
**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): **August 8, 2022**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36306
(Commission File Number)

20-8179278
(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 Material Definitive Agreement.

On August 8, 2022, Eagle Pharmaceuticals, Inc. (the “Company”) and Enalare Therapeutics Inc. (“Enalare”) entered into a Securities Purchase Agreement, pursuant to which the Company has committed to provide equity investments of up to \$55 million in Enalare (the “Purchase Agreement”). Concurrently with the execution of the Purchase Agreement, the Company, Enalare and holders of all of the outstanding capital stock, and any securities or options exercisable for capital stock, of Enalare (the “Securityholders”) entered into a Security Purchase Option Agreement, pursuant to which the Company has the option (the “Purchase Option”) to acquire all of the remaining outstanding shares of Enalare other than those already owned by the Company subject to the terms and conditions of the agreement (the “Option Agreement”).

The Securities Purchase Agreement:

Pursuant to the Purchase Agreement, the Company made an initial equity investment of \$12.5 million (the “Initial Purchase”) in Enalare on August 8, 2022, pursuant to which the Company acquired 12,451 shares of Enalare common stock, par value \$0.0001 per share (the “Common Stock”). The Purchase Agreement also provides for a second investment in the amount of \$12.5 million no later than February 8, 2023, pursuant to which the Company will acquire an additional 12,451 shares of Common Stock (the “Second Purchase” and, together with the Initial Purchase, the “Initial Investment”). The Initial Investment is expected to support the research, development and commercialization of Enalare’s lead compound, ENA001, an agnostic respiratory stimulant for post-surgery respiratory depression. The Purchase Agreement further provides that upon the achievement of certain milestones, the Company will be required to make two additional equity investments in Enalare, each in an aggregate amount of \$15 million. The first \$15 million investment shall occur upon the dosing of the first patient in a Phase 2 human clinical trial of any product containing the active ingredient ENA-001 (a “Product Candidate”) (such investment, the “First Milestone Share Purchase”). If the First Milestone Share Purchase occurs, the Company would purchase a number of shares representing approximately 9.8% of Enalare. The second \$15 million investment shall occur when patient enrollment in the Phase 2 human clinical trial of a Product Candidate reaches 50% (the “Second Milestone Share Purchase” and, together with the First Milestone Share Purchase, the “Milestone Share Purchases”). If the Second Milestone Share Purchase occurs, the Company would purchase a number of shares representing 9.5% of Enalare. Should the completion of the Milestone Share Purchases occur, the Company would own approximately 33% of Enalare’s outstanding Common Stock.

Pursuant to the terms of the Purchase Agreement, Enalare has agreed not to, without the Company’s prior written consent, and subject to certain conditions and exceptions, among other things, enter into (i) a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of Enalare; (ii) a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of Enalare related to any Product Candidate in the United States; (iii) a sale or other disposition (including through the issuance by Enalare of shares of its capital stock) of at least a majority of the voting power of Enalare; (iv) a merger, consolidation or similar transaction following which Enalare is not the surviving corporation; or (v) a merger, consolidation or similar transaction following which Enalare is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise (each a “Corporate Transaction”). In addition, Enalare shall not enter into a Corporate Transaction (i) while either of the Milestone Share Purchases remains unachieved, (ii) until the Company’s obligation to complete the Milestone Share Purchases is terminated under Section 4.3(e) of the Purchase Agreement, (iii) until the Purchase Agreement is terminated by the Company, or (iv) until the Purchase Agreement is terminated by a written agreement executed by the Company and Enalare.

In the event that (i) both Milestone Share Purchases have not occurred prior to June 30, 2027 or (ii) Enalare undergoes a Corporate Transaction without the Company’s prior written consent, the Company shall have no obligation to effect any further Milestone Share Purchase and such obligations shall terminate and be of no further force and effect. The deadline for the Second Purchase and any Milestone Share Purchase may be extended to the extent necessary for the Company to receive any necessary approvals from regulatory authorities under applicable anti-trust laws or to allow for the lapse of any waiting period under applicable.

The Company’s obligation to effect either Milestone Share Purchase may be terminated upon the Company’s exercise of its Purchase Option pursuant to the Option Agreement, which is described in more detail below. Furthermore, following the closing of the Second Purchase, the Company may terminate the Purchase Agreement and the Option Agreement at any time in its sole and absolute discretion with thirty (30) days’ written notice to Enalare.

The Joint Development Committee

Pursuant to the Purchase Agreement, the Company and Enalare have agreed to establish a joint development committee (“JDC”) to oversee Enalare’s development activities in connection with any Product Candidate. Enalare has the right to appoint up to three members and the Company has the right to appoint up to two members to the JDC. For the first two years following the execution of the Purchase Agreement, the JDC shall meet once per calendar quarter. Following the second anniversary of the execution of the Purchase Agreement, the JDC shall meet semi-annually thereafter.

The Security Purchase Option Agreement

Pursuant to the Option Agreement, the Company has the option (but not the obligation) to acquire, in whole, all of the outstanding shares of Enalare other than those already owned by the Company (i) via a direct acquisition option or (ii) by entering into a definitive agreement with Enalare containing the terms, covenants and conditions set forth in the term sheet attached as Exhibit A to the Option Agreement, in each case for an amount equal to approximately \$100 million to \$175 million in the aggregate plus additional amounts as set forth in the agreement. The term of the Purchase Option (the "Option Period") commenced on August 8, 2022 and will end upon the earlier of (x) 90 days following the U.S. Food and Drug Administration ("FDA") communication of proceed to clinical for a Phase 3 clinical study for a Product Candidate or (y) June 30, 2027. Enalare shall not initiate Phase 3 pivotal studies prior to the end of the Option Period and the Company shall have reasonable access to all relevant data and documents following the Phase 3 Milestone (as defined in the Option Agreement).

Pursuant to the Option Agreement, if a Priority Review Voucher were to be granted with respect to the first Product Candidate, ("PRV"), the Company would be required to pay to the royalty recipients 9-12% of all proceeds received from the sale of any such PRV. If the Company were to use the PRV, if any, for an application, it would be required to pay to the royalty recipients an agreed dollar amount.

The Company may terminate the Option Agreement following the closing of the Second Purchase at any time in its sole and absolute discretion with thirty (30) days' written notice to Enalare.

The foregoing is only a brief description of the material terms of the Purchase Agreement, the Option Agreement, the Initial Investment, Milestone Share Purchases and the Purchase Option, and does not purport to be a complete statement of the rights and obligations of the parties under these agreements and the transactions contemplated thereby, and is qualified in its entirety by the full text of the Purchase Agreement and the Option Agreement, copies of which are attached as Exhibit 10.1 and 10.2, respectively, hereto and incorporated by reference herein.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The information contained in Item 1.01 is hereby incorporated into this Item 2.01.

Item 2.02 Results of Operations and Financial Condition.

On August 9, 2022, the Company issued a press release announcing its financial results for the first fiscal quarter ended June 30, 2022 (the "Earnings Release").

A copy of the Earnings Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information included in Item 1.01 above is hereby incorporated by reference in its entirety into this Item 2.03.

Item 7.01 Regulation FD Disclosure.

On August 9, 2022, the Company issued a press release announcing its entry into the Purchase Agreement and the Option Agreement and the Initial Investment.

A copy of the full text of the press release referenced above is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained in this Item 7.01, including Exhibit 99.2, is being "furnished" and shall not be deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

See Exhibit Index attached hereto.

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,” “could,” “should,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” “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 statements regarding: the Company’s financial projections and guidance, including anticipated financial performance for 2022, including expected R&D and SG&A expense; any further investments in Enalare and Enalare’s development programs; the potential exercise of Eagle’s option to acquire all of Enalare’s outstanding shares; the potential benefits and commercial opportunity of Enalare’s product candidates; the potential of Enalare product candidates to immediately expand Eagle’s long-term growth possibilities, if acquired; expectations that the transaction with Enalare will help improve the care of patients undergoing medical treatments, solidify the Company’s leadership position in the hospital and anesthesia space and bring long-term value to the Company’s shareholders; statements regarding expectations with respect to whether and when the Acacia acquisition may be earnings accretive; expectations with respect to synergies; expectations that the acquisition of Acacia Pharma will help improve the care of patients undergoing medical treatments, solidify the Company’s leadership position in the hospital and oncology space and bring long-term value to the Company’s shareholders; the estimated addressable market size and estimated sales figures for BARHEMSYS and BYFAVO and other products or product candidates; the ability of BARHEMSYS and BYFAVO, as well as the Company’s investment in Enalare, serve to diversify and complement its revenue streams and strengthen its advantage in acute care; the ability of Enalare to advance global development and future commercialization of ENA001 and the Company’s potential acquisition of Enalare in the future, subject to the completion of certain milestones; the Company’s ability to pursue additional potential transactions to further diversify its product portfolio and pipeline on favorable terms or at all; the Company’s ability to obtain and maintain regulatory approval of its products and product candidates; 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 Company’s timing and ability to enroll patients in upcoming clinical trials, including for CAL02; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates, including landiolol and its fulvestrant product; the progress and success of the Company’s launch of any products, including vasopressin and PEMFEXY; the addressable market size for, and the ability of the Company to successfully commercialize, its product candidates, including vasopressin and PEMFEXY; the ability of vasopressin to benefit providers and patients as an alternative to Vasostriect; the ability of BARHEMSYS, BYFAVO, landiolol, ENA-001 and other products and product candidates to address unmet clinical needs; the potential market opportunity for the Company’s products or product candidates, including for BARHEMSYS, BYFAVO and landiolol; the period of marketing exclusivity for any of the Company’s products or product candidates, including vasopressin; the resolution of patent litigation and all related settlement terms, including the date of market entry and the potential for earlier market entry under certain circumstances; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates and the Company’s ability to maintain regulatory approval of its products and product candidates; the Company’s clinical development plan for the product candidates in its portfolio; the implementation of certain healthcare reform measures; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; 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 ability of the Company’s executive team to execute on the Company’s strategy and to utilize its cash and other assets to increase shareholder value; and the ability of the Company’s product candidates to deliver value to stockholders; the Company’s ability to deliver value in 2022 and over the long term; the Company’s ability to sustain and accelerate this growth; the Company’s ability to utilize its cash and other assets to increase shareholder value; the Company’s ability to effectively manage and control expenses in line with its budget; and the Company’s plans and ability to advance the products in its pipeline; potential opportunities for, and the Company’s ability to complete, 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 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 recently completed transaction with Acacia Pharma and the transaction with Enalare are not realized; 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, such as 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, including landiolol and ENA001; whether the Company can successfully market and commercialize its products or 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 the Company’s 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 factors in addition to the foregoing that may impact the Company’s financial projects and guidance, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, 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, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 8, 2022, the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, and its other subsequent filings with the SEC, including the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which the Company expects to file with the SEC on August 9, 2022. Readers are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements contained in this Current Report on Form 8-K 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
<u>10.1*†</u>	<u>Securities Purchase Agreement, by and between the Registrant and Enalare Therapeutics Inc., dated August 8, 2022.</u>
<u>10.2*†</u>	<u>Security Purchase Option Agreement, by and between the Registrant, Enalare Therapeutics Inc. and the other parties thereto, dated August 8, 2022.</u>
<u>99.1</u>	<u>Earnings Release, dated August 9, 2022.</u>
<u>99.2</u>	<u>Press Release, dated August 9, 2022.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any omitted schedules upon request by the Securities and Exchange Commission; provided, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedules or exhibits so furnished.

† 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: August 9, 2022

EAGLE PHARMACEUTICALS, INC.

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

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [*], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement, dated as of August 8, 2022 (the “**Agreement**”), is by and between Enalare Therapeutics Inc., a Delaware corporation with its principal offices at 161 Hodge Road, Princeton, NJ 08540 (the “**Company**”), and Eagle Pharmaceuticals, Inc., a Delaware corporation with its principal offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, NJ 07677 (the “**Purchaser**”). Each the Company and Purchaser are a “**Party**” and collectively referred to herein as the “**Parties**.”

WHEREAS, the Company desires to issue and sell to the Purchaser a number of shares (each a “**Share**” and collectively, as applicable, the “**Shares**”) of the common stock, par value \$0.0001 per share (the “**Common Stock**”) of the Company and the Purchaser desires to purchase and acquire the Shares, all on the terms and subject to the conditions as set forth in this Agreement;

WHEREAS, the Purchaser desires to provide further payments and to purchase additional Shares, and the Company desires to issue and sell such Shares, upon the occurrence of certain milestone events as described herein;

WHEREAS, the Company and the Purchaser are executing and delivering this Agreement in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the “**Securities Act**”), and Rule 506 of Regulation D (“**Regulation D**”) as promulgated by the U.S. Securities and Exchange Commission (the “**SEC**”) under the Securities Act;

WHEREAS, simultaneously with the entry into this Agreement, the Company, the Purchaser and all of the Securityholders have entered into a Security Purchase Option Agreement attached hereto as **Exhibit A** (the “**Security Purchase Option Agreement**”), pursuant to which the Securityholders are granting the Purchaser the option to purchase all of the Company capital stock held by such Securityholders on the terms set forth therein, following the execution of such option the Purchaser would hold 100% of the outstanding capital stock of the Company;

WHEREAS, it is a condition to the consummation of the transactions contemplated by this Agreement for the parties to amend and restate the Stockholders’ Agreement in the form attached hereto as **Exhibit B** (the “**A&R Stockholders Agreement**”), pursuant to which the Company will agree to provide certain rights to the Purchaser in respect of the Purchaser’s ownership of the Shares following the entry into this Agreement.

NOW THEREFORE, in consideration of the mutual agreements, representations, warranties and covenants herein contained, the Parties hereto agree as follows:

1. **Definitions.** In addition to those capitalized terms otherwise defined in this Agreement, as used in this Agreement, the following capitalized terms shall have the following respective meanings:

(a) **"Affiliate"** of a Party, means any corporation or other business entity controlled by, controlling or under common control with such Party. For this purpose, "control" shall mean direct or indirect beneficial ownership of fifty percent (50%) or more of the voting or income interest in such corporation or other business entity.

(b) **"Associate"** means (i) a corporation or organization of which such person is an officer or partner or is, directly or indirectly, the beneficial owner of 10 percent or more of any class of equity securities; (ii) any trust or other estate in which such person has a substantial beneficial interest or as to which such person serves as trustee or in a similar capacity; and (iii) any relative or spouse of such person.

(c) **"A&R Stockholders' Agreement"** has the meaning set forth in the Recitals.

(d) **"Business Day"** means any calendar day other than a Saturday, Sunday or other day on which banks in New York City are authorized or required to be closed.

(e) **"Combination Product"** means: [***].

(f) **"Company Owned IP"** means all intellectual property rights owned or purported to be owned by the Company (whether exclusively or jointly with any other Person).

(g) **"Company Registered IP"** shall mean each item of Company Owned IP that is Registered IP.

(h) **"Corporate Transaction"** shall mean any of (i) a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company; (ii) a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company related to the Products in the United States; (iii) a sale or other disposition (including through the issuance by the Company of shares of its capital stock) of at least a majority of the voting power of the Company; (iv) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or (v) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise. It is agreed and understood that the transactions contemplated by the Security Purchase Option Agreement are not a Corporate Transaction for purposes of this Agreement.

(i) **"Development"** or **"Develop"** means all activities that relate to the development of Products, including, but not limited to, all interactions with Regulatory Authorities, management of the clinical development program, and oversight of the manufacturing of clinical supplies and registration batches.

(j) **"Exchange Act"** means the Securities Exchange Act of 1934, as amended

(k) **"FDA"** means the U.S. Food and Drug Administration or successor entity thereto.

- (l) “**First Milestone Date**” means the later of (i) the date of the achievement of the First Milestone Event or (ii) the three-month anniversary of the Second Closing Date.
- (m) “**First Milestone Event**” means the dosing of the first patient at the first trial site for a Phase 2 Clinical Trial for the Initial Indication.
- (n) “**First Milestone Per Share Price**” means a price per share of Common Stock equal to the quotient of:
- (i) \$[***] plus [***]; provided that, (1) [***], and (2) [***]; and
- (ii) the number of fully diluted capital stock of the Company as of the date of the First Milestone Date (including shares of Common Stock issued as a result of the conversion of all securities convertible into Common Stock, and the exercise of all outstanding options and warrants, and all shares of Common Stock reserved and available for future grant under the Stock Plan).
- (o) “**Generic Product**” means, with respect to a particular pharmaceutically active ingredient (including the Product) (“**Original Product**”) and a particular country, any pharmaceutical product that: (a) contains the same active pharmaceutical ingredient(s) as such Original Product, (b) is approved by the regulatory authority in such country as a substitutable generic for such Original Product or otherwise is approved as a therapeutic equivalent to such Product in a manner that relied on or incorporated data submitted by a Person (the “**Filing Entity**”), in connection with the regulatory filings for such Product, including through an ANDA or an application under §505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or any enabling legislation thereof, or any similar procedure outside the United States, in each case now or in the future, and (c) is sold in such country by a Person other than by or on behalf of such Filing Entity.
- (p) “**Governmental Body**” shall mean any national, federal, regional, state, provincial, local, or foreign or other governmental authority or instrumentality, legislative body, court, administrative agency, regulatory body, commission or instrumentality, including any multinational authority having governmental or quasi-governmental powers, or any other industry self-regulatory authority or arbitral body.
- (q) “**Knowledge of the Company**,” or any derivation thereof, means the actual knowledge of [***].
- (r) “**Initial Closing Date**” means the date of the Initial Closing.
- (s) “**Initial Indication**” means the indication or indications for use in the post-operative respiratory depression setting.
- (t) “**Initial Per Share Price**” means \$1,003.91.
- (u) “**Law**” means any federal, state, local, municipal, foreign or other law, statute, constitution, principle of common law, rule, regulation, executive order, injunction, judgment, order, award, decree, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body.

- (v) “**Milestone Closing Date**” means the date of the applicable Milestone Closing.
- (w) “**Milestone Date**” means the First Milestone Date or the Second Milestone Date, as applicable.
- (x) “**Milestone Event**” means the First Milestone Event or the Second Milestone Event, as applicable.
- (y) “**Milestone Investment Amount**” means \$15,000,000.00.
- (z) “**Milestone Representations**” has the meaning set forth in Section 8.1(a)(ii).
- (aa) “**Milestone Share Purchase**” means the First Milestone Share Purchase or the Second Milestone Share Purchase, as applicable.
- (bb) “**Patent(s)**” means all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, foreign equivalents and the like of any of the foregoing.
- (cc) “**Person**” shall be construed as broadly as possible and shall include an individual person, a partnership (including a limited liability partnership), a corporation, an association, a joint stock company, a limited liability company, a trust, a joint venture, an unincorporated organization and a Governmental Body.
- (dd) “**Phase 2 Clinical Trial**” means a human clinical trial of any Product, the principal purpose of which is to evaluate the effectiveness and/or safety of such Product in the target patient population, as described in 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding foreign regulations, and which trial is intended to be the final clinical trial before the initiation of a pivotal clinical trial and to establish the dosing for such pivotal clinical trial.
- (ee) “**Product**” means [***].
- (ff) “**Registered IP**” means all intellectual property rights that are registered, filed, or issued under the authority of any Governmental Body, including all patents, registered copyrights, registered mask works, internet domain name registrations and registered trademarks and all applications for any of the foregoing.
- (gg) “**Regulatory Authorities**” means the FDA and comparable regulatory agencies outside of the United States.
- (hh) “**Second Closing Date**” means the date of the Second Closing.

(ii) “**Second Milestone Date**” means the later of (i) the date of the achievement of the Second Milestone Event in accordance with Section 4.1(b) or (ii) the six-month anniversary of the First Milestone Share Purchase.

(jj) “**Second Milestone Event**” means the fifty percent (50%) enrollment of the first Phase 2 Clinical Trial in accordance with the Phase 2 Clinical Trial protocol for the Initial Indication.

(kk) “**Second Milestone Per Share Price**” means a price per share of Common Stock equal to the quotient of:

(i) \$[***] plus [***]; provided that, (1) [***], and (2) [***]; and

(ii) the number of fully diluted capital stock of the Company as of the date of the Second Milestone Date (including shares of Common Stock issued as a result of the conversion of all securities convertible into Common Stock, and the exercise of all outstanding options and warrants, and all shares of Common Stock reserved and available for future grant under the Stock Plan).

(ll) “**Securityholders**” has the meaning assigned to it in the Security Purchase Option Agreement.

(mm) “**Stockholders’ Agreement**” means the Stockholders’ Agreement of the Company, dated as of November 13, 2020, by and among the Company, the Stockholders (as defined therein), and the Interest Holders (as defined therein).

(nn) “**Tax**” means (i) any and all U.S. federal, state, local and non U.S. taxes, rates, levies, assessments and other charges, duties, impositions and liabilities, including taxes based upon or measured by gross receipts, gross or net income, profits, property, sales, use and occupation, and value added, ad valorem, transfer, franchise, withholding, payroll, recapture, escheat, abandoned or unclaimed property, employment or unemployment, excise and property taxes as well as public imposts, fees, capital or capital stock tax, customs and import duties, stamp tax, franchise tax, goods and services tax and social security charges (including health, unemployment, workers’ compensation and pension insurance), together with all interest, penalties, fines and additions imposed with respect to such amounts, (ii) any liability for the payment of any amounts of the type described in clause (i) above as a result of being (or having been) a member of an affiliated, consolidated, combined, unitary or similar group for any period (including any arrangement for group or consortium relief or similar arrangement), and (iii) any liability for the payment of any amounts of the type described in clauses (i) or (ii) above as a result of any express or implied obligation to indemnify any other Person or as a result of any obligation under any agreement or arrangement with any other Person with respect to such amounts and including any liability for Taxes of a predecessor or transferor or otherwise by operation of Law.

(oo) “**Tax Return**” means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate, claim for refund or other document or information, in each case, filed with or submitted to, or required by Law to be filed with or submitted to, any governmental entity in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax, including any schedule thereto, amendment thereof or attachment thereto.

(pp) “**Third Party**” means any Person other than other than a Party or an Affiliate of a Party.

(qq) “**Transaction Documents**” means this Agreement, the A&R Stockholders' Agreement and the Security Purchase Option Agreement.

2. Sale and Issuance of Shares at the Initial Closing and Second Closing.

2.1 Restated Certificate. The Company shall have adopted and filed with the Secretary of State of the State of Delaware on or before the Initial Closing (as defined below) the Amended and Restated Certificate of Incorporation in the form of **EXHIBIT C** attached to this Agreement (the “**Restated Certificate**”).

2.2 Initial Purchase and Sale of Shares. Subject to and upon the terms and conditions set forth in this Agreement, the Company shall sell and issue to the Purchaser in two closings, and Purchaser shall purchase from the Company, at the Initial Closing, 12,451 Shares at the Initial Per Share Price for an aggregate purchase price of \$12,500,000 million (the “**Initial Purchase**”), and at the Second Closing, 12,451 Shares at the Initial Per Share Price for an aggregate purchase price of \$12,500,000 million (the “**Second Purchase**”). Purchaser acknowledges and agrees that any fractional Share has been rounded down to the nearest whole Share.

