

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM 8-K
CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): June 23, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

**Nevada
(State or Other Jurisdiction
of Incorporation)**

**001-36019
(Commission
File Number)**

**26-1434750
(IRS Employer
Identification No.)**

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TNXP	The NASDAQ Capital Market

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

Emerging growth company ☐

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

Item 1.01. Entry into a Material Definitive Agreement.

Acquisition of Assets from Upsher Smith Laboratories, LLC

Asset Purchase Agreement

On June 23, 2023, Tonix Pharmaceuticals Holding Corp, Inc. (the “Company”) and its wholly owned subsidiary Tonix Medicines, Inc., a Delaware corporation (“Acquisition Sub” and together with the Company, “Purchaser”), entered into that certain Asset Purchase Agreement (the “Asset Purchase Agreement”) with Upsher Smith Laboratories, LLC, a Minnesota limited liability company (“Seller”). Pursuant to the Asset Purchase Agreement, Purchaser will purchase and acquire Seller’s assets related to Seller’s Zembrace® SymTouch® (sumatriptan injection) 3 mg (“Zembrace”) and Tosymra® (sumatriptan nasal spray) 10 mg (“Tosymra”) products (such businesses collectively, the “Business” and the asset purchase, the “Asset Purchase”), inventory related to the Business and assume certain liabilities of Seller. The closing (“Closing”) is expected to occur on June 30, 2023.

As consideration for the Asset Purchase, Purchaser shall pay to Seller \$15 million in cash (the “Cash Purchase Price”), \$12 million of which is payable at Closing and \$3 million of which is payable on the earlier of March 2024 and the completion of the transition services to be provided by Seller, as described below, and approximately \$10 million in cash at Closing to acquire certain Business-related inventories, subject to final adjustment based on actual inventory at the time of Closing.

Purchaser has assumed certain obligations of Seller, including the payment of quarterly earn-out payments on annual net sales from the Business in the U.S. as follows: for Tosymra, 4% for net sales of \$0 to \$30 million, 7% of net sales of \$30 to \$75 million; 9% for net sales of \$75 to \$100 million; 12% for net sales of \$100 to \$150 million; and 15% for net sales greater than \$150 million. Earn-out payments with respect to Tosymra are payable until the expiration or termination of the product’s Orange Book listed patent(s) with respect to the United States or, outside the United States, the expiration of the last valid claim covering the product in the relevant country of the territory. For Zembrace, earn-out payments on annual net sales in the U.S. are 3% for net sales of \$0 to \$30 million, 6% of net sales of \$30 to \$75 million; 12% for net sales of \$75 to \$100 million; 16% for net sales of greater than \$100 million. Such earn-out payments are payable until July 19, 2025. Upon the entry of a generic version of the relevant product, the applicable earn-out rates shall be reduced by 90% percent with respect to Zembrace, and by 66.7% percent for Tosymra. Prior to Purchaser or a licensee filing an application for marketing authorization for either of the products in a permitted country outside the U.S., the parties will negotiate in good faith the earn-out payment rates annual net sales tiers that will apply for such country, based on the market opportunity for the product in such country. If the parties fail to agree, then the earn-out payment rates and annual net sales

tiers described above will apply.

In addition, Purchaser has assumed the obligation to pay an additional 3% royalty on net sales of Tosymra, plus an additional 3% if a patent containing certain claims related to Tosymra issues in the U.S., for 15 years from the first commercial sale of Tosymra in the applicable country or for as long as the manufacture, use or sale of Tosymra in such country is covered by a valid claim of a licensed patent, and up to \$15 million per Tosymra product on the achievement of sales milestones.

The Asset Purchase Agreement contains customary representations, warranties and covenants of the Purchaser and Seller. Subject to certain customary limitations, Purchaser and Seller each agree to indemnify the other party, and their officers, directors, employees and other authorized agents against certain losses related to, among other things, breach of representations, warranties, covenants and agreements as well as any excluded liabilities described therein.

The foregoing summary of the Asset Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Asset Purchase Agreement that is filed herewith as Exhibit 1.01.

The representations, warranties and covenants contained in the Asset Purchase Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to the Asset Purchase Agreement, and may be subject to limitations agreed upon by the contracting parties. Accordingly, the Asset Purchase Agreement is incorporated herein by reference only to provide investors with information regarding the terms of the Asset Purchase Agreement, and not to provide investors with any other factual information regarding the Company or its business, and should be read in conjunction with the disclosures in the Company's periodic reports and other filings with the SEC.

Transition Services Agreement

In connection with the Asset Purchase and of as the Closing date, Purchaser will enter into a Transition Services Agreement (the "Transition Services Agreement") with Seller. Pursuant to the Transition Services Agreement, Seller will provide certain transition services to Purchaser for base fees equal to \$100,000 per month for the first six months, and \$150,000 per months for the seventh through ninth months, plus additional monthly fees for each service category totaling up to \$150,000 per month.

The foregoing description of the Transition Services Agreement does not purport to be complete and is qualified in its entirety to the full text of the Transition Services Agreement, which will be filed as an exhibit on a Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On June 26, 2023, the Company announced the Asset Purchase. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

The Company updated its investor presentation, which is used to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On June 26, 2023 the Company announced the Asset Purchase. Collectively, the Business generated product sales of approximately \$23 million for the full year 2022 based on IQVIA 2022 retail sales data from the National Sales Perspectives ("NSP") audit. The Closing is expected to take place on June 30, 2023. The Company believes the acquisition of the Business is strategic, and in addition to potential growth, over time, the acquisition may help build the Company's commercial capabilities ahead of the potential launch of its TNX-102 SL product candidate for the treatment of fibromyalgia and build a specialty pharmaceuticals business. In addition, the Company believes the Business aligns with its TNX-1900 (intranasal potentiated oxytocin) product candidate, in clinical development for the prevention of chronic migraine, and that the Business will be under the Company's control by the fourth quarter of 2023. U.S. retail sales during 2022 for Zembrace and Tosymra are approximately \$19.6 million and \$3.5 million, respectively, based on IQVIA 2022 retail sales from the NSP audit, and are covered by managed care contracts covering approximately 200 million patients. Net sales are projected at approximately 50% of gross sales. Patent protection for Zembrace and Tosymra are expected through 2036 and 2031, respectively.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) **Exhibit
No.**

Description.

[1.01†](#)
[99.01](#)
[99.02](#)
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Asset Purchase Agreement, dated as of June 23, 2023, by and among Upsher-Smith Laboratories, LLC, Tonix Medicines, Inc. and Tonix Pharmaceuticals Holding Corp.
Press Release of the Company, June 26, 2023
Corporate Presentation by the Company for June 2023
Cover Page Interactive Data File (embedded within the Inline XBRL document)

†The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: June 26, 2023

By: /s/ Bradley Saenger

Bradley Saenger

Chief Financial Officer

EXECUTION VERSION

ASSET PURCHASE AGREEMENT

BY AND AMONG

UPSHER-SMITH LABORATORIES, LLC,

AS SELLER,

TONIX MEDICINES, INC.

AS PURCHASER,

AND

TONIX PHARMACEUTICALS HOLDING CORP.,

AS PARENT

DATED AS OF

June 23, 2023

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ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this “**Agreement**”) dated as of June 23, 2023, is by and among Upsher-Smith Laboratories, LLC, a Minnesota limited liability company having its principal place of business located at 6701 Evenstad Drive, Maple Grove, MN 55369 (the “**Seller**”), Tonix Medicines, Inc., a Delaware corporation having its principal place of business located at 26 Main Street, Suite 101, Chatham, NJ 07928 (the “**Purchaser**”), and, solely for purposes of Section 11.15 (Parent Guaranty), Tonix Pharmaceuticals Holding Corp., a Nevada corporation having its principal place of business located at 26 Main Street, Suite 101, Chatham, NJ 07928 (the “**Parent**”). The Seller, the Purchaser, and the Parent may be collectively referred to herein as the “**Parties**” and each, individually, as a “**Party**”.

RECITALS

WHEREAS, the Purchaser is a wholly-owned subsidiary of the Parent; and

WHEREAS, the Seller desires to sell, transfer and assign to the Purchaser, and the Purchaser desires to acquire and assume from the Seller, all of the Purchased Assets and Assumed Liabilities, all as more specifically, and subject to the terms and conditions, provided herein;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties, intending to be legally bound hereby, do agree as follows:

ARTICLE I DEFINITIONS AND INTERPRETATION

Section 1.01 Defined Terms. Capitalized terms used in this Agreement have the meanings specified in Schedule 1.01 to this Agreement.

Section 1.02 Other Definitional and Interpretive Provisions.

- (a) The words “hereof”, “herein”, “hereto” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement.
 - (b) The terms defined in the singular shall have a comparable meaning when used in the plural and vice versa.
 - (c) The terms “Dollars” and “\$” shall mean United States of America dollars.
 - (d) The term “including” (and with correlative meaning “include”) shall mean “including, without limitation.”
 - (e) Reference to any Person includes such Person’s successors and assigns but, if applicable, only if such successors and assigns are permitted by this Agreement, and reference to a Person in a particular capacity excludes such Person in any other capacity.
 - (f) Reference to any agreement (including this Agreement), document or instrument means such agreement, document or instrument as amended, modified or supplemented and in effect from time to time in accordance with the terms thereof and, if applicable, the terms hereof.
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(g) When a reference is made in this Agreement to an Article, a Section, an Exhibit or a Schedule, such reference shall be to an Article of, a Section of, an Exhibit to or a Schedule to, this Agreement unless otherwise indicated.

(h) The Parties acknowledge that: (i) this Agreement is the result of negotiations between the Parties and shall not be deemed or construed as having been drafted by any one Party; (ii) each Party and its counsel have reviewed and negotiated the terms and provisions of this Agreement (including any exhibits, schedules, and disclosure schedules attached hereto) and have contributed to its revision; (iii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iv) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

ARTICLE II PURCHASE AND SALE

Section 2.01 Purchase and Sale of Purchased Assets

(a) **Purchased Assets.** Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, the Seller shall sell, convey, transfer and assign to the Purchaser, and the Purchaser shall purchase, acquire and assume from the Seller, all of the Seller's right, title, and interest in the Purchased Assets, free from any Encumbrances except for Permitted Encumbrances.

(b) **Excluded Assets.** Other than the Purchased Assets subject to Section 2.01(a), the Purchaser expressly understands and agrees that it is not purchasing or acquiring, and the Seller is not selling, conveying, transferring, or assigning, any other assets or properties of the Seller, and all such other assets and properties shall be excluded from the Purchased Assets (the "**Excluded Assets**").

(c) **Assumed Liabilities.** Upon the terms and subject to the conditions set forth in this Agreement, the Purchaser shall, effective upon the Closing, assume, pay, perform and discharge all Assumed Liabilities.

(d) **Excluded Liabilities.** Except for the Assumed Liabilities, the Purchaser will not acquire any interest in, or obligations in respect of, any Liabilities of the Seller (the "**Excluded Liabilities**"). The Excluded Liabilities include: (i) any Liability in respect to Excluded Taxes, (ii) all Liabilities with respect to any indebtedness for borrowed money of the Seller, (iii) all Liabilities arising out of or relating to the Seller's employment, engagement, potential employment or engagement or termination of employment or engagement of any Person, (iv) all Liabilities arising out of, relating to or in respect of the Acquired Contracts to the extent such Liabilities (A) but for a breach or default by the Seller, would have been paid, performed or otherwise discharged in accordance with their terms prior to the Closing, (B) arise out of a breach or default by the Seller prior to the Closing or (C) otherwise arise from or relate to any act, omission, occurrence or period of time prior to the Closing, (v) all accounts payable or accrued expenses of the Seller except for Purchaser's Prorated Portion of expenses and costs set forth in the Proration Schedule, (vi) all Liabilities arising out of or relating to any Employee Benefit Plan, (vii) all Liabilities arising prior to Closing out of the ownership of the Purchased Assets or operation of the Business, (viii) any Liability of the Seller arising out of or under this Agreement, (ix) any broker fees of the Seller, (x) all Liabilities arising out of or relating to the Excluded Assets; (xi) all Liabilities of Seller arising from or relating to the DRL Purchase Agreement (other than any Liabilities with respect to the Partially Assigned APA that are expressly assumed by Purchaser pursuant to the Assignment and Assumption Agreement Regarding DRL Contracts); and (xii) all Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury or other harm to person or property (regardless of whether such claim is first asserted prior to, on or after the Closing Date), which result from the use or misuse of Products sold on or prior to the Closing Date or otherwise related to the Products sold on or prior to the Closing Date (including all Legal Proceedings relating to any such liabilities).

(e) **Consents.** If the assignment of any Purchased Asset requires the consent of any Person and such consent is not obtained at or prior to the Closing (a) the Seller will use its reasonable best efforts to obtain the written consent of such other Person to the assignment, (b) this Agreement will not constitute an agreement to assign such Purchased Asset until such consent is obtained, and (c) at the Purchaser's election, for up to nine months following Closing, (i) the Seller will continue to maintain and/or perform any such Purchased Asset at the direction and for the risk and benefit of the Purchaser, and the Purchaser will cooperate with the Seller relating to the same, in each case, on such terms and conditions as required to result in the same commercial outcome for both the Seller and the Purchaser as though such Purchased Asset had been assigned to the Purchaser or (ii) the Purchaser may act as agent and attorney-in-fact for the Seller to obtain the benefits thereunder for the Purchaser.

(f) **FDA Letters.**

(i) Within five (5) Business Days of the Closing Date, the Seller shall transmit to Purchaser, via encrypted thumb drive, the complete files for the Acquired Regulatory Approvals (in electronic format) and concurrently submit the Seller FDA Letters to the FDA, notifying the FDA that the Acquired Regulatory Approvals have been transferred to the Purchaser. For clarity, the Seller FDA Letters shall appear as a sequence in such Acquired Regulatory Approvals.

(ii) Within five (5) Business Days of the Purchaser's receipt of the Acquired Regulatory Approvals pursuant to Section 2.01(f)(i), the Purchaser shall (A) upload such files into the Purchaser's regulatory operations system and confirm in writing to the Seller the successful uploading of such files, (B) submit the Purchaser FDA Letters to the FDA, notifying the FDA that the transfer of ownership of the Acquired Regulatory Approvals has been accepted by the Purchaser, and (C) provide an electronic copy of the Purchaser FDA Letters to the Seller (including a copy of the Purchaser FDA Letters submission sequence).

(g) **Delivery of Purchased Assets.**

(i) As soon as practicable following the Closing (but within ten (10) Business Days after the Closing Date), the Seller shall make available to the Purchaser electronically all Purchased Assets held electronically (except as otherwise provided in Section 2.01(f)). Within ten (10) Business Days after the Closing Date, the Seller shall make available to the Purchaser all tangible Purchased Assets for pick-up at the Seller's facilities, at the Purchaser's sole cost, expense and risk (other than the Purchased Inventory, which shall be transferred in accordance with clause (ii) below); provided, that if the Seller finds, locates, discovers or otherwise becomes aware that it possesses any Purchased Assets after the Closing Date, the Seller shall reasonably promptly notify the Purchaser in writing and make such Purchased Assets available for pick-up at the Seller's facilities, at the Purchaser's sole cost, expense and risk.

(ii) The Seller shall deliver the Purchased Inventory to Purchaser or its designee in accordance with the provisions of the Transition Services Agreement.

(h) **Proration Schedule.** Schedule 2.01(h) of the Seller Disclosure Schedules sets forth a listing (the **“Proration Schedule”**) of certain deposits and other prepaid items, which includes certain expenses that the Seller has paid or that are required to be paid by the Seller by Law or contractual obligation in relation to the Purchased Assets or Assumed Liabilities, and which shall be prorated as of the Closing Date because they relate, in all or in part, to a period of time after the Closing Date. At Closing, the Purchaser shall pay to the Seller an amount equal to the Purchaser’s Prorated Portion, which amount is set forth on the Proration Schedule reasonably approved by the Purchaser.

ARTICLE III PURCHASE PRICE

Section 3.01 Purchase Price.

- (a) Amount. The aggregate consideration for the purchase of the Purchased Assets to be paid by the Purchaser (the **“Purchase Price”**) shall be:
- (i) Fifteen Million Dollars (\$15,000,000) in respect of the Purchased Assets (the **“Base Purchase Price”**) and the assumption of the Assumed Liabilities;
 - (ii) the Final Purchased Inventory Value; and
 - (iii) the Purchaser’s Prorated Portion.

Section 3.02 Payment Terms; Transfer Taxes

- (a) Payment of the Purchase Price.
- (i) At the Closing, the Purchaser shall pay to the Seller, by wire transfer of immediately available funds to an account designated in writing by the Seller pursuant to Section 3.02(b), an aggregate amount equal to (A) Twelve Million Dollars (\$12,000,000), *plus* (B) the Estimated Purchased Inventory Value, *plus* (C) the Purchaser’s Prorated Portion, *less* (D) if the Closing occurs on or before June 30, 2023, the Exclusivity Payment Credit Amount (collectively, the **“Closing Cash Consideration”**).
 - (ii) Within five (5) Business Days after the earlier to occur of (A) the date that is 270 days after the Closing Date, or (B) the last day of the TSA Period, the Purchaser shall pay to the Seller, by wire transfer of immediately available funds to an account designated in writing by the Seller pursuant to Section 3.02(b), an aggregate amount equal to Three Million Dollars (\$3,000,000) (the **“Deferred Payment”**).
- (b) Mode of Payment. Any payment to be made to the Seller pursuant to this Agreement shall be made by wire transfer of immediately available funds, in Dollars, to an account designated in writing by the Seller (such designation to be made at least two (2) Business Days prior to the date on which such payment is due). Any payment to be made to the Purchaser pursuant to this Agreement shall be made by wire transfer of immediately available funds, in Dollars, to an account designated in writing by the Purchaser (such designation to be made at least two (2) Business Days prior to the date on which such payment is due).

(c) Transfer Taxes; Recording Fees. All transfer, documentary, sales, use, valued-added, gross receipts, stamp, registration or other similar transfer Taxes (collectively, “**Transfer Taxes**”) incurred in connection with the transfer and sale of the Purchased Assets as contemplated by the terms of this Agreement will be paid fifty percent (50%) by the Purchaser and fifty percent (50%) by the Seller. The Seller shall, at its own expense, file any necessary Tax returns relating to Transfer Taxes and other documentation with respect to any Transfer Taxes. The Purchaser shall provide the Seller with such cooperation and supporting documentation as the Seller may reasonably request in connection with the preparation, execution and filing of such Tax returns. The Parties hereto agree to reasonably cooperate with each other to claim any applicable exemption from, or reduction of, any applicable Transfer Taxes. All recording fees incurred by Purchaser to record Purchaser’s ownership of the Purchased Assets shall be borne by the Purchaser.

(d) Allocation of Purchase Price. The Seller and the Purchaser will allocate the Purchase Price (as adjusted pursuant to this Agreement) (together with any Assumed Liabilities and any other items that are treated as additional consideration for Tax purposes) among the Purchased Assets in a manner consistent with the methodology specified on Exhibit A hereto (the “**Allocation Schedule**”), to be determined by the Purchaser and delivered to the Seller within forty-five (45) days following the final determination of the Final Purchased Inventory Value and the Adjusted Closing Cash Considerations pursuant to Section 3.03. The Seller will be entitled to provide comments thereon to Purchaser within fifteen (15) days following receipt thereof, and the Purchaser shall consider any such comments in good faith and the parties shall cooperate with one another in good faith in order to resolve such comments and agree on a final allocation. The Seller and the Purchaser agree to file their respective IRS Forms 8594 and all federal, state and local Tax returns in accordance with such final allocation and shall not otherwise take any Tax position inconsistent therewith, in each case, unless so required by a determination by an applicable taxing authority. Notwithstanding the forgoing, (x) if the parties are unable to agree on a final allocation, each party shall be permitted to rely on its own allocation for all Tax and reporting purposes, and (y) the Purchaser shall be permitted to make adjustments to such final allocation if the Purchaser reasonably determines that such adjustments are necessary or advisable in the preparation of the Purchaser’s financial statements or for other applicable reporting purposes; provided, however, that the Purchaser shall inform the Seller of any such adjustments.

(e) Withholding.

(i) The Purchaser shall be entitled to deduct and withhold from the amounts otherwise payable pursuant to this Agreement to the Seller such amounts as the Purchaser is required to deduct and withhold under the Code, or any applicable Tax Law, with respect to the making of such payment. Other than with respect to any withholding required as a result of the Seller’s failure to deliver documentation in accordance with Section 4.02(a)(v) or in connection with amounts treated for tax purposes as compensation payments, the Purchaser shall use commercially reasonable efforts to (i) provide the Seller, at least three (3) Business Days prior to any such deduction and withholding, with written notice of its intent to deduct and withhold and (ii) cooperate with Seller in order to reduce or eliminate such deduction and withholding.

(ii) Purchaser shall provide the Seller with a proof of deposit of any Taxes withheld pursuant to Section 3.02(e)(i) with appropriate Governmental Authority within fifteen (15) days of such deposit. Further, the Purchaser shall also provide the Seller with any withholding Tax deduction certificates no later than the time prescribed by, and to the extent required under, applicable Tax Law. To the extent that amounts are withheld in accordance with this Section 3.02(e), such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Seller in respect of whom such deduction and withholding was made.

Section 3.03 Purchased Inventory Value Adjustment. Following the Closing Date, the Closing Cash Consideration will be adjusted as follows:

(a) Inventory Statement Preparation. Attached to this Agreement as Exhibit S is a true, correct and complete list of all Product Inventory that is not Excluded Inventory as of May 31, 2023, including the location and value of each item of inventory, and the estimated Purchased Inventory Value as of May 31, 2023 (the “**May Inventory Statement**”). Within forty-five (45) days after the Closing Date, representatives of the Seller and Purchaser will work together in good faith to prepare a mutually agreed upon inventory statement (the “**June Inventory Statement**”) setting forth the Purchased Inventory as of June 30, 2023, using the same methodologies as used in the preparation of the May Inventory Statement, including the location of each item of Purchased Inventory, and the Purchased Inventory Value as of June 30, 2023 (the “**Final Purchased Inventory Value**”). Purchaser may, at its election and sole cost and expense, conduct an audit of the Product Inventory to aid in the preparation of the Final Purchased Inventory Value. Seller will provide Purchaser and its representatives with reasonable access to the facilities where the Product Inventory is located and Seller’s records with respect to the Product Inventory, as reasonably required by Purchaser to conduct such audit. Without limiting any rights and remedies of Purchaser with respect to any breach of Section 5.13, the June Inventory Statement will be conclusive and binding upon the Parties and the Purchased Inventory Value set forth therein shall be the Final Purchased Inventory Value.

