or the Patent Infringement Lawsuit, concerning the alleged infringement by Dr. Reddy's of the Patents-In-Suit, resulting from the filing by Dr. Reddy's of NDA, No. 215668, and the related certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv).

In addition, within ten business days after the Effective Date, the Parties will submit the Settlement Agreement to the U.S. Federal Trade Commission and U.S. Department of Justice for federal antitrust review.

Mutual Release and Covenant Not to Sue

The Parties each release the counterparty or counterparties from any and all claims relating to (i) the Dr. Reddy's Product and the Dr. Reddy's NDA or its filing, (ii) the Patents-In-Suit or (iii) the Patent Infringement Lawsuit.

The Company and Teva and their respective affiliates also covenant not to sue, assert any claim or otherwise participate in any action or proceeding against, Dr. Reddy's or its affiliates, for infringement of the Patents-In-Suit or any other patents owned or controlled by the Company or Teva now or in the future, subject to certain exceptions.

Limited License

The Company and Teva grant to Dr. Reddy's and its affiliates a non-exclusive and revocable license under the Patents-In-Suit, including any corrections, extensions, reissues or reexaminations, to manufacture, have manufactured, use, sell, offer to sell, and import the Dr. Reddy's Product in the United States beginning on the License Effective Date of November 17, 2027 (subject to FDA approval), or earlier under certain circumstances.

The foregoing description of the Settlement Agreement is not intended to be complete and is qualified in its entirety by reference to the full text of the Settlement Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K.

Safe Harbor for Forward-Looking Statements

This Current Report on Form 8-K 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 "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," "opportunity," "estimate," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: the resolution of patent litigation and all related settlement terms, including dates of market entry and the potential for earlier market entry under certain circumstances and submission of settlement agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice for review; the strength of the Company's intellectual property rights for BENDEKA; and the expected expansion, defense and enforcement of intellectual property rights. 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 ability of Enalare to achieve milestones and deliverables under the BARDA agreement and achieve successful results in the development of ENA-001 and the Company's ability to exercise its option to acquire the remaining outstanding share capital of Enalare; the impacts 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, and the overall impact of the COVID-19 pandemic or other events on the Company's business, financial condition and results of operations; macroeconomic conditions, including rising inflation and uncertain credit and financial markets; 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; and any unanticipated factors in addition to the foregoing that may impact the Company's financial and business projections and guidance and 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. 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.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
10.1#	Settlement Agreement, by and between the Registrant, Teva Pharmaceuticals International GmbH, Cephalon, LLC, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., dated April 4, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Certain confidential information contained in this exhibit has been omitted because it is both (i) not material and (ii) is the type that the Company treats as private or confidential.

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: April 10, 2023

EAGLE PHARMACEUTICALS, INC.

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

Exhibit 10.1

Certain information marked as [***] has been excluded from this exhibit because it is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

SETTLEMENT AND LICENSE AGREEMENT

This SETTLEMENT AND LICENSE AGREEMENT (this "Agreement") is hereby entered into and made effective on April 4, 2023 (the "Effective Date") by and among, on the one hand, Teva Pharmaceuticals International GmbH ("Teva GmbH") and Cephalon, LLC ("Cephalon," together with Teva GmbH, "Teva"), and Eagle Pharmaceuticals, Inc., ("Eagle," together with Teva, "Plaintiffs"), and on the other hand, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"). Plaintiffs and Dr. Reddy's are referred to herein individually as a "Party" and collectively, as the "Parties."

WHEREAS, Eagle owns United States Patent Nos. 8,609,707 ("the '707 patent"); 9,265,831 ("the '831 patent"); 9,572,796 ("the '796 patent"); 9,572,797 ("the '797 patent"); 9,034,908 ("the '908 patent"); 9,144,568 ("the '568 patent"); 9,572,887 ("the '887 patent"); 9,597,397 ("the '397 patent"); 9,597,398 ("the '398 patent"); 9,597,399 ("the '399 patent"); 9,000,021 ("the '021 patent"); 9,579,384 ("the '384 patent"); 10,052,385 ("the '385 patent"); 10,010,533 ("the '533 patent"); and 11,103,483 ("the '483 patent") (collectively, the "Asserted Patents");

WHEREAS, Teva owns United States Patent No. 8,791,270 ("the '270 patent") (collectively with the Asserted Patents, the "Orange Book Patents");