2.3 Initial Closing and Second Closing.

(a) Subject to the satisfaction or waiver of the conditions set forth in Section 8 of this Agreement, the Initial Purchase shall take place on the date hereof (the “**Initial Closing**”) and the Second Purchase shall take place on or before the sixth month anniversary of the Initial Closing on a date selected by the Purchaser in its sole discretion (the “**Second Closing**”).

(b) Within [***] Business Days of the Initial Closing, the Company shall deliver to the Purchaser a stock certificate representing the Shares being purchased and acquired by the Purchaser in the Initial Purchase. Within [***] Business Days following the Second Closing, the Company shall deliver to the Purchaser a stock certificate representing the Shares being purchased and acquired by the Purchaser in the Second Purchase.

(c) At the Initial Closing, the Purchaser shall make payment of the aggregate price of the Initial Purchase in immediately available funds by wire transfer to an account of the Company designated in writing by the Company. At the Second Closing, the Purchaser shall make payment of the aggregate price of the Second Purchase in immediately available funds by wire transfer to an account of the Company designated in writing by the Company.

2.4 Withholding Taxes. The Purchaser and any of its agents or Affiliates shall be entitled to deduct and withhold from any amounts payable or otherwise deliverable pursuant to this Agreement to any Person such amounts as may be required to be deducted or withheld therefrom under any provision of federal, state, local or non-U.S. Tax Law or under any applicable Law, and be provided any necessary Tax forms, including a valid IRS Form W-9 or the appropriate version of IRS Form W-8, as applicable, and any similar information, including any information for U.S. state or local or non-U.S. purposes. To the extent that such amounts are so deducted or withheld, such amounts shall be treated for all purposes under this Agreement as having been paid to the Person to whom such amounts would otherwise have been paid. To the extent that any payment to any Person is not reduced by such deductions or withholdings, such Person shall indemnify Purchaser and its Affiliates for any amounts imposed by any Governmental Body with respect to any such Taxes, together with any costs and expenses relating thereto (including reasonable attorneys' fees and costs of investigation).

3. Joint Development Committee.

3.1 Formation and Role. Promptly, and in any event within [***] days after the date hereof, the Parties shall establish a joint development committee (the “**JDC**”) to oversee the Company’s Development activities in connection with the Products.

3.2 Members. Company shall initially appoint up to three (3) representatives to the JDC, and Purchaser shall initially appoint up to two (2) representatives to the JDC. Each of these representatives will be an officer, employee, consultant, or advisor of the applicable Party having sufficient knowledge regarding the Development of the Products. The JDC may change its size from time to time by the unanimous consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. The JDC shall elect a chairperson among its members by a majority vote of the total number of representatives.

3.3 Meetings. For the first two years following the date hereof, the JDC shall meet once per calendar quarter. Following the second anniversary of the date hereof, the JDC shall meet semi-annually thereafter. Meetings of the JDC may be held in person, by audio or video teleconference, as determined by the Parties. Each Party shall be responsible for all of its own expenses of participating in the JDC. The JDC shall continue to exist until the earlier of (i) the exercise of the Purchase Option (as defined in the Security Purchase Option Agreement) by the Purchaser or (ii) the expiration of the Option Term (as defined in the Security Purchase Option Agreement). The chairperson shall be responsible for calling meeting on thirty (30) days’ prior written notice (which may be delivered by electronic mail). Each Party shall make proposals for agenda items and shall provide all appropriate information with respect to such proposed item at least ten (10) Business Days in advance of the meeting. The chairperson shall prepare and circulate for review and approval of the Parties minutes of each meeting within thirty (30) days from the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JDC.

3.4 Quorum. A quorum of the JDC shall exist whenever there is present at a meeting at least (a) two (2) of the representatives appointed by the Company, and (b) one (1) of the representatives appointed by the Purchaser. If the quorum is met, the JDC shall take action by majority vote of the representatives present at a meeting, or by a written resolution signed by at least (i) two (2) of the representatives appointed by the Company, and (ii) one (1) of the representatives appointed by the Purchaser.

3.5 Duties. The JDC shall:

- (a) review the protocol for Phase 2 Clinical Trial;
- (b) recommend the Initial Indication for Phase 2 Clinical Trial;
- (c) review the strategy of Development for the Products, including reviewing the development plan;
- (d) review the activities and the protocol for the Phase 2 Clinical Trial of the Products proposed to be conducted by or on behalf of Company; and
- (e) undertake such other matters as are specifically assigned to the JDC in this Agreement.

3.6 Limitation of JDC Authority; Information Sharing. The JDC shall be a non-voting body and is intended as an operational and informational sharing committee that discusses Company's Development activities and strategies to reach the Milestone Events. The JDC may suggest actions to both Parties to reach the aforementioned aims under this Agreement, and, where necessary, suggest amendments to this Agreement or any of its Exhibits. However, the JDC shall not have the power to make decisions under this Agreement and, for clarity, the JDC shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; or (c) decide any such issue in a manner that would conflict with the express terms and conditions of this Agreement. In addition, a Party shall not be in breach of this Agreement for failing to follow any suggestions or proposed actions of the JDC nor shall any director or officer of the Company be deemed to have breached his or her fiduciary duties to the Company solely as a result of not following any suggestions or proposed actions of the JDC.

4. Milestone Events Transactions.

4.1 Milestone Share Purchase. Subject to the conditions set forth in Section 8:

(a) Upon the Company's first achievement of the First Milestone Event, the Company shall sell and issue to the Purchaser, and Purchaser shall purchase from the Company, a number of Shares (with any fractional shares being rounded down to the nearest whole Share) equal to the Milestone Investment Amount divided by the First Milestone Per Share Price (the "**First Milestone Share Purchase**"); and

(b) Upon the Company's first achievement of the Second Milestone Event, the Company shall sell and issue to the Purchaser, and Purchaser shall purchase from the Company, a number of Shares (with any fractional shares being rounded down to the nearest whole Share) equal to the Milestone Investment Amount divided by the Second Milestone Per Share Price (the "**Second Milestone Share Purchase**"). In the event the Second Milestone Event is achieved prior to the First Milestone Event, Purchaser shall not be required to complete the Second Milestone Share Purchase until the First Milestone Event is achieved.

4.2 No Repeat Milestones. For the avoidance of doubt, the first Milestone Event achieved by the Company shall be the only triggering event for the obligations and transactions described in this Section 4. Purchaser shall only be obligated to make a maximum of one Milestone Share Purchase for the achievement of each Milestone Event.

4.3 Milestone Closing.

(a) Subject to the satisfaction or waiver of the conditions set forth in Sections 8.1 and 8.2 of this Agreement, each Milestone Share Purchase shall take place on the date that is [***] Business Days after the applicable Milestone Date (each such closing, the "**Milestone Closing**" and together, the "**Milestone Closings**").

(b) Within [***] Business Days of each Milestone Closing, the Company shall deliver to Purchaser a stock certificate representing the Shares being purchased and acquired by Purchaser in the applicable Milestone Share Purchase.

(c) At each Milestone Closing, Purchaser shall make payment of the aggregate amount of the Milestone Investment Amount in immediately available funds by wire transfer to an account of the Company designated in writing by the Company.

(d) Notwithstanding anything contained in Section 4 (including this Section 4.3) to the contrary, the Company shall not enter into a Corporate Transaction (i) while either Milestone Event remains unachieved, (ii) until the Milestone Share Purchase obligation is terminated under Section 4.3(e) below, (iii) until this Agreement is terminated by the Purchaser pursuant to Section 11.20, or (iv) until this Agreement is terminated by a written agreement executed by the Purchaser and the Company.

(e) Notwithstanding anything contained in Section 2 or Section 4 (including this Section 4.3) to the contrary, (i) in the event that both Milestone Events have not occurred prior to June 30, 2027, the Purchaser (and the Company if requested by the Purchaser) shall have no obligation to effect such Milestone Share Purchase and such obligations shall terminate and be of no further force and effect and (ii) the deadline for the Second Closing and any Milestone Closing may be extended to the extent necessary for the Purchaser to receive any necessary approvals from regulatory authorities under applicable anti-trust laws or to allow for the lapse of any waiting period under applicable anti-trust laws; provided, that Purchaser shall use best efforts to obtain such anti-trust clearances.

5. [Reserved.]

6. Representations and Warranties of the Company. The Company hereby represents and warrants to the Purchaser that, except as set forth on the Disclosure Schedule attached as **EXHIBIT D** to this Agreement, the following representations are true and complete as of the date of the Initial Closing (and as of the Second Closing Date and each Milestone Closing in all material respects), except as otherwise indicated. The Disclosure Schedule shall be arranged in sections corresponding to the numbered and lettered sections contained in this Section 6, and the disclosures in any section of the Disclosure Schedule shall qualify other sections in this Section 6 only to the extent it is readily apparent from a reading of the disclosure that such disclosure is applicable to such other sections.

6.1 Incorporation. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and is qualified to do business in each jurisdiction in which the character of its properties or the nature of its business requires such qualification, except where the failure to be in so good standing or to qualify would not have, individually or in the aggregate, a Material Adverse Effect (as defined below) upon the Company. The Company has all requisite corporate power and authority to carry on its business as now being conducted. The Company has no subsidiaries of any kind and does not hold capital stock, membership interest, equity or similar ownership interest in any other Person.

6.2 Capitalization.

(a) The authorized capital of the Company consists, immediately prior to the Initial Closing, of 300,000 shares of common stock, \$0.0001 par value per share (the “**Common Stock**”), 90,000 shares of which are issued and outstanding immediately prior to the Initial Closing. All of the outstanding shares of Common Stock have been duly authorized, are fully paid and nonassessable and were issued in compliance with all applicable federal and state securities laws. The Company holds no Common Stock in its treasury. The Company has not authorized any other series or classes of capital stock, including preferred stock.

(b) The Company has reserved 10,000 shares of Common Stock for issuance to officers, directors, employees and consultants of the Company pursuant to its 2020 Equity Incentive Plan duly adopted by the Board of Directors and approved by the Company stockholders (the “**Stock Plan**”). Of such reserved shares of Common Stock, no shares have been issued pursuant to restricted stock purchase agreements, options to purchase 2,480 shares have been granted and are currently outstanding, and 7,520 shares of Common Stock remain available for issuance to officers, directors, employees and consultants pursuant to the Stock Plan. The Company has furnished to the Purchaser complete and accurate copies of the Stock Plan and forms of agreements used thereunder.

(c) Schedule I sets forth the capitalization of the Company immediately following the Initial Closing including the number of shares of the following: (i) issued and outstanding Common Stock, including, with respect to restricted Common Stock, vesting schedule and repurchase price; (ii) outstanding stock options, including vesting schedule and exercise price; (iii) shares of Common Stock reserved for future award grants under the Stock Plan; (iv) the currently outstanding convertible promissory notes issued by the Company (the “**Notes**”), including the outstanding principal and interest under each Note and the amount of Common Stock that each Note will be convertible into, and (v) warrants or stock purchase rights, if any. Except for (A) the Common Stock to be issued following the conversion of the Notes, and (B) the securities and rights described in Section 6.2(b) of this Agreement, there are no outstanding options, warrants, rights (including conversion or preemptive rights and rights of first refusal or similar rights) or agreements, orally or in writing, to purchase or acquire from the Company any shares of Common Stock, or any securities convertible into or exchangeable for shares of Common Stock.

(d) As of the date of the Initial Closing, all of the Company's stock purchase agreements (that are for the purchase of restricted shares), employment agreements or employment offer letters, and stock option documents contain a provision for the acceleration of vesting (or lapse of a repurchase right) or other changes in the vesting provisions or other terms of such agreement or understanding upon the occurrence of any event or combination of events, including, without limitation, a Change in Control (as defined in the Company's Stock Plan), a change in control as described in the employment agreements or employment offer letters, or in the case where the Company's Stock Plan is not assumed in an acquisition. The Company has never adjusted or amended the exercise price of any stock options previously awarded, whether through amendment, cancellation, replacement grant, repricing, or any other means. Except as set forth in the Restated Certificate, the Company has no obligation (contingent or otherwise) to purchase or redeem any of its capital stock.

(e) The Company believes in good faith that any "nonqualified deferred compensation plan" (as such term is defined under Section 409A(d)(1) of the Code and the guidance thereunder) under which the Company makes, is obligated to make or promises to make, payments (each, a "**409A Plan**") complies in all material respects, in both form and operation, with the requirements of Section 409A of the Code and the guidance thereunder. To the knowledge of the Company, no payment to be made under any 409A Plan is, or will be, subject to the penalties of Section 409A(a)(1) of the Code.

(f) The Company has obtained valid waivers of any rights by other parties to purchase any of the Shares covered by this Agreement.

6.3 Subsidiaries. The Company does not currently own or control, directly or indirectly, any interest in any other corporation, partnership, trust, joint venture, limited liability company, association, or other business entity. The Company is not a participant in any joint venture, partnership or similar arrangement.

6.4 Authorization. All corporate action required to be taken by the Company's Board of Directors and stockholders in order to authorize the Company to enter into the Transaction Documents, and to issue the Shares at the Initial Closing and Second Closing has been taken or will be taken prior to the Initial Closing or the Second Closing, as applicable. All action on the part of the officers of the Company necessary for the execution and delivery of the Transaction Documents, the performance of all obligations of the Company under the Transaction Documents to be performed as of the Initial Closing, and the issuance and delivery of the Shares has been taken or will be taken prior to the Initial Closing. The Transaction Documents, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors' rights generally, or (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

6.5 Valid Issuance of the Shares. The Shares have been duly authorized and, when issued and paid for in accordance with the terms of this Agreement, will be duly and validly issued, fully paid and non-assessable and free and clear of all liens imposed or permitted by the Company, other than restrictions on transfer provided for in the Restated Certificate, the Company's bylaws, this Agreement, the Stockholders' Agreement, or imposed by applicable securities laws. Assuming the accuracy of the representations and warranties of the Purchaser in this Agreement, the Shares will be issued in compliance with all applicable federal and state securities laws. Neither the Company nor, to the knowledge of the Company, any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. Neither the Company nor any person acting on its behalf has, directly or indirectly, made any offers or sales of any Company security or solicited any offers to buy any Company security, under circumstances that would adversely affect reliance by the Company on Section 4(a)(2) for the exemption from registration for the transactions contemplated hereby or would require registration of the Shares under the Securities Act.

6.6 Use of Proceeds. The net proceeds of the sale of the Shares hereunder shall be used by the Company to continue the development of its clinical and preclinical assets and for general corporate purposes, capital expenditures, working capital and general and administrative expenses.

6.7 Compliance with Laws. The Company is, and since September 24, 2019 has been, in compliance in all material respects with all applicable Laws. No investigation, claim, suit, proceeding, audit or other action by any Governmental Body or authority is pending or, to the Knowledge of the Company, threatened in writing against the Company. There is no agreement, judgment, injunction, order or decree binding upon the Company which has or would reasonably be expected to have the effect of prohibiting or materially impairing any business practice of the Company, any acquisition of material property by the Company or the conduct of business by the Company as currently conducted.

6.8 No Conflict. The execution and delivery of the Transaction Documents by the Company and the consummation of the transactions contemplated hereby will not conflict with or result in any violation of or default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation (other than the conversion of the Notes and, in the event the Purchaser exercises its Purchase Option under the Security Purchase Option Agreement, the acceleration of vesting with respect to options issued under the Company's Stock Plan and the lapsing of repurchase rights under stock purchase agreements for the purchase of restricted Shares) or to a loss of a material benefit under (i) any provision of the Restated Certificate of Incorporation or bylaws of the Company or (ii) any agreement or instrument, permit, franchise, license, judgment, order, statute, law, ordinance, rule or regulations applicable to the Company or its properties or assets, except in the case of clause (ii) to the extent that such violations and defaults would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on the Company and its properties and assets. The Company is not in material violation, default or breach under any of its material contracts.

6.9 Tax Matters. The Company has prepared and timely filed all U.S. federal, state and local income tax returns and other material tax returns required to have been filed by it with all appropriate governmental agencies, and all such tax returns are true and correct in all material respects and have been complete in accordance with applicable Laws, and the Company has timely paid all taxes it was required to pay when due (whether or not shown thereon). There are no assessments against the Company and the Company is not subject to any audit or examination of any tax return by any taxing authority. All taxes that the Company is required to withhold or to collect for payment have been duly withheld and collected and timely paid over to the proper governmental entity or Third Party when due. There are no tax liens pending or threatened against the Company or any of its assets or property. There are no outstanding tax sharing agreements or other such arrangements between the Company and any other corporation or entity. The Company is not and has never been a “U.S. real property holding corporation” within the meaning of Section 897 of the Internal Revenue Code of 1986 (“Code”), as amended. The Company has not ever constituted either a “distributing corporation” or a “controlled corporation” in a distribution of stock intended to qualify for Tax-free treatment under Sections 355 or 361 of the Code. The Company is not, and will not become, a “personal holding company” within the meaning of Section 542 of the Code. No claim has ever been made by a governmental entity that the Company is or may be subject to taxation in a jurisdiction in which it does not file tax returns. The Company has never (A) been a member of a group of entities that filed or was required by Law to file a consolidated, combined, unitary or similar Tax Return; (B) been a party to any Tax sharing, indemnification or allocation agreement, nor does the Company owe any amount under any such agreement; or (C) had any liability for the Taxes of any person under Treasury Regulations Section 1.1502-6 (or any similar provision of state, local or non-U.S. Law, and including any arrangement for group or consortium relief or similar arrangements) as a transferee or successor, by contract or agreement, by operation of Law or otherwise. The Company is and always has been properly classified as a domestic C corporation for U.S. federal income Tax purposes, and has comparable status under the laws of any other jurisdiction in which it was required to file any tax return at the time it was required to file such tax return. The Company will not be required to include any income or gain or exclude any deduction or loss from taxable income for any Tax period or portion thereof ending after the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, as a result of (A) any adjustment under Section 481 of the Code (or any corresponding or similar provision of state, local or non-U.S. Tax Law) by reason of a change in a method of accounting, or use of an improper method of accounting for a taxable period that ends on or prior to the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, (B) any closing agreement under Section 7121 of the Code (or any corresponding or similar provision of state, local or non-U.S. Law) entered into on or prior to the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, (C) any installment sale or open transaction disposition made on or prior to the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, or (D) receipt of a prepaid amount or deferred revenue accrued on or prior to the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, other than in the ordinary course of business. The Company does not have, and never has had, any direct or indirect interest in any trust, partnership, corporation, limited liability company, or other “business entity” for U.S. federal income tax purposes. The Company has collected, remitted and reported to the appropriate Tax authority all sales, use, value added, excise and similar Taxes required to be so collected, remitted or reported pursuant to all applicable Tax Laws. The Company has complied in all material respects with all applicable Laws relating to record retention (including to the extent necessary to claim any exemption from Tax collection and maintaining adequate and current resale certificates to support any such claimed exemption). No shares of Company capital stock were issued in connection with the performance of services and subject to vesting for which no valid and timely election was filed pursuant to Section 83(b) of the Code. The Company has delivered or made available to Purchaser correct and complete copies of all election statements under Section 83(b) of the Code, together with evidence of timely filing of such election statements with the appropriate Internal Revenue Service office with respect to any share of Company capital stock that was initially subject to a vesting arrangement (or other “substantial risk of forfeiture” within the meaning of Section 83 of the Code) issued by the Company to any of its employees, non-employee directors, consultants or other service providers. The Company has made available to Purchaser complete and correct copies of all federal income Tax Returns and all other material Tax Returns of the Company relating to Taxes for all taxable periods ending on or after December 31, 2018.

6.10 Title to Properties. The Company has good and marketable title to all real properties and all other material properties and assets owned by them, in each case free from liens, encumbrances and defects, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect; and the Company holds any leased real or personal property under valid and enforceable leases with no exceptions, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

6.11 Employee Matters.

(a) To the Company's knowledge, none of its employees is obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would materially interfere with such employee's ability to promote the interest of the Company or that would conflict with the Company's business. Neither the execution or delivery of the Transaction Documents, nor the carrying on of the Company's business by the employees of the Company, nor the conduct of the Company's business as now conducted and as presently proposed to be conducted, will, to the Company's knowledge, conflict with or result in a breach of the terms, conditions, or provisions of, or constitute a default under, any contract, covenant or instrument under which any such employee is now obligated.

(b) The Company is not delinquent in payments to any of its employees, consultants, or independent contractors for any wages, salaries, commissions, bonuses, or other direct compensation for any service performed for it to the date hereof or amounts required to be reimbursed to such employees, consultants or independent contractors. The Company has complied in all material respects with all applicable state and federal equal employment opportunity laws and with other laws related to employment, including those related to wages, hours, worker classification and collective bargaining. The Company has withheld and paid to the appropriate governmental entity or is holding for payment not yet due to such governmental entity all amounts required to be withheld from employees of the Company and is not liable for any arrears of wages, taxes, penalties or other sums for failure to comply with any of the foregoing.

(c) The Company does not have a present intention to terminate the employment of any senior employee. The employment of each employee of the Company is terminable at the will of the Company. Except as required by law, upon termination of the employment of any such employees, no severance or other payments will become due. The Company has no policy, practice, plan or program of paying severance pay or any form of severance compensation in connection with the termination of employment services.

(d) The Company has not made any representations regarding equity incentives to any officer, employee, director or consultant that are inconsistent with the share amounts and terms set forth in the minutes of meetings of (or actions taken by unanimous written consent by) the Company's Board of Directors.

6.12 Employee and Contractor Agreements. Each current and former founder, employee, consultant, contractor and officer of the Company has executed an agreement with the Company regarding confidentiality and proprietary information substantially in the form or forms delivered to the Purchaser or its counsel (the "**Confidential Information Agreements**"). No current or former employee has excluded works or inventions from his or her assignment of inventions pursuant to such employee's Confidential Information Agreement. Each current and former employee has executed a non-competition and non-solicitation agreement substantially in the form or forms delivered to the Purchaser or its counsel. The Company is not aware that any of its employees is in violation of any agreement described in this Section 6.12. No current or former founder, employee, consultant, contractor or officer of the Company has any ownership right, title, or interest in or to any Company Intellectual Property.

6.13 Corporate Documents. The Certificate of Incorporation and bylaws of the Company as of the date of this Agreement are in the form provided to the Purchaser. The copy of the minute books of the Company provided to the Purchaser contains minutes of all meetings of directors and stockholders and all actions by written consent without a meeting by the directors and stockholders since the date of incorporation and accurately reflects in all material respects all actions by the directors (and any committee of directors) and stockholders.

6.14 ERISA Compliance. A "**Benefit Plan**" is an "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "**ERISA**")) that (i) is established or maintained by the Company or its "ERISA Affiliates" (as defined below), or (ii) provides benefits or compensation to any current or former employee with respect to their employment or services with the Company or an ERISA Affiliate pursuant to a professional employer organization (PEO) agreement (each, a "**Benefit Plan**"); provided that, an employee benefit plan described in (ii) above shall be considered a Benefit Plan only to the extent of the participation of the Company or an ERISA Affiliate in that Benefit Plan. Each Benefit Plan is in compliance in all material respects with ERISA. "**ERISA Affiliate**" means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Code of which the Company is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any Benefit Plan. No Benefit Plan, if such Benefit Plan were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code, in each case except as would not, individually or in the aggregate, have a Material Adverse Effect. Each Benefit Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification. Notwithstanding anything in this subsection Section 6.14 to the contrary, with respect to any representation herein that applies to any "employee benefit plan" that is not established or maintained by the Company or an ERISA Affiliate, such representation shall be deemed to be made to the Company's knowledge.