(b) Adjustment Payment. Upon the determination, in accordance with this Section 3.03, of the Final Purchased Inventory Value, the Closing Cash Consideration as calculated at Closing will be recalculated using the Final Purchased Inventory Value in lieu of the Estimated Purchased Inventory Value (the Closing Cash Consideration as so recalculated is the “**Adjusted Cash Consideration**”).

(i) If the Adjusted Cash Consideration is less than the Closing Cash Consideration (the amount by which the Adjusted Cash Consideration is less than the Closing Cash Consideration is the “**Decrease Amount**”), then, within five (5) business days after the determination of the Adjusted Cash Consideration, the Seller will pay the Decrease Amount to the Purchaser by wire transfer or delivery of other immediately available funds to such accounts designated by the Purchaser.

(ii) If the Adjusted Cash Consideration is greater than the Closing Cash Consideration (the amount by which the Adjusted Cash Consideration is greater than the Closing Cash Consideration is the “**Increase Amount**”), then, within five (5) business days after the determination of the Adjusted Cash Consideration, the Purchaser will pay to the Seller the Increase Amount by wire transfer or delivery of other immediately available funds to such accounts designated by Seller.

- (iii) If the Adjusted Cash Consideration is equal to the Closing Cash Consideration, then no adjustment will be made to the Closing Cash Consideration.

ARTICLE IV CLOSING

Section 4.01 Closing. Subject to the terms and conditions of this Agreement, the consummation of the transactions contemplated in this Agreement (the “**Closing**”) shall take place remotely, via the exchange of electronic copies of the agreements, documents, certificates and other instruments set forth in Section 4.02, on June 30, 2023, upon satisfaction or waiver of the conditions set forth in Article VIII, or at such other time or date as the Seller and the Purchaser may mutually agree upon in writing. The day on which the Closing occurs is referred to herein as the “**Closing Date**”. The Closing shall be deemed to be effective as of 11:59 pm eastern time on the Closing Date.

Section 4.02 Closing Deliverables.

- (a) At the Closing, the Seller shall deliver or cause to be delivered to the Purchaser the following:
- (i) the Bill of Sale, duly executed by an authorized officer of the Seller;
 - (ii) the Assignment and Assumption Agreement, duly executed by an authorized officer of the Seller;
 - (iii) the Assignment and Assumption Agreement Regarding DRL Contracts, duly executed by an authorized officer of the Seller;
 - (iv) the Intellectual Property Assignment Agreements, duly executed by an authorized officer of the Seller;
 - (v) a properly prepared and certified IRS Form W-9, duly executed by the Seller;
 - (vi) the consents, approvals and notices listed on Schedule 4.02(a)(vi) of the Seller Disclosure Schedules (collectively, the “**Required Consents**”);
 - (vii) the Transition Services Agreement, duly executed by an authorized officer of the Seller;
 - (viii) a certificate, dated as of the Closing Date, duly executed by an authorized officer of the Seller, in his or her capacity as such, confirming the satisfaction of the conditions specified in Section 8.02; and
 - (ix) such other documents as the Purchaser may reasonably request to give effect to this Agreement.
- (b) At the Closing, the Purchaser shall deliver to the Seller the following:
- (i) payment of the Closing Cash Consideration;
 - (ii) the Bill of Sale, duly executed by an authorized officer of the Purchaser;

- (iii) the Assignment and Assumption Agreement, duly executed by an authorized officer of the Purchaser;
- (iv) the Assignment and Assumption Agreement Regarding DRL Contracts, duly executed by an authorized officer of the Purchaser;
- (v) the Intellectual Property Assignment Agreements, duly executed by an authorized officer of the Purchaser;
- (vi) the Transition Services Agreement, duly executed by an authorized officer of the Purchaser;
- (vii) a certificate, dated as of the Closing Date, duly executed by an authorized officer of the Purchaser, in his or her capacity as such, confirming the satisfaction of the conditions specified in Section 8.03; and
- (viii) such other documents as the Seller may reasonably request to give effect to this Agreement.

ARTICLE V REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the disclosure schedules attached hereto (the “**Seller Disclosure Schedules**”), the Seller represents and warrants to the Purchaser, that the statements contained in this Article V are true and correct as of the date hereof and as of the Closing Date (unless in each case the particular statement speaks expressly as of a particular date, in which case it is true and correct only as of such date).

Section 5.01 Organization and Authority of the Seller. The Seller is a limited liability company duly organized, validly existing and in good standing under the Laws of the state of Minnesota. The Seller has the requisite power and authority to own and operate the Purchased Assets that it owns and/or operates. The Seller is duly licensed or qualified to do business and is in good standing in each jurisdiction where the ownership of the Purchased Assets and operation of the Business as currently conducted requires such qualification, except where such failure to qualify or be in good standing would not result in a Material Adverse Effect.

Section 5.02 Authority, Non-Contravention, Required Filings

(a) The Seller has the requisite power and authority to execute and deliver this Agreement and the other Transaction Documents to which the Seller is a Party and to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the other Transaction Documents to which the Seller is a Party and the performance by the Seller of its obligations hereunder and thereunder and the consummation by the Seller of the transactions contemplated hereby and thereby, has been duly authorized by all necessary company action on the part of the Seller.

(b) Each of the Agreement and the other Transaction Documents to which the Seller is a Party has been duly executed and delivered by the Seller, and constitutes a legal, valid and binding obligation of the Seller, enforceable against it in accordance with its respective terms, and, assuming due authorization, execution and delivery by the other parties thereto, this Agreement constitutes, and each Transaction Document to which it is a party shall, immediately after the Closing constitute, the Seller’s legal, valid and binding obligation, except as may be, in each case, limited by: (i) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors’ rights generally; and (ii) general equitable principles (whether considered in a proceeding in equity or at Law).

(c) The execution and delivery by the Seller of this Agreement and the other Transaction Documents to which the Seller is a Party, the performance by the Seller of its obligations hereunder and thereunder, and the consummation by the Seller of the transactions contemplated hereby and thereby do not and will not (i) contravene any provision of the Organizational Documents of the Seller, (ii) after giving effect to the Required Consents, constitute a material breach, materially violate the terms, conditions or provisions of, or result in a material default under, materially conflict with, or give to any Person any rights of termination or acceleration of any agreement to which the Seller is a party or is otherwise bound (including the Acquired Contracts), or (iii) violate in any material respect any provision of any Laws applicable to Seller, the Business, or the Purchased Assets.

(d) No Permit, Consent, approval, declaration or filing with, or notice to, any Governmental Authority on the part of the Seller is required in connection with the execution or delivery by the Seller of this Agreement, or the consummation of the transactions contemplated hereby, other than the FDA Letters.

Section 5.03 Absence of Changes. Except as set forth in Schedule 5.03 of the Seller Disclosure Schedules, the Seller has operated and conducted the Business in the ordinary course of business since June 30, 2022. Since June 30, 2022, there has not been any Material Adverse Effect.

Section 5.04 Purchased Assets. The Seller is the sole and exclusive owner of all right, title and interest in and to all of the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances. Upon Closing, good and marketable title to the Purchased Assets will pass to the Purchaser, free and clear of all Encumbrances other than Permitted Encumbrances. Except for the Licensed Know-How and as set forth in Schedule 5.04 of the Seller Disclosure Schedules, the Purchased Assets constitute all of the Intellectual Property, Contracts, Regulatory Documentation and other assets (other than (a) the Seller's Third Party Contracts (as such term is defined in the Transition Services Agreement), (b) Intellectual Property that are licenses for commercial "off-the-shelf" or "shrink-wrap" software, (c) administrative, finance and other infrastructure and back office information technology systems, networks and software, and (d) any employees or sales personnel) held by Seller that are used or held for use in connection with the conduct of the Business or otherwise relate to any Product, any component thereof or any method or process related to the manufacture, administration or use thereof. No Affiliate of Seller holds any right, title or interest in or to any of the Purchased Assets or any other Intellectual Property, Regulatory Documentation, Contract or other asset that is primarily used in connection with or is otherwise necessary for or related to the Exploitation of any of the Products anywhere in the Territory. To the Knowledge of Seller, none of the Licensed Know-How relates to the manufacture of the Products.

Section 5.05 Acquired Contracts.

(a) Each Acquired Contract is a legal, valid, binding obligation of the Seller (and, to the Knowledge of the Seller, each other party thereto), and is enforceable against the Seller (and, to the Knowledge of the Seller, each other party thereto), in accordance with its terms, and is in full force and effect, subject to (i) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors' rights generally and (ii) general equitable principles (whether considered in a proceeding in equity or at Law).

(b) The Seller is not in breach or default in any material respect under any Acquired Contract to which it is a party, and to the Knowledge of the Seller no event has occurred that will (with or without notice or lapse of time) result in a violation or breach by the Seller of any material provision of any Acquired Contract to which it is party. All milestone payments, royalties and other amounts due and payable by Seller pursuant to any Acquired Contract as of or prior to the Closing have been paid in full (other than those royalty obligations which will become due on June 30, 2023, which, for the avoidance of doubt, will be Excluded Liabilities and promptly paid by Seller in the ordinary course of business following the Closing). To the Knowledge of the Seller, there is no breach of, or default under, any material provision of the Acquired Contracts by any other party to such Acquired Contracts. No party to any Acquired Contract has cancelled or withdrawn any such Acquired Contract, nor, to the Knowledge of the Seller, has any party threatened in writing to do so. The Seller has delivered to the Purchaser a true, correct and complete copy of each written Acquired Contract (including all Purchase Orders, schedules, exhibits, appendices and amendments, modifications and waivers relating thereto, as applicable).

(c) Except as set forth in Schedule 5.05(c) of the Seller Disclosure Schedules, the transactions contemplated by this Agreement (i) do not require the consent of any Person to any Acquired Contract and (ii) do not result in a violation or breach of or default under any Acquired Contract.

(d) With respect to the DRL Purchase Agreement, all Milestone Payments (as that term is defined in the DRL Purchase Agreement) have been paid to DRL.

Section 5.06 Compliance with Law; Regulatory Matters.

(a) The Business and the Seller's use of the Purchased Assets is currently being conducted in material compliance with the Acquired Regulatory Approvals and all applicable Laws. No loss, revocation, termination, suspension or expiration of any Acquired Regulatory Approval is pending, reasonably foreseeable, or to the Knowledge of the Seller, threatened, other than the expiration in accordance with the terms thereof.

(b) The Products are being and have been manufactured, stored, distributed, promoted, advertised and otherwise commercialized, as applicable, in material compliance with applicable Law, including those requirements relating to Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices. Neither the Seller, nor, to the Knowledge of the Seller, any contract manufacturing organizations or suppliers involved in connection with the Purchased Assets, have received any (i) written notice from the FDA or any other Governmental Authority, including the Office of Inspector General, any United States Attorney, the Department of Justice or any attorney general of any jurisdiction, alleging that the Seller has been or is in violation of any drug Law, The False Claims Act (31 U.S.C. § 3729–3733) or false claims acts under state Law, or commencing or indicating an intention to conduct an investigation, audit, or review; (ii) written notice of inspectional observation (including those recorded on form FDA 483), establishment inspection report, warning letter, penalty, fine, sanction, request for recall or other remedial action in connection with the Purchased Assets or Products; (iii) other written documents issued by the FDA or any other Governmental Authority alleging lack of compliance with any drug Law by the Seller or any Person engaged by the Seller to provide any service with respect to any Product or (iv) written notice from the FDA recommending or requiring the submission of a 505(b)(2) new drug application with respect to any Product. Neither Seller nor any of its Affiliates has granted any Third Party any right of reference with respect to any of the Acquired Regulatory Approvals.

(c) All reports, documents, claims and notices required to be filed, maintained, or furnished to the FDA or any other drug regulatory agency by the Seller with respect to the Products have been so filed, maintained or furnished and were complete and correct in all material respects on the date filed (or were corrected in or supplemented by a subsequent filing). The Seller, with respect to the Purchased Assets, has delivered to Purchaser true, correct and complete copies of all material correspondence and meeting minutes received from or sent to the FDA and any other similar foreign Governmental Authorities, with respect to the Purchased Assets, including any and all notices of inspectional observations, establishment inspection reports and any other material documents received by the Seller from the FDA or similar foreign Governmental Authorities which relate to the Seller's compliance with regulatory requirements of the FDA or similar foreign Governmental Authorities.

(d) Neither the Seller nor, to the Knowledge of the Seller, any agent of the Seller (including any Person engaged by the Seller to provide any service with respect to a Product) has made an untrue statement or fraudulent statement of material fact to the FDA or any other Governmental Authority or to any physician or customer, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority or to any physician or customer, or committed any material act, made any material statement, or failed to make any material statement that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Fact, Bribery, and Illegal Gratuities", set forth in FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09). Neither the Seller nor, to the Knowledge of the Seller, any agent of the Seller (including any Person engaged by the Seller to provide any service with respect to a Product) has (i) been convicted of any crime or engaged in any conduct that would reasonably be expected to result in, or that has resulted in, debarment or disqualification by any Governmental Authority, or (ii) any knowledge of facts that would lead to a false claim, or debarment, and there are no proceedings pending or threatened that would result in criminal liability or debarment or disqualification by any Governmental Authority.

(e) Neither the Seller, nor, to the Knowledge of the Seller, any Affiliate, director, manager, officer, equity holder, employee, agent or subcontractor of the Seller has (i) used any funds for contributions, gifts, entertainment or other expenses in violation in any material respect of applicable Law, (ii) paid any bribe, kickback or other similar payment, directly or indirectly, to any foreign government official or employee in violation of the Foreign Corrupt Practices Act of 1977 or other applicable Law, (iii) made any other payment of any kind in violation of any Law, to secure any improper advantage for the Purchased Assets or the Seller, or (iv) knowingly incorrectly recorded any transactions in any of the foregoing categories on the books and records of the Seller.

(f) All finished Products sold by the Seller in the twelve (12) months preceding the Closing Date have been manufactured, stored, and distributed in accordance with applicable Law in all material respects.

(g) The Seller has, with respect to the Purchased Assets, complied in all material respects with all state marketing codes of conduct, in the twelve (12) months preceding the Closing Date.

(h) All personal data collected, disclosed, or otherwise processed by or on behalf of the Seller with respect to the Products (only), including any information or data collected during any clinical trials conducted by the Seller with respect to the Products during the development, pre-clinical and clinical testing, manufacture, storage, testing, distribution, supply and administration of the Products, have been in the past twelve (12) months, and are currently being, collected, disclosed, and otherwise processed in material compliance with applicable Law, including HIPAA and the implementing regulations of the United States Department of Health and Human Services, and any foreign equivalent and/or other applicable privacy laws, including by ensuring that all necessary consents or authorizations have been obtained in accordance with applicable Law. The Seller is not a business associate, as that term is defined in 45 C.F.R. § 160.103. To the Knowledge of the Seller, the Seller has not experienced any material security breach resulting in the unauthorized access, use, modification, disclosure, or other processing or misuse of information, data or systems with respect to the Products.

(i) There are no pending requirements to conduct any Phase IV or other clinical studies or to undertake any other commitments to any applicable Governmental Authority with respect to any Product.

(j) The information set forth on Exhibit R as of the date hereof is accurate and complete in all material respects and has been calculated utilizing systems, processes, policies, practices and pricing methodologies that comply with the requirements of the applicable government program.

(k) None of the representations and warranties in this Section 4.12 shall be deemed to relate to environmental matters, employee benefits matters, employment matters, or tax matters.

Section 5.07 Brokers. Except as set forth on Schedule 5.07 of the Seller Disclosure Schedules, no broker, finder or investment banker is entitled to any brokerage or finder's or other fee or commission in connection with this Agreement or the consummation of the transactions contemplated hereby based upon arrangements made by or on behalf of Seller.

Section 5.08 Litigation.

(a) Except as set forth in Section 5.08 of the Sellers Disclosure Schedule, there is no action, claim, demand, suit or other legal proceeding by any Person, or investigation by any Governmental Authority, pending or, to the Knowledge of the Seller, threatened in writing against or by the Seller directly relating to or affecting the Business, the Purchased Assets, or the Assumed Liabilities.

(b) The Seller is not a party or subject to the provisions of any Governmental Order that directly relates to or affects the Business, the Purchased Assets, or the Assumed Liabilities.

Section 5.09 Product Warranty and Liability. In the last twelve (12) months, no Product has been recalled, withdrawn or suspended (whether voluntarily or otherwise) and there is no current plan or any discussions underway at the Seller or, to the Knowledge of the Seller, any Governmental Authority, regarding such a recall, withdrawal or suspension, in each case, other than customer returns made in the ordinary course of business. All Products sold by the Seller or its authorized agents have conformed in all material respects with all relevant product specifications and standards related to such Products. Except for warranties set forth in any of the Acquired Contracts, there are no outstanding product warranties made on any of the Products. There are no existing or, to the Knowledge of the Seller, threatened, product liability, warranty or other similar claims alleging that any Product is defective or fails to meet any product warranties.

Section 5.10 Accounts Receivable; Accounts Payable. Since June 30, 2022, the Seller has continued all pricing, sales, receivables and payables production practices in accordance with the ordinary course of business consistent with past practice and has not engaged in (a) any trade loading or “channel stuffing” practices or any other promotional sales or discount activity with any customers, distributors or otherwise with the intent to accelerate to pre-Closing periods Accounts Receivable that would otherwise be expected (based on past practice) to arise in post-Closing periods or (b) any practice intended to have the effect of postponing to post-Closing periods payments that would otherwise be expected (based on past practice) to be made in pre-Closing periods. Since June 30, 2022, the Seller has continued to pay all accounts (including, but not limited to, with respect to Government Rebates, Discounts and Fees) in accordance with the ordinary course of business consistent with past practice and the payment terms of its suppliers, and none of such payables is delinquent.

Section 5.11 Intellectual Property.

(a) Schedule 5.11(a) of the Seller Disclosure Schedules sets forth a complete and accurate listing of all Product Intellectual Property that is Registered Intellectual Property (collectively, “**Seller Registered IP**”), and for each such item of Seller Registered IP, lists (i) the filing, registration, issuance and grant dates, as applicable, (ii) the identification of such item as owned Intellectual Property or licensed Intellectual Property and, in the case of licensed Intellectual Property, whether the applicable licensed Intellectual Property is exclusively or non-exclusively licensed or sublicensed to the Seller, and (iii) all filing, maintenance, renewal, fees and other deadlines pertaining thereto that are due or otherwise will occur within one hundred and eighty (180) days of the date hereof. The Seller has delivered to the Purchaser true, correct and complete copies of all agreements through which the licensed Product Intellectual Property is licensed to the Seller.

(b) Except with respect to any abandoned Patents, (i) to the Knowledge of the Seller, no facts or event has occurred that rendered any of Seller Registered IP that is issued, granted or registered invalid or unenforceable and (ii) all filings, payments and other actions required to be taken to maintain in full force and effect all Seller Registered IP have been taken. To the Knowledge of the Seller, each of the Patents included in the Seller Registered IP that is licensed Intellectual Property properly identifies each inventor of the claims thereof as determined in accordance with the applicable Law of the jurisdiction in which such Patent is issued or is pending. Each of the Patents that are listed in that certain FDA publication titled “Approved Drug Products With Therapeutic Equivalence Evaluations” (or successor thereto) (the “**Orange Book**”) with respect to the Products (the “**Orange Book Patents**”) is validly listed in the Orange Book in accordance with applicable Laws. Seller has not received any notice of, or is otherwise aware of, any certification filed pursuant to 21 U.S.C. Sections 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) from a Third Party, and Seller is not aware of any plans of any Person to file any such certification.

(c) To the Knowledge of the Seller, the conduct of the Business as currently conducted does not infringe upon, misappropriate or otherwise violate any Intellectual Property (or any rights therein, thereto or thereunder) of any Third Party.

(d) There is no pending, concluded, or threatened in writing Legal Proceeding against the Seller (or, to the Knowledge of the Seller, against any other Person) alleging that (i) the manufacture, use, sale, offer for sale, importation or other Exploitation of the Products in the Territory, (ii) the activities of the Seller with respect to the Products in the Territory, (iii) the Business in the Territory, or (iv) the practice or use of the Product Intellectual Property in the Territory in connection with the manufacture, use, sale, offer for sale, importation or other Exploitation of the Products in the Territory or in connection with the Business in the Territory, in each case ((i)-(iv)), infringes, misappropriates or otherwise violates any Patent (except for any abandoned Patent) or other Intellectual Property (or any rights therein, thereto or thereunder) of any Third Party.

(e) Except as set forth in Schedule 5.11(e) of the Seller Disclosure Schedules, the Seller has not granted any third party any license, sublicense, option, right of reference or other rights with respect to any of the Product Intellectual Property in the Territory, nor is the Seller obligated to pay any royalties or licensing fees to any Third Party in connection with the Product Intellectual Property in the Territory.

(f) Except for the consents set forth in Schedule 5.05(c), none of the execution and delivery of this Agreement, the Transaction Documents or the consummation of the transactions contemplated hereby or thereby, or the performance by the Seller of its obligations hereunder or thereunder, conflicts with, or would result in a loss of, or modification to, any of the Seller's rights in, to or under any Product Intellectual Property or any Intellectual Property licensed to Seller pursuant to an Acquired Contract.

(g) Notwithstanding anything to the contrary in this Agreement or elsewhere, the Seller makes no representations or warranties in relation to any abandoned Patent.

Section 5.12 Tax Matters. The Seller does not have any Liability with respect to any Taxes for which the Purchaser will become liable or that will adversely affect the Purchaser's right to use and enjoy any of the Purchased Assets, free and clear of any Encumbrances. All material Tax returns of the Seller and any of its Affiliates that were required to be filed have been filed, and such Tax returns are true, correct, and complete in all material respects. To the extent failure to do so could adversely impact the Purchaser or the Purchased Assets, all material Taxes due and payable as of the Closing Date by the Seller or any of its Affiliates (whether or not shown on any Tax Returns) have been timely paid.