WHEREAS, Eagle is the holder of New Drug Application No. 208194, which is approved by the Food and Drug Administration ("FDA") for the manufacture and sale of bendamustine hydrochloride injection solution in a 100 mg/4 mL (25 mg/mL) dosage strength for intravenous infusion over ten (10) minutes from a 50 mL infusion bag and used for the treatment of chronic lymphocytic leukemia ("CLL") and non-Hodgkin's lymphoma ("NHL"), which Teva and its Affiliates market in the Territory under the brand name BENDEKA®;

WHEREAS, Eagle and Cephalon entered into an Exclusive License Agreement on February 13, 2015, as amended (the "Exclusive License Agreement"), pursuant to which Eagle granted Cephalon an exclusive license under certain patents, including the Asserted Patents, for the commercialization of the Bendeka® NDA Product (as defined below) in the Territory (as defined below), including the right to sue for patent infringement;

WHEREAS, on or around October 14, 2015, Cephalon assigned its rights in the Exclusive License Agreement to Teva GmbH;

WHEREAS, Dr. Reddy's is the holder of New Drug Application No. 215668, an application which was submitted to the FDA pursuant to 21 U.S.C. § 355(b)(2) seeking approval to market in the United States a generic bendamustine hydrochloride injection solution in a 100 mg/4 mL (25 mg/mL) dosage strength [***] containing a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the Orange Book Patents are not infringed or invalid;

WHEREAS, Plaintiffs have contended that the Asserted Patents are valid and enforceable and that, but for the license granted to Dr. Reddy's under this Agreement, the commercial manufacture, use, sale, offering for sale, or importation of Dr. Reddy's Product (as defined below) in or for the Territory would infringe the Patents-In-Suit (as defined below);

WHEREAS, Dr. Reddy's has contended that the product described in the Dr. Reddy's NDA (as defined below) does not infringe the Asserted Patents and/or that those patents are invalid;

WHEREAS, Plaintiffs and Dr. Reddy's are involved in litigation in the United States District Court for the District of Delaware (the "District Court"), namely Civil Action No. 21-cv-00695 (CFC) (the "Lawsuit"), concerning, *inter alia*, the validity of the Patents-In-Suit, as well as the alleged infringement by Dr. Reddy's of the Patents-In-Suit resulting from the filing by Dr. Reddy's of the Dr. Reddy's NDA and related certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv);

WHEREAS, on May 13, 2021, Plaintiffs filed the Lawsuit against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. and asserted that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. infringed and would infringe the Asserted Patents;

WHEREAS, Plaintiffs have previously sued other defendants Accord Healthcare, Inc. ("Accord"), Apotex Inc. and Apotex Corp. (collectively, "Apotex"), Aurobindo Pharma Limited ("Aurobindo"), Fresenius Kabi USA, LLC ("Fresenius Kabi"), Hospira, Inc. ("Hospira"), Lupin Limited ("Lupin"), Mylan Laboratories Ltd. ("Mylan"), and Slayback Pharma LLC ("Slayback") for infringement of certain of the Orange Book Patents;

WHEREAS, on July 6, 2020, the district court entered judgment for Plaintiffs and against Apotex, Fresenius Kabi, Mylan, and Slayback for infringement and non-invalidity of one or more of the Orange Book Patents in Civil Action No. 17-cv-01154 (CFC);

WHEREAS, Apotex, Fresenius Kabi, and Mylan appealed the District Court's judgment of non-invalidity to the United States Court of Appeals for the Federal Circuit, which affirmed the district court's judgment of non-invalidity in Case No. 20-2134 on August 13, 2021, and denied Apotex and Mylan's Petition for Rehearing *En Banc* on October 15, 2021;

WHEREAS, Apotex filed a petition for a writ of certiorari with the United States Supreme Court in Case No. 21-893 on December 14, 2021, which the Supreme Court denied on February 22, 2022;

WHEREAS, on February 8, 2022, Plaintiffs filed a First Amended Complaint, narrowing their claims to infringement of the '887 patent and the '483 patent (the "Patents-In-Suit");

WHEREAS, on December 7, 2022, the District Court entered a Stipulation and Order that Dr. Reddy's Product (as defined below) does not infringe the claims of the '483 Patent and dismissing the Parties' claims and counterclaims regarding the '483 patent, but subject to vacatur in the event that district court's judgment in Civil Action No. 21-cv-1256 (CFC)(JLH) is vacated, reversed, or modified in the pending appeal from that judgment;

WHEREAS, on January 6, 2023, the District Court entered a Stipulation and Order in which Dr. Reddy's consented to the entry of judgment that the submission of Dr. Reddy's NDA infringes certain claims of the '887 Patent, and use of Dr. Reddy's Product (as defined below) according to Dr. Reddy's proposed labeling would infringe the asserted claims of the '887 patent, to the extent those claims are asserted by Plaintiffs at trial and are found to be valid and enforceable;