6.15 Environmental Matters. The Company is not in violation of any statute, rule, regulation, decision or order of any governmental agency or body or any court, domestic or foreign, relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances (collectively, “**Environmental Laws**”), has not released any hazardous substances regulated by Environmental Law onto any real property that it owns or operates and has not received any written notice or claim it is liable for any off-site disposal or contamination pursuant to any Environmental Laws, which violation, release, notice, claim, or liability would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, and to the Knowledge of the Company, there is no pending or threatened investigation that would reasonably be expected to lead to such a claim.

6.16 No Material Adverse Effect; No Undisclosed Liabilities. Since December 31, 2021 (i) there has been no event, occurrence or development that has had or that could reasonably be expected to have or result in a material adverse effect on the results of operations, assets, business, operations or financial condition of the Company, taken as a whole, (a “**Material Adverse Effect**”), (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables, accrued expenses and other liabilities incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or disclosed in filings made with the SEC, (iii) the Company has not altered its method of accounting, and (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock.

6.17 Permits. The Company possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses (collectively, “**Permits**”), and is operating such businesses in compliance with such Permits, except in each case where the failure to possess such Permits or failure to conduct business in compliance with such permits, would not reasonably be expected to result in a Material Adverse Effect. The Company has not received any notice of proceedings relating to the revocation or modification of any such Permit.

6.18 Intellectual Property.

(a) Section 6.18(a) of the Disclosure Schedule contains a complete and accurate list of all Company Registered IP, including the jurisdiction in which such item of Company Registered IP has been registered or filed and the applicable registration or serial number. Each item of Company Registered IP, other than pending applications, is subsisting, and, to the Knowledge of the Company, valid and enforceable. Each item of Company Registered IP is in material compliance with all Laws and all filings, payments, and other actions required to be made or taken to maintain such item of Company Registered IP. The Company has complied in all material respects with all of its obligations and duties to the respective intellectual property registration offices, including the duty of candor and disclosure to the U.S. Patent and Trademark Office, and all applicable Laws, with respect to all Company Registered IP.

(b) To the Knowledge of the Company, the Company owns, or has adequate rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade dress, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary for or used in connection with the operation of their respective businesses (collectively, the “**Company Intellectual Property**”). The Company has not received a written notice that any of the Company Intellectual Property violates, misappropriates or infringes upon the rights of any Third Party. The Company has no Knowledge of any information, facts or circumstances that would reasonably be expected to result in any challenge to, or otherwise adversely impact, in any material respect, the ownership of any Company Owned IP. No Person has any right of first refusal, option or other right to acquire any right, title or interest in or to, or has any other lien or encumbrance with respect to, any Company Owned IP.

(c) Neither the Company nor the conduct of its business, including the design, development, manufacture, use, sale, licensing, or other provision of any products or services, nor any consultant, employee or other Person that is or was working for the Company, has infringed upon or misappropriated or otherwise violated, or is infringing upon or misappropriating or otherwise violating any intellectual property rights of any other Person.

(d) To the Knowledge of the Company, no Person has infringed or misappropriated or otherwise violated, and no Person is currently infringing or misappropriating or otherwise violating, any Company Owned IP.

(e) The Company has taken commercially reasonable actions to maintain and protect all of the Company Intellectual Property, including the secrecy, confidentiality, and value of its trade secrets and other material confidential information, and the Company has not disclosed any trade secrets or other material confidential Company Intellectual Property to any Third Party other than pursuant to a written confidentiality agreement under which such Third Party agrees to protect such confidential information.

6.19 Absence of Litigation. There is no action, suit, proceeding or, to the Knowledge of the Company, investigation, pending, or, to the Knowledge of the Company, threatened by any Governmental Body against the Company and in which an unfavorable outcome, ruling or finding in any said matter, or for all matters taken as a whole, would have a Material Adverse Effect. The foregoing includes, without limitation, any such action, suit, proceeding or investigation that questions this Agreement or the right of the Company to execute, deliver and perform under same.

6.20 Insurance Coverage. The Company maintains in full force and effect insurance coverage that covers its properties, operations, personnel and businesses, which insurance is in amounts and insures against such losses and risks as are adequate to protect the Company and its business. The Company has not received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance nor has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.

6.21 Brokers and Finders. No Person will have, as a result of the transactions contemplated by the Transaction Documents, any valid right, interest or claim against or upon the Company or the Purchaser for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company. The Purchaser shall have any obligation with respect to any fees, or with respect to any claims made by or on behalf of other Persons for fees, in each case of the type contemplated by this Section 6.21 that may be due in connection with the transactions contemplated by the Transaction Documents.

6.22 No Bad Actors. No “bad actor” disqualifying event described in Rule 506(d)(1)(i)-(viii) of the 1933 Act (a “**Disqualification Event**”) is applicable to the Company or, to the Knowledge of the Company, any Company covered person, except (i) for a Disqualification Event as to which Rule 506(d)(2)(ii-iv) or (d)(3) is applicable.

6.23 Healthcare Regulatory Compliance. The Company (i) is and at all times has been in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any Product manufactured or distributed by the Company, including, without limitation, the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), regulations relating to Good Clinical Practices and Good Laboratory Practices and all other local, state, federal, national, and foreign laws (collectively, the “**Healthcare Laws**”), except for such non-compliance as would not, individually or in the aggregate, have a Material Adverse Effect; (ii) possesses all material licenses, exemptions, certificates, approvals, clearances, authorizations, permits, registrations and supplements or amendments thereto required by any such Healthcare Laws (“**Authorizations**”) and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations, except for such violations as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Body or Third Party (A) alleging that any Product operation or activity is in violation of any Healthcare Laws or Authorizations or (B) has taken or is taking action to materially limit, suspend, materially modify or revoke any Authorizations, nor, to the Knowledge of the Company, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened; (iv) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Healthcare Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission); and (v) is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any Governmental Body. Neither the Company nor, to the Knowledge of the Company, any of its employees, officers, directors, or agents, has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the Knowledge of the Company, is subject to any inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

6.24 Tests and Preclinical and Clinical Trials. To the Knowledge of the Company, the descriptions provided to Purchaser of the results of preclinical studies and clinical trials of the Products conducted by or on behalf of the Company are accurate and complete descriptions in all material respects and fairly present the data derived therefrom as of the date thereof and remain accurate and complete descriptions in all material respects and fairly present the data derived therefrom, as of the Initial Closing Date. To the Knowledge of the Company, there are no other studies or trials of the Products other than those described to the Purchaser, the results of which the Company believes are inconsistent with or reasonably call into question the results provided to Purchaser. The Company has not received any written notices, correspondence or other communications from the Regulatory Authorities or any other governmental agency requiring or threatening the termination, material modification or suspension of any preclinical studies or clinical trials of the Products, other than ordinary course communications with respect to modifications in connection with the design and implementation of such studies or trials.

7. Representations, Warranties and Covenants of the Purchaser. The Purchaser represents and warrants to the Company as of the date hereof (and as of the Second Closing Date and each Milestone Closing Date) as follows:

7.1 Authorization. All action on the part of the Purchaser and, if applicable, its officers, directors and shareholders necessary for the authorization, execution, delivery and performance of this Agreement, the consummation of the transactions contemplated herein has been taken. When executed and delivered, this Agreement will constitute the legal, valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with its terms, except as such may be limited by bankruptcy, insolvency, reorganization or other laws affecting creditors' rights generally and by general equitable principles. The Purchaser has all requisite power or corporate power, whichever is applicable, to enter into this Agreement and to carry out and perform its obligations under the terms of this Agreement.

7.2 Purchase Entirely for Own Account. The Purchaser is acquiring the Shares being purchased by it hereunder for investment, for its own account, and not for resale or with a view to distribution in violation of the Securities Act. Except as set forth in this Agreement, nothing contained herein shall be deemed a representation or warranty by the Purchaser to hold the Shares for any period of time.

7.3 Investor Status; Etc. The Purchaser is an "accredited investor" as defined in Rule 501 of Regulation D promulgated under the Securities Act and was not organized for the purpose of acquiring the Shares. The Purchaser's financial condition is such that it is able to bear the risk of holding the Shares for an indefinite period of time and the risk of loss of its entire investment. The Purchaser has been afforded the opportunity to ask questions of and receive answers from the management of the Company concerning its investment in the Shares and has sufficient knowledge and experience in investing in companies similar to the Company in terms of the Company's stage of development so as to be able to evaluate the risks and merits of its investment in the Company.

7.4 Securities Not Registered. The Purchaser understands that the Shares have not been registered under the Securities Act or the securities laws of any state, or other jurisdiction, by reason of their issuance by the Company in a transaction exempt from the registration requirements of the Securities Act and applicable state securities laws, and that the Shares must continue to be held by the Purchaser unless a subsequent disposition thereof is registered under the Securities Act or exempt from such registration. The Purchaser understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Purchaser must hold the Shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. The Purchaser acknowledges that the Company has no obligation to register or qualify the Shares, or its Common Stock, for resale except as set forth in the A&R Stockholders' Agreement. The Purchaser further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Shares, and on requirements relating to the Company which are outside of the Purchaser's control, and which the Company is under no obligation and may not be able to satisfy.

7.5 No Public Market. The Purchaser understands that no public market now exists for the Shares, and that the Company has made no assurances that a public market will ever exist for the Shares.

7.6 No Conflict. The execution and delivery of the Transaction Documents by the Purchaser and the consummation of the transactions contemplated therein will not conflict with or result in any violation of or default by the Purchaser (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation or to a loss of a material benefit under (i) any provision of the organizational documents of the Purchaser, (ii) any agreement or instrument, permit, franchise, license, judgment, order, statute, law, ordinance, rule or regulations, applicable to the Purchaser or its respective properties or assets or (iii) require the consent, notice or other action by any person under any contract to which the Purchaser is a party, except in the case of clauses (ii) or (iii) where the failure to obtain any requisite consent or notice would not give rise to an event, occurrence or development that has had or that could reasonably be expected to have or result in a material adverse effect on the results of operations, assets, business, operations or financial condition of the Purchaser or its subsidiaries, taken as a whole.

7.7 Consents. All consents, approvals, orders and authorizations required on the part of the Purchaser in connection with the execution, delivery or performance of this Agreement and the consummation of the transactions contemplated herein have been obtained and are effective as of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable (except for filings pursuant to Section 16 or Regulation 13D under the Exchange Act, which shall be filed within the time periods provided for in such regulations).

7.8 Company Representations and Warranties. No representations or warranties have been made to the Purchaser by the Company or any officer, employee, agent, Affiliate, Associate or subsidiary of the Company other than the representations and warranties of the Company contained herein. In purchasing the Shares, the Purchaser specifically disclaims that it is relying on, or has relied upon, any representations or warranties that may have been made by the Company or any other Person other than those contained herein and acknowledges and agrees that the Company has specifically disclaimed any such other representation or warranty made by the Company or any other Person.

8. Conditions Precedent.

8.1 Conditions to the Obligation of the Purchaser to Consummate the Closings. The obligation of Purchaser to consummate the Initial Closing, Second Closing or each Milestone Closing, as applicable, and to purchase and pay for the Shares pursuant to this Agreement is subject to the satisfaction of the following conditions precedent:

(a) Representations and Warranties.

(i) For the Initial Closing, the representations and warranties contained herein of the Company shall be true and correct (it being understood and agreed by the Purchaser that, in the case of any representation and warranty of the Company contained herein which is not hereinabove qualified by application thereto of a materiality standard, such representation and warranty need be true and correct only in all material respects in order to satisfy as to such representation or warranty the condition precedent set forth in the foregoing provisions of this Section 8.1(a)(i)).

(ii) For the Second Closing and each Milestone Closing, the representations and warranties of the Company contained in Sections 6.1, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 6.10, 6.16, 6.17, 6.18, 6.19, 6.21, 6.22, 6.23, 6.24 (together, the “**Milestone Representations**”) shall be true and correct (it being understood and agreed by the Purchaser that, in the case of any representation and warranty of the Company contained herein which is not hereinabove qualified by application thereto of a materiality standard, such representation and warranty need be true and correct only in all material respects in order to satisfy as to such representation or warranty the condition precedent set forth in the foregoing provisions of this Section 8.1(a)(ii); provided that, the representations and warranties contained in Sections 6.18, 6.23 and 6.24 shall be true and correct in all respects except where the failure of such representation and warranties to be so true and correct would not have, or would not reasonably be expected to have, a Material Adverse Effect.

(b) The Company shall have performed all obligations and conditions herein required to be performed or observed by the Company on or prior to the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable.

(c) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, shall have been instituted before any court, arbitrator or Governmental Body, agency or official and shall be pending.

(d) The Company shall have obtained any and all consents, permits, approvals, registrations and waivers necessary for the consummation of the purchase and sale of the Shares and the consummation of the other transactions contemplated by the Transaction Documents, all of which shall be in full force and effect.

(e) The purchase of and payment for the Shares by the Purchaser shall not be prohibited by any law or governmental order or regulation. All necessary consents, approvals, licenses, permits, orders and authorizations of, or registrations, declarations and filings with, any governmental or administrative agency or of any other person with respect to any of the transactions contemplated hereby, other than for Regulation D and state “Blue Sky” filings with respect to the sale of the Shares, shall have been duly obtained or made and shall be in full force and effect.

(f) All instruments and corporate proceedings in connection with the transactions contemplated by this Agreement to be consummated on the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, shall be reasonably satisfactory in form and substance to the Purchaser, and the Purchaser shall have received counterpart originals, or certified or other copies of all documents, including without limitation records of corporate or other proceedings, which it may have reasonably requested in connection therewith.

(g) Any applicable waiting period applicable to the consummation of the transactions contemplated hereby under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or any other applicable anti-trust laws relating to the transactions contemplated hereby shall have expired or been terminated.

(h) There shall have been no Material Adverse Effect with respect to the Company since the date hereof.

(i) At the Initial Closing, the Company and each Securityholder shall have delivered to Purchaser the Security Purchase Option Agreement, executed by a duly authorized officer of the Company and each Securityholder.

(j) The Company shall have executed and delivered:

(i) the Company's wire instructions;

(ii) a copy of the Restated Certificate, certified by the Secretary of State of the State of Delaware within two (2) days of the Initial Closing Date;

(iii) a certificate, signed by a duly elected officer of the Company, certifying as of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, as to the satisfaction of each of the conditions set forth in Section 8.1(a) and 8.1(b);

(iv) a certificate evidencing the formation and good standing of the Company issued by the Secretary of State of the State of Delaware, as of a date within five (5) days of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable;

(v) a certificate executed by the Secretary of the Company and dated as of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, certifying as to (i) the resolutions adopted by the Company's board of directors approving this Agreement, (ii) the Restated Certificate, and (iii) the Company's bylaws, as amended, each as in effect as of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable;

(vi) the A&R Stockholders' Agreement executed by a duly authorized officer of the Company.

8.2 Conditions to the Obligation of the Company to Consummate the Closing. The obligation of the Company to consummate the Initial Closing, Second Closing and each Milestone Closing, as applicable, and to issue and sell to the Purchaser the Shares to be purchased at the Initial Purchase is subject to the satisfaction of the following conditions precedent:

(a) The representations and warranties contained herein of Purchaser shall be true and correct on and as of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, with the same force and effect as though made on and as of the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable (it being understood and agreed by the Company that, in the case of any representation and warranty of a Purchaser contained herein which is not hereinabove qualified by application thereto of a materiality standard, such representation and warranty need be true and correct only in all material respects in order to satisfy as to such representation or warranty the condition precedent set forth in the foregoing provisions of this Section 8.2(a)).

(b) The Purchaser shall have performed all obligations and conditions herein required to be performed or observed by the Purchaser on or prior to Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable.

(c) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, shall have been instituted before any court, arbitrator or Governmental Body, agency or official and shall be pending.

(d) The sale of the Shares by the Company shall not be prohibited by any law or governmental order or regulation. All necessary consents, approvals, licenses, permits, orders and authorizations of, or registrations, declarations and filings with, any governmental or administrative agency or of any other person with respect to any of the transactions contemplated hereby, shall have been duly obtained or made and shall be in full force and effect.

(e) All instruments and corporate proceedings in connection with the transactions contemplated by this Agreement to be consummated on the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, shall be reasonably satisfactory in form and substance to the Company, and the Company shall have received counterpart originals, or certified or other copies of all documents, including without limitation records of corporate or other proceedings, which it may have reasonably requested in connection therewith.

(f) The receipt by the Company of the funds from the Initial Purchase in immediately available funds by wire transfer to an account of the Company designated in writing by the Company to such Purchaser.

9. Legends. Each certificate representing any of the Shares shall be endorsed with the legend set forth below, and Purchaser covenants that, except to the extent such restrictions are waived by the Company, it shall not transfer the Shares represented by any such certificate without complying with the restrictions on transfer described in this Agreement and the legend endorsed on such certificate:

“THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.”

10. Indemnification.

10.1 Indemnification of Purchaser. The Company agrees to indemnify and hold harmless the Purchaser and its Affiliates, and their respective directors, officers, trustees, members, managers, employees, and agents (each, for the purposes of this Section 10, a “**Purchaser Indemnified Party**” and collectively, the “**Purchaser Indemnified Parties**”), for the amount of any and all losses, claims, damages, liabilities and expenses (including reasonable attorneys’ fees and expenses) (collectively, “**Losses**”) actually suffered or incurred by a Purchaser Indemnified Party arising out of or resulting from the Company’s breach of representation, warranty, covenant or agreement made by or to be performed it under the Transaction Documents.

10.2 Indemnification of the Company. The Purchaser agrees to indemnify and hold harmless the Company and its Affiliates (other than the Purchaser if the Purchaser becomes an Affiliate), and their respective stockholders, directors, officers, trustees, members, partners, managers, employees, and agents (each, for the purposes of this Section 10, a “**Company Indemnified Party**”), for the amount of any and all Losses actually suffered or incurred by a Company Indemnified Party arising out of or resulting from the Purchaser’s breach of representation, warranty, covenant or agreement made by or to be performed it under the Transaction Documents.

10.3 Indemnification Procedures.

(a) In the event that any Purchaser Indemnified Party or a Company Indemnified Party, as applicable (an “**Indemnified Party**”), shall sustain or incur any Losses in respect of which indemnification may be sought pursuant to this Section 10, the Indemnified Party seeking indemnification shall assert a claim for indemnification by giving the Company (if the Indemnified Party is a Purchaser Indemnified Party) or the Purchaser (if the Indemnified Party is a Company Indemnified Party) (the Party receiving such notice, the “**Indemnifying Party**”) prompt written notice thereof (an “**Indemnification Notice**”), which notice shall describe in reasonable detail the facts and circumstances upon which the asserted claim for indemnification is based. For purposes of this Section 10.3, any Indemnification Notice that is sent within 15 Business Days of the date upon which the Indemnified Party actually learned of such Loss shall be deemed to have been “prompt notice”. Failure of the Indemnified Party to give the Indemnifying Party prompt notice as provided herein shall not relieve the Indemnifying Party of any of its obligations hereunder except to the extent that the Indemnifying Party is materially prejudiced by such failure.

(b) Upon the receipt of an Indemnification Notice, the Indemnifying Party shall have the right to undertake (at its own expense) the good faith defense, compromise or settlement of the claim on behalf of the Indemnified Party by counsel or representatives of its own choosing, if the Indemnifying Party unconditionally agrees in writing that it shall indemnify the Indemnified Party for all Losses relating to the subject claim. The Indemnifying Party shall keep the Indemnified Party reasonably informed with respect to such defense. If the Indemnifying Party elects to undertake such defense, it shall give notice of such election to the Indemnified Party within 15 Business Days of its receipt of the Indemnification Notice. Notwithstanding the foregoing, the Indemnifying Party may not assume or control the defense if the named parties to the claim (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both by the same counsel would be inappropriate (based on a written opinion of outside counsel to the Indemnified Party) due to actual or potential differing interests between them, in which case the Indemnified Party shall have the right to defend the action and to employ counsel reasonably approved by the Indemnifying Party. In such circumstances, the Indemnifying Party shall reimburse the Indemnified Party for all reasonable costs of a single counsel associated with such defense.

(c) The Indemnified Party shall cooperate with the Indemnifying Party in any defense undertaken by the Indemnifying Party pursuant to Section 10.3(b) and provide the Indemnifying Party with all information and assistance reasonably necessary to permit the Indemnifying Party to pursue such defense. The Indemnifying Party shall have the right in good faith to settle or compromise any such claim, if (i) at least ten Business Days prior notice of such settlement or compromise is given to the Indemnified Party, and (ii) such settlement or compromise does not require the Indemnified Party to take or refrain from taking any action (provided that, Indemnified Party shall not unreasonably withhold its consent to the terms of a mutual release with respect to such claim with the third party making such claim), contain any admission by or on behalf of the Indemnified Party, or otherwise fail to hold Indemnified Party fully harmless with respect to such claim. Notwithstanding the foregoing, in connection with any settlement or compromise of a claim negotiated by the Indemnifying Party, no Indemnified Party shall be required to (A) enter into any settlement that does not include as an unconditional term thereof the delivery to the Indemnified Party of a release from all liability in respect of such claim, or (B) enter into any settlement that attributes by its terms any non-indemnified liability to the Indemnified Party. Except as otherwise provided in the last sentence of Section 10.3(b), the Indemnified Party may retain counsel (at the Indemnified Party’s expense) to monitor or participate in such defense, but the Indemnifying Party shall be entitled to control the defense unless the Indemnified Party agrees in writing to relieve the Indemnifying Party from liability with respect to the subject claim. If the Indemnified Party effects any compromise or settlement of a claim being defended by the Indemnifying Party pursuant to this Section 10.3(c) without the prior written consent of the Indemnifying Party, then the Indemnified Party by so doing forfeits any right to indemnification of Losses with respect to such claim by the Indemnifying Party under this Section 10.

(d) If the Indemnifying Party fails, within 15 Business Days after the date of the Indemnification Notice, to give notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of the subject claim, the Indemnifying Party shall be bound by any determination made in such claim or compromise or settlement effected by the Indemnified Party and shall reimburse the Indemnified Party for all Losses incurred by the Indemnified Party in defending such claim; provided that, the Indemnified Party shall not compromise or settle such claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, delayed or conditioned. The Indemnified Party shall keep the Indemnifying Party advised on a timely basis of significant developments with respect to such defense and permit the Indemnifying Party to participate, at its own election and expense, at any time, in the defense thereof.

10.4 Limitations.

(a) With respect to an indemnifiable Loss, neither Party's aggregate liability to the other Party for such Loss shall not exceed the aggregate dollar amount paid by Purchaser to the Company in connection with its purchase of shares of the Company's Common Stock.

(b) NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES SUFFERED BY THE OTHER PARTY (INCLUDING WITHOUT LIMITATION DAMAGES FOR HARM TO BUSINESS, LOST REVENUES, LOST SAVINGS, OR LOST PROFITS SUFFERED BY THE OTHER PARTY), REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, WARRANTY, STRICT LIABILITY, OR TORT, INCLUDING WITHOUT LIMITATION NEGLIGENCE OF ANY KIND WHETHER ACTIVE OR PASSIVE, AND REGARDLESS OF WHETHER THE PARTIES KNEW OF THE POSSIBILITY THAT SUCH DAMAGES COULD RESULT. EACH PARTY HEREBY RELEASES THE OTHER PARTY (AND EACH INDEMNIFIED PARTY) FROM ANY SUCH CLAIM.