Section 5.13 Purchased Inventory. The Purchased Inventory (a) meets its respective specifications in all material respects, (b) has been manufactured in accordance with current Good Manufacturing Practices, (c) has not been adulterated (within the meaning of 21 U.S.C. § 351 or similar applicable Law) or misbranded (within the meaning of 21 U.S.C. § 352 or similar applicable Law), (d) is suitable for administration to humans, (e) is usable in the Business in accordance with applicable Laws, and (f) at the Closing Date, has a remaining shelf life of at least eighteen (18) months except as set forth on Section 5.13 of the Disclosure Schedules. No Purchased Inventory is held on a consignment basis.

Section 5.14 Insurance. The Seller maintains insurance policies with respect to the current Business of the types and in the amounts customarily carried by businesses of similar size in the same industry.

Section 5.15 Financial Statements. Section 5.15 of the Seller Disclosure Schedules sets forth true and complete copies of (i) the draft audited abbreviated financial statements for the Business as of and for the twelve (12) month periods ending March 31, 2023 (the “**Balance Sheet Date**”) and March 31, 2022 (collectively, the “**Abbreviated Financial Statements**”) and (ii) an unaudited schedule of Seller’s revenues and expenses for the Business for the period from January 1, 2023 through March 31, 2023 (the “**Q1 2023 Revenues and Expenses**”). The Abbreviated Financial Statements and the Q1 2023 Revenues and Expenses (a) have been prepared in accordance with the books and records of Seller, which are true, complete and correct in all material respects, and (b) have been prepared in conformity with GAAP applied on a consistent basis and fairly present in all material respects the financial condition and assets and liabilities of the Business as of the respective dates thereof and the revenue and direct expenses of the Business for the respective periods then ended.

Section 5.16 No Other Representations and Warranties. Except for the representations and warranties contained in this Article V (including the related portions of the Seller Disclosure Schedules) and the Transaction Documents to which the Seller is a party, neither the Seller nor any other Person has made or makes any other express or implied representation or warranty, either written or oral, on behalf of the Seller, including any representation or warranty as to the accuracy or completeness of any information regarding the Seller, the Business, or the Purchased Assets furnished or made available to the Purchaser or its representatives (including the Confidential Information Memorandum dated November 28, 2022 and any information, documents or material made available to Purchaser in any data room or otherwise, management presentations or in any other form in expectation of the transactions contemplated hereby) or as to the future revenue, profitability or success of the Business, or any representation or warranty arising from statute or otherwise in law.

ARTICLE VI REPRESENTATIONS AND WARRANTIES OF PURCHASER

The Purchaser represents and warrants to the Seller that the statements contained in this Article VI are true and correct as of the date hereof and on the Closing Date.

Section 6.01 Organization and Authority of the Purchaser. The Purchaser is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware and has the requisite power and authority to own and operate its business as presently conducted. The Purchaser is duly qualified to do business and in good standing in each jurisdiction where the operations of its business requires such qualification, except where the failure to be so qualified or in such good standing will not prevent or delay the ability of the Purchaser to consummate the transactions contemplated by this Agreement and the other Transaction Documents.

Section 6.02 Authority; Non-Contravention, Required Filings

(a) The Purchaser has the requisite corporate power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party and to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery by the Purchaser of this Agreement and the other Transaction Documents to which the Purchaser is a party, and the performance by the Purchaser of its obligations hereunder and thereunder, and the consummation by the Purchaser of the transactions contemplated hereby and thereby, has been duly authorized by all necessary corporate action on the part of the Purchaser.

(b) This Agreement and the other Transaction Documents to which the Purchaser is a party have been duly executed and delivered by the Purchaser and each constitutes a valid and binding obligation of the Purchaser, enforceable against it in accordance with its terms, and, assuming due authorization, execution and delivery by the Seller, this Agreement constitutes, and each Transaction Document to which it is a party shall, after the Closing constitute, the Purchaser's legal, valid and binding obligation, in each case subject to: (i) the effects of bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting the enforcement of creditors' rights generally; and (ii) general equitable principles (whether considered in a proceeding in equity or at Law).

(c) The execution and delivery by the Purchaser of this Agreement and the other Transaction Documents to which the Purchaser is a party, the performance by the Purchaser of its obligations hereunder or thereunder, and the consummation by the Purchaser of the transactions contemplated hereby and thereby do not and will not (i) contravene any provision of the Organizational Documents of Purchaser, (ii) constitute a material breach, materially violate the terms, conditions or provisions of, or result in a material default under, conflict with, or give to any Person any rights of termination, amendment, acceleration or cancellation of any contract or agreement to which the Purchaser is a party or is otherwise bound, or (iii) violate any provision of any Laws to which the Purchaser is subject; except in the cases of clauses (ii) and (iii), where the conflict, violation, breach, default, grants to others of any rights of termination, amendment, acceleration or cancellation of, or notice, if any, would not reasonably be expected to prevent or materially delay the ability of the Purchaser to consummate the transactions contemplated by this Agreement.

(d) No Permit, Consent, waiting period expiration or termination, approval or authorization of, or designation, declaration or filing with, any Governmental Authority on the part of the Purchaser is required in connection with the execution or delivery by the Purchaser of this Agreement or the consummation of the transactions contemplated hereby other than the FDA Letters.

Section 6.03 Legal Proceedings. There are no Legal Proceedings pending or, to the Knowledge of the Purchaser, threatened against or by the Purchaser or any Affiliate of the Purchaser, that are reasonably likely to prohibit or restrain the ability of the Purchaser to enter into this Agreement or consummate the transactions contemplated hereby.

Section 6.04 Brokers. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of the Purchaser.

Section 6.05 Sufficiency of Funds. The Purchaser and the Parent have sufficient cash on hand or other sources of immediately available funds to enable the Purchaser to make payment of the Purchase Price (including the Closing Cash Consideration and the Deferred Payment) and consummate the transactions contemplated by this Agreement.

Section 6.06 Solvency. Immediately after the Closing, and after giving effect to the transactions contemplated by this Agreement, the Purchaser will be Solvent.

Section 6.07 No Other Warranties. The Purchaser acknowledges and agrees that: (i) the only representations, warranties, and covenants made by the Seller are the representations, warranties, and covenants expressly set forth in this Agreement, the other Transaction Documents and the certificates and documents delivered hereunder and thereunder; (ii) in making its decision to enter into this Agreement and to consummate the transactions contemplated hereby, the Purchaser has relied solely upon the express representations and warranties of the Seller set forth in this Agreement and the other Transaction Documents; and (iii) the Purchaser has not relied upon any other representations or other information made or supplied by or on behalf of the Seller (including the Confidential Information Memorandum dated November 28, 2022 and any information, documents or material made available to Purchaser in any data room or otherwise and any information provided by the Seller's advisors or in management presentations) and the Purchaser will not have any right or remedy arising out of any such other representations or information. The Purchaser acknowledges and agrees that, except as expressly provided in Article V, (A) the sale of the Purchased Assets is "as is" and "where is," and (B) the Purchaser is acquiring the Purchased Assets without any other representation or warranty, written or oral, statutory, express or implied, including any warranty of merchantability, fitness of any asset for a particular purpose, title, or non-infringement.

Section 6.08 No Other Representations and Warranties. Except for the representations and warranties contained in this Article VI and the Transaction Documents to which the Purchaser is a party, the Purchaser has not made any other express or implied representation or warranty, either written or oral, on behalf of the Purchaser, including any representation or warranty as to the accuracy or completeness of any information regarding the Purchaser furnished or made available to the Seller or its representatives.

ARTICLE VII COVENANTS

Section 7.01 Conduct of Business Prior to the Closing.

(a) Except (i) to the extent compelled or required by applicable Law, (ii) as set forth in Section 7.01 of the Seller Disclosure Schedule, or (iv) as consented to in writing by the Purchaser (which consent shall not be unreasonably withheld or delayed), during the period from the date hereof to the Closing Date (the “**Interim Period**”), the Seller shall conduct the Business in the ordinary course, consistent with past practice, and to the extent consistent therewith (w) not engage in (i) any trade loading or “channel stuffing” practices or any other promotional sales or discount activity with any customers, distributors or otherwise with the intent to accelerate to pre-Closing periods Accounts Receivable that would otherwise be expected (based on past practice) to arise in post-Closing periods or (ii) any practice intended to have the effect of postponing to post-Closing periods payments that would otherwise be expected (based on past practice) to be made in pre-Closing periods, (x) use commercially reasonable efforts to maintain the Purchased Assets and to preserve its current relationships and goodwill with customers, suppliers and others having business dealings with the Business, (y) maintain its books and records of the Business in the usual, regular and ordinary manner, on a basis consistent with past practice, and (z) use commercially reasonable efforts to preserve the goodwill and ongoing operations of its Business and otherwise maintain the Purchased Assets in good condition, ordinary wear and tear excepted, on a basis consistent with past practices. For the avoidance of doubt, the Parties acknowledge that any ordinary course increase in customer orders in anticipation of the July 4th holiday weekend will not constitute “channel stuffing” for purposes of this Section 7.01.

Section 7.02 Access to Information Prior to the Closing. During the Interim Period, the Seller shall give the Purchaser and its authorized representatives reasonable access during regular business hours to all books and records of the Business as the Purchaser may reasonably request; provided, that (a) the Seller shall not be required to take any action which could, in Seller’s sole discretion, constitute a waiver of the attorney-client or other privilege, compromise the Seller’s Confidential Information not related to the Business, or cause significant competitive harm to the Seller and its businesses, including the Business, if the transactions contemplated by this Agreement are not consummated, and (b) the Seller shall not be obligated to supply the Purchaser with any information which, on the advice of the Seller’s legal counsel, is, or could reasonably be, under a contractual or legal obligation not to supply. Prior to the Closing, without the prior written consent of the Seller, which may be withheld for any reason, the Purchaser shall not contact any suppliers to, or customers of, the Business except in connection with its own business in the ordinary course of business.

Section 7.03 Exclusivity. The Seller agrees that until June 30, 2023, the Seller shall not, and shall cause each of its officers, managers, directors and employees not to, directly or indirectly (a) solicit, initiate, encourage or accept any other Acquisition Proposal or (b) participate in any discussions, conversations, negotiations or other communications regarding, or furnish to any other Person any information with respect to, or otherwise cooperate in any way, assist or participate in, facilitate or encourage any effort or attempt by any other Person to seek to do any of the foregoing concerning an Acquisition Proposal. For the purposes hereof, “**Acquisition Proposal**” shall mean any proposal or offer from any Person relating to any direct or indirect acquisition or purchase of all or any portion of the Business or the Purchased Assets (other than items of the Purchased Inventory in the ordinary course of business), whether effected by sale of assets, sale of stock, merger or otherwise. Notwithstanding anything to the contrary in this Section 7.03, (i) the Seller may inform a Third Party, in response to an unsolicited communication regarding, or that could lead to, an Acquisition Proposal, that the Seller is bound by the terms of this Section 7.03, and (ii) the Seller may inform a Third Party, with whom a confidentiality agreement was entered into prior to the date hereof in connection with a potential Acquisition Proposal, that the Seller is bound by a sale agreement relating to the Business and the Purchased Assets and by the terms of this Section 7.03 and that the Seller is not permitted to provide further information in this respect other than what has been publicly disclosed.

Section 7.04 Notice of Developments.

(a) During the Interim Period, the Seller shall promptly notify the Purchaser in writing (i) if any representation or warranty of the Seller set forth in this Agreement was untrue when made so that the condition set forth in Section 8.02(a) could not be satisfied, (ii) of any development occurring after the date of this Agreement that would prevent the condition set forth in Section 8.02(a) or Section 8.02(d) from being satisfied, (iii) upon receiving any written notice or other written communication from any Person alleging that the consent of such Person is required in connection with the consummation of the transactions contemplated by this Agreement or the Transaction Documents, or (iv) upon becoming aware of any Legal Proceeding relating to the transactions contemplated in this Agreement.

(b) During the Interim Period, the Purchaser shall promptly notify the Seller in writing (i) if any representation or warranty of the Purchaser set forth in this Agreement was untrue when made so that the condition set forth in Section 8.03(a) could not be satisfied, (ii) of any development occurring after the date of this Agreement that would prevent the condition set forth in Section 8.03(a) or Section 8.03(c) from being satisfied, (iii) upon receiving any written notice or other written communication from any Person alleging that the consent of such Person is required in connection with the consummation of the transactions contemplated by this Agreement or the Transaction Documents, or (iv) upon becoming aware of any Legal Proceeding relating to the transactions contemplated in this Agreement.

Section 7.05 Confidentiality. From and after the Closing:

(a) The Confidentiality Agreement will terminate without further action by the Parties thereto.

(b) Subject to its obligations under the Transition Services Agreement, the Seller shall treat as confidential and shall safeguard any and all Confidential Information of the Purchaser (which shall include all information, knowledge, and data regarding the Products, the Purchased Assets, and the Assumed Liabilities) by using the same degree of care, but no less than a reasonable standard of care, to prevent the unauthorized use, dissemination, or disclosure of such Confidential Information as the Seller used with respect thereto prior to the execution of this Agreement.

(c) The Purchaser shall treat as confidential and shall safeguard any and all Confidential Information of the Seller (which shall not include any information, knowledge, and data regarding the Products, the Purchased Assets, and the Assumed Liabilities) except as otherwise agreed to by the Seller in writing; provided, however, that nothing in this Section 7.05(c) shall prevent the disclosure of any such Confidential Information to any managers, directors, officers, employees, Affiliates or professional advisors of the Purchaser to whom such disclosure is necessary in the conduct of the Purchaser's business if such Persons are informed by the Purchaser of the confidential nature of such information and are directed by the Purchaser to comply with the provisions of this Section 7.05(c).

(d) The Purchaser and the Seller acknowledge that the confidentiality obligations set forth herein shall not extend to information, knowledge and data that is publicly available or becomes publicly available through no act or omission of the Party owing a duty of confidentiality, or becomes available on a non-confidential basis from a source other than the Party owing a duty of confidentiality so long as such source is not known by such Party to be bound by a confidentiality agreement with or other obligations of secrecy to the other Party.

(e) In the event the Purchaser, on the one hand, or the Seller, on the other hand, is requested pursuant to, or required by, applicable Law to disclose any of the Seller's or the Purchaser's, respectively, Confidential Information, it will notify the other Parties in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party's sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, provided that such Party furnishes only that portion of the Confidential Information that such Party is advised by counsel is legally required, and if confidential treatment is available such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Confidential Information.

(f) In the event of a breach of the obligations hereunder by the Purchaser or the Seller, the non-breaching party(ies), in addition to all other available remedies, will be entitled to injunctive relief to enforce the provisions of this Section 7.05(f) in any court of competent jurisdiction, without the necessity of posting a bond and the burden of proving actual damages.

Section 7.06 Preservation of Books and Records.

- (a) The Seller shall have the right to retain copies of all books and records relating to the Purchased Assets relating to periods ending on or prior to the Closing Date, provided that such books and records are kept confidential in accordance with the Seller's normal confidentiality procedures and the provisions of Section 7.05.
- (b) The Purchaser shall preserve and keep, or cause to be preserved and kept, the books and records relating to the Purchased Assets in the possession of the Purchaser or their Affiliates for the longer of: (i) any applicable statute of limitations; and (ii) a period of seven (7) years from the Closing Date.
- (c) During such retention period:
- (i) the Seller and its representatives shall, upon reasonable notice and solely for the purpose of preparing Tax returns and financial statements or otherwise complying with Seller's legal obligations, have access during normal business hours to examine, inspect and copy such books and records; and
- (ii) the Purchaser shall provide, or cause to be provided to, the Seller and its representatives, access to such books and records relating to the Purchased Assets as they shall reasonably request in connection with any Legal Proceeding (other than a Legal Proceeding between or among the Parties and/or any of their respective Affiliates) to which any of them are parties or in connection with the requirements of any Law applicable to them;
- provided, however,* that any such access pursuant to either of the preceding clauses (i) and (ii) shall be subject to Purchaser's reasonable security measures and conducted in a manner not to unreasonably interfere with Purchaser's businesses or operations.
- (d) No Party shall be obligated to provide the other Party with access to any books or records pursuant to this Section 7.06 where such access would violate any Law.

Section 7.07 Non-Competition.

- (a) Without the express written consent of the Purchaser (which may be given or withheld in the Purchaser's sole discretion), the Seller shall not, until July 19, 2027 (the "**Non-Compete Period**"), but subject, in each case, to Seller's obligations under Section 7.11 hereof and the Transition Services Agreement, with respect to each country in the Territory, directly or indirectly market, distribute or sell in the Territory:
- (i) any prescription pharmaceutical product (A) containing the same active ingredient and, with respect to the Tosymra Product, an absorption enhancer, and (B) with the same route and mode of administration and same dosage strength as the applicable Product; and (C) which is marketed for the same indication as any Product; or
- (ii) with respect to the Tosymra Product only, any pharmaceutical product (A) containing any triptan (including sumatriptan) and an absorption enhancer, (B) with the same route and mode of administration and same dosage strength as the Tosymra Product and (C) which is marketed for the same indication as the Tosymra Product,

(any such product described in (i) and (ii) above being a “Competing Product”).

(b) Notwithstanding the above, the foregoing shall not apply to any Competing Product that is acquired by the Seller after the Closing Date through a merger or acquisition of, or a collaboration or joint venture with, a Third Party that owns one or more Competing Products as part of a larger portfolio of products which portfolio contains any products in addition to the Competing Product; provided, however, that in the event that a Competing Product acquired pursuant to the foregoing has not yet been launched in the Territory at the time of such acquisition, Seller shall not launch such Competing Product in the Territory prior to the expiration of the Non-Compete Period for the relevant Product in the relevant Territory; provided, further, the Seller shall use commercially reasonable efforts to either divest to a Third Party that is not an Affiliate of Seller or cease Exploitation of such Competing Product (whether or not the Competing Product was launched in the Territory at the time of such acquisition) within twelve (12) months of the acquisition date of such product (and that for the avoidance of doubt, the foregoing proviso shall not serve as a restriction on the Seller from licensing or divesting such Competing Product to a Third Party); and provided, further, that in the event the Seller licenses or divests such Competing Product to a Third Party, the Seller shall not be deemed to be assisting a Third Party by providing due diligence, assisting such Third Party with transitional matters or taking other ordinary course actions in connection with such divestiture or license (but, in connection with such a license, this exception shall not allow the Seller to assist such licensee with its marketing and sales strategies for such Competing Product), or continuing to market, distribute or sell an acquired Competing Product in the Territory if such Competing Product had already been launched in the Territory prior to such acquisition.

(c) Notwithstanding anything to the contrary, Purchaser will not, directly or indirectly: (i) at any time challenge (or authorize, direct or assist any other Person to challenge) the validity or enforceability of any of the Patents or any other patents owned by Purchaser or any of its Affiliates that cover a Product or (ii) at any time prior to expiration of all applicable Patents and any such other patents covering a product, file any application for regulatory approval of a generic pharmaceutical product that references such Product as the reference listed drug.

Section 7.08 Transfer of Acquired Regulatory Approvals

(a) The Seller and the Purchaser shall establish a mutually acceptable and prompt communication and interaction process to ensure the orderly transfer of the Acquired Regulatory Approvals. The Seller and the Purchaser shall use all commercially reasonable efforts to take any actions required by any Governmental Authority to effect the transfer of the Acquired Regulatory Approvals from the Seller to the Purchaser, and shall cooperate with each other in order to effectuate the foregoing transfer of the Acquired Regulatory Approvals. The Seller may retain an archival copy of any Acquired Regulatory Approvals including supplements and records that are required to be kept under 21 C.F.R. §314.81.

(b) Following the Closing, each of the Parties shall use its commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary for it to do under applicable Laws to consummate and make effective the transactions contemplated by this Agreement, which actions shall include making all required registrations and filings with, and seeking all required Consents of, Governmental Authorities and furnishing all information required by applicable Law or requested by such Governmental Authorities. Each Party shall cooperate fully with the other Party in promptly seeking to make such required registrations and filings and obtain all required Consents. The Parties shall not willfully take any action that will have the effect of delaying, impairing or impeding the making of such required registrations and filings or the receipt of any required Consents.

(c) The Seller will reasonably cooperate with the Purchaser in disclosing any relevant records and reports which are required to be made, maintained and reported pursuant to applicable Law in the Territory with respect to the Acquired Regulatory Approvals and coordinating with the Purchaser to make an orderly and prompt transition of the Purchased Assets as soon as practicable after the Closing.

Section 7.09 Public Announcements. The Seller and the Purchaser agree that each shall be permitted to issue a press release with respect to the execution and delivery of this Agreement and the transactions contemplated hereby, which press release shall be substantially in the form of the press release attached as Exhibit Q. Except for the press release referred to in the foregoing sentence, neither the Seller nor the Purchaser shall issue any press release or make any public announcement with respect to this Agreement and the transactions contemplated hereby without obtaining the prior written consent of the other Party, except as may be required by Law or stock exchange rules and regulations upon the advice of counsel and only if the disclosing Party (x) provides the non-disclosing Party with an opportunity to first review the release or other public announcement, (y) consults with the non-disclosing Party (whether such Party is named in such publicity, news release or public announcement or not) at a reasonable time prior to its release to allow the non-disclosing Party to comment thereon (provided that the foregoing shall not prevent the disclosing Party from proceeding with such release or other public announcement by any applicable deadline required under applicable Law or stock exchange rules or regulations if the non-disclosing Party fails to timely respond to such requests) and (z) after its release, shall provide the non-disclosing Party with a copy thereto. If a Party, based on the advice of its counsel, determines that this Agreement or exhibits thereto must be filed with the United States Securities and Exchange Commission ("SEC"), then such Party, prior to making any such filing, shall provide the other Parties and their counsel with a redacted version of this Agreement which it intends to file, and will give due consideration to any comments provided by such other Parties or their counsel and use commercially reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by such other Parties or their counsel; provided, however, that the Party filing this Agreement or its exhibits will not be required to seek confidential treatment of any information that it determines it is required to publicly disclose based on advice of counsel. Following the Closing, the Purchaser shall be entitled to make such public announcements as it deems appropriate related to the Products; provided however that except as otherwise provided above, without the Seller's prior written consent, no such announcement shall contain any reference to the Agreement or the terms set forth therein or the Seller or actions taken with respect to the Products prior to the Closing Date other than references consistent with those previously approved by the Seller in writing.

Section 7.10 Further Assurances. Except as otherwise set forth in Section 7.08, subject to the terms and conditions set forth herein and to applicable Law, each of the Parties hereto shall cooperate and use their respective commercially reasonable efforts to take, or cause to be taken, all appropriate action, and do, or cause to be done (including the execution and delivery of any additional documents and instruments as may be required), and assist and cooperate with the other Party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated in this Agreement, including the satisfaction of the respective conditions set forth in Article VIII.