WHEREAS, the Parties desire and agree to enter into this Agreement to avoid the costs, uncertainty, and risk associated with continued litigation of this matter, including the pending Lawsuit, and to permit entry of generic competition prior to the expiration of the Patents-In-Suit upon the terms and subject to the conditions set forth herein, and Dr. Reddy's agrees not to make, have made, use, sell, offer for sale or import the Dr. Reddy's Product in the Territory before the License Effective Date (as defined below) except as expressly permitted by the terms and conditions of this Agreement;

WHEREAS, this Agreement is the only agreement between the Parties related to the settlement of the Lawsuit with respect to the Dr. Reddy's NDA and the Dr. Reddy's Product; and

WHEREAS, no Party has received any consideration from any other Party for its entry into this Agreement other than that which is described in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants herein contained and the consideration described herein, the sufficiency and receipt of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

1. **DEFINITIONS**

1.1 "Affiliates" means, with respect to a Party, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, "control" (including the terms "controlled by" and "under common control with") of a business entity means the direct or indirect ownership of more than fifty percent (50%) of the voting stock or other ownership interest in such entity; or the direct or indirect ownership of the power to direct the management and policies of the other entity by any means whatsoever. For clarity, legal counsel for a Party are not Affiliates.

1.2 "ANDA" means an abbreviated new drug application filed pursuant to 21 U.S.C. § 355(j).

1.3 "ANDA Product" means a pharmaceutical product that (a)(i) is a bendamustine hydrochloride solution, and (ii) is therapeutically equivalent to the Bendeka® NDA Product, as manufactured or sold for use in the Territory in a 100 mg/4 mL (25 mg/mL) dosage strength in a multiple-dose vial, and (iii) has an FDA approved label [***] and (b) is sold, offered for sale or distributed under an ANDA that references the Bendeka® NDA Product as the reference-listed drug, and is filed or otherwise controlled by a person or entity other than Plaintiffs or their Affiliates. For the avoidance of doubt, the Dr. Reddy's Product is not an ANDA Product, and ANDA Product does not include (1) [***], or (2) [***].

1.4 [***]

1.5 "Bendeka® NDA" means NDA No. 208194, and any current or future amendments or supplements thereto, including additional indications, additional dosage strengths, or additional infusion bag volumes between 25 to 100 mL that are added to NDA No. 208194 after the Effective Date.

1.6 "Bendeka® NDA Product" means the bendamustine hydrochloride solution product that is the subject of the Bendeka® NDA and marketed in the Territory under the BENDEKA® trademark or any successor trademark thereto in a 100 mg/4 mL (25 mg/mL) dosage strength for intravenous infusion over ten (10) minutes from a 50 mL infusion bag and used for the treatment of CLL and NHL, [***]

1.7 "Controlled" means, with respect to any patent right granted to Dr. Reddy's, and/or regulatory exclusivity waived by the relevant Plaintiff, under this Agreement, the ownership of, or exclusive license rights to, such patent right and/or regulatory exclusivity waived by the relevant Plaintiff or its Affiliates that permits such Plaintiff or its Affiliates to grant such patent right or waive such regulatory exclusivity to Dr. Reddy's without violating the terms of any agreement or other arrangement with any Third Party or being obligated to pay any royalties or other consideration therefor. Notwithstanding the foregoing, with respect to any patent right and/or regulatory exclusivity Controlled by an Affiliate of a Plaintiff, such patent right and/or regulatory exclusivity will only be treated as "Controlled" under this Agreement for so long as such Affiliate remains an Affiliate of such Plaintiff.

1.8 "Dr. Reddy's NDA" means NDA No. 215668 as of the Effective Date and

(a) any amendments and supplements thereto, [***]

(b) [***],

[***].

1.9 "Dr. Reddy's Product" means the NDA Product that is the subject of the Dr. Reddy's NDA.

1.10 "Final Court Decision" means a decision by a court on the merits (e.g., after a trial or summary judgment motion) whereby such court enters final judgment from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

1.11 "License Effective Date" means the earliest to occur of the following:

(a) November 17, 2027;

(b) the date of a Final Court Decision in favor of a Third Party holding all of the adjudicated and unexpired claims of the Licensed Patents [***];

provided, however, that a License Effective Date under this clause (b) shall in no event occur or be deemed to occur [***];

(c) the date of a decision by the United States Patent Trial and Appeal Board ("PTAB") from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken, that all of the adjudicated and unexpired claims of the Licensed Patents are unpatentable;

provided, *however*, that a License Effective Date under this clause (c) shall occur or be deemed to occur, [***], if (i) the Third Party in whose favor the PTAB decides is a Third Party PIV Filer and (ii) [***];

(d) the date on which all of the Patents-In-Suit have expired, become permanently abandoned or disclaimed, withdrawn, or delisted from the Orange Book.