11. Miscellaneous Provisions.

11.1 Survival of Warranties. Subject to the limitations and other provisions of this Agreement, the respective representations and warranties given by the Parties shall survive each of the Initial Closing, the Second Closing and the Milestone Closings for a period of one year from each such closing and each covenant and agreement contained herein shall survive until fully performed by the applicable Party. Notwithstanding the foregoing, any claims asserted in good faith (to the extent known at such time) and in writing by notice from the non-breaching Party to the breaching Party prior to the expiration of the above survival period shall not thereafter be barred by the expiration of the relevant representation or warranty and such claims shall survive until finally resolved.

11.2 Public Statements or Releases. The initial press release with respect to the execution of this Agreement shall be a joint press release to be prepared by Purchaser and the Company (the "**Initial Press Release**"). Following such Initial Press Release, Purchaser shall control the form, content and timing of any other public disclosure or announcement of this Agreement or the transactions contemplated hereby; provided that, nothing in this Agreement (i) shall limit either Party's ability to make public disclosures reasonably deemed required by such Party under applicable Law, (ii) shall prohibit the Company from sharing press releases and communications previously approved by the Purchaser, (iii) shall prohibit the Company from releasing any public communications consented to by the Purchaser (which consent shall not be unreasonably withheld), or (iv) shall prohibit the Company from releasing public communications that restate information that was in the Initial Press Release. Following the Initial Closing, the Company shall cooperate with Purchaser with respect to any filing on Current Report on Form 8-K regarding the Transaction Documents within the time period required by the Exchange Act. The parties acknowledge that this Agreement may be filed as an exhibit to the Purchaser's SEC Filings.

11.3 Consolidated Financials. With respect to any time period for which the Purchaser (in its sole discretion) is required to use the equity method of accounting with respect to the Purchaser's investment in or relationship with the Company (or to otherwise consolidate, reflect or incorporate the financial statements or financial results of the Company with or into the financial statements or financial results of the Purchaser), the Company will reasonably cooperate with the Purchaser to provide in an accurate, complete and timely manner such information and access to such Company personnel as may be necessary for or reasonably requested by the Purchaser to satisfy (x) the requirements of applicable law and regulation, the SEC, any other governmental authority, exchange or self regulatory organization, in each case as such requirements relate to the financial statements and financial results of the Company, and (y) the reasonable requests of the Purchaser's auditors.

11.4 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the sale of the Shares by the Company under this Agreement as required under Regulation D. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to the Purchaser at the Initial Closing Date, the Second Closing Date, or each Milestone Closing Date, as applicable, under applicable securities or “Blue Sky” laws of the states of the United States and shall provide evidence of such actions promptly upon request of the Purchaser.

11.5 Further Assurances. Each Party agrees to, and shall cause their respective Affiliates to, cooperate fully with the other Party and to execute such further instruments, documents and agreements and to give such further written assurances, as may be reasonably requested by the other Party to better evidence and reflect the transactions described herein and contemplated hereby, and to carry into effect the intents and purposes of this Agreement and to consummate the transactions contemplated by the Transaction Documents.

11.6 Rights Cumulative. Each and all of the various rights, powers and remedies of the Parties shall be considered to be cumulative with and in addition to any other rights, powers and remedies which such Parties may have at law or in equity in the event of the breach of any of the terms of this Agreement. The exercise or partial exercise of any right, power or remedy shall neither constitute the exclusive election thereof nor the waiver of any other right, power or remedy available to such Party.

11.7 Corporate Transaction. Should the Company undergo a Corporate Transaction in breach of this Agreement, Sections 4 and all other obligations to effect either Milestone Share Purchase shall terminate. In the event of an M&A Closing (as defined in the Security Purchase Option Agreement), Section 4 and all other obligations to effect either Milestone Share Purchase shall also terminate at the M&A Closing (as defined in the Security Purchase Option Agreement).

11.8 Pronouns. All pronouns or any variation thereof shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person, persons, entity or entities may require.

11.9 Notices.

(a) Any notices, correspondence, requests, consents, claims, demands, waivers and other communications required or permitted to be given hereunder (collectively, “correspondence”) shall be sent by postage prepaid first class mail, courier or recognized overnight mail service or delivered by hand to the Party to whom such correspondence is required or permitted to be given hereunder. The date of giving any correspondence shall be the date of its actual receipt.

(b) All correspondence to the Company shall be addressed as follows:

Enalare Therapeutics Inc.
161 Hodge Road
Princeton, New Jersey 08540
Attention: [***]
Email: [***]

with a copy to (which copy shall not constitute notice):

Coviello Weber & Dahill LLP
707 Westchester Avenue, Suite 300
White Plains, NY 10604
Attention: Paul R. Weber, Esq.
Email: pweber@cwdlaw.com

(c) All correspondence to the Purchaser shall be addressed as follows:

Eagle Pharmaceuticals, Inc.
50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
Attention: [***]

With a copy to (which copy shall not constitute notice):

Cooley LLP
500 Boylston Street
Boston, MA 02116
Attention: Marc Recht and Miguel J. Vega
Email: mrecht@cooley.com; mvega@cooley.com
Fax No.: 617.937.2400

(d) Any Party may change the address to which correspondence to it is to be addressed by notification as provided for herein.

11.10 Captions. The captions and paragraph headings of this Agreement are solely for the convenience of reference and shall not affect its interpretation.

11.11 Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provisions shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such part or provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the Parties.

11.12 Specific Performance and Equitable Remedies. Each of the Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the non-breaching counterparty shall be entitled to equitable remedies, including, but not limited to, obtaining an injunction and/or specific performance of the terms hereof, in addition to any other remedy to which they are entitled at law or in equity.

11.13 Governing Law. This Agreement and all matters arising out of or relating to this Agreement shall be governed by and construed in accordance with the internal and substantive laws of the State of Delaware, without regard to any choice or conflict of laws provision or rule thereof.

11.14 Dispute Resolution. The Parties hereby (a) irrevocably and unconditionally submit to the jurisdiction of the state courts of Delaware and to the jurisdiction of the U.S. District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of Delaware or the U.S. District Court for the District of Delaware, and (c) waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

11.15 Waiver of Jury Trial. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY TO THIS AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (B) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 11.15.

11.16 Waiver. No waiver of any term, provision or condition of this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or be construed as, a further or continuing waiver of any such term, provision or condition or as a waiver of any other term, provision or condition of this Agreement.

11.17 Expenses. Each Party will bear its own costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisors and accountants, in connection with this Agreement and the transactions contemplated hereby, whether or not the Initial Closing, the Second Closing and/or the Milestone Closings shall have occurred.

11.18 Assignment. Subject to the express terms of this Agreement, the rights and obligations of the Parties shall inure to the benefit of and shall be binding upon any authorized successors and permitted assigns of each Party in accordance with this Agreement. Purchaser may not assign its rights or obligations under this Agreement or designate another person (i) to perform all or part of its obligations under this Agreement or (ii) to have all or part of its rights and benefits under this Agreement, in each case without the prior written consent of the Company. Notwithstanding the foregoing, Purchaser may assign this Agreement and the rights and obligations hereunder (A) to any Affiliate of Purchaser (provided the Company receives reasonably satisfactory evidence that such Affiliate is able to meet its obligations hereunder), or (B) to a successor to all or substantially all of the assets of Purchaser (irrespective of the nature of the transaction, whether by way of stock sale, asset sale or otherwise). The Company may not assign its rights or obligations under this Agreement without the prior written consent of the Purchaser. In the event of any assignment in accordance with the terms of this Agreement, the assignee shall specifically assume and be bound by the provisions of the Agreement by executing and agreeing to an assumption agreement reasonably acceptable to the other Party. Any assignment or transfer in violation of this section shall be void.

11.19 No Third-Party Beneficiaries. This Agreement is for the sole benefit of the Parties hereto and their authorized successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

11.20 Entire Agreement; Termination. This Agreement, along with any confidentiality agreement signed by the Purchaser for the benefit of the Company and/or its Affiliates and the Transaction Documents, constitutes the sole and entire agreement among the Parties respecting the subject matter hereof and supersedes all prior and contemporaneous agreements, negotiations, understandings, representations and statements respecting the subject matter hereof, whether written or oral. Notwithstanding anything to the contrary in this Agreement or the Transaction Documents, following the Second Closing and the Purchaser's purchase of \$25,000,000 of Shares, the Purchaser may terminate this Agreement and the Transaction Documents (including the Security Purchase Option Agreement) at any time in its sole and absolute discretion with thirty (30) days' written notice to the Company. It is understood, agreed and acknowledged that upon any such termination, Purchaser shall retain any Common Stock acquired pursuant to this Agreement prior to the effectiveness of such termination; provided that, (a) Sections 11.4, 11.7, 11.8, 11.9, 11.12, 11.13, 11.14, 11.16 and 11.18 shall survive any such termination, and (b) if this Agreement is terminated as provided in this Section 11.20, the Security Purchase Option Agreement shall also be deemed terminated as of such date without further action on the part of any Person.

11.21 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

11.22 Amendments and Waivers. This Agreement may be amended, modified or supplemented at any time only by written agreement signed by the Company and the Purchaser, and any failure of the Company to comply with any term or provision of this Agreement may be waived by Purchaser, and any failure of Purchaser to comply with any term or provisions of this Agreement may be waived by Company, at any time by an instrument in writing signed by or on behalf of such other Party, but such waiver shall not operate as a waiver of, or estoppel with respect to, any subsequent or other failure to comply; provided that, following an M&A Closing (as defined in the Security Purchase Option Agreement), this Agreement may only be amended in accordance with Section 12(b) of the Security Purchase Option Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Securities Purchase Agreement to be duly executed as of the day and year first above written.

ENALARE THERAPEUTICS INC.

By: /s/ Herman Cukier
Name: Herman Cukier
Title: President & CEO

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Name: Scott Tarriff
Title: President and Chief Executive Officer

[Signature Page to Securities Purchase Agreement]

EXHIBIT A
SECURITY PURCHASE OPTION AGREEMENT

- See attached.

EXHIBIT B
A&R STOCKHOLDERS' AGREEMENT

- See attached.

EXHIBIT C
RESTATED CERTIFICATE

- See attached.

EXHIBIT D

DISCLOSURE SCHEDULES

This Disclosure Schedule is made and given pursuant to Section 6 of the Securities Purchase Agreement, dated as of August 8, 2022 (the “**Agreement**”), by and between Enalare Therapeutics Inc., a Delaware corporation (the “**Company**”), and Eagle Pharmaceuticals, Inc., a Delaware corporation (the “**Purchaser**”). All capitalized terms used but not defined herein shall have the meanings as defined in the Agreement, unless otherwise provided. The Section numbers below correspond to the Section numbers of the representations and warranties in the Agreement; provided that, any information disclosed herein under any Section number shall be deemed to be disclosed and incorporated into any other Section number under the Agreement where such disclosure is readily apparent from the face of such disclosure. Nothing in this Disclosure Schedule is intended to broaden the scope of any representation or warranty contained in the Agreement or to create any covenant. Inclusion of any item in this Disclosure Schedule (a) does not represent a determination that such item is material or establish a standard of materiality and (b) does not represent a determination that such item did not arise in the ordinary course of business. This Disclosure Schedule includes brief descriptions or summaries of certain agreements and instruments, copies of which have been made available to Purchaser via email or an online data room or other repository that is open to the Purchaser. Such descriptions do not purport to be comprehensive and are qualified in their entirety by reference to the text of the documents described, true and complete copies of which have been provided to the Purchaser or its counsel.

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SECURITY PURCHASE OPTION AGREEMENT

This Security Purchase Option Agreement (the “*Agreement*”) is entered into as of August 8, 2022 (the “*Effective Date*”), by and among (i) Enalare Therapeutics Inc., a Delaware corporation (the “*Company*”), (ii) the holders of the outstanding capital stock of the Company set forth on Schedule A hereto (the “*Stockholders*”), (iii) the holders of certain convertible promissory notes of the Company (collectively, the “*Notes*” and each, a “*Note*”) set forth on Schedule B hereto (the “*Noteholders*”), (iv) the holders of options to acquire capital stock in the Company set forth on Schedule C hereto (the “*Optionholders*”), (v) the holders of warrants to acquire capital stock in the Company set forth on Schedule D hereto (the “*Warrantholders*”) and together with the Stockholders, Noteholders and Optionholders, the “*Securityholders*”) and (vi) Eagle Pharmaceuticals, Inc., a Delaware corporation (the “*Purchaser*”, and together with the Company, Stockholders and Optionholders, each a, “*Party*” and together, the “*Parties*”).

RECITALS

WHEREAS, the Company and the Purchaser are parties to the Stock Purchase Agreement, dated as of the date hereof (the “*Purchase Agreement*”), and it is a condition to the closing of the sale of the Common Stock of the Company, par value \$0.0001 per share (the “*Common Stock*”), that the Company, Stockholders and Optionholders execute and deliver this Agreement to the Purchaser;

WHEREAS, the Stockholders collectively hold 90,000 shares of Common Stock, and each individual Stockholder holds the number of shares of Common Stock set forth opposite his or her name on Schedule A hereto and, following the Conversion, the Noteholders collectively hold 30,735 shares of Common Stock, and each individual Noteholder holds the number of shares of Common Stock set forth opposite his or her name on Schedule B hereto following the Conversion (the “*Outstanding Common Stock*”);

WHEREAS, the Optionholders collectively hold the option to acquire 2,480 shares of Common Stock, and each individual Optionholder holds an option to acquire the number of shares of Common Stock set forth opposite his or her name on Schedule C hereto (the “*Outstanding Options*”) and the Warrantholders collectively hold the warrants exercisable for 4,591 shares of Common Stock, and each individual Warrantholder holds warrants to acquire the number of shares of Common Stock set forth opposite his or her name on Schedule D hereto (the “*Outstanding Warrants*”) and together with the Outstanding Common Stock and Outstanding Options, the “*Outstanding Securities*”); and

WHEREAS, the Parties desire to set forth the terms and conditions under which the Company shall have the right, but not the obligation, to purchase all of the Outstanding Securities on the terms set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and agreements set forth above and herein contained, the receipt and sufficiency of which the Parties acknowledge, the Parties agree as follows:

AGREEMENT

1. Conversion of Indebtedness.

(a) As of the Effective Date, each Noteholder and the Company hereby agrees and acknowledge that the balance under such Noteholder's convertible notes (the "**Balance**") has been converted (the "**Conversion**") into the number of shares of Common Stock set forth on Schedule B (the "**Conversion Shares**"). Notwithstanding the terms of the Notes, each Noteholder acknowledges and agrees that as of the Effective Date, the aggregate outstanding principal amount of each Note, together with all accrued and unpaid interest thereon, is as set forth across from such Noteholder's name on Schedule B. Each Noteholder further agrees that the principal and accrued interest for each such Noteholder's Note(s) shall be calculated as of August 5, 2022. To the extent that additional interest accrues so that the total amount otherwise due to a Noteholder under a Note is in excess of the amount set forth on Schedule B, each such Noteholder hereby irrevocably waives any such additional interest. For the avoidance of doubt, no fractional shares of Common Stock will be issued as Conversion Shares and in lieu of any fractional Conversion Shares to which such Noteholder would otherwise be entitled, the Company shall pay such Noteholder cash equal to such fraction multiplied by the price at which such Noteholder's Note converts. Following the Conversion, the undersigned Noteholder agrees and acknowledges that such Noteholder will be a party to this Agreement as a Stockholder and will be subject to the covenants and obligations applicable to the Stockholders under this Agreement.

(b) Each undersigned Noteholder agrees and acknowledges that the issuance of the Conversion Shares pursuant the Notes constitutes full satisfaction of the Company's obligations with respect to the Balance, and as of the Effective Date any and all obligations, liabilities, claims, expenses, liens, actions, rights and interests the Noteholder has or may have in the future arising in respect of the Balance are hereby extinguished and terminated, or otherwise are hereby forgiven and waived to the full extent of the law, and the Company is hereby released from the same to the full extent of the law. The Noteholder hereby agrees to promptly take any further action and to execute any and all additional documents or instruments requested by the Company to release the Company from its obligations under the Balance.

(c) Upon issuance of the Conversion Shares in accordance with Section 1(a) above, all obligations of the Company (including outstanding principal, interest or any other amounts) under the Notes will be fully satisfied and discharged, and the Notes will automatically be terminated and of no further force or effect. Each Noteholder acknowledges and agrees that the Notes and any and all side letters and similar agreements entered into between such Noteholder and the Company in connection with the Notes and all obligations set forth therein shall be terminated and of no further force or effect (whether or not actually delivered to the Company). Other than Noteholder's right to receive the Conversion Shares, each Noteholder hereby waives, on behalf of itself, any and all demands, claims, suits, actions, causes of actions, proceedings, assessments and rights with respect to the Notes and any related agreements underlying the Notes, including, without limitation: (i) any principal or interest payments due as of the date hereof in excess of the amounts to be converted into Conversion Shares pursuant hereto; (ii) any right to notice of the conversion of the Conversion Shares; and (iii) any rights arising from any past or present default or event of default under the Notes.

(d) The Noteholder agrees and covenants that it will promptly execute and deliver to the Company such further instruments and documents and take such further action as the Company may reasonably require in order to carry out the full intent and purpose of this Agreement, including, for the avoidance of doubt, all financing documents executed by the investors in connection with the Qualified Financing (as defined in the Notes) in accordance with Section 3(d) of the Notes, and to comply with state or federal securities laws or other regulatory approvals, including causing any Affiliates of the Noteholder to take any actions that are necessary or appropriate to fulfill the terms and provisions of this Conversion Agreement. For purposes of this Agreement, “*Affiliate*” of a Party, means any corporation or other business entity controlled by, controlling or under common control with such Party. For this purpose, “control” shall mean direct or indirect beneficial ownership of fifty percent (50%) or more of the voting or income interest in such corporation or other business entity.

2. Right to Purchase. The Securityholders hereby irrevocably grant to the Purchaser the right to purchase (the “*Purchase Option*”), and the Securityholders hereby irrevocably agree to promptly sell to the Purchaser, all of the Outstanding Securities at any time following the date hereof until the expiration of the Option Term as set forth in Section 7. The Purchaser may exercise the Purchase Option in its sole and absolute discretion. As more fully set forth in the Definitive Agreement (as defined below), the Outstanding Securities shall be sold free and clear of any liens.

3. Procedures.

(a) The Purchase Option may be exercised by the Purchaser by service of a written notice substantially in the form attached hereto as **EXHIBIT B** (the “*Call Exercise Notice*”) on the Securityholders and Company at any time following date hereof (and prior to termination of the Purchase Option pursuant to Section 7). The Purchaser’s delivery of the Call Exercise Notice shall be revokable, in the Purchaser’s reasonable discretion, within [***] Business Days of the Company delivering to the Purchaser a substantially complete disclosure schedule under the Definitive Agreement. For the purposes of this Section 3(a), the date of exercise of the Purchase Option is the date on which the Purchaser serves the Call Exercise Notice on the Securityholders and Company (such date, the “*Call Notice Date*”).

(b) The sale of the Outstanding Securities to the Purchaser shall be documented in a definitive agreement (the “*Definitive Agreement*”) containing the terms, covenants and conditions set forth in the Term Sheet attached hereto as **EXHIBIT A** (the “*Term Sheet*”). The Parties shall use commercially reasonable efforts to enter into the Definitive Agreement within [***] days of the Purchaser delivering the Call Exercise Notice, and the Securityholders hereby irrevocably agree to vote all shares of capital stock that they hold in the Company in favor of the transactions contemplated by the Definitive Agreement as long as the Definitive Agreement does not materially deviate from the terms and conditions set forth in the Term Sheet attached hereto as **EXHIBIT A**.

(c) Notwithstanding the foregoing, the Purchaser, in its sole and absolute discretion, may elect to exercise the Purchase Option and acquire the Outstanding Securities pursuant to this Agreement rather than pursuant to the terms of the Term Sheet and the Definitive Agreement (the “*Direct Acquisition Option*”). Following the determination of the Valuation Amount (as defined below), the Direct Acquisition Option may be exercised by the Purchaser by service of a written notice substantially in the form attached hereto as **EXHIBIT C** (the “*Direct Acquisition Notice*”) on the Securityholders and Company at any time following date hereof (and prior to termination of the Purchase Option pursuant to Section 7). The Purchaser’s delivery of the Direct Acquisition Notice shall be revokable in the Purchaser’s reasonable discretion if the Company, the Company’s business or the Company’s products suffer a material adverse event in between the Direct Notice Date and the Acquisition Closing. For the purposes of this Section 3(c), the date of exercise of the Direct Acquisition Option is the date on which the Purchaser serves the Direct Acquisition Notice on the Securityholders and Company (the “*Direct Notice Date*”). Upon the written request of the Purchaser, the Company and the Purchaser shall promptly cooperate to determine the Valuation Amount (as defined below), which written request may be delivered by Purchaser prior to or after the Purchaser delivers the Call Exercise Notice or Direct Acquisition Notice.

(d) The consummation of the transactions contemplated by the Direct Acquisition Option shall take place remotely through the exchange of documents on a date to be designated by the Purchaser and consented to by the Company, such consent to not be unreasonably withheld, delayed or conditioned; provided, that if the Parties are unable to agree on a date for the Acquisition Closing, the consummation of the transaction contemplated by the Direct Acquisition Option shall take place [***] days after the Direct Notice Date (the “**Direct Acquisition Closing Date**”). On the Direct Acquisition Closing Date:

(i) Each Stockholder shall deliver to Purchaser a customary release of claims relating to the transaction contemplated by this Agreement and their equity ownership in the Company and any other documentation as may be reasonably requested by the Purchaser;

(ii) Each Stockholder shall deliver to the Purchaser an executed stock power in the form attached hereto as **EXHIBIT D** (the “**Stock Power**”), representing the assignment of all Outstanding Securities held by such Stockholder to the Purchaser in exchange for such Stockholder’s portion of the Direct Acquisition Consideration;

(iii) Each Optionholder shall deliver to the Purchaser an executed option termination agreement in the form attached hereto as **EXHIBIT E** (the “**Option Termination Agreement**”), terminating the Outstanding Options held by such Optionholder in exchange for the Optionholder’s portion of the Direct Acquisition Consideration as specified in the Option Termination Agreement;

(iv) Each Warrantholder shall deliver to the Purchaser an executed warrant termination agreement in the form attached hereto as **EXHIBIT F** (the “**Warrant Termination Agreement**”), terminating the Outstanding Warrants held by such Warrantholder in exchange for the Warrantholder’s portion of the Direct Acquisition Consideration as specified in the Warrant Termination Agreement;

(v) The Purchaser shall pay to each Stockholder, by wire transfer of immediately available funds, each Stockholder’s portion of the Direct Acquisition Consideration (as defined below);

(vi) The Purchaser shall deposit with the Company the aggregate amount of the Direct Acquisition Consideration that is due to the Optionholders that are employees of the Company for payment through the Company's standard payroll practices; and

(vii) The Purchaser shall pay to each Optionholder that is not an employee of the Company (a "**Non-Employee Optionholder**"), by wire transfer of immediately available funds, each Non-Employee Optionholder's portion of the Direct Acquisition Consideration.