Section 7.11 NDC Numbers, Product Returns, Rebates and Chargebacks

(a) NDC Numbers/ Product Identifiers Following the Closing Date, Purchaser shall use commercially reasonable efforts to establish its own NDC Numbers and product identifiers relating to the Products as soon as practicable after the Closing. Purchaser shall register with FDA to obtain its own NDC Numbers and product identifiers with respect to the Products and shall use commercially reasonable efforts to have labeling created containing NDC Numbers for use on Product on order or to be ordered following the Closing. Notwithstanding the foregoing, the Parties acknowledge and agree that Purchaser shall be permitted (and is hereby licensed) to use with Seller's NDC Number, product identifier and Seller Trade Dress in connection with (i) the sale and distribution of (A) any existing finished product Purchased Inventory, (B) any quantities of Products for which orders have been placed as of Closing and (C) any validation batches of Zembrace Product that as of Closing are anticipated to be produced by INCOG Biopharma Services, Inc. after Closing, in each case until such Purchased Inventory and inventory of ordered Product and Zembrace Product validation batches in Seller's labeling is exhausted (the "**Seller Label Product End Date**") and (ii) any Marketing Materials included in the Purchased Assets, until the Seller Label Product End Date.

(b) Product Returns

(i) Following the Closing, the Seller shall be financially and legally responsible for the return costs and any refunds of the purchase price associated with any customer or wholesaler returns of Product ("**Product Returns**") for (A) any Product from manufacturing lots from which all Product units were sold by Seller on or prior to the Closing Date and (B) its proportional share, determined pursuant to Section 7.11(b)(v) below, of Product Returns of Product from manufacturing lots from which Product was sold by both Seller on or prior to the Closing Date and by Purchaser after the Closing Date ("**Split Lots**"). The Purchaser shall be financially and legally responsible for the return costs and any refunds of the purchase price associated with Product Returns for (A) any Products from manufacturing lots from which all Product units are sold by Purchaser after the Closing Date and (B) its proportional share, determined pursuant to Section 7.11(b)(v) below, of Product Returns of Product from Split Lots. Exhibit N sets forth the lot and batch numbers of Product sold by the Seller identifying (A) that quantity of Product that is within twelve (12) months of such Product's expiration dating as of the Closing Date and is therefore eligible for return ("**Eligible Product**"), and (B) that quantity of Product sold by Seller as of the Closing Date from each Split Lot.

(ii) Except as set forth herein or in the Transition Services Agreement, each Party shall process all Products bearing such Party's NDC Numbers and product identifiers that are subject to a Product Return (the "**Returned Product**") and that are received after the Closing Date, irrespective of which Party sold such Returned Product. Such processing by such Party shall also include, if permitted by Law, the destruction of all Returned Product by such Party, or the customer, as applicable. With respect to Product Returns received by a Party that are the financial or legal responsibility of the other Party as set forth in Section 7.11(b)(i), the receiving Party will only issue return credits for any Returned Product that is the financial or legal responsibility of the other Party after such time that such issuing Party has received the Returned Product from the customer, unless such other Party agrees in advance to waive the customer's return of the expired, damaged, defective or otherwise unsalable Products.

(iii) Each of the Purchaser and the Seller agree that unless required by Law, it will not, directly or indirectly, take any action that would provide any incentive to, or otherwise intentionally induce, customers to return Products, except as the Parties may otherwise mutually agree or except for any action taken in the respective Party's ordinary course of business consistent with its past practice.

(iv) To the extent a Party provides a return credit or otherwise remits payment in respect of a Liability associated with a Product Return for a Product that is the financial or legal responsibility of the other Party pursuant to Section 7.11(b)(i), the providing or remitting Party shall provide such other Party with an invoice for such return credit or other payment and such other Party shall remit payment on such invoice on or before the date that is thirty (30) days following such other Party's receipt of such invoice, provided that such invoices describe the payments in reasonable detail and include documentation reasonably supporting the Party responsible for such Liability.

(v) In case of Product Returns of Product from a Split Lot, Product Returns received by both Parties for such Product are shared in proportion of the sales made by both the Seller and the Purchaser from such Split Lot. In order to compute each Party's share of Product Returns, the Parties shall determine each Party's proportional share of such Product Returns from such Split Lot as of the Closing Date by dividing each of the Seller's and the Purchaser's sales of Product from such Split Lot by the total units of Product in such Split Lot.

(c) Government Programs.

(i) Responsibility for rebates, discounts and fees pursuant to any government rebate and/or discounts programs with respect to government claims for Products ("**Government Rebates, Discounts and Fees**") shall be allocated between the Seller and the Purchaser as follows:

(A) The Seller shall be financially responsible for (x) all Government Rebates, Discounts and Fees with respect to Products dispensed to patients covered by Medicare on or prior to the Closing Date and during the sixty (60) day period following the Closing Date, and (y) 66% of all Government Rebates, Discounts and Fees incurred with respect to Products dispensed to patients covered by Medicaid during the calendar quarter following the Closing Date (each such period, as applicable, the "**Government Rebates, Discounts and Fees Tail Period**").

(B) The Seller shall be responsible for calculating and reporting statutory Product pricing under its labeler code until inventory in Seller's NDC is depleted in the distributors for sales to various government agencies. The Seller will provide to the Purchaser such calculations and reports of statutory Product pricing prior to submission.

(C) [Intentionally Omitted.]

(D) The Purchaser shall be responsible for submitting a Request for Modification (RFM) to the VA National Acquisition Center upon the Closing to roll over the Seller's Product NDC Numbers under its Federal Supply Schedule Contract, and the Purchaser shall use commercially reasonable efforts to facilitate such roll over as mutually agreed by the Parties in accordance with the Transition Services Agreement.

(E) The Purchaser shall promptly following the Closing communicate to all wholesalers its responsibility to honor 340B/PHS purchases made under the Seller's Product NDC Numbers following the Government Rebates, Discounts and Fees Tail Period.

(F) The Seller shall use commercially reasonable efforts to terminate the Seller's Product NDC Number from Seller's Federal Supply Schedule and 340B/PHS agreements immediately following the Government Rebates, Discounts and Fees Tail Period and upon the Purchaser confirming adding its Product NDC Number to both the Purchaser's Federal Supply Schedule and 340B/PHS agreements.

(G) The Purchaser shall be financially responsible for administering all Government Rebates, Discounts and Fees with respect to the Products dispensed to patients beginning on the day following the expiration of the applicable Government Rebates, Discounts and Fees Tail Period.

(H) It is understood and agreed that the Purchaser shall have the right to request through the Seller any claims level data (including dispense date) contained in any report from a state rebate program which shall be used for purposes of determining the date of such claim or for state rebate dispute purposes. In the event the Purchaser determines an invoice or claim for Government Rebates, Discounts and Fees should be disputed, the Seller shall make commercially reasonable efforts to cooperate with the Purchaser to dispute such claim or invoice.

(ii) If either the Purchaser, on the one hand, or a Seller, on the other hand (the "**Non-Responsible Party**") receives an invoice with respect to a Government Rebates, Discounts and Fees that is the responsibility of the other Party (the "**Responsible Party**"), such Non-Responsible Party shall promptly provide a copy of such invoice to the Responsible Party and such Responsible Party shall have fifteen (15) days following receipt of such invoice to notify the Non-Responsible Party that it intends to dispute such invoice. If the Responsible Party does not so notify the Non-Responsible Party within such fifteen (15) day period, such Non-Responsible Party shall be permitted to remit payment in respect of such invoice on the Responsible Party's behalf and the Responsible Party shall reimburse the Non-Responsible Party for such payment pursuant to the terms of Section 7.11(c)(iii). If the Responsible Party provides such notice to the Non-Responsible Party within such 15-day period then the Responsible Party shall promptly initiate a dispute of such invoice at its sole cost and expense and shall be liable for all reasonable costs and expenses (including reasonable attorney fees) of the Non-Responsible Party required to prosecute the disputed invoice. In the event that an invoice is disputed under this Section 7.11(c)(i) by the Responsible Party, the Non-Responsible Party shall not remit payment in respect of such invoice without the Responsible Party's prior written consent; provided that any late fees, interest or other penalties that are ultimately owing due to delayed payment on such invoice shall be satisfied by the Responsible Party and provided further that notwithstanding the foregoing, the Non-Responsible Party may, in its sole discretion, pay any such disputed invoice without the consent of the Responsible Party, but in such case the Non-Responsible Party shall be entitled to reimbursement by the Responsible Party only with respect to amounts if any, that are finally owing following settlement of the related dispute.

(iii) Subject to Section 7.11(c)(i), to the extent that a Non-Responsible Party remits payment in respect of Government Rebates, Discounts and Fees which are payable by the Responsible Party, the Responsible Party shall reimburse the other Party on or before the date that is thirty (30) days following receipt of such undisputed invoices from such Non-Responsible Party, provided that such invoices describe in reasonable detail the payments made by such Non-Responsible Party.

(iv) The Parties will cooperate in good faith to timely share with each other such detailed data and methodology information as may be reasonably necessary to facilitate appropriate price calculations for their respective NDC Numbers for the Products. Without limiting the foregoing:

(A) No later than ten (10) Business Days following the Closing Date, Seller will provide Purchaser with (a) the base date AMP (as described in 42 U.S.C. § 1396r-8(c)(2)) (along with any materials from which the calculation of the base date AMP was derived, including a record of any assumptions made in the calculation), current AMP and current Federal Supply Schedule price for the Products and (b) the additional information set forth on Exhibit R. Seller will also provide, at the request of Purchaser, and in a reasonable time and manner, sales and pricing data in its possession or control for the Products with respect to the base date AMP if required in order for Purchaser to comply with applicable Law. Seller will not restate the base date AMP of either Product without Purchaser's prior written approval, which approval may be withheld for any or no reason, subject to compliance with applicable eMedicaid legal requirements.

(B) Seller will provide Purchaser with Seller's reported monthly and quarterly AMPs, Best Prices, Nominal Sales, Customary Prompt Payment Discounts, URA and PHS prices for each reporting period until the date sales and pricing data for the Products under Seller's NDC Numbers are no longer required for such calculations. Seller will also provide to Purchaser the most recent calendar quarter and Annual NFAMPs and Federal Ceiling Price for each Product. In addition, Seller will provide to Purchaser such historical (going back at least 12 months prior to the Closing Date) pricing, sales, transactional, customer and data pertaining to the Products as may be reasonably requested by Purchaser in connection with Purchaser's calculating and reporting prices on Purchaser's NDC Numbers to any government program.

(C) All information provided by each Party to the other Party pursuant to this Section 7.11(c)(i)(iv) will be accurate and complete in all material respects and will be calculated utilizing systems, processes, policies, practices and pricing methodologies that comply with the requirements of the applicable government program.

(d) Chargeback Claims.

(i) The Parties acknowledge that Seller does not have commercial chargeback agreements, and that chargebacks arise only with respect to the Seller's Federal Supply Schedule and 340B/PHS agreements. The Seller shall be financially and legally responsible for all chargeback claims ("**Chargeback Claims**") related to Products sold under the Seller's customer contracts (including Seller's Federal Supply Schedule and 340B/PHS agreements) by the wholesaler or distributor. Prior to the Closing Date and for the duration of the Government Rebates/Discounts/Fees Tail Period, the Purchaser shall process (subject to the Transition Services Agreement) and be financially and legally responsible only for Chargeback Claims related to Products sold under the Purchaser's customer contracts by the wholesaler or distributor. Notwithstanding the foregoing, the Parties acknowledge that the VA National Acquisition Center must approve the removal of Products from the Seller's Federal Supply Schedule before the responsibility of processing such claims is transferred from the Seller to the Purchaser. Until such approval is obtained (and thereafter, to the extent provided in the Transition Services Agreement), the Seller shall continue to be responsible for processing the Federal Supply Schedule Chargeback Claims on the Purchaser's behalf to the extent provided in the Transition Services Agreement and the Purchaser shall reimburse the Seller as set forth in the Transition Services Agreement. The Purchaser and the Seller agree that (A) the Seller's financial liability for the Chargeback Claims shall be limited to those customers with which the Seller has chargeback obligations as of the Closing Date and (B) any such chargebacks issued by the Seller shall be made in accordance with terms and conditions of the Seller's obligations with respect to each customer and shall be solely based on the terms and conditions of the Seller's agreements with the respective customer.

(ii) If a Non-Responsible Party receives a Chargeback Claim that is the responsibility of the Responsible Party, such Non-Responsible Party shall promptly provide a copy of such Chargeback Claim to the Responsible Party and such Responsible Party shall have fifteen (15) days following receipt of such Chargeback Claim to notify the Non-Responsible Party that it intends to dispute such invoice. If the Responsible Party does not so notify the Non-Responsible Party within such fifteen (15) day period, such Non-Responsible Party shall be permitted to remit payment in respect of such Chargeback Claim on the Responsible Party's behalf and the Responsible Party shall reimburse the Non-Responsible Party for such payment pursuant to the terms of Section 7.11(d)(iii). If the Responsible Party provides such notice to the Non-Responsible Party within such fifteen (15) day period then the Responsible Party shall promptly initiate a dispute of such Chargeback Claim at its sole cost and expense and shall be liable for all reasonable costs and expenses (including reasonable attorney fees) of the Non-Responsible Party required to prosecute the disputed Chargeback Claim. In the event that a Chargeback Claim is disputed under this Section 7.11(d)(ii) by the Responsible Party, the Non-Responsible Party shall not remit payment in respect of such Chargeback Claim without the Responsible Party's prior written consent; provided that any late fees, interest or other penalties that are ultimately owing due to delayed payment on such Chargeback Claim shall be satisfied by the Responsible Party and provided further that notwithstanding the foregoing, the Non-Responsible Party may, in its sole discretion, pay any such disputed Chargeback Claim without the consent of the Responsible Party, but in such case the Non-Responsible Party shall be entitled to reimbursement by the Responsible Party only with respect to amounts if any, that are finally owing following settlement of the related dispute.

(iii) Subject to Section 7.11(d)(ii), to the extent a Non-Responsible Party processes Chargeback Claims which are the responsibility of Responsible Party, the Responsible Party shall reimburse the Non-Responsible Party on or before the date that is thirty (30) days following receipt of such undisputed invoices from such Non-Responsible Party, provided that such invoices describe in reasonable detail the payments made by such Non-Responsible Party.

(iv) Following the Closing, except as expressly set forth hereinabove, the Purchaser shall be responsible to provide all price, price increase and justification for price increase to all Governmental Authorities, including all applicable federal and state agencies. In addition, following the Closing, the Purchaser shall be responsible for all state and federal reporting relating to state or federal drug price transparency requirements for any and all Products sold under the Seller's NDC Number or product identifier, unless specifically requested and paid for by the Purchaser under the Transition Services Agreement.

(c) Rebates Under PBM Contracts

(i) Subject to the Seller's obligations under the Transition Services Agreement, the Seller shall be permitted to terminate each pharmacy benefits management ("PBM") contract of the Seller providing for payment of commercial rebates and administrative fees with respect to the Products (**PBM Rebate Contracts**), provided that the Seller has no Liability to the Purchaser in the event that any PBM Rebate Contract is terminated by any party other than the Seller, including automatic termination as a result of the transactions contemplated by this Agreement. Notwithstanding the foregoing, the Seller shall continue to honor all such PBM Rebate Contracts for the period necessary to comply with the transition and/or termination language thereof. Notwithstanding anything to the contrary provided herein or elsewhere, the Seller shall be permitted to take such actions necessary (including providing notice to PBMs, terminating any PBM Rebate Contracts, or assigning any PBM Rebate Contracts to the extent such notice or assignment is mandated pursuant to the terms of such PBM Rebate Contract) to comply with any PBM Rebate Contracts or any related payer agreements. Promptly following the Closing, the Seller and the Purchaser shall each issue their own respective letters (as mutually agreed upon) to each PBM advising such PBM of the Seller's sale of the Products and the allocation of responsibilities in connection with the PBM Rebate Contracts and associated rebate and administrative fees.

(ii) The Purchaser shall use commercially reasonable efforts following the Closing to negotiate and enter into contracts with PBMs and related payers relating to the PBM Rebate Contracts that Seller continues to have obligations following the Closing with respect to any Product, which shall enable the Seller to terminate its respective PBM Rebate Contracts.

(iii) To the extent provided in the Transition Services Agreement, the Seller will process and be responsible for the administration and payment, in accordance with the terms of the relevant PBM Rebate Contract, of all rebates and administrative fees related to the Products sold under the PBM Rebate Contracts; *provided, however*, that the Purchaser will be financially responsible, and shall reimburse the Seller, for those commercial rebates and administrative fees which relate to sales of the Product that occur after the thirty (30) day period following the Closing Date, except for the PBM related commercial rebates and administrative fees that relate to the channel inventory as determined by the Parties from the Closing Date inventory reports (852 data) provided by the Seller to the Purchaser within three (3) Business Days of the Closing, which shall be the responsibility of the Seller.

(iv) With respect to any PBM rebate or administrative fees for which the Purchaser is financially responsible under this Section 7.11(e)(iii), payment shall be made promptly within thirty (30) days to the Seller upon submission to the Purchaser of invoices that describe the requested payments in reasonable detail.

(v) After termination of the PBM Rebate Contracts, if Seller is required to pay any rebates to any PBMs for the coverage extended to the Products, then solely with respect to Products sold by the Purchaser to its direct purchasing wholesale and retail customers after the Closing Date, the Purchaser shall be financially responsible for such rebates and shall promptly reimburse the Seller within thirty (30) days after the Purchaser's receipt of the invoices for those commercial rebates and administrative fees paid by the Seller.

(f) Patient Services Assistance and Specialty Distribution Programs. The Seller's agreements with third parties concerning the provision of patient services, including Seller's co-pay program, e-voucher program and hub services ("Patient Services Programs"), are included in the Acquired Contracts. The Seller will manage those Acquired Contracts to the extent provided in the Transition Services Agreement.

(g) Medicare Part D Rebates. Seller will be financially responsible for all claims for rebates in connection with a Medicare Part D Prescription Drug Plan ("Medicare Part D Rebates") with respect to Products dispensed to patients on or before the date that is thirty (30) days after the Closing Date (the **Medicare Part D Rebate Cutoff Date**). Purchaser will be financially responsible for all claims for Medicare Part D Rebates with respect to Products dispensed to patients after the Medicare Part D Rebate Cutoff Date.

Section 7.12 Drug Supply Chain Security Act From and after the Closing Date, the Seller shall maintain product serialization data related to the Products sold by the Seller prior to the Closing or during the TSA Period in Seller's label for so long as is required by applicable Law. From and after the Closing Date, the Purchaser shall maintain product serialization data related to the Products sold by the Purchaser after the Closing in Seller's label for so long as is required by applicable Law. The Seller shall field serialization inquiries and promptly communicate all such inquiries in writing to the Purchaser. The Purchaser shall be responsible for payment of the costs and for investigating and responding to serialization inquiries, providing a written copy of all such investigations and responses to the Seller.

Section 7.13 Insurance. As from the Closing Date, the Purchaser shall maintain, with respect to the Business, insurance policies of the types and in the amounts customarily carried by businesses of similar size in the same industry, including customary coverage for all Purchased Inventory in the Seller's possession, wherever located, and product liability insurance.

Section 7.14 Product Financial Information.

(a) On or before July 28, 2023, the Seller will provide to the Purchaser an unaudited quarterly schedule of Seller's revenues and expenses with respect to the Business for the period from January 1, 2022 through June 30, 2023, prepared in accordance with GAAP.

(b) The Parties acknowledge that Seller's auditor which prepared the Abbreviated Financial Statements (KPMG) has indicated that KPMG expects to deliver a final audit opinion based on the Abbreviated Financial Statements, along with a consent for Parent to disclose the information included therein in its public filings pursuant to applicable securities laws, by July 14, 2023. Seller will reasonably cooperate with Purchaser in coordinating and communicating with KPMG with respect to the foregoing.

Section 7.15 License to Licensed Know-How. Seller hereby grants to Purchaser a perpetual, irrevocable, non-exclusive, paid up, royalty-free, transferable, sublicenseable license in the Territory under the Licensed Know-How to make, have made, use, sell, offer to sell, import, reproduce, prepare derivative works, distribute, perform, display and otherwise fully Exploit the Products and any other dose strengths, formulations and other versions thereof or improvements thereto, in each case solely to the extent such Products or other products are intended to be sold in the Territory.

Section 7.16 Compliance with Retained Agreement and Partially Assigned APA . From and after the Closing Date, the Seller shall not commit any material breach of the Retained Agreement, and the Purchaser shall not commit any material breach of the Partially Assigned APA.

ARTICLE VIII CONDITIONS TO CLOSING

Section 8.01 Conditions to Obligations of All Parties. The obligations of the Parties to consummate the transactions contemplated by this Agreement are subject to the fulfillment prior to or at the Closing of each of the following conditions (any or all of which may be waived by both Parties):

(a) No Injunction. No Governmental Authority or federal or state court of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any statute, rule, regulation, Governmental Order or other notice (whether temporary, preliminary or permanent) (collectively, the "**Restraints**"), in any case which is in effect and which prevents or prohibits consummation of the transactions contemplated by this Agreement; provided, that each of the Parties shall use its commercially reasonable efforts to cause any such Restraint to be vacated or lifted.

Section 8.02 Conditions to Obligations of the Purchaser. The obligations of the Purchaser to consummate the transactions contemplated by this Agreement are subject to the fulfillment prior to or at the Closing of each of the following conditions (any or all of which may be waived in whole or in part by the Purchaser):

(a) Representations and Warranties. The representations and warranties of the Seller contained in Article V hereof which are modified by Material Adverse Effect shall be true and correct as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which representations and warranties shall be true and correct as of such specific date). The representations and warranties of the Seller contained in Article V hereof which are not modified by Material Adverse Effect shall be true and correct as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which representations and warranties shall be true and correct as of such specific date), except to the extent that the failure to be so true and correct would not have a Material Adverse Effect.

(b) Performance. The Seller shall have performed and complied in all material respects with all agreements and covenants required by this Agreement to be so performed or complied with by the Seller at or prior to the Closing.

(c) Deliveries. The Purchaser shall have received the deliveries contemplated by Section 4.02(a).