[***].

1.12 "Licensed Patents" means the Patents-In-Suit, any corrections, extensions (including pediatric exclusivities), reissues, or reexaminations of such patents, and any amended claims of such patents arising out of an *inter partes* review, post-grant review, or other patent proceeding.

1.13 "NDA" means a new drug application filed pursuant to 21 U.S.C. § 355(b)(2).

1.14 "NDA Product" means a pharmaceutical product that (a)(i) is a bendamustine hydrochloride solution, (ii) is therapeutically equivalent to the Bendeka® NDA Product, as manufactured or sold for use in the Territory in a 100 mg/4 mL (25 mg/mL) dosage strength in a multiple-dose vial, and (iii) has an FDA approved label [***] and (b) is sold, offered for sale or distributed under an NDA that references the Bendeka® NDA Product as the reference-listed drug and is filed or otherwise controlled by a person or entity other than Plaintiffs or their Affiliates. For the avoidance of doubt, an NDA Product does not include (1) [***], or (2) [***].

1.15 "Orange Book" means FDA's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations.

1.16 "Other Patents" means, other than the Licensed Patents, any other patent, including but not limited to Orange Book Patents that are not Patents-In-Suit, or patent applications, and any corrections, extensions (including pediatric exclusivities), reissues, or reexaminations of such other patents or amended claims of such other patents arising out of an *inter partes* review, post-grant review, or other patent proceeding Controlled now or in the future by a Plaintiff or any of its Affiliates that claim or cover the making, using, selling, offering for sale or importation of the Dr. Reddy's Product or components therein solely for use in the Dr. Reddy's Product in the Territory.

1.17 "Territory" means [***].

1.18 "Third Party" means any entity or person that is not a Party or an Affiliate of a Party.

2. **SETTLEMENT; DISMISSAL; RELEASE**

2.1 All of the terms and conditions set forth in this Agreement shall be binding on the Parties and their Affiliates as of the Effective Date.

2.2 Dismissal. In consideration of the mutual benefits of entering into this Agreement, the Parties shall enter into and cause to be filed with the District Court, within five (5) days of the Effective Date, a joint motion to dismiss with prejudice all claims, defenses, and counterclaims as between Plaintiffs and Dr. Reddy's in the Lawsuit, substantially in the form attached hereto as Exhibit 1 (the "STIPULATION AND PROPOSED ORDER").

2.3 Release. In settlement of the disputed claims in the Lawsuit, and in consideration of the mutual execution of this Agreement and the mutual agreement to be legally bound by the terms hereof, each Plaintiff, on the one hand, and Dr. Reddy's, on the other hand, on behalf of itself and its predecessors, successors, assigns, shareholders, officers, directors, employees, trustees, agents, representatives, licensees, licensors, parents, subsidiaries and Affiliates and all others claiming by, through and under them, hereby fully, finally, irrevocably and forever (but subject to this Section 2.3) releases, relinquishes, acquits and discharges the other Party and its predecessors, successors, assigns, shareholders, officers, directors, employees, agents, representatives, licensees, licensors, parents, subsidiaries, Affiliates, customers, suppliers, importers, manufacturers, and distributors [***], if any, from any and all claims, demands, causes of action, liabilities, losses, all manner of actions, judgments, settlements, interest, damages, punitive damages and other damages or costs of whatever nature (including costs, expenses, and attorneys' fees), whether known or unknown, foreseen or unforeseen, certain or contingent, accruing before the Effective Date, arising out of, derived from, predicated upon, or relating to the Dr. Reddy's Product and Dr. Reddy's NDA or its filing; provided, however, that nothing herein shall (i) constitute a release of any obligations of Plaintiffs or Dr. Reddy's (or their respective Affiliates) under this Agreement or prevent a Party from invoking the continuing jurisdiction of the District Court in the Lawsuit to enforce the terms and provisions of this Agreement or (ii) prevent or impair the right of any Party to bring a proceeding in court or any other forum for a breach of this Agreement or any representation, warranty, or covenant herein, or with respect to any product other than the Dr. Reddy's Product, or any proceeding outside of the Territory. Notwithstanding anything to the contrary, nothing included herein is intended to restrict, limit, or otherwise abrogate any rights Dr. Reddy's and its Affiliates have under 35 U.S.C. § 271(e)(1).