(e) As used in this Agreement, the "**Direct Acquisition Consideration**" shall mean (i) the greater of (a) \$100,000,000.00 or (b) the Valuation Amount calculated as of the Call Notice Date or the Direct Notice Date, as applicable, which shall not be greater than \$175,000,000.00 (ii) *plus* the product equal to (A) [***], as applicable (the "**Acquisition Closing**"), multiplied by a percentage equal to (B) [***]. [***]. For purposes of this Subsection 3(e), the following terms shall have the following meanings:

(i) "**Valuation Amount**" shall mean an amount equal to [***].

(ii) "**Indebtedness**" shall mean the outstanding principal amount of, and all interest and other amounts accrued in respect of and all amounts payable at retirement of, (a) any indebtedness for borrowed money of the Company, (b) any obligation of the Company evidenced by bonds, debentures, notes or other similar instruments, (c) any reimbursement obligation of the Company with respect to letters of credit (including standby letters of credit to the extent drawn upon), bankers' acceptances or similar facilities issued for the account of the Company, (d) any obligation of the type referred to in clauses (a) through (c) of another person or entity the payment of which the Company has guaranteed or for which the Company is responsible or liable, directly or indirectly, jointly or severally, as obligor or guarantor, (e) any known tax liabilities and (f) any deferred revenue.

(f) The Company shall use reasonable best efforts to promptly (and in any event within [***] days following notice from the Purchaser) prepare and deliver true and complete copies of all audited, unaudited and proforma financial statements that Purchaser will be required to file with the Securities and Exchange Commission (the "**SEC**") in connection with the consummation of the Purchase Option (including the Direct Acquisition Option) and such financial statements shall be prepared in accordance with generally accepted accounting principles and Regulation S-X in a manner suitable for filing with the SEC. Notwithstanding anything to the contrary herein, all time periods with respect to the exercise of the Purchase Option and Direct Acquisition Option, the execution of a Definitive Agreement and the closing of such acquisition shall be tolled pending the preparation and delivery of such financial statements. The Company shall cause its independent auditors to deliver an audit report in connection with any audited financial statements and a consent allowing Purchaser to file such auditor report with the SEC.

(g) Notwithstanding the foregoing, the deadline for the closing on the Purchase Option (including the Direct Acquisition Option) may be extended to the extent necessary for the Purchaser to receive any necessary approvals from regulatory authorities under applicable anti-trust laws or to allow for the lapse of any waiting period under applicable anti-trust laws; provided, that Purchaser shall use best efforts to obtain such anti-trust clearances.

4. Power of Attorney. As security for the performance by the Securityholders of his, her or its obligations under this Agreement, in the event the Purchaser exercises its Purchase Option, each Securityholder hereby grants an irrevocable proxy and power of attorney to the Purchaser, with power to take all necessary actions and execute and deliver all documents and/or written consent of the stockholders to consummate the sale and purchase of the Outstanding Securities pursuant to the Direct Acquisition Option or the Definitive Agreement, as applicable (“**Power of Attorney**”); provided that, the Purchaser shall not exercise the foregoing Power of Attorney unless the Securityholder has failed to comply with his, her or its obligations pursuant to this Agreement and in any case within [***] Business Days following the request by Purchaser. This Power of Attorney is coupled with an interest and shall survive, and shall not be affected by, the subsequent death, disability, incompetency or bankruptcy of the Securityholder. This Power of Attorney shall not, without the prior written consent of the Purchaser, be superseded or revoked by any proxy or power of attorney granted by the Securityholder simultaneously herewith or subsequent hereto.

5. Phase 3 Milestone.

(a) Within [***] Business Days of the Company achieving the Phase 3 Milestone, the Company shall deliver a notice (the “**Phase 3 Notice**”) to the Purchaser pursuant to Section 15 of this Agreement confirming the achievement of the Phase 3 Milestone. As used in this Agreement, the “**Phase 3 Milestone**” means the Company’s receipt of a communication from the U.S. Food and Drug Administration (“**FDA**”) after the completion of the Phase 2 Clinical Trial (as defined in the Purchase Agreement) that can be reasonably interpreted as not precluding the Company to proceed to a phase 3 clinical trial involving the Company’s Product (as defined in the Purchase Agreement) (the “**Company Product**”). The term “**Business Day**” shall have the meaning ascribed to it in the Purchase Agreement.

(b) Prior to and following the Phase 3 Milestone, the Company shall, to the extent practicable, provide the Purchaser with at least [***] days’ advance notice of any meetings, consultations or appointments with FDA representatives relating to the Company Product (an “**FDA Meeting**”); provided that, if the FDA or the Company requests a meeting with the other and [***] days’ advance notice is not practicable, the Company shall provide the Purchaser with notice of the requested meeting by the FDA or the Company within twenty-four hours (24) of such request. The Company shall use commercially reasonable efforts to allow representatives of the Purchaser to attend any such FDA Meetings, and the Company shall provide Purchaser copies of any data, documentation and information prepared in connection with any such FDA Meeting and all communications with the FDA for the Purchaser to review, discuss and comment or, if not practicable or legally permitted, shall provide Purchaser with a copy or summary thereof as soon as reasonably practicable thereafter.

(c) Following the Phase 3 Milestone, the Company hereby agrees and covenants not to initiate phase 3 pivotal studies involving the Company Product until the termination of the Purchase Option as set forth in Section 7. The Company further agrees and covenants to provide the Purchaser with reasonable access to the Company’s personnel, data, documentation, systems and information relating to the Company Product following the Phase 3 Milestone, including any communications received from the FDA.

6. Royalties.

(a) Royalty Term. Purchaser's obligation to pay royalties under this Section 6 shall commence [***] and shall continue with respect to sales of all Products on a country-by-country basis until [***] years after the First Commercial Sale of the first Product in such country ("**Royalty Term**").

(b) Royalty Rates. Following the closing of the Acquisition and during the Royalty Term, Purchaser shall pay to the Royalty Recipients a [***]% royalty on the Net Sales of all Products for the first [***] months after the First Commercial Sale in such country (the "**Initial Royalty Period**"); provided that, with respect to any Net Sales of Products to a United States Governmental Body, the Post-Initial Period Royalty Rates shall apply and such sales shall be included in the calculation of Annual Net Sales of Product. Following the Initial Royalty Period, Purchaser shall pay to the Royalty Recipients the following royalties on the Annual Net Sales of Products, equal to the following percentages of such Net Sales (the "**Post-Initial Period Royalty Rates**"):

Annual Net Sales of Products	Royalty Rate
Annual Net Sales of Products (as defined below) equal to or less than	9%
Annual Net Sales of Products greater than	12%

For purposes of this Agreement, "**Annual Net Sales of Products**" means [***].

For clarity, the Initial Royalty Period is determined on a country-by-country basis. By way of example, if the First Commercial Sale of a Product occurs in the United States, then the Initial Royalty Period will end [***] months after such First Commercial Sale in the United States for any and all Products, and thereafter Purchaser will pay royalties at the applicable Post-Initial Period Royalty Rate on Net Sales of all Products in the United States. Then, if there is a First Commercial Sale of a Product in Germany, the Initial Royalty Period will end [***] months after such First Commercial Sale in Germany, and thereafter Purchaser will pay royalties at the applicable Post-Initial Period Royalty Rate on Net Sales for any and all Products in Germany in addition to the United States.

(c) Royalty Adjustment.

(i) If Purchaser, its Affiliate or sublicensee becomes obligated to make payment to a Third Party with respect to intellectual property rights owned or controlled by such Third Party reasonably necessary for the Development, manufacture, use or sale of the Products (including with respect to any pharmaceutically active ingredient that is not a Product (excluding Other Product) but is sold in combination with a Product (whether or not in fixed dosage form)) (such amount, a "**Third Party Payment Amount**"), the Royalty Recipients' portion of such Third Party Payment Amount shall be equal to the then applicable Post-Initial Period Royalty Rate multiplied by the Third Party Payment Amount (the "**Deduction Amount**") and Purchaser may deduct the Deduction Amount from the amounts payable to the Royalty Recipients under this Section 6; provided that, such deduction shall not reduce the amounts so payable to the Royalty Recipients to less than [***] percent ([***]%) of the amount that would otherwise be due hereunder. Purchaser may carry forward to subsequent calendar quarters any deductions that it was not able to deduct as a result of the foregoing proviso. Notwithstanding the foregoing, in no event shall any royalty adjustment under this Section 6(c) apply to the TP Royalty (as defined in Section 6(e) below).

(ii) If the Product is neither (i) Covered by a Valid Claim of a Patent controlled by Purchaser or any of its Affiliates in the country for which such Product is sold nor (ii) subject to any Regulatory Exclusivity in such country, the royalty payable by Purchaser with respect to such Product in such country shall be reduced by [***] percent ([***]%) of the amount otherwise payable pursuant to Section 6(b). Notwithstanding the foregoing, the reduction in this Section 6(c)(ii) shall not apply with respect to a Product in a calendar quarter in a particular country if a reduction is made under Section 6(c)(iii) below for such Product in such quarter in such country.

(iii) If in any country during the Royalty Term for a Product, Generic Products to such Product are sold by any Third Party that is not a sublicensee, and the aggregated (all package sizes) sales turnover of the Product in such country (measured in unit sales) is less than [***]% of the aggregated sales volume of such Product for the calendar quarter immediately prior to the launch of the Generic Product in such country, then the then-applicable royalty rates (i.e., as set forth in Section 6(b)) and as such royalties may have been further reduced pursuant to Section 6(c)(i), subject to Section 6(c)(v) for such calendar quarter for Product sold in such country will be reduced by [***] percent ([***]%) of the royalty rates then applicable. If, in any country during the Royalty Term for a Product, Generic Products to such Product are sold by any Third Party that is not a sublicensee, and the aggregated (all package sizes) sales turnover of the Product in such country (measured in unit sales) is less than [***]% of the aggregated sales volume of such Product for the calendar quarter immediately prior to the launch of the Generic Product in such country, then the then-applicable royalty rates (i.e., as set forth in Section 6(b) and as such royalties may have been further reduced pursuant to Section 6(c)(i), subject to Section 6(c)(v)) for such calendar quarter for Product sold in such country will be reduced by [***] percent ([***]%) of the royalty rates set forth in Section 6(b). All such determinations of unit sales shall be based upon a mutually acceptable calculation method using market share data provided by a reputable and mutually agreed upon provider, such as IQVIA.

(iv) No more than one royalty payment shall be due under this Agreement with respect to a sale of a particular Product (e.g., even if such Product is Covered by multiple Valid Claims or multiple patents).

(v) Notwithstanding anything to the contrary, with respect to any Product in any calendar quarter, the operation of Section 6(c)(i), Section 6(c)(ii) and Section 6(c)(iii) above, individually or in combination, shall not reduce by more than [***] percent ([***]%) the royalties that would otherwise have been due under Section 6(b) with respect to Net Sales of such Product in the applicable country(ies) during such calendar quarter.

(d) Payment. Commencing with the calendar quarter in which the First Commercial Sale of the first Product occurs, Purchaser shall pay the Royalty Recipients equitably based on a pro rata ratio of the total number of capital stock held by the Royalty Recipients (or, their respective predecessors-in-interest, as applicable) at the time of the closing of the Acquisition (“*Pro Rata Basis*”) within [***] days following the end of each such calendar quarter during the Royalty Term.

(e) TP Royalty. If Purchaser or its Affiliates Divests one or more Products to a Third Party for commercialization in a territory other than the United States (i.e., divestiture shall not be based on the location of the Third Party), Purchaser shall pay to the Royalty Recipients on a Pro Rata Basis a [***] percent ([***]%) royalty on any sales or non-sales related revenue either Purchaser or its Affiliates receives from such Third Party (“*TP Royalty*”) within [***] days following receipt of such revenue; provided that, (a) such TP Royalty shall not be greater than [***] (\$[***]), and (b) such TP Royalty shall not be subject to any royalty adjustment. For clarity, Purchaser’s obligation to pay the TP Royalty shall survive any Change of Control of Purchaser or the Company.

(f) PRV. If Purchaser or any of its Affiliates determines to sell the first Priority Review Voucher granted with respect to the Product (“*PRV*”), Purchaser shall pay to the Royalty Recipients on a Pro Rata Basis [***] percent ([***]%) of all proceeds received from the sale of such PRV within [***] days of the consummation of the sale of the PRV. If Purchaser or any of its Affiliates determines to use the PRV for an application of Purchaser or any of its Affiliates, Purchaser shall pay to the Royalty Recipients on a Pro Rata Basis [***] Dollars (\$[***]) within [***] days of the submission of such application.

(g) Late Payments. In the event any royalty payments or other payments due to the Royalty Recipients under this Section 6 are not paid when due hereunder, Purchaser shall pay to the Royalty Recipients interest charges at the rate of [***] percent ([***]%) per annum on the total royalty payments or other payments due hereunder under paid in full.

(h) Reporting. At such times as Purchaser shall deliver a royalty payment to the Royalty Recipients under Section 6(b), Section 6(d) or Section 6(e) hereof, Purchaser shall also deliver to each of Herman Cukier, Daniel Motto, and Dr. Joseph V. Pergolizzi, Jr (the “*Designated Persons*”) a written report detailing all sales, if any, made of Products during the calendar quarter giving rise to the royalty payment (or such other applicable period), and detailing the amount of Net Sales made during such calendar quarter and showing its calculations the royalty payments due to the Royalty Recipients pursuant to Section 6(c) or Section 6(d) hereof, as applicable. The Designated Persons shall be responsible for distributing each report to the Royalty Recipients. Each report shall include at least the following:

(i) The dollar amount of Net Sales, on a country-by-country basis, of Products sold by and/or for Purchaser or its Affiliates or any Licensees;

(ii) an accounting for Net Sales, showing the details of all deductions from the gross amounts invoiced by Purchaser and its Affiliates and any Licensees; and

(iii) the royalty amounts due to the Royalty Recipients;

Each such report shall be signed by an officer of Purchaser and shall be certified as true, correct, and complete. Purchaser's failure to submit a royalty report as provided in this Section 6(h) shall constitute a breach of this Agreement.

(i) Records. Purchaser and its Affiliates shall keep (and shall cause each Licensee to keep) complete, true and accurate records and books in reasonably sufficient detail for the purpose of showing its calculation of Net Sales as well as any amounts payable to the Royalty Recipients hereunder. Records and books shall be kept at Purchaser's (or Licensee's, as applicable) principal place of business, for at least thirty-six (36) months following the end of the calendar year to which such books and records pertain.

(j) Audit. The books and records referred to in Section 6(j) shall be open to inspection by the Designated Persons as well as their respective accountants, attorneys, agents or advisors (each, a "**Designated Persons' Representative**") reasonably acceptable to Purchaser, upon at least twenty (20) days' prior written notice to Purchaser, during normal business hours during the Royalty Term and for a period of three (3) years thereafter, for the purpose of verifying the Purchaser's calculations of Net Sales and Purchaser's royalty statement. Such audits may not (a) be conducted for any calendar year ending more than thirty-six (36) months prior to the date of the request, (b) be conducted more than once each calendar year per Designated Person, or (c) be repeated for any calendar quarter. Purchaser shall ensure that any Licensee will provide the Designated Persons with such access to any books and records maintained by the Licensee. In the event such audit is conducted by a Designated Persons' Representative, such Designated Persons' Representative shall provide to Purchaser (y) a preliminary copy of its audit report at the same time it provides such audit report to the Designated Persons and (z) the final audit report containing its conclusions regarding any audit. Any Designated Person or Designated Persons' Representative conducting an audit shall enter into a confidentiality agreement with Purchaser and shall not disclose or use the confidential information except to the extent necessary to conduct the audit.

(k) Assumption by Acquirer. During the Royalty Term, Purchaser shall not (and shall ensure that none of its Affiliates do not) Divest any rights with respect to any Product to any Person (an "**Acquirer**"), unless the Acquirer agrees in writing (a) to assume and be bound by all of the provisions of this Section 6 (including, but not limited to this Section 6(k)), to the same extent that such provisions apply to Purchaser, and (b) that each Royalty Recipient is an intended third party beneficiary of the foregoing. Purchaser shall deliver a copy such agreement signed by an Acquirer to each Royalty Recipient prior to or at the time of the closing of the transaction pursuant to which rights with respect to a Product are Divested to the Acquirer.

(l) Definitions. As used in this Section 6, the following terms shall have the following respective meanings:

(i) "**Acquisition**" means Purchaser's acquisition of all the outstanding securities of the Company pursuant to the terms of this Agreement.

(ii) “**Change of Control**” means, with respect to a Party: (i) a merger, reorganization or consolidation involving such Party in which the holders of the voting securities of such Party outstanding immediately prior thereto cease to beneficially own at least fifty percent (50%) of the combined voting power of the surviving entity, directly or indirectly, immediately after such merger, reorganization or consolidation; or (ii) a transaction in which an entity or individual, or group of entities and/or individuals acting in concert, acquires more than fifty percent (50%) of the voting equity securities of such Party.

(iii) “**Combination Product**” means: [***]. [***] are each referred to as the “**Other Product(s)**”.

(iv) “**Cover**” shall mean, with respect to a claim of a Patent and a Product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such Product (considering claims of patent applications to be issued as then pending).

(v) “**Development**” or “**Develop**” means all activities that relate to the development of Products, including, but not limited to, all interactions with Regulatory Authorities, management of the clinical development program, and oversight of the manufacturing of clinical supplies and registration batches.

(vi) “**Divest**” means the sale, license, sublicense, assignment, or transfer (in any manner) of all or any of the right, title, or interest in and to a Product to a Third Party.

(vii) “**First Commercial Sale**” means, on a country-by-country basis, the first commercial sale, transfer or disposition for monetary value of any Product for use or consumption by a Third Party end user, in each case, after all approvals, licenses, registrations or authorizations of any Governmental Body that are necessary for the manufacturing, use, storage, import, transport and sale of such first Product in a regulatory jurisdiction, including in each case, pricing and reimbursement approval, have been obtained for such country and where such sale, disposition or transfer results in a recordable Net Sale in accordance with Purchaser’s or its Affiliate’s, applicable accounting practices (consistently applied).

(viii) “**Generic Product**” means, with respect to a particular pharmaceutically active ingredient (including the Product (“**Original Product**”) and a particular country, any pharmaceutical product that: (a) contains the same active pharmaceutical ingredient(s) as such Original Product, (b) is approved by the regulatory authority in such country as a substitutable generic for such Original Product or otherwise is approved as a therapeutic equivalent to such Product in a manner that relied on or incorporated data submitted by a Person (the “**Filing Entity**”), in connection with the regulatory filings for such Product, including through an ANDA or an application under §505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or any enabling legislation thereof, or any similar procedure outside the United States, in each case now or in the future, and (c) is sold in such country by a Person other than by or on behalf of such Filing Entity.

(ix) “**Governmental Body**” shall mean any national, federal, regional, state, provincial, local, or foreign or other governmental authority or instrumentality, legislative body, court, administrative agency, regulatory body, commission or instrumentality, including any multinational authority having governmental or quasi-governmental powers, or any other industry self-regulatory authority or arbitral body.

(x) “**Licensee**” means a Third Party to whom Purchaser or any of its Affiliates grants a license to offer for sale, sell, have sold, or otherwise commercialize any Product, and any sublicensees (through multiple tiers) of any of the foregoing. “Licensee” shall not be deemed to include any distributor, wholesaler or reseller of a Product who is not responsible for marketing or promotion of such Product.

(xi) “**Phase 2 Clinical Trial**” means a human clinical trial of any Product, the principal purpose of which is to evaluate the effectiveness and/or safety of such Product in the target patient population, as described in 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding foreign regulations, and which trial is intended to be the final clinical trial before the initiation of a pivotal clinical trial and to establish the dosing for such pivotal clinical trial.

(xii) “**Regulatory Authorities**” means the FDA and comparable regulatory agencies outside of the United States.

(xiii) “**Regulatory Exclusivity**” means, with respect to a Product, any exclusive marketing rights or data exclusivity rights conferred by the applicable Regulatory Authority with respect to the Product, other than a Patent, including, but not limited to, orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, or pediatric exclusivity.

(xiv) “**Patent(s)**” means all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, foreign equivalents and the like of any of the foregoing.

(xv) “**Product**” means [***]; “**Products**” means, collectively, [***].

(xvi) “**Royalty Recipient**” means the Persons that were Company stockholders at the time of the closing of the Acquisition (other than Purchaser or its Affiliates), and any of their respective successors, assigns and estates, as applicable.

(xvii) “*Net Sales*” means, [***]:

- (A) [***];
- (B) [***];
- (C) [***];
- (D) [***];
- (E) [***];
- (F) [***]; and
- (G) [***].

Notwithstanding the foregoing, amounts received or invoiced by Purchaser or its Affiliates for the sale of Products among Purchaser and its Affiliates shall not be included in the computation of Net Sales hereunder. Net Sales shall be accounted for in accordance with U.S. GAAP in all instances.

Transfers, use or sales of Products for research, Development (including for clinical studies), promotional or advertising purposes or as donations or the like or as “treatment IND sales,” “named patient sales,” “compassionate use sales” or pursuant to any expanded access programs, in each case, shall not be included in Net Sales.

For purposes of calculating Net Sales on sales of Combination Products, the gross amount received for any Product included in a Combination Product shall be calculated by multiplying the gross amount received for such Combination Product by the fraction $A/(A+B)$, where “A” is the gross amount received for such Product sold separately without the Other Product and “B” is the gross amount received for the Other Product sold separately, in each case in the same country and calendar quarter. In the event that such Product and any Other Product are not sold separately in material amounts in the same country and calendar quarter, the gross amount received for such Product shall be reasonably determined by Purchaser based upon the relative value of the Product and the Other Product included in the Combination Product. In the event of a dispute with respect to such allocation, either Party may submit the matter to dispute resolution pursuant to Section 11.14 of the Purchase Agreement.

(xviii) “*Third Party*” means any Person other than other than a Party or an Affiliate of a Party.

(xix) “*Valid Claim*” means (a) a claim of an issued, unexpired patent controlled by Purchaser that has not been revoked, disclaimed, abandoned or held invalid or unenforceable by court or other body of competent jurisdiction in an unappealed or unappealable decision, or (b) a claim of a pending patent application that has not been cancelled, withdrawn, abandoned, or finally rejected by an administrative agency action from which no appeal can be taken and that has not been pending for more than seven (7) years from the date of filing of the earliest priority patent application to which such pending patent application is entitled to claim benefit.

7. Term of the Option. The Purchase Option shall be effective as of the execution of this Agreement and shall terminate if the Purchaser does not exercise the Purchase Option upon the earlier of (a) within ninety (90) days of receiving the Phase 3 Notice from the Company, or (b) by June 30, 2027 (the “*Option Term*”).