(d) No Material Adverse Effect. During the Interim Period, no change, effect, development, event or circumstance shall have occurred that has had, individually or in the aggregate, a Material Adverse Effect.

Section 8.03 Conditions to Obligations of the Seller. The obligations of the Seller to consummate the transactions contemplated by this Agreement are subject to the fulfillment prior to or at the Closing of each of the following conditions (any or all of which may be waived in whole or in part by the Seller):

(a) Representations and Warranties. The representations and warranties of the Purchaser contained in Article VI hereof shall be true and correct as of the Closing Date as though made as of the Closing Date (except for representations and warranties which address matters only as of a specific date, which representations and warranties shall be true and correct as of such specific date), except to the extent that the failure to be so true and correct would not have a Purchaser Material Adverse Effect.

(b) Performance. The Purchaser shall have performed and complied in all material respects with all agreements and covenants required by this Agreement to be so performed or complied with by the Purchaser at or prior to the Closing.

(c) Deliveries. The Seller shall have received the deliveries contemplated by Section 4.02(b).

(d) No Material Adverse Effect. During the Interim Period, no change, effect, development, event or circumstance shall have occurred that has had, individually or in the aggregate, a Purchaser Material Adverse Effect.

ARTICLE IX INDEMNIFICATION

Section 9.01 Survival.

(a) The representations and warranties contained in Article V and Article VI of this Agreement (other than the Fundamental Representations) shall survive the Closing until the close of business on the twelve (12) month anniversary of the Closing Date. The Fundamental Representations shall survive until the six (6) year anniversary of the Closing Date. All covenants and agreements contained in this Agreement, whether of the Purchaser or the Seller, shall survive the Closing Date until the six (6) year anniversary of the Closing Date or until the expiration date for such covenant or agreement specified in this Agreement, if sooner. Any claims for Losses arising out of or caused by or relating to fraud shall survive until the six (6) year anniversary of the Closing Date. The representations and warranties of the Seller are bargained for assurances.

(b) All claims by any Indemnified Party pursuant to this Article IX must be made on or before the applicable survival date, it being understood that so long as the Indemnified Party gives written notice of a claim on or prior to the applicable survival date, such representations and warranties and covenants shall continue to survive solely with respect to such claim until such claim is fully and finally resolved in accordance with the terms of this Agreement.

Section 9.02 Indemnification by Seller. Subject to the terms and conditions of this Article IX, from and after the Closing, the Seller shall indemnify and defend the Purchaser, its Affiliates, and each of their respective employees, managers, directors, officers, equity holders, agents, and representatives (collectively, the “**Purchaser Group**”), against, and shall hold each of them harmless from, any and all Losses incurred or sustained by the Purchaser Group that arise out of, relate to or result from:

(a) any inaccuracy in or breach of any of the representations or warranties of the Seller contained in this Agreement or certificate or instrument delivered by or on behalf of the Seller pursuant to this Agreement or in any Transaction Document (excluding the Transition Services Agreement);

(b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by the Seller pursuant to this Agreement or in any Transaction Document (excluding the Transition Services Agreement); or

(c) any Excluded Assets or any Excluded Liabilities.

Section 9.03 Indemnification by Purchaser. Subject to the terms and conditions of this Article IX, from and after the Closing, the Purchaser shall indemnify and defend the Seller, its Affiliates, and each of their respective employees, managers, directors, officers, equity holders, agents, and representatives (collectively, the “**Seller Group**”), against, and shall hold each of them harmless from, any and all Losses incurred or sustained by the Seller Group that arise out of, relate to or result from:

(a) any inaccuracy in or breach of any of the representations or warranties of the Purchaser contained in this Agreement or in any certificate or instrument delivered by or on behalf of the Purchaser pursuant to this Agreement or in any Transaction Document (excluding the Transition Services Agreement);

(b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by the Purchaser pursuant to this Agreement or in any Transaction Document (excluding the Transition Services Agreement); or

(c) any Assumed Liabilities, including any and all Liabilities, obligations and commitments owed by Purchaser to DRL and Promius under the Assignment and Assumption Agreement regarding DRL Contracts.

Section 9.04 Notice of Direct Claims.

(a) If any of the Persons to be indemnified under this Article IX (the “**Indemnified Party**”) has suffered or incurred any Loss subject to indemnification under this Article IX that does not involve a Third Party Claim, the Indemnified Party shall so notify the Party responsible for providing indemnification therefor under this Agreement (the “**Indemnifying Party**”) promptly in a writing describing such Loss, the basis for indemnification hereunder, the amount or estimated amount of such Loss, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this Agreement in respect of which such Loss shall have occurred. A failure by the Indemnified Party to give notice in a timely manner pursuant to this Section 9.04(a) (so long as a notice pursuant to this Section 9.04(a) is given before the expiration of the applicable period set forth in Section 9.01) shall not limit the obligation of the Indemnifying Party under this Article IX, except to the extent such Indemnifying Party is prejudiced by failure to give such notice in a timely manner.

(b) Except when a notice, report or other filing must be filed immediately pursuant to applicable Law, the Indemnified Party shall provide notice and an opportunity to comment to the Indemnifying Party before the Indemnified Party files any report, notification or filing with any Governmental Authority or Third Party in connection with an event that would be reasonably likely to result in a Loss subject to the indemnification provisions of Section 9.02 or Section 9.03. In the event the Indemnified Party is required to file such a report, notification or filing immediately, the Indemnified Party shall provide simultaneous notice to the Indemnifying Party when it submits such report, notification or filing to the applicable Governmental Authority.

Section 9.05 Third Party Claims.

(a) If any Legal Proceeding is instituted by or against a Third Party with respect to which the Indemnified Party intends to seek indemnity under this Article IX (a “**Third Party Claim**”), the Indemnified Party shall promptly notify the Indemnifying Party of such Third Party Claim (such notice describing, to the extent practicable, such matter in reasonable detail and such being accompanied by a copy of any written notice of the Third Party claimant to the Indemnified Party asserting the Third Party Claim) and tender to the Indemnifying Party the conduct or defense of such Third Party Claim. A failure by the Indemnified Party to give notice in a timely manner pursuant to this Section 9.05(a) (so long as a notice pursuant to this Section 9.05(a) that includes any written notice of the Third Party claimant is given before the expiration of the applicable period set forth in Section 9.01) and to tender the conduct or defense of the Third Party Claim in a timely manner pursuant to this Section 9.05(a) shall not limit the obligation of the Indemnifying Party under this Article IX, except (i) to the extent such Indemnifying Party is prejudiced thereby, and (ii) to the extent expenses are incurred during the period in which notice was not provided.

(b) The Indemnifying Party shall have the right to defend the Indemnified Party against such Third Party Claim. If the Indemnifying Party notifies the Indemnified Party that the Indemnifying Party elects to assume the defense of the Third Party Claim (such election to be without prejudice to the right of the Indemnifying Party to dispute whether such claim is an indemnifiable Loss under this Article IX), then the Indemnifying Party shall have the right to defend such Third Party Claim with counsel selected by the Indemnifying Party, in all appropriate proceedings, to a final conclusion or settlement at the discretion of the Indemnifying Party in accordance with this Section 9.05(b). The Indemnifying Party shall have full control of such defense and proceedings, including any compromise or settlement thereof; provided, however, that the Indemnifying Party shall not enter into any settlement agreement without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing, such consent shall not be required if (i) the settlement agreement contains a complete and unconditional general release by the Third Party asserting the Third Party Claim to all Indemnified Parties affected by the claim and (ii) the settlement agreement does not contain any sanction or restriction upon the conduct or operation of any business by the Indemnified Party or its Affiliates or otherwise adversely impact any such business or any of the Purchased Assets. The Indemnified Party may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnifying Party pursuant to this Section 9.05(b), and the Indemnified Party shall bear its own costs and expenses with respect to such participation.

(c) If the Indemnifying Party does not notify the Indemnified Party that the Indemnifying Party elects to defend the Indemnified Party pursuant to Section 9.05(b) within sixty (60) days after receipt of any Claim Notice, then the Indemnified Party shall defend, and be reimbursed for its reasonable cost and expense (but only if the Indemnified Party is actually entitled to indemnification hereunder) in regard to the Third Party Claim with counsel selected by the Indemnified Party, in all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnified Party. In such circumstances, the Indemnified Party shall defend any such Third Party Claim in good faith and have full control of such defense and proceedings; provided, however, that the Indemnified Party may not enter into any compromise or settlement of such Third Party Claim if indemnification is to be sought hereunder, without the Indemnifying Party's consent (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party may participate in, but not control, any defense or settlement controlled by the Indemnified Party pursuant to this Section 9.05(c), and the Indemnifying Party shall bear its own costs and expenses with respect to such participation; provided, however, if at any time the Indemnifying Party acknowledges in writing that such Third Party Claim is an indemnifiable Loss under this Article IX, the Indemnifying Party shall be entitled to assume the defense of such Third Party Claim in accordance with Section 9.05(b).

(d) If requested by the Indemnifying Party, the Indemnified Party agrees, at the sole cost and expense of the Indemnifying Party (but only if the Indemnified Party is actually entitled to indemnification hereunder), to reasonably cooperate with the Indemnifying Party and its counsel in contesting any Third Party Claim which the Indemnifying Party elects to contest, including providing access to documents, records and information. In addition, the Indemnified Party will make its personnel reasonably available at no cost to the Indemnifying Party for conferences, discovery, proceedings, hearings, trials or appeals as may be reasonably required by the Indemnifying Party. The Indemnified Party also agrees to reasonably cooperate with the Indemnifying Party and its counsel in the making of any related counterclaim against the Person asserting the Third Party Claim or any cross complaint against any Person and executing powers of attorney to the extent necessary.

Section 9.06 Limitations on Indemnification.

(a) Threshold. Notwithstanding the other provisions of this Article IX, other than claims for Losses arising out of, or caused by or relating to fraud, the Seller shall not be liable to provide indemnification for any Losses arising from or in connection with matters described under Section 9.02(a) suffered by any Indemnified Party unless and until the aggregate amount of all such Losses suffered by the Indemnified Parties exceeds, on a cumulative basis, an amount equal to One Hundred Fifty Thousand Dollars (\$150,000) (the "**Seller Indemnity Threshold**"), at which point the full amount of all Losses suffered by the Indemnified Parties shall be recoverable, subject to Section 9.06(b). No Losses shall be included in determining whether the Seller Indemnity Threshold has been reached unless a notice seeking indemnification for such Losses has been given by the Purchaser Group to the Seller in accordance with Section 9.04(a) or Section 9.05(a), as applicable.

(b) **Cap.** Other than claims for Losses arising out of, or caused by or relating to fraud, in no event shall the Seller be liable to provide indemnification pursuant to Article IX for Losses arising from or in connection with matters described under Section 9.02(a) in the aggregate in excess of an amount equal to One Million Eight Hundred Thousand Dollars (\$1,800,000) (the “**Seller Indemnity Cap**”); provided, however, that (i) the Seller Indemnity Cap shall not apply to Losses arising from any breach of a Fundamental Representation and (ii) the Seller Indemnity Cap shall not apply to Losses arising from or relating to breach of Section 5.13 or otherwise related to the Purchased Inventory (however, Seller’s aggregate liability with respect to breach of Section 5.13 or otherwise related to the Purchased Inventory shall not exceed the Purchased Inventory Value paid by Purchaser).

(c) **Purchaser Threshold and Cap.** Other than claims for Losses arising out of, or caused by or relating to fraud, in no event shall the Purchaser be liable to provide indemnification pursuant to Article IX for Losses arising from or in connection with matters described under Section 9.03(a) suffered by any Indemnified Party unless and until the aggregate amount of all such Losses suffered by the Indemnified Parties exceeds, on a cumulative basis, an amount equal to One Hundred Fifty Thousand Dollars (\$150,000) (the “**Purchaser Indemnity Threshold**”), at which point the full amount of all Losses suffered by the Indemnified Parties shall be recoverable up to an amount equal to One Million Eight Hundred Thousand Dollars (\$1,800,000) (the “**Purchaser Indemnity Cap**”); provided, however, that the Purchaser Indemnity Cap shall not apply to Losses arising from any breach of a Fundamental Representation. No Losses shall be included in determining whether the Purchaser Indemnity Threshold has been reached unless a notice seeking indemnification for such Losses has been given by the Seller Group to the Purchaser in accordance with Section 9.04(a) or Section 9.05(a), as applicable.

(d) Without limiting the effect of any of the limitations set forth in this Section 9.06, in no event shall a Party’s aggregate liability for indemnification obligations under this Article IX exceed the Purchase Price actually paid by it for the Purchaser, or actually received by it for the Seller, hereunder, except (i) in the case of fraud with respect to the representations and warranties made by the Seller or the Purchaser in this Agreement, and (ii) with respect to any Losses arising from or in connection with the matters described in Section 9.02(b), Section 9.02(c), 9.03(b), or 9.03(c).

Section 9.07 Setoff Rights. Neither Party shall have any right of setoff against any amounts due and payable under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under any other Transaction Document; provided, however, that if, at the time when payment of the Deferred Payment is due to Seller, Seller has not paid Losses for which Seller is liable pursuant to this Article IX, Purchaser shall have the right to reduce the Deferred Payment by up to the amount of such unpaid Losses (not to exceed the Deferred Payment), and shall pay any remaining balance of the Deferred Payment to Seller. If the Purchaser elects to exercise such right hereunder, the Purchaser must (a) give the Seller written notice of such election no later than ten (10) Business Days prior to the date upon which the applicable payment is due and payable in accordance with the terms of this Agreement, which shall include the amount under this Agreement to be reduced from the Deferred Payment, and (b) obtain the Seller’s prior written approval of such reduction amount (such approval not to be unreasonably withheld, conditioned or delayed).

Section 9.08 Exclusion of Certain Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, EXCEPT FOR CLAIMS OR LOSSES ARISING OUT OF OR CAUSED BY OR RELATING TO FRAUD, AND WITHOUT LIMITING A PARTY’S INDEMNIFICATION OBLIGATIONS WITH RESPECT TO THIRD PARTY CLAIMS, NO INDEMNIFIED PARTY SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, TREBLE, REMOTE, SPECIAL, EXEMPLARY, OPPORTUNITY COST, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR, MEASURED BY OR BASED ON LOST PROFITS, LOSS OF REVENUE OR INCOME, DIMINUTION IN VALUE, MULTIPLE OF EARNINGS, PROFIT OR CASH FLOWS, OR OTHER SIMILAR MEASURES OR FOR ANY LOSS OF BUSINESS REPUTATION OR OPPORTUNITY THAT ARISES OUT OF OR RELATES TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR ANY LIABILITY RETAINED OR ASSUMED HEREUNDER.

Section 9.09 Purchaser's Opportunity to Review. The Purchaser acknowledges that it and its representatives have received or been afforded the opportunity to review prior to the date of this Agreement all written materials furnished or made available, as the case may be, to the Purchaser on or prior to the date of this Agreement in connection with the transactions contemplated by this Agreement. The Purchaser further acknowledges and agrees that (i) other than the representations and warranties of the Seller specifically contained in this Agreement and the other Transaction Documents to which Seller is a Party, neither the Seller nor any other Person has made any representation or warranty either expressed or implied (A) with respect to the Purchased Assets, the Assumed Liabilities or the transactions contemplated hereby or (B) as to the accuracy or completeness of any information regarding the Purchased Assets, the Assumed Liabilities or the transactions contemplated hereby or by any other agreements related hereto furnished or made available to the Purchaser and its representatives, (ii) the Purchaser has not relied on any representation or warranty from the Seller or any other Person in determining to enter into this Agreement, except as expressly set forth in this Agreement and the other Transaction Documents to which Seller is a Party and (iii) no Person who is part of the Purchaser Group shall have any claim or right to indemnification pursuant to this Article IX and neither the Seller nor any other Person shall have or be subject to any Liability to the Purchaser Group (or any Person who is part of such group) or any other Person with respect to any information, documents or materials furnished by the Seller or any of their representatives or agents to the Purchaser (it being understood that this clause (iii) does not supersede or otherwise affect the representations and warranties of the Seller specifically contained in this Agreement or the other Transaction Documents). Without limiting the generality of the foregoing, the Purchaser acknowledges and agrees that the Seller does not make any representations or warranties relating to the maintenance, repair, condition, design, performance or marketability of any Purchased Asset, including merchantability or fitness for a particular purpose. The Purchaser acknowledges and agrees that, except as expressly provided in this Agreement and the other Transaction Documents, it shall obtain rights in the Purchased Assets in their present condition and state of repair, "as is" and "where is".

Section 9.10 Adjustment to Purchase Price. The Seller and the Purchaser agree to treat all payments made either to or for the benefit of the other Party pursuant to this Article IX as adjustments to the Purchase Price for tax purposes to the extent permitted under applicable tax Law.

Section 9.11 Reimbursement. If an Indemnified Party recovers an amount from a Third Party in respect of a Loss that is the subject of indemnification hereunder after all or a portion of such Loss has been paid by an Indemnifying Party pursuant to this Article IX, the Indemnified Party shall promptly remit to the Indemnifying Party the amount received from the Third Party in respect thereof.

Section 9.12 Losses Net of Insurance. In determining the amount of Losses in respect of a claim under this Article IX, there shall be deducted an amount equal to the amount of any Third Party insurance proceeds actually received (net of direct collection expenses) by an Indemnified Party making such claim with respect to such Losses, provided that the foregoing shall not (i) require an Indemnified Party to proceed or seek action or recovery from any such Third Party as a requirement hereunder or as a condition to seeking or recovering indemnification from any Indemnifying Party hereunder (but the Indemnified Party shall use its commercially reasonable efforts (without any obligation to incur out-of-pocket costs) to recover under insurance policies or indemnity, contribution or other similar agreements for any Losses and promptly notify in reasonable detail any such recovery to the Indemnifying Party and reimburse it in accordance with the provisions of Section 9.11 hereof, if applicable), or (ii) be construed or interpreted as a guaranty of any level or amount of insurance recovery with the provisions of Section 9.11 hereof, if applicable with respect to any Losses hereunder or as a requirement to maintain any insurance or to make any claim for insurance as a condition to any indemnification hereunder.

Section 9.13 Subrogation. To the extent that the Indemnifying Party makes or is required to make any indemnification payment to the Indemnified Party, the Indemnifying Party shall be entitled to exercise, and shall be subrogated to, any rights and remedies (including rights of indemnity, rights of contribution and other rights of recovery) that the Indemnified Party may have against any other Person with respect to any Losses to which such indemnification payment is directly related.

Section 9.14 Sole Remedy/Waiver. Should the Closing occur, the remedies provided for in this Article IX shall be the sole and exclusive remedies of any Indemnified Party in respect of this Agreement, the Purchased Assets, the Products, the Excluded Assets, the Assumed Liabilities, the Excluded Liabilities or the transactions contemplated hereby, other than (i) for actions for specific performance or other equitable remedies, (ii) for claims arising out or related to Article III, or (iii) for claims against a Party directly arising out of fraud of such Party in respect of a provision of this Agreement. In furtherance of the foregoing, each Party hereby waives (on behalf of itself and the relevant Indemnified Parties) any provision of applicable Law to the extent that it would limit or restrict the agreement contained in this Section 9.14.

Section 9.15 Seller Disclosure Schedules. From the date hereof through the Closing Date, the Seller shall have the right to modify, amend and/or supplement the Seller Disclosure Schedules solely to reflect events that first arise after the date hereof, by delivering any such modifications, amendments and/or supplements to the Purchaser in writing. For purposes of determining whether the conditions to Closing in Article VIII are satisfied, the Seller Disclosure Schedules shall only be deemed to include the information contained therein on the date hereof (but shall be deemed accepted for purposes of the conditions to Closing in Article VIII if the Purchaser does not object within three (3) Business Days of receipt of any modification, amendment and/or supplement in writing). For purposes of determining whether the Seller is subject to any claim for indemnification under this Article IX following the Closing Date for a breach of any representation or warranty under this Agreement, the Seller Disclosure Schedules shall be deemed to include the information contained therein on the date hereof and such other information as may be set forth in any modification, amendment and/or supplement to the Seller Disclosure Schedules delivered by the Seller to the Purchaser, if and to the extent accepted or deemed accepted by the Purchaser, pursuant to this Section 9.15.

**ARTICLE X
TERMINATION**

Section 10.01 Termination. This Agreement may be terminated and the transactions contemplated hereby may be abandoned:

- (a) at any time, by mutual written agreement of the Seller and the Purchaser; or
- (b) at any time, by either the Seller or the Purchaser if any Restraint having any of the effects set forth in Section 8.01(a) of this Agreement shall be in effect and have become final and non-appealable; or
- (c) by written notice from the Purchaser,
 - (i) if a breach of or failure to perform any representation, warranty, covenant or agreement on the part of the Seller set forth herein shall have occurred, which breach or failure to perform (i) would give rise to the failure of a condition set forth in Section 8.02(a) or Section 8.02(b) resulting in, or reasonably expected to result in, a Material Adverse Effect, and (ii) after receipt by a Seller of written notice from the Purchaser of such breach or failure to perform, cannot be or has not been cured or waived on or prior to the Closing, provided, that the Purchaser is not then in breach with respect to any of its representations, warranties, covenants or other agreements contained in this Agreement.
- (d) by written notice from the Seller,
 - (i) if a breach of or failure to perform any representation, warranty, covenant or agreement on the part of the Purchaser set forth herein shall have occurred, which breach or failure to perform (A) would give rise to the failure of a condition set forth in Section 8.03(a) or Section 8.03(b) resulting in, or reasonably expected to result in, a Material Adverse Effect, and (B) after receipt by the Purchaser of written notice from the Seller of such breach or failure to perform, cannot be or has not been cured or waived on or prior to the Closing, provided, that the Seller is not then in breach with respect to any of its representations, warranties, covenants or other agreements contained in this Agreement, or
- (e) by written notice by either the Seller or the Purchaser to the other Party(ies), at any time if the Closing shall not have occurred on or prior to June 30, 2023 (other than in the cases referred in Section 10.01(b), Section 10.01(c) and Section 10.01(d)) provided, that the right to terminate this Agreement under this Section 10.01(e) shall not be available to a Party if the action or inaction of such Party or any of its Affiliates has been a principal cause of or resulted in the failure of the Closing to occur on or before such date and such action or failure to act constitutes a breach of this Agreement.