2.4 Unknown Claims. Each Party, on behalf of itself and its Affiliates, hereby expressly waives and relinquishes any and all provisions, rights and benefits conferred by Section 1542 of the California Civil Code, which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN TO HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Further, each Party, on behalf of itself and its Affiliates, and its and their respective directors, officers, members, managers, partners, employees, agents, representatives, assigns, predecessors, successors or other related persons or entities, expressly waive and relinquish all rights and benefits afforded by any law in any other jurisdiction similar to Section 1542 of the California Civil Code.

2.5 Admissions. [***]

2.6 Agreement to Abide by License Effective Date. [***]

2.7 No Assignment of Claims. Each Party represents and warrants and covenants that it has not heretofore assigned or transferred, and will not assign or otherwise transfer, to any person or entity any matters released by such Party in Section 2.3, and each such Party agrees to indemnify and hold harmless the other Parties and the other persons and entities released under Section 2.3 from and against all such released matters arising from any such alleged or actual assignment or transfer.

2.8 Reliance on Agreement. For the avoidance of doubt, nothing herein shall be construed as an admission or waiver as to any factual or legal matter by any Party or its Affiliates with respect to (a) any jurisdiction outside of the Territory, (b) any products other than the Dr. Reddy's Product or (c) any patents other than the Licensed Patents or Other Patents solely with respect to the Dr. Reddy's Product and Dr. Reddy's NDA. No Party shall seek to rely upon or enter this Agreement or any admission herein into evidence in any proceeding other than a proceeding relating to a claimed breach of this Agreement.

3. **LICENSE; RESTRICTIONS**

3.1 License Grant related to Bendeka® NDA Product. [***]

3.2 [***]

3.3 No Other Licenses; Disclaimer. [***]

3.4 Covenant Not to Challenge and Assist Challenges to the Licensed Patents and Other Patents related to Bendeka® NDA Product. [***]

3.5 Covenant Not to Sue related to Bendeka® NDA Product. As part of the license rights granted in this Section 3, with respect to the Dr. Reddy's Product including the components therein solely for use in the Dr. Reddy's Product, and the Dr. Reddy's NDA, and effective on the License Effective Date and, [***], Plaintiffs and their Affiliates irrevocably covenant not to sue (provided Dr. Reddy's has not materially breached this Agreement, and subject to Section 5.3), assert any claim or otherwise participate in any action or proceeding against, Dr. Reddy's and its Affiliates, and their respective importers, suppliers, manufacturers, distributors [***] and customers for infringement of the Licensed Patents and Other Patents solely with respect to Dr. Reddy's or its Affiliates' (a) making, having made, using, selling, offering for sale, and importation of Dr. Reddy's Product in or for the Territory as of and following the License Effective Date pursuant to Section 3.1 [***] and (b) [***]. Plaintiffs shall impose the foregoing covenant not to sue on its Affiliates and any Third Party to which Plaintiffs may assign license, sublicense, or otherwise transfer any rights to or under (in each case, that includes the right to assert) the Licensed Patents or Other Patents.

3.6 Regulatory Approval.

(a) [***].

(b) Each Plaintiff hereby agrees to waive, with respect to the Dr. Reddy's Product, any regulatory exclusivities as of the Effective Date and Controlled by that Plaintiff that may prevent approval or marketing of the Dr. Reddy's Product in the Territory as of the License Effective Date pursuant to Section 3.1 [***]. For the avoidance of doubt, each Plaintiff shall cause any Affiliates to waive as applicable, with respect to the Dr. Reddy's Product, any regulatory exclusivities, existing as of the Effective Date and Controlled by that Plaintiff that may prevent approval or marketing of the Dr. Reddy's Product in the Territory as of the License Effective Date pursuant to Section 3.1 [***].

(c) If requested by Dr. Reddy's, Plaintiffs and their Affiliates shall reasonably promptly provide written notice to FDA evidencing the license rights, covenant not to sue and waiver of regulatory exclusivities granted to Dr. Reddy's as set forth in this Agreement with respect to the Dr. Reddy's NDA and Dr. Reddy's Product and indicating that Plaintiffs and their Affiliates have no objection to final approval of the Dr. Reddy's NDA, and shall confirm to Dr. Reddy's that it has done so and Dr. Reddy's shall then also provide a copy of Plaintiffs' correspondence to FDA if required by FDA. [***].