8. Representations and Warranties of the Securityholders. Each Securityholder hereby represents and warrants to the Purchaser that the following representations and warranties are true and complete as of the date of this Agreement:

(a) Ownership of Securities. Securityholder is the sole record, legal and beneficial owner of that number and class of shares of Common Stock set forth opposite the Securityholder's name on Schedule A or is the sole and beneficial owner of an option to acquire that number and class of shares of Common Stock set forth opposite the Securityholder's name on Schedule B. The Outstanding Securities constitute Securityholder's only equity or security interest in the Company and Securityholder has no rights to directly or indirectly acquire additional shares of Common Stock. The Outstanding Securities (a) are not, and as of the closing of the Definitive Agreement will not be, subject to any liens, claims, options, charges, rights of first refusal or other encumbrances (any of the foregoing, a "Lien") (other than Liens created pursuant to this Agreement), and (b) have not been transferred, assigned or otherwise disposed of by Securityholder and Securityholder has not entered into any agreement to transfer, assign or otherwise dispose of the Outstanding Securities (other than pursuant to this Agreement).

(b) Power, Authorization and Validity. Securityholder has all requisite power and legal capacity to enter into this Agreement and to perform his, her or its obligations under this Agreement. The execution and delivery of this Agreement by Securityholder and the consummation by Securityholder of the transactions contemplated hereby have been duly authorized by all necessary action, if any, on the part of Securityholder. This Agreement has been duly executed and delivered by Securityholder and constitutes, or when executed by Securityholder shall constitute, a valid and binding obligation of Securityholder, enforceable against Securityholder in accordance with its terms, subject only to the effect, if any, of (i) applicable bankruptcy, insolvency, reorganization, moratorium and other similar laws affecting the enforcement of the rights of creditors generally and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies.

(c) No Consents. No consent, approval, order, authorization, release or waiver of, or registration, declaration or filing with, any governmental authority is necessary or required to be made or obtained by Securityholder to enable Securityholder to lawfully execute and deliver, enter into, and perform its, his or her obligations under this Agreement.

(d) No Conflict. Neither the execution and delivery by Securityholder of this Agreement or any other transaction contemplated by this Agreement: (a) conflicts with, or, with or without notice or lapse of time (or both), results in a termination, breach, impairment or violation of, or constitutes a default under, or requires the consent, release, waiver or approval of, or notice to, any third party under, (i) if Securityholder is an entity, any provision of the organizational or governing documents of Securityholder, each as currently in effect, (ii) any applicable law, or (iii) any contract to which Securityholder is a party or by which Securityholder or its, his or her assets are bound or otherwise affected; or (b) results in the creation of any Lien on any of the Outstanding Securities.

(e) Legal Proceedings. There is no private or governmental action, inquiry, claim, mediation, arbitration, counterclaim, proceeding, suit, hearing, litigation, audit or investigation, in each case whether civil, criminal, administrative, judicial or investigative, or any appeal therefrom (each of the foregoing, a “**Legal Proceeding**”) to which Securityholder is a party (either directly or indirectly) and that relates in any way to the Outstanding Securities or any of the transactions contemplated hereby or thereby. To the knowledge of Securityholder, no such Legal Proceeding has been threatened.

(f) Review. Securityholder has carefully read this Agreement and Securityholder has had reasonable time and opportunity to discuss this Agreement with Securityholder’s financial, legal and other advisors, to the extent Securityholder has determined necessary, prior to executing this Agreement. Securityholder has such knowledge and experience in business and financial matters to enable Securityholder to understand and form an investment decision with respect thereto. Securityholder understands and acknowledges that the Purchaser is entering into this Agreement in reliance upon Securityholder’s execution and delivery of this Agreement and agreement to be bound hereby and by the terms of the Definitive Agreement (including with respect to Securityholder’s indemnification obligations hereunder and thereunder).

9. Covenants of the Company. The Company hereby acknowledges and agrees that, during the Option Term, the Company:

(a) Shall use commercially reasonable best efforts to maintain and preserve intact the business of the Company as currently conducted and to maintain reasonably satisfactory relationships with suppliers, customers, distributors, Company employees and other persons or entities having material business relationships with the Company.

(b) Shall not take any of the following actions without the prior written consent of the Purchaser, such consent to not be unreasonably withheld, delayed or conditioned:

(i) authorize the creation or reclassification of, or issue or obligate itself to issue shares of, any shares of any additional class or series of capital stock or debt securities that rank senior to the Common Stock with respect to the distribution of assets on the liquidation, sale, change of control, dissolution or winding up of the Company or other similar events, the payment of dividends, rights of redemption, and any other rights, preferences or privileges; provided that, for the avoidance of doubt, nothing herein shall be construed as restricting an optionholder or recipient of an award under the Stock Plan (as defined in the Purchase Agreement) from exercising its option or award pursuant to the terms thereof and the terms of the Stock Plan (as defined in the Purchase Agreement);

(ii) enter into a Corporate Transaction (as such term is defined in the Purchase Agreement);

(iii) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Company other than (A) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Company or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then-current fair market value thereof, and (B) the Company’s exercise of its right of first refusal under Section 3.1 of the Amended and Restated Stockholders’ Agreement of the Company, dated as of the Effective Date, as may be amended from time to time in accordance with its terms;

- (iv) sell or dispose of any assets having an aggregate value exceeding \$500,000, other than the sale of inventory in the ordinary course of business consistent with past practice;
- (v) acquire any assets outside of the ordinary course of business having an aggregate value exceeding \$500,000;
- (vi) make any capital expenditures or expenditures in respect of capital additions having an aggregate value exceeding \$500,000;
- (vii) settle or agree to settle any Legal Proceeding in an amount greater than \$1,000,000 in the aggregate;
- (viii) make any material change in any method of financial accounting or accounting practice;
- (ix) to the extent it may affect the Company, (i) make, revoke or modify any material tax election, (ii) except as required by changes in applicable law, change any annual accounting period for taxes, (iii) adopt or change any tax accounting method, except as required by changes in applicable law, (iv) enter into any closing or other agreement with a taxing authority with respect to taxes, (v) settle or compromise any tax claim or assessment, consent to the extension or waiver of the limitation period applicable to any tax claim or assessment, (vi) surrender any right to claim a refund of taxes, or (vii) file any tax return other than on a basis consistent with past practice;
- (x) enter into any commercialization license, option, joint development or other contract relating or pertaining to the Company Product outside the ordinary course of business;
- (xi) waive any claims or rights with a value in excess of \$500,000;
- (xii) (A) incur any indebtedness for borrowed money in an aggregate amount exceeding \$500,000 except for unsecured indebtedness, obligations and/or liabilities or (B) impose any Lien upon any of the assets of the Company, other than in the ordinary course of business and consistent with past practice;
- (xii) hire a new President or Chief Executive Officer or other officer having similar duties and responsibilities customarily delegated to the President or Chief Executive Officer; or
- (xiii) agree or commit to do any of the foregoing.

(c) Shall cause any new recipient of securities of the Company, including any securities convertible into capital stock of the Company, to become a party to this Agreement as a Securityholder as a condition to the issuance of such capital and become subject to the Purchase Option obligations set forth herein. For the avoidance of doubt, the Company shall be permitted to continue to grant awards under the Stock Plan (as defined in the Purchase Agreement) subject to such grantees becoming a party to this Agreement in accordance with this Section 9(c).

10. Restrictions on Transfer.

(a) Other than as a function of law (e.g., death or divorce), no Securityholder, at any time, shall be permitted to, directly or indirectly, Transfer any of its Common Stock without the prior written consent of the Purchaser, such consent to not be unreasonably withheld, delayed or conditioned; provided, however, that the undersigned Securityholder agrees that it will be a condition to the transfer of any Common Stock by function of law that such transferred Common Stock continue to be subject to the Purchase Option obligations set forth herein and the undersigned Securityholder shall further undertake to take any actions necessary to ensure such obligations will continue, be recognized and enforced.

(b) As used in this Section 10, “*Transfer*” shall mean any sale, assignment, disposition, exchange, pledge, encumbrance, hypothecation, foreclosure or other transfer of such Common Stock or capital stock of the Company or any participation or interest therein, in each case whether directly or indirectly (including pursuant to a derivative transaction) in any direct or indirect company holding any Common Stock or capital stock of the Company (including, for the avoidance of doubt, if the Securityholder is an entity, the transfer of any equity interests or other securities in any direct or indirect parent entity holding equity interests or other securities in the Securityholder).

11. Representations and Warranties of the Company. The Company hereby represents and warrants to the Purchaser that the following representations and warranties are true and complete as of the date of this Agreement:

(a) Authorization; Binding Obligations. The Company has the requisite power and authority to execute, deliver and perform this Agreement and all other agreements contemplated hereby, and the Company’s execution, delivery and performance of this Agreement and all other agreements contemplated hereby has been duly authorized by all required action. This Agreement constitutes a valid and legally binding obligation of the Company, enforceable in accordance with its terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors’ rights generally and by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(b) No Conflict. The execution, delivery and performance of and compliance with this Agreement by the Company will not result in any violation or breach by the Company of any of its formation or governance documents, or any term of any indenture, mortgage, deed of trust or other agreement, instrument, court order, judgment, decree, statute, rule or regulation to which the Company is a party or by which the Company is bound and will not be in conflict with or constitute a default under any such term or result in the creation of any mortgage, pledge, lien, encumbrance or charge upon any of the properties or assets of the Company. There is no action, suit or proceeding pending or, to the knowledge of the Company, currently threatened against the Company that questions the legality, validity or enforceability of this Agreement or the right of the Company to enter into this Agreement.

12. Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

13. Amendments and Waivers.

(a) Prior to the Purchaser's purchase of all the Outstanding Securities, whether consummated by a closing under the Definitive Agreement or by the Purchaser electing to exercise the Direct Acquisition Option (the closing of such purchase and sale, an "**M&A Closing**"), this Agreement may only be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the Company (on its behalf and on behalf of the Securityholders pursuant to the Company PoA) and the Purchaser. For purposes of amending or waiving any right under this Agreement as provided in the foregoing sentence, each Securityholder hereby grants an irrevocable proxy and power of attorney to the Company, with power to take all necessary actions and execute and deliver all documents necessary to amend this agreement or waive any rights on behalf of such Securityholder (the "**Company PoA**"); provided that, the consent of the Securityholder shall be required for any amendment that is targeted as such individual Securityholder. This Company PoA is coupled with an interest and shall survive, and shall not be affected by, the subsequent death, disability, incompetency or bankruptcy of the Securityholder. This Company PoA shall not, without the prior written consent of the Purchaser and the Company, be superseded or revoked by any proxy or power of attorney granted by the Securityholder simultaneously herewith or subsequent hereto. Notwithstanding the foregoing, the Company PoA shall be automatically terminated without the further action of any Person at the time of an M&A Closing, in which case the provisions of Section 13(b) shall apply.

(b) Notwithstanding the provisions of Section 13(a) above, following an M&A Closing, if any, this Agreement may only be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of a Majority of the Royalty Recipients (as defined below) and the Purchaser; provided that, the consent of a Royalty Recipient shall be required for any amendment that is targeted as such individual Royalty Recipient. For purposes hereof, a "**Majority of the Royalty Recipients**" means, measured immediately prior to the M&A Closing, Royalty Recipients collectively holding at least [***]% of the shares of Common Stock measured solely amongst the Royalty Recipients (for the avoidance of doubt, excluding any shares of Common Stock owned by Purchaser or its Affiliates immediately prior to such M&A Closing).

14. Interpretation and Construction; Termination. This Agreement and the Transaction Documents (as defined in the Purchase Agreement) constitute the entire Agreement and understanding among the Parties pertaining to the subject matter contained herein and supersedes all prior and contemporaneous agreements, representations, and understandings of the Parties. No covenant, representation, or condition not expressed in this Agreement shall affect or be deemed to interpret, change, or restrict the express provisions hereof. The headings in this Agreement are for the convenience of reference only and shall not affect the interpretation of this Agreement. This Agreement may be terminated as set forth in Section 11.20 of the Purchase Agreement; provided that, (a) this Agreement may not be terminated by the Purchaser following an M&A Closing, (b) Sections 1, 14, 16, 17, 18, 19, 20, and 22 shall survive any such termination, and (c) if this Agreement is terminated as set forth in Section 11.20 of the Purchase Agreement, the Purchase Agreement shall also be deemed terminated as of such date without further action on the part of any Person (as defined in the Purchase Agreement).

15. Notices. All notices and other communications required or permitted hereunder shall be in writing in English and given by delivery in person, by electronic mail with confirmation of delivery, by overnight delivery by a nationally recognized private courier, or by U.S. mail postage prepaid, certified mail. Any such notice or communication shall be deemed to have been received for the purposes of this Agreement (a) in the case of personal delivery, on the date of such delivery if a Business Day or, if not a Business Day, the next succeeding Business Day, (b) in the case of nationally-recognized private courier (including overnight delivery by such courier), on the next Business Day after the date when sent, (c) in the case of email, on the date of such delivery when receipt is confirmed, and (d) in the case of mailing by U.S. mail, on the fifth Business Day following that on which the piece of mail containing such communication is deposited with the U.S. Postal Service. All notices shall be addressed as set out below or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance with this Section 15:

(i) if to the Purchaser:

Eagle Pharmaceuticals, Inc.
50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
Attention: [***]

With a copy to (which copy shall not constitute notice):

Cooley LLP
500 Boylston Street
Boston, MA 02116
Attention: Marc Recht and Miguel J. Vega
Email: mrecht@cooley.com; mvega@cooley.com
Fax No.: 617.937.2400

(ii) if to the Company:

Enalare Therapeutics Inc.
161 Hodge Road
Princeton, New Jersey 08540
Attention: [***]
Email: [***]

With a copy to (which copy shall not constitute notice):

Coviello Weber & Dahill LLP
707 Westchester Avenue, Suite 300
White Plains, NY 10604
Attention: Paul R. Weber, Esq.
Email: pweber@cwdlaw.com

(iii) if to the Securityholders, to the address, facsimile or email address set forth opposite his, her or its name on Schedule A and Schedule B, as applicable.

16. Successors and Assigns. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be transferred or assigned, in whole or in part, by operation of law or otherwise by any Party without the prior written consent of the other Parties. Notwithstanding the foregoing, the Purchaser may assign this Agreement and its rights and obligations hereunder (a) to any Affiliate of Purchaser (provided the Company receives reasonably satisfactory evidence that such Affiliate is able to meet its obligations hereunder), or (B) to a successor to all or substantially all of the assets of the Purchaser (irrespective of the nature of the transaction, whether by way of stock sale, asset sale or otherwise). In the event of any assignment in accordance with the terms of this Agreement, the assignee shall specifically assume and be bound by the provisions of the Agreement by executing and agreeing to an assumption agreement reasonably acceptable to the Purchaser and the Company. Any purported transfer or assignment without such consent shall be void. Subject to the preceding sentence, this Agreement shall be binding upon, inure to the benefit of and be enforceable by, the Parties and their respective successors, transferees and assigns.

17. Further Assurances. Each Party agrees to execute such further documents and instruments and to take such further actions as may be reasonably necessary to carry out the purposes and intents of this Agreement.

18. Expenses. Except as expressly provided in this Agreement, each of the Purchaser and the Company will bear their own costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisors and accountants, in connection with this Agreement and the transactions contemplated hereby. Each Securityholder may engage its own counsel, financial advisors and accountants, in connection with this Agreement and the transactions contemplated hereby and if it does, it shall bear all such costs and expenses individually.

19. No Third-Party Beneficiaries. Except as otherwise provided in this Agreement, nothing in this Agreement is intended to, or will, create any rights to any party other than the Parties.

20. Governing Law. This Agreement shall be governed in all respects by the internal laws of the State of Delaware, without regard to conflict of law principles that would result in the application of any law other than the law of the State of Delaware.

21. Jurisdiction; Venue. With respect to any disputes arising out of or related to this Agreement, each Party irrevocably consents to the exclusive jurisdiction of, and venue in, the Court of Chancery in the State of Delaware, agrees that process may be served upon them in any manner authorized by the laws of the State of Delaware for such persons and waives, and covenants not to assert or plead, any objection which such party might otherwise have to such jurisdiction, venue and process.

22. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

23. Remedies; Prevailing Party. Any Party having any rights under any provision of this Agreement will be entitled to enforce its rights under this Agreement to recover damages and costs (including attorneys' fees) caused by any breach of any provision of this Agreement and to exercise all other rights existing in its favor. Each Party hereby acknowledges and agrees that money damages may not be an adequate remedy for any breach of the provisions of this Agreement and that any Party may in its sole discretion apply to any court of law or equity of competent jurisdiction (without posting any bond or deposit) to seek specific performance and/or other injunctive relief in order to enforce or prevent any violations of the provisions of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, each of the parties has executed this Security Purchase Option Agreement as of the day and year first above written.

SECURITYHOLDERS:

[***]

[Signature Page to Security Purchase Option Agreement]

IN WITNESS WHEREOF, each of the parties has executed this Security Purchase Option Agreement as of the day and year first above written.

PURCHASER:

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff

Name: Scott Tarriff

Title: President & Chief Executive Officer

[Signature Page to Security Purchase Option Agreement]

IN WITNESS WHEREOF, each of the parties has executed this Security Purchase Option Agreement as of the day and year first above written.

COMPANY:

ENALARE THERAPEUTICS INC.

By: /s/ Herman Cukier

Name: Herman Cukier

Title: President & CEO

[Signature Page to Security Purchase Option Agreement]

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Schedule A

Stockholders

<u>Name</u>	<u>Number of Shares of Common Stock Held</u>	<u>Contact Information</u>
[***]	[***]	[***]

Schedule B

Noteholders

<u>Name</u>	<u>Note Agreement</u>	<u>Balance</u>	<u>Number of Shares of Common Stock Held Following Conversion</u>	<u>Contact Information</u>
[**]	[**]	[**]	[**]	[**]

Schedule C

Optionholders

<u>Name</u>	<u>Number of Shares of Common Stock Underlying Options</u>	<u>Contact Information</u>
[**]	[**]	[**]

Schedule D

Warrantholders

<u>Name</u>	<u>Number of Shares of Common Stock Underlying Warrants</u>	<u>Contact Information</u>
[**]	[**]	[**]

Exhibit A

TERM SHEET

SUMMARY OF PRINCIPAL TERMS OF PROPOSED DEFINITIVE TRANSACTION

The following is a summary of the principal terms for the proposed acquisition of Enalare Therapeutics, Inc. (the “**Transaction**”). This summary is not intended to, and does not, bind any party or create any legal rights or obligations among any parties. No party will be obligated to consummate the Transaction unless and until all definitive agreements with respect thereto are negotiated, executed and delivered.

Topic	Terms
Parties	<ol style="list-style-type: none">(1) Eagle Pharmaceuticals, Inc., a Delaware corporation (“Parent”)(2) A newly formed Delaware corporation and wholly owned subsidiary of Parent (“Merger Sub”) (in the event of a merger structure)(3) At Parent’ option, Enalare Therapeutics Inc., a Delaware corporation (the “Company”)(4) A representative, agent and attorney-in-fact (the “Securityholder Representative”) of the Company’s stockholders, optionholders and warrant holders (the “Company Securityholders”)(5) In the event of a stock purchase, the holders of capital stock, options, warrants and other securities of the Company (the “Company Securityholders”)
Transaction Structure	Parent would acquire the Company by means of either (at Parent’s election) (1) a statutory merger (the “ Merger ”), pursuant to which Merger Sub would merge with and into the Company and the Company would be the surviving corporation of such merger (the “ Surviving Corporation ”) or (2) a stock purchase transaction. To the extent possible, the Transaction will be structured as a simultaneous sign and close.
Principal Definitive Agreement	The principal definitive agreement providing for the Transaction would be an Agreement and Plan of Merger (the “ Definitive Agreement ”) to be prepared by Parent. For the avoidance of doubt, this summary does not purport, and is not intended, to include an exhaustive list of all the terms that Parent may ultimately propose in the Definitive Agreement.
Other Transaction Agreements	Concurrently with the execution of the Definitive Agreement, certain other definitive agreements would be executed and delivered in connection with the Transaction, including: <ol style="list-style-type: none">(1) a restrictive covenant agreement, in form and substance reasonably acceptable to Parent, pursuant to which certain C-level executives or members of senior management that are also Company Securityholders to be identified by Parent would agree not to compete with the Company (Enalare Therapeutics Inc.) as the business is conducted at the time of the execution of the Definitive Agreement and not solicit or hire employees for the longer of (a) three years following the Closing (as defined below) and (b) one year after the termination of his/her employment, or disclose confidential information regarding, the Company (the “Restrictive Covenant Agreement”), with such agreement to be effective as of the Closing;(2) Agreements terminating the outstanding options of the Company in the form agreed to by the Company, Parent and the Company Securityholders in the Security Purchase Option Agreement, dated August [●], 2022 (the “Call Option Agreement”);(3) Agreements terminating the outstanding warrants of the Company in the form agreed to in the Call Option Agreement; and(4) A customary joinder agreement to the Merger Agreement, executed by Company’s securityholders.