Section 10.02 Procedure and Effect of Termination In the event of the termination of this Agreement and the abandonment of the transactions contemplated hereby, written notice thereof shall be given by a terminating Party to the other Party, and this Agreement shall terminate and the transaction contemplated hereby shall be abandoned without further action by any of the Parties. If this Agreement is terminated pursuant to Article X:

- (a) The Purchaser shall promptly cause to be returned to the Seller or destroy all documents and information obtained in connection with this Agreement and the transactions contemplated hereby and all documents and information obtained in connection with the Purchaser's investigation of the Business from the Seller or their representatives, including any copies made by or supplied to the Purchaser or any of the Purchaser's agents or representatives of any such documents or information.

(b) No Party hereto shall have any obligation or liability to the other Party hereto, except that the Parties hereto shall remain bound by the provisions of this Article X and Article XI and by the provisions of Section 7.05 (Confidentiality); provided, that (i) nothing herein shall relieve a defaulting or breaching Party from any liability or damages arising out of its breach of any covenant or agreement in this Agreement and (ii) in the event of any termination of this Agreement by Purchaser pursuant to Section 10.01(c)(i) or by Seller pursuant to Section 10.01(e), Seller shall pay Purchaser an amount equal to the Exclusivity Payment Credit Amount within five (5) Business Days of the date of such termination.

ARTICLE XI MISCELLANEOUS

Section 11.01 Expenses. Except as otherwise provided in this Agreement, the Seller, on the one hand, and the Purchaser, on the other hand, shall bear their own expenses incurred in connection with the negotiation and execution of this Agreement, each other agreement, document and instrument contemplated by this Agreement, and the consummation of the transactions contemplated hereby and thereby.

Section 11.02 Notices. All notices, requests, consents, claims, demands, waivers, and other communications hereunder shall be in writing and shall be deemed to have been given: (i) when delivered, if delivered personally to the intended recipient; (ii) when received by the addressee, if sent by an internationally recognized overnight courier service; (iii) on the date sent by email (with confirmation of receipt of the email and any attachments); or (iv) on the fifth (5th) day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective Parties at the following addresses (or at such other address for a Party as shall be specified in a notice given in accordance with this Section 11.02):

(a) if to the Seller:

Upsher-Smith Laboratories, LLC
6701 Evenstad Drive
Maple Grove, MN 55369
Email: Rich.Fisher@upsher-smith.com
Attention: President

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

Upsher-Smith Laboratories, LLC
6701 Evenstad Drive
Maple Grove, MN 55369
Email: Brent.Eilefson@upsher-smith.com
Attention: General Counsel

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

Ballard Spahr LLP
80 South Eighth Street, Suite 2000
Minneapolis, MN 55402
Email: rummelb@ballardspahr.com
Attention: Barbara Rummel

(b) if to the Purchaser:

Tonix Medicines, Inc.
26 Main Street, Suite 101
Chatham, NJ 07928
Email: seth.lederman@tonixpharma.com
Attention: Seth Lederman, CEO

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

Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, New Jersey 07068
Email: mlerner@lowenstein.com
Attention: Michael J. Lerner, Esq.

(c) if to the Parent:

Tonix Pharmaceuticals Holding Corp.
26 Main Street, Suite 101
Chatham, NJ 07928
Email: seth.lederman@tonixpharma.com
Attention: Seth Lederman, CEO

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

Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, New Jersey 07068
Email: mlerner@lowenstein.com
Attention: Michael J. Lerner, Esq.

Section 11.03 Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement in such jurisdiction or invalidate or render unenforceable such term or provision in any other jurisdiction.

Section 11.04 Entire Agreement. This Agreement, together with the Exhibits hereto, the Seller Disclosure Schedule, the other Transaction Documents and the Confidentiality Agreement, constitute the entire agreement, and supersedes all prior and contemporaneous agreements and understandings (both written and oral), among the Parties regarding the subject matter hereof.

Section 11.05 Successors and Assigns; Assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Seller may assign its rights or obligations hereunder without the prior written consent of the Purchaser. Purchaser may not assign its rights or obligations hereunder prior to July 19, 2024 without the prior written consent of the Seller; provided, however, that the Purchaser may assign, without the consent of the Seller, any or all of its rights and interests hereunder to one or more of its Affiliates in which case, the Purchaser shall remain jointly and severally liable for any default by such assignee of such obligations and Liabilities of the Purchaser under this Agreement and the Transaction Documents. Notwithstanding anything to the contrary provided herein, any assignee shall agree in writing to assume all obligations and Liabilities of the assigning Party under this Agreement and the Transaction Documents. Any assignment in breach of the provisions of this Section 11.05 shall be null and void *ab initio*.

Section 11.06 No Third Party Beneficiaries. This Agreement is for the sole benefit of the Parties hereto and their respective successors and permitted assigns. Nothing in this Agreement, express or implied, is intended to or shall confer on any other Person any legal or equitable right, benefit, or remedy of any nature whatsoever.

Section 11.07 Amendment and Waiver. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each Party hereto. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the Party so waiving. No waiver by any Party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Section 11.08 Governing Law; Jurisdiction.

(a) This Agreement and its negotiation, execution, performance or non-performance, interpretation, termination, construction and all claims or causes of action (whether in contract, in tort, at Law or otherwise) that may be based upon, arise out of, or relate to this Agreement, or the transactions contemplated hereby (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in connection with this Agreement or as an inducement to enter this Agreement), shall be exclusively governed by, and construed in accordance with, the Laws of the State of Delaware regardless of Laws that might otherwise govern under any applicable conflict of laws principles.

(b) Any Legal Proceeding based upon, arising out of, or related to this Agreement and its negotiation, execution, performance, non-performance, interpretation, termination, construction or the transactions contemplated hereby shall be heard and determined in the Court of Chancery in the City of Wilmington, New Castle County, Delaware or, in the event such court lacks subject matter jurisdiction, the United States District Court sitting in Wilmington, Delaware or, in the event such federal district court lacks subject matter jurisdiction, then in the Superior Court in the City of Wilmington, New Castle County, Delaware. The Parties hereto hereby irrevocably submit to the exclusive jurisdiction and venue of such courts in any such Legal Proceeding and irrevocably and unconditionally waive the defense of an inconvenient forum, or lack of jurisdiction to the maintenance of any such Legal Proceeding. The consents to jurisdiction and venue set forth herein shall not constitute general consents to service of process in the State of Delaware and shall have no effect for any purpose except as provided in this Section 11.08(b) and shall not be deemed to confer rights on any Person other than the Parties hereto. Each Party hereto agrees that the service of process upon such Party in any Legal Proceeding arising out of or relating to this Agreement shall be effective if notice is given by overnight courier at the address set forth in Section 11.02. Each of the Parties also agrees that any final, non-appealable judgment against a Party in connection with any Legal Proceeding arising out of or relating to this Agreement shall be conclusive and binding on such Party and that such award or judgment may be enforced in any court of competent jurisdiction, either within or outside of the United States. A certified or exemplified copy of such award or judgment shall be conclusive evidence of the fact and amount of such award or judgment.

Section 11.09 WAIVER OF JURY TRIAL. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HERETO HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY LEGAL PROCEEDING (WHETHER IN CONTRACT, IN TORT, AT LAW OR OTHERWISE) BASED UPON, ARISING OUT OF, OR RELATED TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THE PARTIES HERETO ACKNOWLEDGE THAT THIS WAIVER IS A MATERIAL INDUCEMENT TO ENTER INTO A BUSINESS RELATIONSHIP, THAT EACH HAS ALREADY RELIED ON THE WAIVER IN ENTERING INTO THIS AGREEMENT AND THAT EACH WILL CONTINUE TO RELY ON THE WAIVER IN THEIR RELATED FUTURE DEALINGS. THE PARTIES HERETO FURTHER WARRANT AND REPRESENT THAT EACH HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT EACH KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. THIS WAIVER IS IRREVOCABLE, MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING, AND THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THE TRANSACTIONS CONTEMPLATED HEREBY. IN THE EVENT OF LITIGATION, THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

Section 11.10 Specific Performance. The Seller, on the one hand, and the Purchaser, on the other hand, acknowledge and agree that the breach of this Agreement or other failure to perform any provision of this Agreement would cause irreparable damage to the other and such other Party will not have an adequate remedy at law. Therefore, the Parties shall be entitled to seek specific performance of the terms of this Agreement in addition to any other remedy to which they are entitled at law or in equity.

Section 11.11 No Other Duties. The only duties and obligations of the Parties under this Agreement are as specifically set forth in this Agreement, and no other duties or obligations shall be implied in fact, Law or equity, or under any principle of fiduciary obligation.

Section 11.12 Reliance on Counsel and Other Advisors. Each Party has consulted such legal, financial, technical or other expert as it deems necessary or desirable before entering into this Agreement. Each Party represents and warrants that it has read, knows, understands and agrees with the terms and conditions of this Agreement.

Section 11.13 Bulk Transfer Laws. The Parties hereby waive compliance with the provisions of any so-called “bulk transfer laws” of any U.S. jurisdiction in connection with the sale of the Purchased Assets to Purchaser, it being understood that any Liabilities arising out of any failure to comply with the requirements and provisions of any bulk sales, bulk transfer or similar Laws of any jurisdiction shall be treated as Excluded Liabilities.

Section 11.14 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.

Section 11.15 Parent Guaranty.

(a) The Parent hereby unconditionally guarantees to the Seller the due and punctual performance of the obligations of the Purchaser under all provisions of this Agreement and the Transaction Documents that are required to be performed at or prior to the Closing, as well as the obligations of the Purchaser under Section 3.02(a)(ii) and the Transition Services Agreement (which shall be the only obligations to be performed after the Closing that are subject to this guaranty). This guaranty is provided solely with respect to the matters set forth in the foregoing sentence and is an irrevocable guaranty of payment and performance (and not just of collection) and shall continue in effect notwithstanding any extension or modification of the terms of Agreement or any other act or event which might otherwise operate as a legal or equitable discharge of the Parent under this guaranty. This guaranty shall terminate upon payment of the Deferred Payment.

(b) A separate Legal Proceeding to enforce this guaranty may be brought and prosecuted against the Parent, irrespective of whether any Legal Proceeding is brought against the Purchaser or any other Person or whether the Purchaser and/or any other Person is joined in any such Legal Proceeding. The liability of the Parent under this guaranty will, to the fullest extent permitted under applicable Law, be absolute and unconditional, irrespective of: (i) any release or discharge of any obligation of the Purchaser under this Agreement resulting from any change in the corporate existence, structure or ownership of the Purchaser, or any insolvency, bankruptcy, reorganization or other similar proceeding affecting the Purchaser or any of its assets; or (ii) any amendment or modification of this Agreement, or any change in the manner, place or terms of payment or performance of the guaranteed obligations or any other obligation of the Purchaser hereunder, or any change or extension of the time of payment or performance of, alteration of, the guaranteed obligations or any other obligation of the Purchaser hereunder, any liability incurred directly or indirectly in respect thereof, or any amendment or waiver of, or any consent to, any departure from the terms of this Agreement or the documents entered into in connection herewith, provided however, that the Parent shall be entitled to the benefits of any contractual or other claims, counterclaims, defenses, setoffs or other rights and remedies that are available to the Purchaser under this Agreement.

(c) The Parent hereby waives any and all notice of the creation, extension or accrual of the guaranteed obligations under this guaranty and notice of or proof of reliance by the Seller Entities upon this guaranty or acceptance of this guaranty. The guaranteed obligations under this guaranty will conclusively be deemed to have been created, contracted or incurred in reliance upon this guaranty, and all dealings between the Parent and the Seller will likewise be conclusively presumed to have been had or consummated in reliance upon this guaranty.

(d) The Parent irrevocably waives acceptance, presentment, demand, protest and any notice in respect of this guaranty not provided for herein.

(e) The Parent has the requisite power and authority to execute and deliver this Agreement and to perform its obligation hereunder to pay, when and if due, the guaranteed obligations. The execution, and delivery of this Agreement, and the performance by the Parent of its obligation to pay, when and if due, the guaranteed obligations, have been duly authorized by all necessary action on the part of the Parent, and no other action is necessary on the part of the Parent to authorize this Agreement or the payment, when due, of the guaranteed obligations.

(f) This Agreement has been duly executed and delivered by the Parent and constitutes a legal, valid and binding obligation of the Parent, enforceable against the Parent in accordance with its terms, except as limited by (i) bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or other similar Laws relating to creditors' rights generally and (ii) general principles of equity, whether such enforceability is considered in a proceeding in equity or at Law.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first written above by their respective duly authorized officers.
As Seller:

UPSHER-SMITH LABORATORIES, LLC

By: /s/Rich Fisher

Name: Rich Fisher

Title: President & COO

TONIX MEDICINES, INC.

By: /s/ James Hunter

Name: James Hunter

Title: President

As Parent:

TONIX PHARMACEUTICALS HOLDING CORP.

By: /s/ Seth Lederman

Name: Seth Lederman

Title: Chief Executive Officer

[Signature page to Asset Purchase Agreement]

SCHEDULE 1.01

DEFINITIONS

“**Accounts Receivable**” shall mean all accounts receivable (determined in accordance with GAAP) owed by any Third Party to the Seller or any of its Affiliates arising from, or held in connection with, the sale and delivery of any of the Products prior to the Closing.

“**Acquired Contracts**” shall mean those Contracts specifically listed on Exhibit B, including those Purchase Orders, listed in Annex A attached thereto, as may be amended or supplemented upon the mutual agreement of the Parties prior to the Closing.

“**Acquired Regulatory Approvals**” shall mean (i) the new drug application number 208223 and Investigational New Drug (IND) Application 118668 for Zembrace SymTouch (DFN-11) and all amendments and supplements thereto filed with the FDA as of the Closing Date, (ii) the new drug application number 210884 and Investigational New Drug (IND) Application 108088 for (Tosymra) (DFN-02) and all amendments and supplements thereto filed with the FDA as of the Closing Date and (iii) all files, records and correspondence relating to the foregoing (i) and (ii).

“**Acquisition Proposal**” shall have the meaning set forth in Section 7.03.

“**Affiliate**” of a Person or Party shall mean any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person or Party. The term “**control**” (including the terms “**controlled by**” and “**under common control with**”) shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person or Party, whether through the ownership of voting securities, by contract or otherwise.

“**Agreement**” shall have the meaning set forth in the Preamble.

“**Allocation Schedule**” shall have the meaning set forth in Section 3.02(d).

“**Assignment and Assumption Agreement**” shall mean the certain Assignment and Assumption Agreement, to be entered into on the Closing Date by and among the Purchaser and the Seller in the form attached hereto as Exhibit C.

“**Assignment and Assumption Agreement Regarding DRL Contracts**” means the Assignment and Assumption Agreement Regarding DRL Contracts to be entered into at the Closing between the Seller and Purchaser, substantially in the form attached hereto as Exhibit D.

“**Assumed Liabilities**” shall mean the following Liabilities of Seller (in each case, excluding (i) any Liability that arises from or relates to any act, omission, occurrence or period of time prior to the Closing or any breach of this Agreement or any other Transaction Document by Seller and (ii) any Excluded Liability set forth in clauses (i) through (xi) of Section 2.01(d)):

- a) Liabilities arising under or relating to the Acquired Regulatory Approvals after the Closing Date;

- b) Liabilities arising out of or relating to the ownership or operation of the Business and the Purchased Assets after the Closing Date;
- c) Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury or other harm to person or property, which result from the use or misuse of Products manufactured and/or sold after the Closing Date or otherwise related to the Products manufactured and/or sold after the Closing Date (including all Legal Proceedings relating to any such liabilities);
- d) Liabilities, obligations and commitments arising out of or relating to any Product recall in the Territory which such recall was instituted after the Closing Date, to the extent related to Products manufactured and/or sold after the Closing Date;
- e) subject to Section 7.11, Liabilities, obligations and commitments arising out of or relating to any chargebacks related to any Products manufactured and/or sold after the Closing Date;
- f) advertising and promotional Liabilities, obligations and commitments arising out of or relating to, directly or indirectly, the marketing, distribution or sale of the Products after the Closing Date;
- g) Liabilities, obligations or commitments arising out of or relating to any Acquired Contract to the extent incurred after the Closing Date;
- h) subject to Section 7.11, Liabilities, obligations and commitments arising out of or relating to the return of any Products manufactured and/or sold after the Closing Date;
- i) Liabilities, obligations or commitments arising out of or relating to any Legal Proceeding relating to the Purchased Assets for which the cause of action arises after the Closing Date;
- j) subject to Section 7.11, PBM rebated Liabilities, all managed care and PBM rebates in each case arising after the Closing Date relating to Product sold after the Closing Date including those processed and paid by the Seller with respect to the Products;
- k) subject to Section 7.11, copay assistance liability payable after the Closing Date with respect to the Products sold after the Closing Date;
- l) any and all Liabilities assumed by Purchaser under the Assignment and Assumption Agreement Regarding DRL Contracts; and
- m) all other Liabilities, obligations and commitments of whatever kind and nature, primary or secondary, direct or indirect, absolute or contingent, known or unknown, whether or not accrued, arising out of or relating to, directly or indirectly: (i) the Products manufactured and/or sold after the Closing Date or (ii) the Purchaser's ownership or operation of the Business or the Purchaser's ownership, sale or lease of any of the Purchased Assets, in each case to the extent arising after the Closing Date.

“**Base Purchase Price**” shall have the meaning set forth in Section 3.01(a)(i).

“**Bill of Sale**” shall mean the bill of sale for the conveyance of the Purchased Assets, entered into between the Seller and the Purchaser on the Closing Date.

“**Business**” shall mean the clinical testing, development, seeking regulatory approval, manufacture, marketing, promotion, commercialization, sale and distribution of the Products, in each case to the extent undertaken with respect to a Product intended to be sold in the Territory.

“**Business Day**” shall mean any day other than a Saturday, Sunday, or other day on which commercial banks located in New York, New York are authorized or required by Law to be closed for business.

“**Chargeback Claims**” shall have the meaning set forth in Section 7.11(d).

“**CIS Countries**” means Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Turkmenistan, Tajikistan, Ukraine and Uzbekistan.

“**Closing**” and “**Closing Date**” shall have the meaning set forth in Section 4.01.

“**Closing Cash Consideration**” shall have the meaning set forth in Section 3.02(a).

“**Code**” shall mean the Internal Revenue Code of 1986, as amended.

“**Competing Product**” shall have the meaning set forth in Section 7.07.

“**Confidential Information**” shall mean, with respect to a Party, all information, data, documents, agreements, files, and other materials, whether disclosed orally or disclosed or stored in written, electronic, or other form or media, which is obtained from or disclosed by a Party or its representatives, whether obtained before or on or after the date hereof, relating to such Party, its business, any of its Affiliates or any of their respective businesses, or the Purchased Assets, including all notes, analyses, compilations, reports, forecasts, studies, samples, and other documents prepared by or for the other Party which contain or otherwise reflect or are derived or based in whole or in part on such information, data, documents, agreements, files, or other materials. The term Confidential Information as used herein does not include information that: (a) at the time of disclosure or thereafter is generally available to and known by the public, other than as a result of disclosure by the receiving Party or any of its representatives in violation of this Agreement; or (b) is or becomes available to the receiving Party on a non-confidential basis from a source other than the disclosing Party provided that such source, to the receiving Party’s knowledge after reasonable inquiry, is not and was not bound by a confidentiality agreement with respect to such information or otherwise prohibited from transmitting such information by a contractual, legal, or fiduciary obligation; or (c) has been independently acquired or developed by the receiving Party without reference to the Confidential Information.

“Confidentiality Agreement” shall mean the confidentiality agreement between the Seller and the Parent dated November 21, 2022.

“Consent” shall mean any and all notices to, consents, approvals, clearances, ratifications, permissions, authorizations or waivers from Third Parties, including from any Governmental Authority.

“Contract” shall mean all contracts, leases, deeds, mortgages, licenses, instruments, notes, commitments, undertakings, indentures, joint ventures and all other agreements, commitments and legally binding arrangements, whether written or oral.

“DRL” means Dr. Reddy’s Laboratories Limited.

“DRL Purchase Agreement” means that certain Asset Purchase Agreement dated June 13, 2019 (as amended by the First Amendment to Asset Purchase Agreement dated as of July 19, 2019 and as may be further amended from time to time), by and among Seller, DRL and Promius.

“Eligible Product” shall have the meaning set forth in Section 7.11(b)(i).

“Encumbrances” shall mean any charge, claim, community property interest, pledge, condition, equitable interest, lien (statutory or other), option, reversionary interest, security interest, mortgage, easement, encroachment, right of way, right of first refusal, or restriction of any kind, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership.

“Estimated Purchased Inventory Value” means the Purchased Inventory Value calculated as of May 31, 2023, as set forth in the May Inventory Statement attached as Exhibit S.

“Excluded Assets” shall have the meaning set forth in Section 2.01(b).

“Excluded Inventory” shall mean any Product Inventory that does not meet the requirements of Section 5.13.

“Excluded Liabilities” shall have the meaning set forth in Section 2.01(d).

“Excluded Taxes” means (a) all Taxes of Seller, or for which Seller is liable, for any taxable period, including, but not limited to, (i) all Taxes of any member of an affiliated group as defined in Section 1504 of the Code (or any similar combined, consolidated or unitary group defined under state, local or foreign income Tax Law) of which Seller (or any predecessor of Seller) is or was a member on or prior to the Closing Date, including pursuant to Treasury Regulation Section 1.1502-6 or any analogous or similar state, local or foreign Law; (ii) all Taxes of Seller imposed on Purchaser as a transferee or successor, by contract or pursuant to any Law (including, but not limited to, in connection with the failure to comply with any bulk transfer statutes), which Taxes arise from an event or transaction occurring before the Closing, and (iii) payments required under any Tax allocation, sharing or similar agreement (whether oral or written) entered into by Seller on or prior to the Closing Date; (b) all Taxes relating to any of the Excluded Assets or the Excluded Liabilities, in both cases, for any taxable period; (c) all Taxes attributable to the Business or its operations, or to ownership or use of any of the Purchased Assets or the Assumed Liabilities, in both cases, for any taxable period ending on or prior to the Closing Date and, with respect to any taxable period beginning before and ending after the Closing Date, for the portion of such taxable period ending on the Closing Date; and (d) Seller’s portion of any Transfer Taxes as provided in Section 3.02(c).

“Excluded Territory” shall mean Brazil, Russia, India, Greater China (Mainland China, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China, and Taiwan) and the CIS Countries.

“Exclusivity Payment Credit Amount” shall mean \$250,000.