3.7 Impact of Granting Certain Licenses to Third Parties. [***]

3.8 Plaintiffs' Regulatory Covenants. [***]

4. **FTC REVIEW**

4.1 This Agreement shall be submitted to the federal antitrust agencies pursuant to the Medicare Modernization Act within ten (10) business days of its execution. Each Party shall notify the other Parties when it has submitted this Agreement to such agencies. The Parties hereby agree that they will work in good faith to resolve any related issues and endeavor to modify this Agreement in view of any objections from such federal antitrust agencies, but no Party shall be required to accept any terms that materially change or modify the purposes of this Agreement.

5. **TERM AND TERMINATION**

5.1 Term. Unless earlier terminated in accordance with the terms of this Section 5, the term of this Agreement will commence on the Effective Date and will remain in effect until the expiration of the last to expire of the Licensed Patents. For the avoidance of doubt, the respective terms of the Licensed Patents include any term extensions or adjustments to which the Licensed Patents are entitled, in each case whether granted or allowed before, on, or after the Effective Date, and the term of this Agreement shall run until the last to expire of such extensions and pediatric exclusivities, whenever granted.

5.2 Termination for Cause. [***], each of Plaintiffs and Dr. Reddy's may terminate this Agreement at any time in the event that the other Party or any of its Affiliates materially breaches this Agreement [***].

5.3 Effect of Expiration or Termination. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. [***]. In addition, [***] shall survive expiration or termination of this Agreement.

5.4 Equitable Remedies; Termination for Breach.

If Dr. Reddy's or any of its Affiliates materially breaches [***] then this Agreement shall not be subject to cure and is automatically terminated. [***]

6. **[***]**

7. **CONFIDENTIALITY; PUBLICITY**

7.1 The Parties hereby agree that, except to enforce this Agreement or unless otherwise agreed to by the Parties in writing or as required by law, the Parties, their Affiliates and their respective employees, officers, directors and other representatives shall not publish or otherwise disclose the contents of this Agreement, except that (a) each Party may disclose this Agreement (i) to its attorneys, advisors, consultants, agents (including Dr. Reddy's manufacturer(s)), and representatives who in each case are subject to obligations of confidentiality consistent with this Agreement, and (ii) if any Party becomes required to disclose this Agreement by law, regulation or order of a court or administrative agency, including reporting requirements to the U.S. Securities and Exchange Commission or by the rules or regulations of any stock exchange to which the Parties are subject, (b) the Parties may communicate with the FDA on a confidential basis prior to the License Effective Date concerning the approval of the Dr. Reddy's NDA and the licenses and waivers provided for herein, (c) Plaintiffs may disclose such terms as may be necessary or useful in connection with any proceeding, agreement or settlement discussions relating to the Licensed Patents, Other Patents, or any bendamustine hydrochloride product, including the License Effective Date defined in this Agreement and the fact that the License Effective Date belongs to Dr. Reddy's, and (d) [***]. In the event disclosure is required under the foregoing clause (a)(ii), the Party making such disclosure shall (1) provide the other Parties with as much advance notice as reasonably practicable of the required disclosure, (2) cooperate with the other Parties in an attempt to prevent or limit the disclosure, and (3) limit any disclosure to the specific purpose at issue.

7.2 Each Party may, with the prior written approval of the other Party (such approval not to be unreasonably withheld), issue a press release or make a public announcement at any time following the Effective Date indicating that the Parties have settled the Lawsuit, and that Dr. Reddy's has the right to market the Dr. Reddy's Product in the Territory beginning November 17, 2027, or earlier based on certain circumstances; *provided, however*, that notwithstanding the foregoing, Eagle shall have the right to issue a press release substantially in the form of Exhibit 2, without the prior written approval of Dr. Reddy's; and *provided further* that such press release or announcement may be issued on subsequent occasions without further consent from Dr. Reddy's, *provided* that such release or announcement is the same or substantially similar or consistent with Exhibit 2. Except as permitted hereunder, the terms of this Agreement shall remain confidential.

8. **REPRESENTATIONS AND WARRANTIES**

8.1 Each Party represents and warrants to the other, as of the Effective Date of this Agreement, that:

(a) Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) Such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(c) This Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms;

(d) To the knowledge of the Parties, the execution, delivery, and performance of this Agreement does not conflict with any agreement, instrument, or understanding, oral or written, to which such Party is bound nor violate any law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it;

(e) Such Party represents and warrants that it has been advised by its counsel of its rights and obligations under this Agreement and enters into this Agreement freely, voluntarily, and without duress; and

(f) Such Party represents and warrants that it is not relying on any promises, inducements, or representations other than those provided herein.