Execution of Definitive Agreement	The parties shall use commercially reasonable efforts to enter into the Definitive Agreement to effect the Transaction within [***] days of Parent delivering the Call Exercise Notice (as defined in the Call Option Agreement) or such other date as Parent and the Company mutually agree. The closing of the Definitive Agreement (the “ Closing ”) shall be as set forth in the Definitive Agreement and the Definitive Agreement shall contain customary closing conditions, including the receipt of any clearances necessary with applicable anti-trust laws or other regulatory bodies.
Consideration Payable at Closing	<p>At the Closing, Parent shall acquire all of the outstanding shares and terminate all other securities of the Company other than those owned by Parent for an amount equal to the greater of (the “Purchase Price”):</p> <p>(i) \$100 million; or</p> <p>(ii) an amount equal to [***] (such final valuation amount, the “Valuation Amount”); provided further that, in no event shall the purchase price be greater than \$175 million (the “Cap”).</p> <p>For avoidance of doubt, the Purchase Price would be paid for the Company shares owned by persons other than Parent and not prorated based on Parent’s existing ownership.</p> <p>At Closing, the Purchase Price shall (i) be increased the product of (A) [***] to (B) [***], (ii) be reduced by [***], (iii) be reduced by [***], and (iv) be subject to [***] (the “Closing Payment”). [***].</p> <p>The calculation of the Closing Payment shall be subject to a customary post-closing adjustment whereby Parent shall deliver to the Securityholder Representative Parent’s calculation of the Closing Payment and be allowed to recover from the Securityholders if it is determined that the Purchase Price at Closing was higher than the final Purchase Price (the “Purchase Price Offset”).</p> <p>Additionally, a portion of the Closing Payment in an amount equal to [***] shall be placed into a separate escrow account to serve as Parent’s remedy for certain indemnification obligations of the Company set forth in the Definitive Agreement (the “Indemnity Escrow”). A portion of the Closing Payment in an amount to be determined by Parent shall also be placed into a separate escrow account to serve as the first line of recovery for Parent in the event of a Purchase Price Offset (the “Purchase Price Escrow”) which amount shall be released from the Purchase Price Escrow within [***] days of the parties agreement (or as determined by the independent accounting firm) as to the final working capital.</p> <p>Finally, the Company Securityholders may place a portion of the Purchase Price in a separate account to be administered by the Company Securityholder Representative to cover the Company Securitholder Representative’s costs and expenses incurred in connection with its representation of the Company Securityholders (the “Expenses Fund”).</p>

<p>Effects of the Transaction</p>	<p>If structured as a Merger, at the time the Merger becomes effective (the “<i>Effective Time</i>”), as a result of the Merger and without any action on the part of any of Parent, Merger Sub, the Company or any Company Securityholder:</p> <ol style="list-style-type: none"> (1) <u>Outstanding Shares of Merger Sub Common Stock</u>. Each share of common stock of Merger Sub issued and outstanding immediately prior to the Effective Time would be converted into and become one share of common stock of the Surviving Corporation; (2) <u>Treasury Shares of the Company</u>. Any shares of capital stock of the Company that are treasury shares as of immediately prior to the Effective Time would be cancelled and cease to exist (“<i>Cancelled Shares</i>”); (3) <u>Outstanding Shares of Company Common Stock</u>. Each share of common stock of the Company issued and outstanding immediately prior to the Effective Time (other than Cancelled Shares or dissenting shares) would be cancelled and converted into the right to receive, in cash, without interest, the per share portion (determined on a fully diluted basis) of: <ol style="list-style-type: none"> (a) the Closing Payment; (b) any amount released from the Indemnity Escrow for payment to Company Securityholders; (c) any amount released from the Purchase Price Escrow for payment to Company Securityholders; and (d) any amount released from the Expense Fund for payment to Company Securityholders; <p>in each case, subject to any required withholding taxes; and</p> (4) <u>Company Options and Warrants</u>. Each vested option and warrant to purchase shares of common stock of the Company that is unexpired and unexercised as of immediately prior to the Effective Time would automatically be converted into the right to receive for each share that is subject to such option or warrant, in cash, without interest, the per share portion (determined on a fully diluted basis) of: <ol style="list-style-type: none"> (a) the Closing Payment, less the per share exercise price of such option or warrant; (b) any amount released from the Indemnity Escrow for payment to Company Securityholders; (c) any amount released from the Purchase Price Escrow for payment to Company Securityholders; and (d) any amount released from the Expense Fund for payment to Company Securityholders; <p>in each case, subject to any required withholding taxes and subject to such holder delivering an executed option cancellation agreement or warrant cancellation agreement, as applicable. Any unvested options shall be cancelled for no consideration.</p> <p>In structured as a stock purchase, the payments in clauses (3) and (4) above will apply.</p> <p>Parent would have no obligation to make any payment pursuant to the Definitive Agreement unless and until it first received from the Company or the Securityholder Representative a schedule setting forth the portion thereof payable to each Company Securityholder and instructions for disbursement thereto (each, a “<i>Payment Schedule</i>”). Parent would be entitled to rely on each Payment Schedule in making such payment without investigation and would have no liability for any errors that may be contained in any Payment Schedule.</p>
--	--

<p>Release of Indemnity Escrow, Purchase Price Escrow and Expense Fund</p>	<p>Promptly following the date that is [***] months after the date of the Closing, any remaining balance of the Indemnity Escrow would be released for disbursement to the Company Securityholders; <i>provided, however</i>, that, if there are any indemnifications claims pending, the applicable portion of the Indemnity Escrow would not be so released until such claims are finally resolved and satisfied.</p> <p>If, pursuant to the post-Closing adjustment procedures with respect to the Closing Payment, it is determined that (1) the final Closing Payment equals or exceeds the estimated Closing Payment or (2) the estimated Closing Payment exceeds the final Closing Payment by an amount that is less than the Purchase Price Escrow, then either the full amount of the Purchase Price Escrow or the portion of the Purchase Price Escrow in excess of the amount by which the estimated Closing Payment exceeds the final Closing Payment, as applicable, would be released for disbursement to the Company Securityholders. If, pursuant to the post-Closing adjustment procedures with respect to the Closing Payment, it is determined that the estimated Closing Payment exceeds the final Closing Payment by an amount that is greater than the Purchase Price Escrow, Parent may recover from the Company Securityholders an amount equal to such shortfall.</p> <p>As soon as reasonably determined by the Securityholder Representative that the Expense Fund is no longer required to be held by the Securityholder Representative, the remaining portion of the Expense Fund would be released for disbursement to the Company Securityholders.</p>
<p>Representations and Warranties of the Company</p>	<p>The Definitive Agreement will contain customary representations and warranties. The following representations and warranties will be considered “<i>Fundamental Representations</i>” for purposes of the Definitive Agreement: [***],[***]. The representations and warranties in the Definitive Agreement that are not [***] or [***] are referred to herein as the “<i>Standard R&Ws</i>.”</p> <p>[***]</p>

<p>Indemnification</p>	<p><u>Survival:</u> The representations, warranties, covenants and agreements contained in the Definitive Agreement would survive the Closing as follows:</p> <ol style="list-style-type: none"> (1) [***]; (2) [***]; (3) [***]; and (4) [***]. <p><u>Indemnification Provisions:</u></p> <p>(1) Each Company Securityholder would, severally but not jointly, indemnify Parent, Merger Sub, the Surviving Corporation (if applicable) and each of their respective affiliates and representatives (the “<i>Parent Indemnitees</i>”) from and against such Company Securityholder’s pro rata share of any losses that such Parent Indemnitee directly or indirectly incurs related to:</p> <ol style="list-style-type: none"> (a) [***]; (b) [***]; (c) [***]; (d) [***]; (e) [***]; or (f) [***]. <p>For the avoidance of doubt, each party subject to a Restrictive Covenant Agreement shall be liable for its own breaches thereof and in no event shall any Company Securityholder (other than the Company Securityholder that is party of the Restrictive Covenant Agreement) be liable for such party’s breaches.</p> <p>(2) Parent would indemnify Parent the Company Securityholders and their respective affiliates and representatives (each, a “<i>CS Indemnitee</i>” the “<i>CS Indemnitees</i>”) from and against any losses that a CS Indemnitee directly or indirectly incurs related to:</p> <ol style="list-style-type: none"> (a) [***]; or (b) [***]. <p><u>Order of Recovery:</u></p> <p>(1) Parent Indemnities would seek recovery for indemnification claims as follows:</p> <ol style="list-style-type: none"> (a) [***]; (b) [***]; and (c) [***]. <ol style="list-style-type: none"> (2) [***]. (3) [***]. (4) [***].
-------------------------------	---

Other Indemnification Matters:

For purposes of indemnification, all materiality qualifiers contained in the Company's representations and warranties would be disregarded, both for purposes of determining whether true and correct and for purposes of calculating losses.

[***];

[***].

An indemnified party shall take all reasonable steps to mitigate any loss upon becoming aware of any event or circumstance that would be reasonably expected to, or does, give rise thereto; provided that no indemnified party shall be obligated to make a claim, commence litigation or initiate a dispute against a third party that is a customer or vendor of such indemnified party.

NO PARTY WILL BE LIABLE TO ANY OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES SUFFERED BY THE OTHER PARTY (INCLUDING WITHOUT LIMITATION DAMAGES FOR HARM TO BUSINESS, LOST REVENUES, LOST SAVINGS, OR LOST PROFITS SUFFERED BY THE OTHER PARTY), REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, WARRANTY, STRICT LIABILITY, OR TORT, INCLUDING WITHOUT LIMITATION NEGLIGENCE OF ANY KIND WHETHER ACTIVE OR PASSIVE, AND REGARDLESS OF WHETHER A PARTY KNEW OF THE POSSIBILITY THAT SUCH DAMAGES COULD RESULT. THE PARTIES SHALL RELEASE THE OTHER PARTIES (AND EACH INDEMNIFIED PARTY) FROM ANY SUCH CLAIM.

All indemnification payments made under this Agreement shall be treated by the parties as an adjustment to the Purchase Price for tax purposes, unless otherwise required by law.

The parties agree that their sole and exclusive remedy with respect to any and all claims for any breach of any representation, warranty, covenant, agreement or obligation set in the Definitive Agreement or otherwise relating to the subject matter of the Definitive Agreement, shall be pursuant to the indemnification provisions set forth in the Definitive Agreement.

For the avoidance of doubt, the foregoing does not purport, and is not intended, to be an exhaustive list of all the changes that Parent may ultimately propose to the indemnification provisions in the Definitive Agreement.

Expenses	All costs and expenses incurred in connection with the Definitive Agreement and the transactions contemplated thereby (including fees and disbursements of counsel, financial advisors and accountants) that are not otherwise paid prior to the closing date shall be borne by the party which incurs such cost or expense; <u>provided that</u> , all fees incurred in connection with any (a) filings under the HSR Act, (b) any other regulatory filing and (c) the premium for the R&W Policy shall be borne equally by Parent, on the one hand, and by the Company, on the other hand. Any tail insurance premiums shall be borne by the Company.
Specific Performance	Each party would be entitled to specific performance of the terms of the Definitive Agreement and immediate injunctive relief, without the necessity of proving the inadequacy of money damages as a remedy, in addition to any other remedy at law or in equity.
Governing Law; Exclusive Forum	The Definitive Agreement would be interpreted, construed and governed in accordance with the laws of the State of Delaware without regard to the conflicts of law principles thereof, and the parties would irrevocably submit to the jurisdiction of state and federal courts in the State of Delaware in respect of the interpretation and enforcement of the Definitive Agreement.

Exhibit B

CALL EXERCISE NOTICE

Exhibit C

Direct Acquisition Notice

Exhibit D
Stock Power

Exhibit E

Option Termination Agreement

Exhibit F

Warrant Termination Agreement

For Immediate Release

Eagle Pharmaceuticals Reports Second Quarter 2022 Results

- Q2 2022 net loss was \$(0.74) per basic and diluted share and adjusted non-GAAP net income was \$1.58 per basic and \$1.56 per diluted share
- Total revenue for Q2 2022 was \$74.1 million, compared to \$48.1 million in Q2 2021, primarily reflecting product sales of vasopressin and PEMFEXY[®]
- First half 2022 adjusted non-GAAP earnings per basic share¹ more than doubled to \$5.60 from full year 2021 adjusted non-GAAP earnings per basic share, outperforming any full year in the Company's history
 - First half 2022 revenue of \$190 million exceeds full year 2021 revenue of \$171.5 million
 - First half 2022 net sales of vasopressin and PEMFEXY combined totaled \$99.4 million
- Cash and net receivables totaled \$122.5 million at June 30, 2022, after the acquisition of Acacia Pharma Group plc ("Acacia")
- Completed acquisition of Acacia, adding two FDA-approved new chemical entities, BARHEMSYS[®] and BYFAVO[®], with strong patent protection and expanding footprint in acute care sector with peak sales potential of \$275 million²
- Strengthened hospital pipeline through equity stake in, and an option to acquire, Enalare Therapeutics Inc ("Enalare")³. This investment brings a pipeline of three leading indications in which ENA-001, a novel agnostic respiratory stimulant, is the most advanced candidate, with the potential to come to market for post operative respiratory depression in 2026 and community drug overdose thereafter, if approved
- Supported the AOP Orphan Pharmaceuticals GmbH, a member of the AOP Group ("AOP Health"), submission of new drug application for landiolol, an ultra-selective Beta-1 Adrenergic Blocker; FDA decision on approval expected mid 2023 with potential for up to five years of new chemical entity exclusivity

WOODCLIFF LAKE, NJ—August 9, 2022—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced financial results for the three months ended June 30, 2022.

¹ Adjusted non-GAAP net income, adjusted non-GAAP earnings per share, adjusted non-GAAP R&D expense and adjusted non-GAAP SG&A expense are non-GAAP financial measures. For descriptions and reconciliations of these non-GAAP financial measures to their most comparable GAAP financial measures, please see below and the tables at the end of this press release.

² These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

³ Please reference the Company's press release on Enalare issued on August 9, 2022

Business and Recent Highlights:

- Completed the acquisition of Acacia on June 9, 2022, providing Eagle with two currently marketed, acute care, hospital products, both of which are new chemical entities (“NCEs”) with strong patent protection:
 - BARHEMSYS⁴ is the first and only antiemetic approved by the FDA for rescue treatment of postoperative nausea and vomiting despite prophylaxis⁵
 - BYFAVO⁶ for injection is indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less, with an estimated total addressable market in procedural sedation of more than \$0.4 billion per year⁷ in the U.S.
 - Combined addressable market is an estimated \$3.1 billion per year⁸
 - Projected annual peak sales of \$275 million⁹ in the United States
- Acquired an equity stake in, with an option to purchase, Enalare, adding a portfolio of novel NCEs with strong intellectual property protection, from the mid-2030s into the 2040s, including composition of matter patents. Enalare’s lead compound, ENA-001 is an investigational, one-of-a-kind NCE being developed as an agnostic respiratory stimulant for multiple patient populations experiencing acute respiratory depression. The initial targeted indications include: post-operative respiratory depression, the most advanced development program; community drug overdose; and Apnea of Prematurity, a common condition in preterm infants. The Company believes this acquisition strengthens Eagle’s position as a diversified pharmaceutical company and a leader in hospital/anesthesia.
- Supported AOP’s submission of new drug application (“NDA”) for landiolol, an ultra-selective Beta-1 Adrenergic Blocker, seeking approval for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter. FDA decision with respect to approval is expected mid-2023, and enrollment of the study of pediatric patients with supraventricular tachycardia is underway in Europe.
- Appointed pharmaceutical industry veteran, Debra M. Hussain, as Senior Vice President, Head of Commercial.

Financial Highlights

Second Quarter and First Half 2022

- Total revenue for Q2 2022 was \$74.1 million, compared to \$48.1 million in Q2 2021, primarily reflecting product sales of vasopressin and PEMFEXY.
- Q2 2022 net loss was \$(9.5) million, or \$(0.74) per basic and diluted share, compared to net income of \$3.6 million, or \$0.28 per basic and \$0.27 diluted share, in Q2 2021.
- Q2 2022 adjusted non-GAAP net income was \$20.3 million, or \$1.58 per basic and \$1.56 per diluted share, compared to adjusted non-GAAP net income of \$12.4 million, or \$0.95 per basic and \$0.93 diluted share, in Q2 2021.
- Cash and cash equivalents were \$36.6 million, net accounts receivable was \$85.9 million, and debt was \$50.0 million, as of June 30, 2022.

⁴ <https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf>

⁵ FDA labels for other recommended treatments do not include treatment after failed prophylaxis.

⁶ <https://bynder.acaciapharma.com/m/403e8c343b2922de/original/Byfavo-PI.pdf>

⁷ These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

⁸ These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

⁹ These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

“Our 2022 results to date are bearing out the vision that we have been articulating for Eagle for some time. It’s only midyear, and we have already turned in the best earnings performance in the history of our company. Our first-half earnings per share are more than twice our full-year 2021 numbers. As we look to sustain and accelerate this growth, we continue to support our commercial launches and broaden our portfolio through acquisitions, such as Acacia and the potential to acquire Enalare, both of which enhance our position in hospitals and critical care,” stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

“The addition of BARHEMSYS and BYFAVO, the planned launch of landiolol next year, if approved, CAL02, and now our investment in Enalare, puts us well on our way to becoming a diverse pharmaceutical company. We are pleased that we have delivered on our previously stated aspirations and believe we are well positioned to use 2022 as a springboard for further growth,” concluded Tarriff.

Second Quarter 2022 Financial Results

Total revenue for the three months ended June 30, 2022 was \$74.1 million, as compared to \$48.1 million for the three months ended June 30, 2021.

Q2 2022 PEMFEXY product sales were \$16.5 million and vasopressin product sales were \$11.3 million.

Q2 2022 RYANODEX[®] product sales were \$8.8 million, compared to \$7.9 million in the second quarter of 2021.

Q2 2022 BELRAPZO[®] product sales were \$8.1 million, compared to \$7.6 million in the second quarter of 2021.

Royalty revenue was \$24.9 million in the second quarter of 2022, compared to \$28.5 million in the second quarter of 2021. BENDEKA royalties were \$23.0 million in the second quarter of 2022, compared to \$27.8 million in the second quarter of 2021.

A summary of total revenue is outlined below:

	Three Months Ended June 30,	
	2022	2021
	(unaudited)	(unaudited)
Revenue (in thousands):		
Product sales, net	\$ 49,201	\$ 19,621
Royalty revenue	24,935	28,503
Total revenue	<u>\$ 74,136</u>	<u>\$ 48,124</u>

Gross margin was 68% during the second quarter of 2022, as compared to 78% in the second quarter of 2021. The decrease in gross margin was driven by revenue mix, primarily the launch of PEMFEXY and vasopressin.

R&D expense was \$11.4 million for the second quarter of 2022, compared to \$9.9 million for the second quarter of 2021. The increase was primarily due to clinical expense for fulvestrant and spend on CAL02. Excluding stock-based compensation and other non-cash and non-recurring items, adjusted non-GAAP R&D expense during the second quarter of 2022 was \$10.8 million.

SG&A expenses in the second quarter of 2022 totaled \$36.8 million compared to \$16.6 million in the second quarter of 2021. This increase was primarily related to external legal spend for the acquisition of Acacia, severance costs, and sales and marketing expenses associated with the launch of PEMFEXY. Excluding stock-based compensation and other non-cash and non-recurring items, second quarter 2022 adjusted non-GAAP SG&A expense was \$15.2 million.

Net loss for the second quarter of 2022 was \$(9.5) million, or \$(0.74) per basic and diluted share, compared to net income of \$3.6 million, or \$0.28 per basic and \$0.27 per diluted share, in the second quarter of 2021, as a result of the factors discussed above.

Adjusted non-GAAP net income for the second quarter of 2022 was \$20.3 million, or \$1.58 per basic and \$1.56 per diluted share, compared to adjusted non-GAAP net income of \$12.4 million, or \$0.95 per basic and \$0.93 diluted share, in the second quarter of 2021.

2022 Full Year Expense Guidance

- Adjusted non-GAAP R&D expense for the full year 2022 is expected to be in the range of \$46 million to \$50 million, as compared to \$32.5 million in 2021.
- Adjusted non-GAAP SG&A expense for the full year 2022 is expected to be in the range of \$62 million to \$66 million, as compared to \$54.9 million in 2021.

Liquidity

As of June 30, 2022, Eagle had \$36.6 million in cash and cash equivalents and \$85.9 million in net accounts receivable, and \$50.0 million in outstanding debt. Therefore, as of June 30, 2022, Eagle had cash plus net receivables of \$122.5 million.

Conference Call

As previously announced, Eagle management will host its second quarter 2022 conference call as follows:

Date	August 9, 2022
Time	8:30 A.M. ET
Toll free (U.S.)	800-445-7795
International	203-518-9843
Webcast (live and replay)	www.eagleus.com , under the “Investor + News” section

A replay of the conference call will be available for two weeks after the call's completion by dialing 800-938-0997 (U.S.) or 402-220-1541 (International) and entering conference call ID EGRXQ222. The webcast will be archived for 30 days at the aforementioned URL.

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 vasopressin, 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 information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “could,” “should,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” “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 Company’s financial projections and guidance, including anticipated financial performance for 2022, including expected R&D and SG&A expense; any further investments in Enalare and Enalare’s development programs; the potential exercise of Eagle’s option to acquire all of Enalare’s outstanding shares; the potential benefits and commercial opportunity of Enalare’s product candidates; the potential of Enalare product candidates to immediately expand Eagle’s long-term growth possibilities, if acquired; statements regarding expectations with respect to whether and when the Acacia acquisition may be earnings accretive; expectations with respect to synergies; expectations that the acquisition of Acacia Pharma will help improve the care of patients undergoing medical treatments, solidify the Company’s leadership position in the hospital and oncology space and bring long-term value to the Company’s shareholders; the estimated addressable market size and estimated sales figures for BARHEMSYS and BYFAVO and other products or product candidates; the ability of BARHEMSYS and BYFAVO, as well as the Company’s investment in Enalare, serve to diversify and complement its revenue streams and strengthen its advantage in acute care; the ability of Enalare to advance global development and future commercialization of ENA001 and the Company’s potential acquisition of Enalare in the future, subject to the completion of certain milestones; the Company’s ability to pursue additional potential transactions to further diversify its product portfolio and pipeline on favorable terms or at all; the Company’s ability to obtain and maintain regulatory approval of its products and product candidates; 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 Company’s timing and ability to enroll patients in upcoming clinical trials, including for CAL02; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates, including landiolol and its fulvestrant product; the progress and success of the Company’s launch of any products, including vasopressin and PEMFEXY; the addressable market size for, and the ability of the Company to successfully commercialize, its product candidates, including vasopressin and PEMFEXY; the ability of vasopressin to benefit providers and patients as an alternative to Vasotrist; the ability of BARHEMSYS, BYFAVO, landiolol and other products and product candidates to address unmet clinical needs; the potential market opportunity for the Company’s products or product candidates, including for BARHEMSYS, BYFAVO and landiolol; the period of marketing exclusivity for any of the Company’s products or product candidates, including vasopressin; the resolution of patent litigation and all related settlement terms, including the date of market entry and the potential for earlier market entry under certain circumstances; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates and the Company’s ability to maintain regulatory approval of its products and product candidates; the Company’s clinical development plan for the product candidates in its portfolio; the implementation of certain healthcare reform measures; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; 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 ability of the Company’s executive team to execute on the Company’s strategy and to utilize its cash and other assets to increase shareholder value; and the ability of the Company’s product candidates to deliver value to stockholders; the Company’s ability to deliver value in 2022 and over the long term; the Company’s ability to sustain and accelerate this growth; the Company’s ability to utilize its cash and other assets to increase shareholder value; the Company’s ability to effectively manage and control expenses in line with its budget; and the Company’s plans and ability to advance the products in its pipeline; potential opportunities for, and the Company’s ability to complete, 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 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 recently completed transaction with Acacia Pharma are not realized; 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 factors in addition to the foregoing that may impact the Company’s financial projects and guidance, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, 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, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 8, 2022, the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, and its other subsequent filings with the SEC, including the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which the Company expects to file with the SEC on August 9, 2022. 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.

Non-GAAP Financial Performance Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted non-GAAP net income, adjusted non-GAAP earnings per share attributable to Eagle, adjusted non-GAAP R&D expense and 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.

Adjusted non-GAAP net income and related earnings per share information excludes amortization expense, stock-based compensation expense, depreciation expense, severance, acquisition related costs, legal settlement, non-cash interest expense, fair value adjustments on equity investment, convertible promissory note related credit losses, fair value adjustments related to derivative instruments, accretion of discount on convertible promissory note, foreign currency exchange loss and the tax effect of these adjustments.

Adjusted non-GAAP R&D expense excludes stock-based compensation expense and depreciation expense.

Adjusted non-GAAP SG&A expense excludes stock-based compensation expense, amortization expense, depreciation expense, severance, legal settlement and acquisition related costs.

The Company believes the use of non-GAAP financial measures helps indicate underlying trends in the Company's business and are important in comparing current results with prior period results and understanding projected operating performance. Non-GAAP financial measures provide the Company and its investors with an indication of the Company's baseline performance before items that are considered by the Company not to be reflective of the Company's ongoing results. See the attached reconciliation tables for details of the amounts excluded and included to arrive at certain of the non-GAAP financial measures.

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. Reconciliations of the components of projected adjusted non-GAAP R&D and adjusted non-GAAP SG&A to their most comparable GAAP financial measures is not provided because the quantification of projected GAAP R&D and SG&A and the reconciling items between projected GAAP to adjusted non-GAAP R&D and SG&A cannot be reasonably calculated or predicted at this time without unreasonable efforts. For example, with respect to GAAP R&D and SG&A, 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 transactions. Such unavailable information could be significant such that actual GAAP R&D and SG&A would vary significantly from projected GAAP and adjusted non-GAAP R&D and adjusted non-GAAP SG&A.