“Exploit” (and related terms such as **“Exploitation”** or **“Exploited”**) means to manufacture, have manufactured, import, export, use, have used, sell, offer for sale, have sold, research, develop (including seeking, obtaining or maintaining regulatory approvals), test, commercialize, register, hold or keep (whether for disposal or otherwise), transport, distribute, promote, market, supply or otherwise dispose of, or to license or otherwise permit any Person to conduct any of the foregoing.

“FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.

“FDA Letters” shall mean the Seller FDA Letter and the Purchaser FDA Letter.

“Final Purchased Inventory Value” shall mean the Purchased Inventory Value as finally determined pursuant to Section 3.03.

“Fundamental Representations” means, with respect to the Seller, the representations in Section 5.01, Section 5.02, Section 5.04, Section 5.07, and Section 5.12, and with respect to the Purchaser, the representations in Section 6.01, Section 6.02, Section 6.04, and Section 6.06.

“GAAP” shall mean generally accepted accounting principles in the United States, consistently applied.

“Good Clinical Practices” means the FDA’s standards for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials contained in 21 C.F.R. Parts 50, 54, 56 and 312.

“Good Laboratory Practices” means the FDA’s standards for conducting non-clinical laboratory studies contained in 21 C.F.R. Part 58.

“Good Manufacturing Practices” means the current good manufacturing practices for drugs, devices and combination products contained in 21 C.F.R. Parts 4, 210, 211, and 820 as in effect at the time of manufacture.

“Government Rebates, Discounts and Fees” shall have the meaning set forth in Section 7.11(c)(i).

“Government Rebates, Discounts and Fees Tail Period” shall have the meaning set forth in Section 7.11(c)(i)(A).

“Governmental Authority” shall mean any federal, state, local or foreign government, or political subdivision thereof, any regulatory or administrative authority, any agency or instrumentality of any such government or political subdivision, or any self-regulated organization or other non-governmental regulatory authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of Law), or any arbitrator, court or tribunal of competent jurisdiction.

“Governmental Order” shall mean any order, writ, judgment, injunction, decree, stipulation, determination, or award entered by or with any Governmental Authority.

“HIPAA” shall mean the Health Insurance Portability and Accountability Act of 1996.

“Indemnified Party” shall have the meaning set forth in [Section 9.04\(a\)](#).

“Indemnifying Party” shall have the meaning set forth in [Section 9.04\(a\)](#).

“Intellectual Property” shall mean any and all intellectual property and proprietary rights of any kind or nature, whether protected, created or arising under any Law, including all: (i) Patents, (ii) Know-How, (iii) trademarks, (iv) domain names and URLs, (v) copyrights, mask works, and works of authorship, (vi) registered designs, (vii) rights in databases, compilations of data and data, including all personally identifiable information and clinical trial data, and all aggregated data, (viii) moral rights, rights of publicity and other rights to use or exploit the name, image and likeness of any individual, (ix) rights under applicable Laws in customer lists, supplier lists, pricing and cost information, and business and marketing plans, in any form whether or not specifically listed herein, all rights to limit the use or disclosure of any of the foregoing, and all embodiments of, and all documentation relating to, any of the foregoing, (x) rights under applicable Laws in software (including both object codes and source codes) and application programming interfaces, (xi) rights under applicable Laws to bring an action for infringement, dilution, misappropriation or other impairment or violation of rights and to receive damages, proceeds or any other legal or equitable protections and remedies with respect to any of the foregoing, and (xii) similar or equivalent rights to any of the foregoing recognized by any Governmental Authority anywhere in the Territory.

“Intellectual Property Assignment Agreements” shall mean those certain Assignment of Patents, Assignment of Trademarks, and Assignment of Domain Names to be entered into on the Closing Date by and between the Purchaser and the Seller which are parties thereto in the forms attached hereto as [Exhibit E-1](#) (Assignment of Patents), [Exhibit E-2](#) (Assignment of Trademarks), and [Exhibit E-3](#) (Assignment of Domain Names).

“Interim Period” shall have the meaning set forth in [Section 7.01\(a\)](#).

“Know-How” shall mean all technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, formulae, designs, drawings, assembly procedures, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written or electronic form.

“Knowledge of the Seller” shall mean the actual knowledge after due inquiry of any of the individuals listed on Exhibit E.

“Law” shall mean any statute, law, ordinance, regulation, rule, code, Order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority.

“Legal Proceeding” shall mean any judicial, administrative or arbitral action, suit, proceeding (public or private), litigation, investigation, hearing, or any other claim or proceeding by or before a Governmental Authority.

“Liability” shall mean, with respect to any Person, any indebtedness, liabilities, obligation, commitment, expense, claim, complaint, deficiency, guaranty or endorsement of or by such Person of any type, whether or not accrued, absolute, contingent, matured, unmatured, liquidated, unliquidated, determined or determinable, known or unknown.

“Licensed Know-How” shall mean any Know-How owned or controlled by the Seller on the date hereof that (i) is not included in the Purchased Assets but (ii) relates to any Product, any component thereof, and/or any method or process related to the Exploitation of any of the foregoing.

“Limited License Agreements” shall mean (a) that certain Limited Intellectual Property License Agreement (Tosymra), dated July 19, 2019, among Seller, DRL, and Promius, and (b) that certain Limited Intellectual Property License Agreement (Zembrace), dated July 19, 2019, among Seller, DRL, and Promius.

“Loss” or “Losses” shall mean actual out-of-pocket losses, damages, liabilities, taxes, costs or expenses, including reasonable attorneys’ fees.

“Marketing Materials” shall mean all advertising, marketing, market research, sales and promotional materials, product literature, advertising and display and other promotional materials and data, and training and educational materials, scientific and commercial publications, television masters, website content and other materials in whatever medium (e.g., audio, electronic, visual or print), including any such files and materials held at external agencies, that are used or held for use in connection with the Products in the Territory or that relate to the Business or the Purchased Assets, but excluding Seller Trade Dress (except to the extent actually included on any of the Purchased Inventory).

“Material Adverse Effect” means any effect that is materially adverse to the Exploitation of the Products; provided, however, that none of the following shall be deemed, either alone or in combination, to constitute a Material Adverse Effect, or be taken into account in determining whether there has or will be a Material Adverse Effect: (a) changes or effects that are generally applicable in the economies (including changes in interest or exchange rates) of any country in which Purchased Assets are located or in which any of the Parties to this Agreement operate, or in the securities, syndicated loan, credit or financial markets of any such country; (b) changes in general legal, tax, regulatory, political or economic conditions affecting the exploitation of the Products in general or within the relevant jurisdiction; (c) changes in GAAP; (d) changes or effects that arise out of or are attributable to (i) the acts or omissions of, or circumstances affecting, the Purchaser and/or its Affiliates, or (ii) the transactions contemplated by this Agreement or changes or effects that arise out of or are attributable to the negotiation, execution, public announcement or performance of this Agreement; (e) changes or effects that generally affect the markets in which the Products are exploited; (f) changes or effects that arise out of or are attributable to the commencement, occurrence, continuation or intensification or reduction or cessation of any war (whether or not declared), sabotage, armed hostilities or acts of terrorism, (g) changes or effects that arise out of or are attributable to earthquakes, hurricanes or other natural disasters, epidemics or other outbreaks of disease; (h) changes or effects that relate to any failure by the Seller to meet internal projections or forecasts for any period (including with respect to the Purchased Assets or Products) or that arise out of or are attributable to market conditions with respect to the Products, including pricing dynamics, sales results, the availability of generic alternatives or alternative therapies and treatments or the availability of patent rights; (i) any action taken by the Seller as contemplated or permitted by this Agreement or with the Purchaser’s consent; (j) any matter disclosed in the Seller Disclosure Schedules to this Agreement, including in each case, any adverse effect that occurs after the date of this Agreement but that arises out of or results from any such matter; or (k) any existing event or occurrence or circumstance of which the Purchaser has Knowledge as of the date hereof.

“**NDC Number**” shall mean a unique 3-segment number that identifies the labeler/vendor, the product and the trade package size. The NDC Numbers for the Products are set forth on Exhibit G.

“**Non-Responsible Party**” shall have the meaning set forth in Section 7.11(c)(i).

“**Orders**” shall mean all judgments, orders, writs, injunctions, decisions, rulings, decrees and awards of any Governmental Authority.

“**Organizational Documents**” shall mean with respect to a Person (other than an individual), the documents by which such Person was organized (such as a certificate of incorporation, certificate of limited partnership or articles of organization, and including any certificates of designation for preferred stock or other forms of preferred equity) and which relate to the internal governance of such Person (such as bylaws, a partnership agreement or an operating, limited liability or members agreement), all, as amended.

“**Partially Assigned APA**” has the meaning set forth in the Assignment and Assumption Agreement regarding DRL Contracts.

“**Party**” or “**Parties**” shall have the meaning set forth in the preamble.

“**Patient Service Programs**” shall have the meaning set forth in Section 7.11(f).

“**Patents**” shall mean the patents and pending patent applications set forth in Exhibit H, and all reissues, reexaminations, divisionals, continuations, continuations-in-part, provisional and continued examinations, extensions, restorations or renewals of such patents and patent applications.

“**PBM**” shall have the meaning set forth in Section 7.11(e).

“**PBM Rebate Contract**” shall have the meaning set forth in Section 7.11(e)(i).

“Permitted Encumbrances” shall mean: (a) liens for Taxes not yet due and payable, (b) mechanics’, warehousemen’s, bailees’ and other like liens incurred in the ordinary course of business for amounts not delinquent or in default and which are not, individually or in the aggregate, significant, or (c) the restrictions set forth in the Limited License Agreements.

“Person” shall mean an individual, a limited liability company, joint venture, a corporation, a partnership, an association, a trust, a division or operating group of any of the foregoing or any other entity or organization.

“Product Inventory” shall mean all inventory owned by the Seller or any of its Affiliates immediately prior to Closing related to the Products (including finished products and intermediates, inventory in Seller’s Trade Dress, work-in-process, raw materials, active product ingredients, excipients, packaging materials and components, devices and device components and product samples wherever located). For the avoidance of doubt, “Product Inventory” shall not include any consigned inventory.

“Products” shall mean the products set forth on Exhibit G.

“Product Domains” shall mean the internet domains set forth in Exhibit I.

“Product Intellectual Property” shall mean collectively the Patents, Product Domains, Know-How (to the extent such Know-How is related solely and exclusively to the Products in the Territory), Product Trademarks and Product Trade Dress. For the avoidance of doubt, Product Intellectual Property does not include the Licensed Know-How.

“Product Returns” shall have the meaning set forth in Section 7.11(b)(i).

“Product Trade Dress” shall mean the trade dress, logos and designs listed on Exhibit J, excluding any items that are specifically identified on Exhibit J as being the Seller Trade Dress.

“Product Trademarks” shall mean the trademarks, service marks, logos, slogans and trade names (whether or not registered), in the Territory, including all variations, derivations, combinations, registrations applications for registration or renewals of the foregoing and all goodwill associated therewith, as listed on Exhibit K.

“Promius” means Promius Pharma, LLC.

“Proration Schedule” shall have the meaning set forth in Section 2.01(h).

“Purchase Orders” shall mean all open purchase orders and statements of work of the Seller relating to the Business and listed in Annex A attached to Exhibit B.

“Purchase Price” shall have the meaning set forth in Section 3.01(a).

“Purchased Assets” shall mean (A) the Product Intellectual Property, (B) the Acquired Regulatory Approvals, (C) the Regulatory Documentation, (D) the Acquired Contracts, (E) the Marketing Materials, (F) the Purchased Inventory, (G) the Purchase Orders, (H) all rights of Seller or any of its Affiliates under non-disclosure or confidentiality, non-compete, or non-solicitation agreements with any third parties to the extent relating to the Business or any of the Purchased Assets, (I) all rights and claims of the Seller or any of its Affiliates against any Person related to the Business or any of the Purchased Assets, whether mature, contingent or otherwise, and whether in tort, contract or otherwise, including, without limitation, causes of action, unliquidated rights and claims under or pursuant to all warranties, representations and guarantees made by manufacturers, suppliers or vendors, claims for refunds, rights of off-set and credits of all kinds and all other general intangibles (in each case, except to the extent related to any of the Excluded Liabilities), (J) to the extent permitted by and available under the applicable policy, the benefit of coverage provided by all current and expired insurance policies of Seller or any of its Affiliates to the extent they relate to the Business or any of the Purchased Assets and/or Assumed Liabilities, (K) all books, files and records related to any of the foregoing and (L) all goodwill associated with any of the foregoing.

“**Purchased Inventory**” shall mean the Product Inventory, excluding any Excluded Inventory.

“**Purchased Inventory Value**” shall mean, without duplication, an aggregate amount equal to (i) the value of the Purchased Inventory valued at Seller’s standard cost, plus (ii) the amounts prepaid by the Seller prior to the Closing in respect of the Purchased Inventory.

“**Purchaser**” shall have the meaning set forth in the preamble.

“**Purchaser FDA Letters**” shall mean the letters from the Purchaser to the FDA, in substantially the forms attached as Exhibit M, duly executed by the Purchaser, providing notification of the transfer to the Purchaser of all rights of the Seller in and to the Acquired Regulatory Approvals.

“**Purchaser Group**” shall have the meaning set forth in Section 9.02.

“**Purchaser Indemnity Cap**” shall have the meaning set forth in Section 9.06(c).

“**Purchaser Indemnity Threshold**” shall have the meaning set forth in Section 9.06(c).

“**Purchaser Material Adverse Effect**” shall mean (i) a material adverse effect on the ability of the Purchaser to consummate the transactions contemplated hereby and fulfill its obligations hereunder or (ii) any fact, event or circumstance that would be reasonably likely to delay in any material respect the consummation of the transactions contemplated hereby.

“**Purchaser’s Prorated Portion**” means the amount equal to the Purchaser’s portion of the prorated expenses and other items, which the Purchaser shall pay to the Seller at Closing and is set forth on the Proration Schedule.

“**Quarter**” shall mean each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

“**Registered Intellectual Property**” shall mean, in the Territory, all (i) copyright registrations and applications, (ii) trademark registrations and applications and material unregistered trademarks, (iii) domain name registrations, (iv) registered designs, and (v) issued Patent and Patent applications (whether or not abandoned), and in each case, that are either owned (solely or jointly with others) by, or licensed to, the Seller.

“Regulatory Authority(ies)” means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the exploitation of Products thereto in the Territory, including the FDA.

“Regulatory Documentation” shall mean all (a) applications (including all investigational new drug (INDs) and the Acquired Regulatory Approvals), registrations, licenses, authorizations and approvals; (b) correspondence and reports submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including all adverse event files and complaint files; (c) chemistry, manufacturing and controls data and documentation (including, but not limited to, batch records, master batch production records, standard operating procedures that specifically pertain to the Products, testing logs, sample logs, laboratory logs, and stability logs), preclinical and clinical studies and tests, (d) records maintained under record keeping or reporting requirements of the FDA or any Governmental Authority; and (e) clinical and other data contained or relied upon in any of the foregoing; in each case solely to the extent relating to the Products in any jurisdiction in the Territory, owned by or in the possession of the Seller.

“Required Consents” shall have the meaning set forth in Section 4.02(a)(vi).

“Responsible Party” shall have the meaning set forth in Section 7.11(c)(i).

“Restraints” shall have the meaning set forth in Section 8.01(a).

“Retained Agreement” shall have the meaning set forth in the Assignment and Assumption Agreement Regarding DRL Contracts.

“Returned Product” shall have the meaning set forth in Section 7.11(b)(ii).

“SEC” shall have the meaning set forth in Section 7.09.

“Seller” shall have the meaning set forth in the preamble.

“Seller Group” shall have the meaning set forth in Section 9.03.

“Seller Disclosure Schedules” shall have the meaning set forth in the introductory sentence to ARTICLE V.

“Seller FDA Letters” shall mean the letters from the Seller to the FDA in substantially the forms attached as Exhibit L, duly executed by the Seller, providing notification of the transfer to Purchaser of all rights of the Seller in and to the Acquired Regulatory Approvals.

“Seller Indemnity Cap” shall have the meaning set forth in Section 9.06(b).

“Seller Indemnity Threshold” shall have the meaning set forth in Section 9.06(a).

“Seller Registered IP” shall have the meaning set forth in Section 5.11(a).

“**Seller Trade Dress**” shall mean the trademarks, trade names, brands, corporate names or similar items owned and/or used by the Seller, other than the Product Trademarks.

“**Solvent**” shall mean used with respect to any Person, shall mean that, as of any date of determination, (a) the amount of the “fair saleable value” of the assets of such Person on a going concern basis will, as of such date, exceed (i) the value of all “liabilities of such Person, including contingent and other liabilities” as of such date, as such quoted terms are generally determined in accordance with applicable United States federal Laws governing determinations of the insolvency of debtors and (ii) the amount that will be required to pay the probable liabilities of such Person on its existing debts (including contingent liabilities) as such debts become absolute and matured, (b) such Person will not have, as of such date, an unreasonably small amount of capital for the operation of the businesses in which it is engaged or proposed to be engaged following such date and (c) such Person will be able to pay its liabilities, including contingent and other liabilities, as they mature. For purposes of this definition, each of the phrases “not have an unreasonably small amount of capital for the operation of the businesses in which it is engaged or proposed to be engaged” and “able to pay its liabilities, including contingent and other liabilities, as they mature” means that such Person will be able to generate enough cash from operations, asset dispositions or refinancing, or a combination thereof, to meet its obligations as they become due.

“**Taxes**” shall mean all federal, state, local, foreign and other income, gross receipts, sales, use, production, ad valorem, transfer, value-added, goods and services, franchise, registration, profits, license, lease, service, service use, escheat, withholding, payroll, employment, unemployment, estimated, excise, severance, environmental, stamp, occupation, premium, property (real or personal), real property gains, windfall profits, customs, duties, local body, or other taxes, fees, assessments or charges of any kind whatsoever in the nature of taxes, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties, whether disputed or not, and including any obligations to indemnify or otherwise assume or succeed to the Tax liability of another Person.

“**Territory**” shall mean the entire world excluding the Excluded Territory.

“**Third Party**” shall mean any Person other than the Parties.

“**Third Party Claim**” shall have the meaning set forth in Section 9.05(a).

“**Tosymra Product**” shall have the meaning set forth in Exhibit G.

“**Transaction Documents**” shall mean the (a) Agreement, (b) Bill of Sale, (c) Intellectual Property Assignments, (d) Assignment and Assumption Agreement, (e) Assignment and Assumption Agreement Regarding DRL Contracts, (f) the Transition Services Agreement and (g) any other agreement, certificate or documents executed in connection with the transactions contemplated hereunder.

“**Transfer Taxes**” shall have the meaning set forth in Section 3.02(c).

“**Transition Services Agreement**” shall mean the certain Transition Services Agreement, to be entered into on the Closing Date by and among the Purchaser and the Seller in the form attached hereto as Exhibit P.

“**TSA Period**” means the date that begins on the Closing Date and ends upon expiration or termination of the Transition Services Agreement in its entirety in accordance with its terms.

“**United States**” shall mean the United States of America and its territories and possessions.

“**Zembrace Product**” shall have the meaning set forth in Exhibit G.

EXHIBIT A
ALLOCATION SCHEDULE METHODOLOGY

See attached.

EXHIBIT B
ACQUIRED CONTRACTS

B-1

EXHIBIT C
ASSIGNMENT AND ASSUMPTION AGREEMENT

C-1

EXHIBIT D

ASSIGNMENT AND ASSUMPTION AGREEMENT REGARDING DRL CONTRACTS

D-1

EXHIBIT E
INTELLECTUAL PROPERTY ASSIGNMENT AGREEMENTS

EXHIBIT F
KNOWLEDGE OF THE SELLER

EXHIBIT G

PRODUCTS

G-1

EXHIBIT H

PATENTS

H-1

EXHIBIT I
PRODUCT DOMAINS

EXHIBIT J
PRODUCT TRADE DRESS

EXHIBIT K
PRODUCT TRADEMARKS

K-1

EXHIBIT L
SELLER FDA LETTER

L-1

EXHIBIT M
PURCHASER FDA LETTER

M-1

EXHIBIT N
ELIGIBLE PRODUCT LOT AND BATCH NUMBERS

N-1

EXHIBIT O

[INTENTIONALLY OMITTED]

EXHIBIT P
TRANSITION SERVICES AGREEMENT

EXHIBIT Q
PRESS RELEASE

Q-1

EXHIBIT R

ADDITIONAL GOVERNMENT PRICE REPORTING INFORMATION

R-1

EXHIBIT S
MAY INVENTORY STATEMENT

S-1

Tonix Pharmaceuticals Enters into Agreement to Acquire Two FDA-Approved, Marketed Migraine Products from Upsher-Smith Laboratories, LLC

Zembrace® SymTouch® (sumatriptan injection) and Tosymra® (sumatriptan nasal spray) are Indicated for the Treatment of Acute Migraine in Adults

Strategic Acquisition Helps Build Tonix's Commercial Capabilities and Infrastructure Ahead of Potential Launch of TNX-102 SL for the Treatment of Fibromyalgia

Acute Migraine Products Complement Tonix's Current Intranasal Clinical Development Program of TNX-1900 for Migraine Prevention

Injection and Nasal Spray Products that Bypass the Gastrointestinal Tract Have the Potential to Provide Treatment Options for Migraine Associated with Nausea

CHATHAM, N.J., June 26, 2023 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix Pharmaceuticals or Tonix) and its wholly-owned subsidiary Tonix Medicines, Inc. (Tonix Medicines), a clinical-stage biopharmaceutical company, today announced that they have entered into an agreement to acquire two currently-marketed products from Upsher-Smith Laboratories, LLC (Upsher-Smith): Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg. Zembrace SymTouch and Tosymra are both indicated for the treatment of acute migraine with or without aura in adults. Zembrace SymTouch is the only branded sumatriptan autoinjector professionally promoted in the United States and is designed for ease of use and favorable tolerability with a low 3 mg dose.^{1,3} Tosymra is a novel intranasal sumatriptan product formulated with a permeation enhancer that provides rapid and efficient absorption of sumatriptan.^{4,5} Collectively, these products generated product sales of approximately \$23 million for the full year 2022. ⁶ Zembrace SymTouch and Tosymra each may provide onset of migraine pain relief in as few as 10 minutes for some patients and currently have patent protection to 2036 and 2031, respectively.^{1,4}

Under the terms of the agreement with Upsher-Smith:

- § Tonix Medicines will make an upfront payment of \$12 million in cash to Upsher-Smith at closing and an additional \$3 million in March 2024, or upon earlier conclusion of the transition services period.
- § In addition, Tonix Medicines will pay approximately \$10 million in cash to Upsher-Smith at closing to acquire certain product-related inventories.
- § To support the transition of the products, Upsher-Smith has agreed to provide certain commercial operations, regulatory and other transition services to Tonix Medicines for up to nine months after closing, in exchange for agreed upon service fees.
- § The assets to be acquired include New Drug Applications issued by the U.S. Food & Drug Administration for the products, as well as patents and trademarks related to the products in the United States and in certain countries outside the United States.
- § The closing is expected to take place on June 30, 2023.