8.2 Defendant Representations and Warranties. As of the Effective Date, Dr. Reddy's represents and warrants that: (a) Dr. Reddy's is the true owner of the Dr. Reddy's NDA; (b) Dr. Reddy's has received no notice or claim and knows of no reason for the assertion of any notice or claim contesting clause (a); and (c) Dr. Reddy's has the authority to bind its Affiliates to the extent that the rights and obligations of such Affiliates are referred to in this Agreement.

8.3 Plaintiffs Representations and Warranties. As of the Effective Date, Plaintiffs represent and warrant that they have the right and authority to (a) enter into this Agreement, (b) settle the Lawsuit between the Parties, and (c) grant the license rights to Dr. Reddy's as set forth in this Agreement.

8.4 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF APPLICABLE LAW.

9. **GENERAL PROVISIONS**

9.1 Waiver. None of the provisions of this Agreement will be considered waived by any Party unless such waiver is agreed to, in writing, by authorized agents of such Party. The failure of a Party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law will not be deemed a waiver of any rights of any Party.

9.2 Choice of Law and Remedies. The law of the State of Delaware shall govern this Agreement, the interpretation and enforcement of its terms and any claim or cause of action (in law or equity), controversy or dispute arising out of or related to it or its negotiation, execution or performance, whether based on contract, tort, statutory or other law, in each case without giving effect to any conflicts-of-law or other principle requiring the application of the law of any other jurisdiction. The United States District Court for the District of Delaware shall have exclusive jurisdiction in all matters arising under this Agreement, and the Parties hereto expressly consent and submit to the personal and subject matter jurisdiction of the United States District Court for the District of Delaware in connection with matters arising out of or related to this Agreement, and if jurisdiction in the United States District Court for the District of Delaware is not possible, will submit any dispute arising out of or related to this Agreement to another court of competent jurisdiction in the State of Delaware. This Agreement does not limit or restrict the remedies available to any Party for the breach of another Party, and the Parties expressly reserve any and all remedies available to them, at law or in equity, for breach of this Agreement or otherwise.

9.3 Costs. Each Party shall each bear its own costs and legal fees associated with the negotiation and preparation of, and performance under, this Agreement and any activities related to the implementation of this Agreement.

9.4 Entire Agreement. This Agreement constitutes the entire agreement among the Parties relating to the subject matter hereof and supersedes all previous agreements and understandings, oral or written, with respect to such matters.

9.5 Notice. All notices or other communications hereunder shall be deemed to have been duly given and made if in writing and if served by personal delivery upon a Party, if delivered by a reputable overnight express courier service (charges prepaid), or if sent by email (with confirmation receipt) to the person at the address set forth below, or such other address as may be designated in writing hereafter, in the same manner, by such person as follows:

If to **Teva**: Teva Pharmaceuticals
Morris Corporate Center III
400 Interpace Parkway, Bldg. A
Parsippany, NJ 07054
Attn: [***], Chief Legal Officer

with copies to:

[***]; and
[***]

with a copy to (with such copy not constituting notice):

Williams & Connolly LLP
680 Maine Ave. SW
Washington, DC 20024
Attn: [***]

If to **Eagle**: Eagle Pharmaceuticals, Inc.
50 Tice Blvd, Suite 315
Woodcliff Lake, NJ 07677
Attn: [***], General Counsel

with a copy to (with such copy not constituting notice):

Latham & Watkins LLP
555 Eleventh Street NW
Suite 1000
Washington, DC 20004
Attn: [***]

If to **Dr. Reddy's:** [***]
Vice President, Intellectual Property
Dr. Reddy's Laboratories, Inc.
107 College Road East
Princeton, New Jersey 08540
Phone: (609) 375-9839
Fax: (609) 375-9938
[***]

with a copy to (with such copy not constituting notice):

[***]
Perkins Coie LLP
700 Thirteenth Street NW, Suite 800
Washington, D.C. 20005-3960
Phone: 202-654-6200
Fax: 202-654-9135
[***]

Such notices will be deemed to have been given on the date delivered in the case of delivery by personal delivery or overnight courier or on the date actually received in the case of email delivery.

9.6 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. If, however, any provision of this Agreement is held to be invalid, illegal, or unenforceable for any reason, the Parties shall negotiate in good faith for a substitute provision to continue the intent and purpose of such invalid provisions, and the validity, legality, and enforceability of the remaining provisions shall not be in any way impaired thereby.

9.7 Amendments. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

9.8 Descriptive Headings. The captions and descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

9.9 Third-Party Benefit. None of the provisions of this Agreement shall be for the benefit of, or enforceable by, any Third Party except as otherwise expressly provided herein.