These non-GAAP financial measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. The Company strongly encourages investors to review its consolidated financial statements and publicly-filed reports in their entirety and cautions investors that the non-GAAP financial measures used by the Company may differ from similar measures used by other companies, even when similar terms are used to identify such measures.

Investor Relations for Eagle Pharmaceuticals, Inc.:

Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

-- Financial tables follow --

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share amounts)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 36,562	\$ 97,659
Accounts receivable, net	85,920	41,149
Inventories	57,712	21,908
Prepaid expenses and other current assets	14,262	11,890
Total current assets	<u>194,456</u>	<u>172,606</u>
Property and equipment, net	1,459	1,636
Intangible assets, net	112,474	10,671
Goodwill	43,057	39,743
Deferred tax asset, net	23,244	18,798
Other assets	7,066	10,278
Total assets	<u>\$ 381,756</u>	<u>\$ 253,732</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 19,971	\$ 16,431
Accrued expenses and other liabilities	67,150	32,338
Current debt	21,843	25,607
Total current liabilities	<u>108,964</u>	<u>74,376</u>
Long-term debt	28,018	—
Deferred tax liability	4,536	—
Other long-term liabilities	2,256	2,903
Total liabilities	<u>143,774</u>	<u>77,279</u>
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 17,549,023 and 16,903,034 shares issued as of June 30, 2022 and December 31, 2021, respectively	18	17
Additional paid in capital	358,377	325,779
Accumulated other comprehensive income (loss)	2,281	(94)
Retained earnings	110,470	75,862
Treasury stock, at cost, 4,278,831 and 4,111,622 shares as of June 30, 2022 and December 31, 2021, respectively	(233,164)	(225,111)
Total stockholders' equity	<u>237,982</u>	<u>176,453</u>
Total liabilities and stockholders' equity	<u>\$ 381,756</u>	<u>\$ 253,732</u>

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(In thousands, except share and per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue:				
Product sales, net	\$ 49,201	\$ 19,621	\$ 139,289	\$ 36,741
Royalty revenue	24,935	28,503	50,721	52,632
Total revenue	<u>74,136</u>	<u>48,124</u>	<u>190,010</u>	<u>89,373</u>
Operating expenses:				
Cost of product sales	21,171	7,907	46,347	16,349
Cost of royalty revenue	2,493	2,850	5,072	5,263
Research and development	11,437	9,911	17,545	24,199
Selling, general and administrative	36,832	16,636	59,014	36,515
Total operating expenses	<u>71,933</u>	<u>37,304</u>	<u>127,978</u>	<u>82,326</u>
Income from operations	2,203	10,820	62,032	7,047
Interest income	244	163	398	198
Interest expense	(552)	(422)	(918)	(844)
Other (expense) income	(7,763)	(5,013)	(9,720)	487
Total other (expense) income, net	<u>(8,071)</u>	<u>(5,272)</u>	<u>(10,240)</u>	<u>(159)</u>
(Loss) income before income tax provision	(5,868)	5,548	51,792	6,888
Income tax provision	(3,582)	(1,936)	(17,184)	(3,697)
Net (loss) income	\$ (9,450)	\$ 3,612	\$ 34,608	\$ 3,191
(Loss) earnings per share attributable to common stockholders:				
Basic	\$ (0.74)	\$ 0.28	\$ 2.71	\$ 0.24
Diluted	\$ (0.74)	\$ 0.27	\$ 2.67	\$ 0.24
Weighted average number of common shares outstanding:				
Basic	12,836,116	13,108,998	12,773,727	13,116,370
Diluted	12,836,116	13,262,164	12,951,788	13,293,920

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net income	\$ 34,608	\$ 3,191
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	(4,445)	1,119
Depreciation expense	345	378
Noncash operating lease expense related to right-of-use assets	593	508
Amortization expense of intangible assets	2,197	1,412
Fair value adjustments on equity investment	3,230	(400)
Stock-based compensation expense	8,795	10,789
Convertible promissory note related credit losses	62	100
Amortization of debt issuance costs	236	236
Fair value adjustments related to derivative instrument	620	(188)
Accretion of discount on convertible promissory note	(91)	(56)
Loss on foreign currency exchange rates	1,281	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(44,312)	(1,981)
Inventories	(8,862)	(219)
Prepaid expenses and other current assets	(6)	(1,802)
Accounts payable	2,931	4,868
Accrued expenses and other liabilities	29,006	1,710
Other assets and other long-term liabilities, net	193	(594)
Net cash provided by operating activities	<u>26,381</u>	<u>19,071</u>
Cash flows from investing activities:		
Purchase of Acacia, net of cash acquired	(75,416)	—
Purchase of property and equipment	(168)	(269)
Purchase of convertible promissory note	—	(5,000)
Net cash used in investing activities	<u>(75,584)</u>	<u>(5,269)</u>
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,500	1,608
Employee withholding taxes related to stock-based awards	(1,341)	(1,551)
Payment of debt	(4,000)	(4,000)
Repurchases of common stock	(8,053)	(4,297)
Net cash used in financing activities	<u>(11,894)</u>	<u>(8,240)</u>
Net (decrease) increase in cash and cash equivalents	<u>(61,097)</u>	<u>5,562</u>
Cash and cash equivalents at beginning of period	<u>97,659</u>	<u>103,155</u>
Cash and cash equivalents at end of period	<u>\$ 36,562</u>	<u>\$ 108,717</u>
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	\$ 10,570	\$ 4,300
Interest	525	625

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP NET INCOME AND
ADJUSTED NON-GAAP EARNINGS PER SHARE (UNAUDITED)
(In thousands, except share and per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net (loss) income - GAAP	\$ (9,450)	\$ 3,612	\$ 34,608	\$ 3,191
Adjustments:				
Cost of product revenues:				
Amortization expense	1,466	301	2,197	602
Research and development:				
Stock-based compensation expense	601	641	1,244	1,536
Depreciation expense	44	54	92	107
Severance	-	-	-	274
Selling, general and administrative:				
Stock-based compensation expense	3,899	3,640	7,551	9,253
Acquisition related costs	9,849	-	11,339	-
Amortization expense	-	405	-	810
Depreciation expense	124	134	253	271
Severance	7,742	28	7,791	334
Legal settlement	-	-	300	-
Other:				
Non-cash interest expense	278	118	396	236
Fair value adjustments on equity investment	700	5,200	3,230	(400)
Convertible promissory note related credit losses	26	-	62	100
Fair value adjustments related to derivative instrument	6,239	(188)	5,631	(188)
Accretion of discount on convertible promissory note	(45)	(56)	(90)	(56)
Foreign currency exchange loss	798	-	798	-
Tax effect of the non-GAAP adjustments	(1,956)	(1,489)	(2,935)	(403)
Adjusted non-GAAP net income	<u>\$ 20,315</u>	<u>\$ 12,400</u>	<u>\$ 72,467</u>	<u>\$ 15,667</u>
Adjusted non-GAAP earnings per share:				
Basic	\$ 1.58	\$ 0.95	\$ 5.67	\$ 1.19
Diluted	\$ 1.56	\$ 0.93	\$ 5.60	\$ 1.18
Weighted average number of common shares outstanding:				
Basic	12,836,116	13,108,998	12,773,727	13,116,370
Diluted	12,997,602	13,262,164	12,951,788	13,293,920

EAGLE PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO ADJUSTED NON-GAAP EBITDA (UNAUDITED)
(In thousands)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>		<u>Twelve Months Ended</u>	<u>Twelve Months</u>
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>	<u>June 30,</u>	<u>Ended</u>
					<u>2022</u>	<u>December 31,</u>
						<u>2021</u>
Net (loss) income - GAAP	\$ (9,450)	\$ 3,612	\$ 34,608	\$ 3,191	\$ 22,790	\$ (8,627)
Add back:						
Interest expense, net of interest income	308	259	520	646	949	1,075
Income tax provision	3,582	1,936	17,184	3,697	17,566	4,079
Depreciation and amortization expense	1,634	894	2,542	1,790	4,512	3,760
Add back:						
Stock-based compensation expense	4,500	4,281	8,795	10,789	17,561	19,555
Fair value adjustments on equity investment	700	5,200	3,230	(400)	9,800	6,170
Expense of acquired in-process research & development	-	-	-	-	15,339	15,339
Convertible promissory note related credit losses	26	-	62	100	720	758
Fair value adjustments related to derivative instrument	6,239	(188)	5,631	(188)	5,133	(686)
Foreign currency exchange loss	798	-	798	-	798	-
Legal Settlement	-	-	300	-	300	-
Acquisition related costs	9,849	-	11,339	-	11,339	-
Severance	7,742	28	7,791	608	9,267	2,084
Adjusted Non-GAAP EBITDA	<u>\$ 25,928</u>	<u>\$ 16,022</u>	<u>\$ 92,800</u>	<u>\$ 20,233</u>	<u>\$ 116,074</u>	<u>\$ 43,507</u>

Important Safety Information for BARHEMSYS® (amisulpride)⁴ Injection

Contraindication

BARHEMSYS is contraindicated in patients with known hypersensitivity to amisulpride.

QT Prolongation

BARHEMSYS causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 5 mg or 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid BARHEMSYS in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions

Common adverse reactions reported in $\geq 2\%$ of adult patients who received BARHEMSYS 5 mg (n=748) and at a higher rate than placebo (n=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).

Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of BARHEMSYS-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.

The most common adverse reaction, reported in $\geq 2\%$ of adult patients who received BARHEMSYS 10 mg (n=418) and at a higher rate than placebo (n=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

Use in Specific Populations

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

BARHEMSYS may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after BARHEMSYS treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of BARHEMSYS.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

Avoid BARHEMSYS in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m²). The pharmacokinetics of amisulpride in patients with severe renal impairment have not been adequately studied in clinical trials. Amisulpride is known to be substantially excreted by the kidneys, and patients with severe renal impairment may have increased systemic exposure and an increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment

(eGFR ≥ 30 mL/min/1.73 m²).

Drug Interactions

- BARHEMSYS causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of BARHEMSYS in patients taking droperidol.
 - ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
 - Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and BARHEMSYS. Avoid using levodopa with BARHEMSYS.
-

Important Safety Information for BYFAVO™ (remimazolam)⁵ 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

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.



For Immediate Release

Eagle Pharmaceuticals Takes Equity Stake in, with Option to Acquire, Enalare Therapeutics to Advance Global Development of ENA-001, a Novel Agnostic Respiratory Stimulant

-- ENA-001 is currently in development for: post-operative respiratory depression, community drug overdose, and Apnea of Prematurity --

-- Approval for post-operative respiratory depression expected in 2026 and community drug overdose thereafter --

-- ENA-001 works peripherally by inhibiting Big Potassium (BK) ion channels in the carotid bodies, which are located in the neck. By inhibiting these channels, ENA-001 utilizes the body's own ventilation control system to stimulate breathing and it does so across multiple causes (etiologies) of respiratory depression. This, and the ability of ENA-001 to address respiratory depression associated with multiple agents (e.g. opioids, benzodiazepines, propofol), differentiates it from other available options --

Key Highlights

- Transaction broadens Eagle's acute care portfolio with ENA-001, a new chemical entity ("NCE") with a unique mechanism of action being developed as an agnostic respiratory stimulant for potential use in multiple patient populations experiencing acute respiratory depression.
- The initial targeted indications include:
 - o **Post-operative Respiratory Depression.** Respiratory depression is common in patients recovering from surgery and anesthesia. Up to 36% of patients¹ are at high risk of post-operative respiratory depression which is associated with increased risk of in-hospital mortality, increased length of stay and higher cost. ENA-001 has the potential to treat respiratory depression without interfering with analgesia (pain suppression) or sedation.

¹ Khanna, Ashish K., Bergese, Sergio D., et al; PRODIGY Group Collaborators. Prediction of Opioid-Induced Respiratory Depression on Inpatient Wards Using Continuous Capnography and Oximetry: An International Prospective, Observational Trial. *Anesthesia & Analgesia*. Volume 113, Issue 4, October 2020.

- o **Community Drug Overdose.** Drug overdose deaths are at a record high² and polysubstance abuse is increasingly common³. Current therapeutic options are limited in that they only address a single substance of abuse, typically opioids, and are associated with inducing a withdrawal syndrome. Naloxone is an opioid receptor antagonist indicated only for known or suspected opioid induced depression and may precipitate acute withdrawal. ENA-001 has the potential to treat respiratory depression associated with polysubstance abuse without inciting the withdrawal effect experienced with opioid antagonists, a potential safety consideration.
- o **Apnea of Prematurity (AoP).** The incidence of AoP increases with decreasing birthweight and gestational age. 25% of neonates weighing less than 2,500 g at birth suffer from AoP. 75% of infants born at 28-29 weeks will have AoP and the incidence remains as high as 14% for infants born at 32-33 weeks⁴. Pharmacologic treatment for these neonates is limited to caffeine (methylxanthines), the most widely used first-line treatment option. ENA-001 would be used potentially as monotherapy or in conjunction with current standard of care, caffeine.
- Represents strong strategic fit with Eagle’s specialized sales and marketing organization and current and expanding portfolio of hospital and anesthesia products.
- Eagle will make a \$25 million investment in Enalare Therapeutics (“Enalare”), \$12.5 million which will be paid now and another \$12.5 million in six months, followed by two additional potential equity investments of \$15 million each contingent upon the achievement of development milestones for ENA-001. In connection with the equity investment, the two companies also entered into an agreement providing Eagle the option to acquire the remaining outstanding shares.
- ENA-001 is expected to enter a Phase 2 study with the first patient by early 2023. The trial is expected to recruit about 200 subjects over one year. The Company anticipates a 2026 launch for post-operative respiratory depression, and community drug overdose thereafter.

WOODCLIFF LAKE, NJ, and PRINCETON, NJ —August 9, 2022—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”), and Enalare Therapeutics Inc (“Enalare”) today announced an agreement for Eagle to make an equity investment of \$25 million in Enalare, a clinical-stage privately held biopharmaceutical company dedicated to developing novel therapies for patients suffering from life-threatening acute respiratory and critical care conditions. The investment also includes an exclusive option for Eagle to acquire all remaining issued and outstanding Enalare stock upon the achievement of development milestones as set forth in the agreement.

² National Institute on Drug Abuse (2022)
<https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>

³ Centers for Disease Control and Prevention (2021)
<https://www.cdc.gov/drugoverdose/deaths/other-drugs.html>

⁴ Bohin, S., Field, D.J., *The Epidemiology of Neonatal Respiratory Disease, Early Human Development*, Volume 37, Issue 2, May 1994,

As part of the transaction, Eagle will invest up to approximately \$55 million, which is expected to occur over the next two years subject to the achievement by Enalare of certain milestones on an agreed upon timeline. The investment consists of an upfront investment of \$25 million, \$12.5 million now and \$12.5 to be paid in six months, and two potential follow-on equity investments of \$15 million each contingent upon (i) the commencement of the ENA-001 Phase 2 clinical trial, and (ii) the ENA-001 Phase 2 clinical trial reaching 50% enrollment. Eagle and Enalare have also entered into an agreement providing Eagle the option to acquire the all remaining Enalare shares for an aggregate purchase price ranging from \$100-\$175 million plus royalty rights ranging from 9%-12% on all future global net sales of any Enalare product, paid to the ex-Eagle holders of Enalare shares at the time of acquisition.

The transaction is expected to provide Eagle with products protected by intellectual property rights, including composition of matter patents, which potentially provide patent term into the mid-2030s to the early 2040s. The Company believes these products have the potential to address significant unmet medical needs for millions of patients worldwide suffering from acute respiratory depression, including those in the hospital post-operative care setting, those experiencing community drug overdose, and preterm infants suffering a common condition known as Apnea of Prematurity.

- Enalare’s lead compound, ENA-001, is an investigational, one-of-a-kind NCE designed as an agnostic respiratory stimulant.
 - o It has been shown to be well tolerated in restoring breathing drive and responsiveness in five Phase 1 human studies.
 - o Recent topline results of Enalare’s Phase 1 Study 108 indicate that ENA-001 successfully achieved the study’s primary endpoint. It was shown to be safe and well-tolerated and was able to reverse propofol-induced dampening of ventilatory responsiveness in the population studied.
 - o Enalare is planning to initiate a Phase 2 clinical study for use in this patient population in the near term.
 - o Approval for post-operative respiratory depression expected in 2026, and community drug overdose thereafter.
 - ENA-001 is also being developed in an Intramuscular (“IM”) Formulation in partnership with the Biomedical Advanced Research and Development Authority (“BARDA”) (contract number 75A50121C00044) for the potential use in patients experiencing drug overdose in a community setting and as a potential medical countermeasure for mass casualty events. This effort is also supported via a grant from the National Institute on Drug Abuse (NIDA: award number R44DA057133), a division of the National Institutes of Health. Enalare is planning to complete the required preclinical activities with the IM formulation in the near term and to begin human clinical studies in the first half of next year.
-

- In addition, Enalare is developing ENA-001 for the treatment of Apnea of Prematurity (“AoP”), a condition commonly affecting infants born preterm in which they experience shallow or intermittent stoppage of breathing. Persistent AoP can cause near- and long- term neurological development risks to the infant. ENA-001 has received Rare Pediatric Disease designation from the U.S. Food and Drug Administration (“FDA”) in the treatment of AoP, which potentially provides for a priority review voucher if the product is approved for this indication. Enalare is currently executing an animal proof-of-concept study with ENA-001 in the treatment of AoP and expects to further pursue orphan drug designation and initiate human clinical trials.

“By adding Enalare’s highly differentiated and complementary NCE to our portfolio, we immediately expand Eagle’s long-term growth possibilities. We believe ENA-001 has enormous potential to address important unmet medical needs. It is an agnostic respiratory stimulant with what we view as compelling clinical and health economic value propositions. It is also an ideal fit within our current hospital critical care portfolio, comprised of four approved and two investigational products. BARHEMSYS[®], the only proven antiemetic for the treatment of post-operative nausea and vomiting (“PONV”), BYFAVO^{®5}, the first new drug approved for procedural sedation in decades, RYANODEX[®], and vasopressin are all in market. If approved, landiolol, an ultra-short acting cardio-selective IV beta-blocker, and CAL02, a first-in-class anti-infective agent to treat severe bacterial pneumonia will join our currently approved products to create a formidable hospital/anesthesia product portfolio,” stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

“We plan to leverage our strong balance sheet and usher ENA-001 toward a potential 2026 launch. This is a great opportunity for Eagle and one that furthers our transformation into a diversified, branded pharmaceutical company with long-duration assets in acute care,” concluded Tarriff.

“This partnership is an exciting step forward in the development of ENA-001 and for the millions of patients worldwide that can benefit from such a novel agnostic respiratory stimulant,” stated Herm Cukier, President and CEO of Enalare Therapeutics. “Our partnership with Eagle provides us access to capital and a robust infrastructure and commercial platform to develop and potentially launch our product. Without added headcount or expense, Eagle will be able to rely on our experienced and highly regarded team as we move onto Phase 2 and 3 trials, which we believe will successfully demonstrate ENA-001’s ability to improve patient respiratory capacity. We look forward to a close and productive working relationship and supporting Eagle in the successful development of Enalare’s products,” concluded Cukier.

Transaction Rationale

- Enalare’s intellectual property with potential patent duration through the mid 2030s to early 2040s offers Eagle access to complementary and diversified revenue streams;

⁵ <https://bynder.acaciapharma.com/m/403e8c343b2922de/original/Byfavo-PI.pdf>

- Eagle believes there is a compelling commercial opportunity for Enalare’s lead drug candidate, ENA-001:
 - o Agnostic respiratory stimulant with first-in-class mechanism of action;
 - o Studied in more than 100 human subjects to date;
 - o Differentiated product that significantly expands long-term sales potential and durability of Eagle’s hospital business;
 - o Synergistic fit with Eagle’s current and expanding portfolio of hospital products, with overlap of customer channel and decision makers;
 - o Timing of launch, if approved, aligns with anticipated Eagle commercial capacity;
 - o Provides the opportunity for strategic expansion into adjacent therapeutic and customer channels.

About ENA-001

ENA-001 is an investigational new chemical entity (“NCE”) being developed by Enalare for multiple potential indications, including the prevention and treatment of post-operative respiratory depression. With its novel mechanism-of-action and based on findings to date, it could potentially improve the lives of those impacted by several life-threatening conditions including community drug overdose, post-operative respiratory depression, and apnea of prematurity. If approved, ENA-001 would offer new treatment options for physicians, emergency responders, and caregivers addressing acute respiratory depression across multiple patient populations in multiple settings.

About Enalare Therapeutics Inc

Enalare Therapeutics Inc is a clinical-stage biopharmaceutical company dedicated to developing novel therapies for patients suffering from life-threatening acute respiratory and critical care conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity.

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 vasopressin, 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 “anticipated,” “forward,” “will,” “would,” “could,” “should,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” “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 statements regarding: any further investments in Enalare and Enalare’s development programs; expectations with respect to synergies; expectations that the transaction with Enalare will help improve the care of patients undergoing medical treatments, solidify the Eagle’s leadership position in the hospital and anesthesia space and bring long-term value to Eagle’s shareholders; expectations with respect to the achievement of development milestones and any further investments by Eagle in Enalare; estimated addressable market size and estimated sales figures; Eagle’s marketing, product development, partnering and growth strategy, including relating to the commercialization of BARHEMSYS and BYFAVO and other products and product candidates and Eagle’s ability to expand the application of ENA-001, BARHEMSYS and BYFAVO; anticipated timelines of development programs, including with respect to ENA-001; the timing, scope or likelihood and timing of regulatory filings and approvals for Eagle’s and Enalare’s product candidates, including ENA-001 and Landiolol; the ability of ENA-001, BARHEMSYS, BYFAVO, Landiolol and other products and product candidates to address unmet clinical needs; the potential market opportunity for products or product candidates, including for BARHEMSYS, BYFAVO, Landiolol and ENA-001; expectations regarding expansion of the Company’s product portfolio, including with respect to the intellectual property of Enalare and any potential future transactions; the ability of Eagle’s executive team to execute on Eagle’s strategy and build stockholder value; the ability of Eagle’s sales force to commercialize products; expectations regarding Eagle’s future growth and the expansion of Eagle’s growth possibilities as a result of the Enalare transaction; and the ability of the Company’s product candidates to deliver value to stockholders. 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 Eagle’s recently completed transaction with Acacia Pharma and the transaction with Enalare are not realized; the impacts of the COVID-19 pandemic and geopolitical events such as the conflict in Ukraine, including disruption or impact in the sales of Eagle’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 Eagle’s business, financial condition and results of operations; macroeconomic conditions, such as rising inflation and uncertain credit and financial markets; whether Eagle will incur unforeseen expenses or liabilities or other market factors; whether Eagle will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of Eagle’s or its partners’ product candidates, including Landiolol and ENA-001; whether Eagle can successfully market and commercialize its products or product candidates; the success of Eagle’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 Eagle’s 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 Eagle’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 factors in addition to the foregoing that may impact Eagle’s financial projects and guidance, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that may cause Eagle’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, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 8, 2022, Eagle’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, and its other subsequent filings with the SEC, including Eagle’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which Eagle expects to file with the SEC on August 9, 2022. 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.

Investor Relations for Eagle Pharmaceuticals, Inc.

Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

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

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.