9.10 Assignment. Dr. Reddy's will not assign this Agreement or any part hereof or any interest herein (whether by operation of law or otherwise) without the prior written consent of Plaintiffs (such consent not to be unreasonably withheld, conditioned, or delayed); provided, however, that Dr. Reddy's may assign this Agreement in whole without such prior consent (a) to any Affiliate of Dr. Reddy's (for as long as such assignee remains an Affiliate of Dr. Reddy's); or (b) to any successor entity in the case of a merger, consolidation, change in control or sale of all or substantially all of the assets related to this Agreement. Plaintiffs may assign this Agreement or any part hereof or any interest herein (whether by operation of law or otherwise) without the prior written consent of Dr. Reddy's, provided that in either case, (i) each assigning party shall provide written notice to the other Parties of any permitted assignment of this Agreement, and (ii) such successor agrees in writing for the benefit of the non-assigning Party to assume all of the obligations of the assigning Party. No assignment will be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment will relieve any assigning Party of responsibility for the performance of its obligations hereunder. Any purported assignment in violation of this Section 9.10 will be null and void *ab initio*. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns. For clarity, any successors or permitted assigns to this Agreement are permitted to assign the Agreement as if they were an original Party or Parties to this Agreement, subject to the same terms and obligations regarding assignment under this Section 9.10 that apply to the original Party or Parties to the Agreement.

9.11 Counterparts; Electronic Delivery. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of electronic mail, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any Party hereto or to any such agreement or instrument, each other Party hereto or thereto shall re-execute original forms thereof and deliver them to all other Parties.

[SIGNATURES FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

CEPHALON, LLC

By: s/ Edgar Nouss
Name: Edgar Nouss
Title: Director, Marketing Oncology and Vaccines

By: s/ Colman Ragan
Name: Colman Ragan
Title: VP & GC North America, IP Litigation

TEVA PHARMACEUTICALS INTERNATIONAL GMBH

By: s/ Deepa Xavier
Name: Deepa Xavier
Title: General Manager

By: s/ Pascal Guichard
Name: Pascal Guichard
Title: Member of the Management

EAGLE PHARMACEUTICALS, INC.

By: s/ Robert Chang
Name: Robert Chang
Title: Vice President, Intellectual Property

DR. REDDY'S LABORATORIES, LTD.

By: s/ Erez Israeli
Name: Erez Israeli
Title: Chief Executive Officer

DR. REDDY'S LABORATORIES, INC.

By: s/ Marc Kikuchi
Name: Marc Kikuchi
Title: CEO North America Generics

EXHIBIT 1

[Attached]

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, *et al.*,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-695-CFC
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
Defendants.		

STIPULATION AND [PROPOSED] ORDER

By virtue of a settlement agreement between the parties, and pursuant to Federal Rules of Civil Procedure 41(a)(l) and 41(c), Plaintiffs Teva Pharmaceuticals International GmbH, Cephalon, LLC, and Eagle Pharmaceuticals, Inc. (collectively, "Plaintiffs") and Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") hereby stipulate and agree that Plaintiffs' action against Dr. Reddy's with respect to Dr. Reddy's NDA Product, including all claims and defenses asserted by Plaintiffs against Dr. Reddy's and all claims and defenses asserted by Dr. Reddy's against Plaintiffs with respect to Dr. Reddy's NDA Product, are hereby dismissed with prejudice and without costs, disbursements, or attorneys' fees to any party. It is further stipulated that the U.S. District Court for the District of Delaware retains jurisdiction to enforce and resolve any disputes arising under the Agreement.

Respectfully submitted,

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
Emily S. DiBenedetto (No. 6779)
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Attorneys for Plaintiff Eagle Pharmaceuticals, Inc.

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Wilmington, DE 19801
(302) 999-1540
stamoulis@swdelaw.com

Attorneys for Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

IT IS SO ORDERED this _____ day of _____, 2023

The Honorable Colm F. Connolly

EXHIBIT 2

[Attached]

Eagle Pharmaceuticals Reaches Settlement Agreement with Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. Related to BENDEKA® (bendamustine hydrochloride)

Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle") today announced that it has reached a settlement agreement with Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"). Eagle asserted its Orange Book-listed patents against Dr. Reddy's related to their new drug application referencing BENDEKA®. Under the settlement agreement, Dr. Reddy's has the right to market its product beginning November 17, 2027, or earlier based on certain circumstances. The settlement agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The settlement with Dr Reddy's follows Eagle's previously announced settlement with Hospira, Inc. ("Hospira") and Accord Healthcare, Inc. ("Accord") related to their new drug applications referencing BENDEKA®.