"Approximately 16% of Americans suffer from migraines, which represents about 40 million patients in the U.S. ⁷," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Sumatriptan remains the acute migraine 'gold standard' treatment for many patients and continues to represent the largest segment of the market in terms of unit sales.⁸ With migraine pain relief possible in as few as ten minutes for some patients and convenient administration, we believe both Zembrace SymTouch and Tosymra are well-suited to address the unmet needs of patients using traditional or emerging oral acute migraine medications, particularly for rapid-onset treatment."

"Despite increasing options for prevention and treatment of migraine, migraine headaches and breakthrough migraine headaches remain significant unmet needs, and can lead to emergency room visits," said Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals. "For adults needing acute treatment of migraine, Zembrace SymTouch and Tosymra have the potential to be first-line treatments or 'rescue' medications for breakthrough migraines, due to their fast onset of action and high pain-relief rates. For certain patients who present to ERs, Zembrace SymTouch and Tosymra also provide ER staff a straightforward acute treatment option. Additionally, because both of these products bypass the gastrointestinal tract, they have the potential to provide a treatment option for migraines complicated by severe nausea and vomiting."

"These two products are a strategic fit for our company, and we look forward to working with Upsher-Smith to ensure a smooth product transition. To that end, this transaction includes established manufacturing and supplier relationships that allow for a seamless transition of manufacturing and supply chain responsibilities. The franchise today is supported by managed care contracts covering approximately 200 million lives. During the transition, we expect to secure our own contracts," said James Hunter, Executive Vice President of Commercial Operations at Tonix Pharmaceuticals and President of Tonix Medicines.

Dr. Lederman concluded, "In addition to the potential growth that these two on-market products represent over time, the acquisition helps build Tonix's commercial capabilities ahead of the potential launch of our TNX-102 SL product candidate for the treatment of fibromyalgia. In addition, these products align strongly with our TNX-1900 (intranasal potentiated oxytocin) product candidate, in clinical development for the prevention of chronic migraine. This is an important step in the evolution of Tonix into a fully integrated pharmaceutical company."

Zembrace SymTouch (sumatriptan injection) 3 mg is the only actively promoted brand of sumatriptan autoinjector in the United States (other sumatriptan autoinjector products on the market are Imitrex® and generics to Imitrex®). It has a unique low dose and has demonstrated onset of migraine pain relief in as few as 10 minutes (17% of patients vs. 5% for placebo).⁹ Zembrace SymTouch also demonstrated migraine pain freedom for 46% of patients (vs 27% for placebo) at 2 hours in a single-attack, double-blind study (N=230).² Zembrace SymTouch currently has patent protection to 2036. Tosymra (sumatriptan nasal spray) 10 mg employs Intravail® permeation enhancer technology and is pharmacokinetically equivalent to 4 mg subcutaneous sumatriptan.^{3,4} Tosymra delivers migraine pain relief in as little as 10 minutes with just one spray for some patients (13% vs. 5% for placebo).^{4, 9,10} Tosymra currently has patent protection to 2031.

Nearly 40 million people in the United States suffer from migraine⁶ and it has been recognized as the second leading cause of disability in the world.¹¹ Migraine is characterized by debilitating attacks lasting four to 72 hours with multiple symptoms, including pulsating headaches of moderate to severe pain intensity often associated with nausea or vomiting, and/or sensitivity to sound (phonophobia) and sensitivity to light (photophobia).¹²

References:

1. Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC: February 2021.
2. Landy, S. et al. Efficacy and safety of DFN-11 (sumatriptan injection, 3 mg) in adults with episodic migraine: a multicenter, randomized, double-blind, placebo-controlled study. *J Headache Pain*. 19, 69 (2018).
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4. Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC: Feb 2021.
5. Maggio ET. Intravail®: highly effective intranasal delivery of peptide and protein drugs. *Expert Opinion Drug Delivery*. 2006;3(4):529-539.
6. IQVIA 2022 retail sales from the National Sales Perspectives (NSP) audit within the SMART database estimates Zembrace sales of ~\$19.6 M and Tosymra sales of ~\$3.5 M
7. Buse et al. Burden of Illness Among People with Migraine and ≥ 4 Monthly Headache Days While Using Acute and/or Preventive Prescription Medications for Migraine. *Journal of Managed Care & Specialty Pharmacy*. 2020;26(10):1334-1343.
8. Upsher-Smith Laboratories; Data on File; 2023
9. Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. *Arch Neurol*. 1992;49(12):1271-1276.
10. Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. *Clinical Therapeutics*. 2006;28(4):517-526.
11. GBD 2016 Headache Collaborators. Global, regional, and national burden of migraine and tension-type headache, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet Neurol* 2018;17(11):954-976.
12. Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

Zembrace® SymTouch® (sumatriptan Injection): IMPORTANT SAFETY INFORMATION

Zembrace SymTouch (Zembrace) can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw

-
- pain or discomfort in your arms, back, neck, jaw or stomach
 - shortness of breath with or without chest discomfort
 - breaking out in a cold sweat
 - nausea or vomiting
 - feeling lightheaded

Zembrace is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, dihydroergotamine.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the components of Zembrace

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever

- cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet
 - increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
 - medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
 - serotonin syndrome, a rare but serious problem that can happen in people using Zembrace, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
-

- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Zembrace include: pain and redness at injection site; tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace. For more information, ask your provider.

This is the most important information to know about Zembrace but is not comprehensive. For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). You can also visit www.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

INDICATION AND USAGE

Zembrace is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.

Tosymra® (sumatriptan nasal spray): IMPORTANT SAFETY INFORMATION

Tosymra can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop Tosymra and get emergency medical help if you have any signs of heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Tosymra is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Do not use Tosymra if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- severe liver problems
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your healthcare provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider if you are not sure if your medicine is listed above.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any ingredient in Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Tosymra may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- cramping and pain in your legs or hips, feeling of heaviness or tightness in your leg muscles, burning or aching pain in your feet or toes while resting, numbness, tingling, or weakness in your legs, cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure

- medication overuse headaches from using migraine medicine for 10 or more days each month. **If your headaches get worse, call your provider.**
- serotonin syndrome, a rare but serious problem that can happen in people using Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. **Call your provider right away if you have** mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Tosymra include: tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Tosymra. For more information, ask your provider.

This is the most important information to know about Tosymra but is not comprehensive. For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). You can also visit www.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

INDICATION AND USAGE

Tosymra is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

Tosymra is not used to treat other types of headaches such as hemiplegic or basilar migraines or cluster headaches.

Tosymra is not used to prevent migraines. It is not known if Tosymra is safe and effective in children under 18 years of age.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with topline results expected in the first quarter of 2024. TNX-4300 (estianeptine) is a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer's disease and Parkinson's disease. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the third quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the first quarter of 2024. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

**All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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Zembrace, SymTouch and Tosymra are registered trademarks of Upsher-Smith Laboratories, LLC. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc. All other marks are the property of their respective owners.



Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

Investment Highlights



DIVERSE PIPELINE

Tonix's core focus is on **central nervous system** disorders, but we also target unmet needs across multiple therapeutic areas including **immunology**, **infectious disease** and **rare disease**.



IN-HOUSE CAPABILITIES

Investment in domestic, **in-house, R&D and manufacturing** to accelerate development timelines and improve the ability to respond to pandemics.



STRATEGIC PARTNERSHIPS

Partnering strategically with other **biotech companies**, **world-class academic and non-profit research organizations** to bring innovative therapeutics to market faster.



FINANCIAL POSITION

Tonix had approximately **\$72 M in cash and cash equivalents** as of 3/31/23. Tonix has no debt.



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Pipeline: Key Clinical Programs

Candidates*	Indication	Status/Next Milestone
TNX-102 SL ¹	Fibromyalgia (FM) Long COVID (PASC ²)	Mid-Phase 3 - >50% enrolled Phase 2 enrollment complete
TNX-1300 ³	Cocaine Intoxication - <i>FDA Breakthrough Designation</i>	Mid-Phase 2, Targeted 3Q 2023 Start
TNX-1900 ⁴	Prevention of Chronic Migraine	Phase 2 - enrolling ⁵
TNX-601 ER	Depression	Phase 2 - enrolling ⁶
TNX-2900 ⁷	Prader-Willi Syndrome - <i>FDA Orphan Drug Designation</i>	Phase 2 ready
TNX-1500 ⁸	Organ Transplant Rejection/ Autoimmune Conditions	Phase 1, Targeted 3Q 2023 Start
TNX-801 ⁹	Smallpox and mpox vaccine	Phase 1, Targeted 1Q 2024 Start

*All of Tonix's product candidates are investigational new drugs or biologics and none has been approved for any indication.

¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets) also has active INDs for Agitation in Alzheimer's Disease (AAD), Alcohol Use Disorder (AUD), and Posttraumatic Stress Disorder (PTSD). All indications are Phase 2 ready.

²Post-Acute Sequelae of COVID-19.

³TNX-1300 (double-mutant cocaine esterase) is licensed from Columbia University.

⁴Acquired from Trigemina; license agreement with Stanford University; Planned investigator-initiated Binge Eating Disorder (BED) study is expected start 2Q 2023.

⁵A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900

⁶Phase 1 trial for formulation development was completed outside of the U.S.; Other potential indications include PTSD and neurocognitive dysfunction from steroids

⁷Co-exclusive license agreement with French National Institute of Health and Medical Research (Inserm)

⁸anti-CD40L humanized monoclonal antibody – IND cleared

⁹Live attenuated vaccine based on horsepoxvirus



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Five Late-Stage CNS Programs to be in the Clinic by 2023¹ Three studies Enrolling Now



Active Studies

- **In Phase 3:**

- TNX-102 SL for fibromyalgia (>50% enrolled)

Potential Pivotal Study

- **In Phase 2:**

- TNX-102 SL for fibromyalgia-type Long COVID (enrollment complete)
- TNX-1900 for migraine headache (new mechanism for US patients)
- TNX-601 ER for major depressive disorder (new mechanism for US patients)

Potential Pivotal Study

Entering Phase 2

- **In 3Q 2023:**

- TNX-1300 for cocaine intoxication (FDA Breakthrough Therapy Designation)

Potential Pivotal Study

¹Not approved for any indication

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5

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**ACQUISITION OF
MARKETED
MIGRAINE
PRODUCTS**

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Agreement to Acquire Two Marketed Proprietary Migraine Drugs from Upsher-Smith Laboratories

Zembrace® SymTouch® (sumatriptan injection) 3 mg¹

Tosymra® (sumatriptan nasal spray) 10 mg²

- Each indicated for the treatment of acute migraine with or without aura in adults
- Sumatriptan remains the acute migraine 'gold standard' treatment for many patients and continues to represent the largest segment of the market in terms of unit sales³
- Each may provide migraine pain relief in as few as 10 minutes for some patients^{1,2,4,5}
- Each bypasses GI tract – provides convenient administration
- Patents to 2036 (Zembrace) and 2031 (Tosymra)

Combined US retail sales ~\$23 M (Zembrace ~\$19.6 M and Tosymra ~\$3.5 M)⁶

- Projecting net sales approximately ~50% of gross sales

Managed care contracts covering ~200 M lives

- Deal includes a transition period during which Tonix expects to secure its own contracts

¹Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2021 - For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). – Important Safety Information is provided in the appendix

²Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; Feb 2021. For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). – Important Safety Information is provided in the appendix

³Upsher-Smith Laboratories, LLC; Data On File, 2023

⁴Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. Arch Neurol. 1992;49(12):1271-1276.

⁵Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. Clinical Therapeutics. 2006;28(4):517-526.

⁶QVIA, 2022 sales from the National Sales Perspectives (NSP) audit within the SMART database estimates Zembrace sales of ~\$19.6 M and Tosymra sales of ~\$3.5 M

Zembrace, SymTouch and Tosymra are registered trademarks of Upsher-Smith Laboratories, LLC. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc.

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Agreement with Upsher-Smith Laboratories

• Terms

- Tonix Medicines has agreed to make an upfront payment of \$12 million in cash to Upsher-Smith at closing and an additional \$3 million in March 2024, or upon earlier conclusion of the transition services period.
- In addition, Tonix Medicines has agreed to pay approximately \$10 million in cash to Upsher-Smith at closing to acquire certain product-related inventories.
- To support the transition of the products, Upsher-Smith has agreed to provide certain commercial operations, regulatory and other transition services to Tonix Medicines for up to nine months after closing, in exchange for agreed upon service fees.
- The assets to be acquired include New Drug Applications issued by the U.S. Food & Drug Administration for the products, as well as patents and trademarks related to the products in the United States and in certain countries outside the United States.

Timing

- The Asset Purchase Agreement was signed on June 23, 2023
- The closing is expected to take place on June 30, 2023





Jim Hunter – President of Tonix Medicines

Validus Pharmaceuticals (2007-2018)

- CEO (12 years)
- Co-founded with Tonix CEO Seth Lederman
- Company started with acquisition of Marplan® (isocarboxazid)
- Subsequently acquired products from Shire, Roche, Novartis and Sanofi
- Established profitable, fully functional Pharma company

Novartis Pharmaceuticals (1997-2001)

- Executive Director – Neuroscience Sales
- Launched and supported products in Schizophrenia, Epilepsy, Migraine (DHE-45), Parkinson's and Alzheimer's

Ciba Geigy Pharmaceuticals (1984-1997)

- Various positions in Finance, Marketing, Sales
- Executive Director – Northeast Business Unit
 - Responsible for GP and Hospital sales force, managed care

Areas of responsibility and expertise include:

- Financial analysis
- Business development
- Marketing strategy
- Sales force management
- Supply chain management
- Regulatory and quality operations
- Distribution
- Contracting: Government programs and managed care
- P&L responsibility



Zembrace® SymTouch® (sumatriptan injection) 3 mg

Indication

- Indicated for the treatment of acute migraine with or without aura in adults

Design

- Only branded sumatriptan autoinjector professionally promoted in the United States
- Designed for ease of use and favorable tolerability with a low 3 mg dose¹⁻⁴

Patents

- Patents to 2036

Clinical evidence

- Demonstrated onset of migraine pain relief in as few as 10 minutes (17% of patients vs. 5% for placebo)²
- Demonstrated migraine pain freedom for 46% of patients (vs 27% for placebo) at 2 hours) in a single-attack, double-blind study (N=230)³

¹Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2021.

²Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. Arch Neurol. 1992;49(12):1271-1276.

³Landy, S. et al. Efficacy and safety of DFN-11 (sumatriptan injection, 3 mg) in adults with episodic migraine: a multicenter, randomized, double-blind, placebo-controlled study. J Headache Pain. 19, 69 (2018).

⁴Brand-Schieber E, Munjal S, Kumar R, et al. Human factors validation study of 3 mg sumatriptan autoinjector, for migraine patients. Med Devices (Auckl). 2016;9:131-137.



Tosymra® (sumatriptan nasal spray) 10 mg

Indication

- Indicated for the treatment of acute migraine with or without aura in adults

Design

- Novel intranasal sumatriptan product formulated with a permeation enhancer (Intravail® technology) that provides rapid and efficient absorption of sumatriptan^{1,2}
- Pharmacokinetically equivalent to 4 mg subcutaneous (s.c.) sumatriptan¹

Patents

- Patents to 2031

Clinical evidence

- Tosymra® delivers migraine pain relief in as little as 10 minutes with just one spray for some patients (13% vs. 5% for placebo)¹⁻³

¹Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; 2019.

²Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. Arch Neurol. 1992;49(12):1271-1276.

³Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. Clinical Therapeutics. 2006;28(4):517-526.

Intravail is a trademark of Aegis, a subsidiary of Neurelis



Value to Tonix of Marketed Proprietary Migraine Drugs

Prepare for the launch of TNX-102 SL for fibromyalgia

- Commercial capabilities prior to expected launch of TNX-102 SL may speed market uptake
- Potential to facilitate launch of TNX-1900 for prevention of chronic migraine once approved
 - Overlap of prescribers and patients between acute migraine and chronic migraine indications

Grow commercial CNS sales capability

- Improve sales and margins of these migraine products
 - Targeting sampling to potential users
 - Decreasing certain costs
- Explore specialty pharmacy channel

Build a specialty pharma business

- Further product acquisitions
- Several companies have bought or built commercial capabilities prior to the launch of their internally-developed products



Potential for Zembrace and Tosymra in Evolving Migraine Market

Documented efficacy of Zembrace^{1,2} and Tosymra³⁻⁵ as abortive treatments for acute migraine

- Migraine pain relief possible in as few as 10 minutes for some patients and convenient administration
- Potential to address the unmet needs of patients using traditional or emerging oral acute migraine medications, particularly for rapid-onset treatment

Zembrace and Tosymra have potential as first-line or rescue medications

- Depending on patient need, prescribers may utilize to treat acute migraine either first-line or in the rescue position in a comprehensive migraine toolbox
- Fast onset of action, high pain-relief rates
- For certain patients who present to ERs, Zembrace and Tosymra also provide ER staff a straightforward treatment option

¹Zembrace SymTouch [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; 2019.

²Landy, S. et al. Efficacy and safety of DFN-11 (sumatriptan injection, 3 mg) in adults with episodic migraine: a multicenter, randomized, double-blind, placebo-controlled study. *J Headache Pain*. 19, 69 (2018).

³Tosymra [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; Feb 2021.

⁴Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. *Arch Neurol*. 1992;49(12):1271-1276.

⁵Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. *Clinical Therapeutics*. 2006;28(4):517-526.

Intravall is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc.



Administration of Zembrace and Tosymra Bypass the GI Tract

Bypassing the gastrointestinal (GI) tract is a potential advantage for treating acute migraine

- Potential to provide a treatment option for migraines complicated by severe nausea and vomiting

Need for acute non-oral treatments

- GI absorption may be inconsistent in migraineurs due to gastric stasis (also called “gastroparesis”)¹⁻⁴
- Nausea and vomiting are symptoms of migraine⁵

¹Arca KN, et al. 2022. *Curr Neurol Neurosci Rep*. 22(12):813-821

²Tfelt-Hansen PC. 2017. *Cephalalgia*. 37(9):892-901

³Parkman HP. 2013. *Headache*. 53 Suppl 1:4-10.

⁴Aurora SK, et al. 2013. *Cephalalgia*. 33(6):408-15

⁵Pierce M. 2013. *Headache*. 53 Suppl 1:17-20.

Targeted Promotion

Health care providers who prescribe injections/intranasal drugs

- Potential early adopters

ER physicians

- Migraine patients are common in ERs

Nurse Practitioners (NPs) and Physician Assistants (PAs)

- Increasingly, NPs and PAs provide care for significant numbers of patients
- Prescribe medicines
- Dedicated conferences and professional societies

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Strategic Fit

We expect commercial business of Zembrace and Tosymra will be under our control in 4Q: same time as projected fibromyalgia topline for TNX-102 SL

- With success in F307 trial, commercial business is expected to speed TNX-102 SL launch
- Commercial business has potential to expand
 - Potential for “Growth Equity” investors to fund subsequent product acquisitions
 - Debt can be part of financing strategy for subsequent acquisitions

Acquiring subsequent commercial products is easier than buying the first products

- Licenses, accounting, managed care relationships facilitate acquisitions

Commercial sales is a viable business strategy

- Historically recession-proof
- Opportunities for new products as big pharma focuses on cell- and gene-therapies
- Room for innovation in evolving reimbursement market
 - Constant evolution in Managed care, Medicare/Medicaid, specialty pharmacies, etc.

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TNX-102 SL*

Cyclobenzaprine (Protectic®) Pipeline in a Product

A unique, sublingual formulation of cyclobenzaprine designed to optimize delivery and absorption

Potent binding and antagonist activities at the serotonergic-5-HT_{2A}, adrenergic- α ₁, histaminergic-H₁, and muscarinic-M₁ cholinergic receptors to facilitate restorative sleep

Innovative and proprietary PROTECTIC® Rapid drug exposure following nighttime administration

Differentiators:

Relative to Oral Cyclobenzaprine

- Lower daytime exposure
- Avoids first-pass metabolism
- Reduces risk of pharmacological interference from major metabolite

Relative to Standard of Care

- Potential for better tolerability while maintaining efficacy
- Not scheduled with no recognized abuse potential

Patents Issued

*TNX-102 SL has not been approved for any indication.

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Fibromyalgia

Status: Mid-Phase 3

- One positive Phase 3 study (RELIEF) completed
- Second Phase 3 study (RALLY) missed primary endpoint
- Confirmatory Phase 3 study (RESILIENT) is currently enrolling
 - >50% enrolled

Next Steps: Topline results expected 4Q 2023

Fibromyalgia-Type Long COVID

Status: Phase 2

- Phase 2 study (PREVAIL) has completed enrollment of 60 patients

Next Steps: Topline results expected 3Q 2023

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TNX-102 SL*: Fibromyalgia Cyclobenzaprine Protectic® Sublingual Tablets



CNS PORTFOLIO

PROFILE

Fibromyalgia (FM) is a chronic pain disorder resulting from amplified sensory and pain signaling within the CNS

- Affects an estimated 6-12 million adults in the U.S., approximately 90% of whom are women¹
- Symptoms include chronic widespread pain, nonrestorative sleep, fatigue, and cognitive dysfunction
- Patients struggle with daily activities, have impaired quality of life, and frequently are disabled
- Physicians and patients report common dissatisfaction with currently marketed products



When the check engine light malfunctions, the light is on even though the car is not malfunctioning

Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Fibromyalgia

Additional Indications: Long COVID, PTSD, Agitation in Alzheimer's, Alcohol Use Disorder

Status: One Positive Phase 3 study RELIEF completed²

Second Phase 3 study RALLY missed primary endpoint

Confirmatory Phase 3 study RESILIENT is currently enrolling

Next Steps: Topline results expected 4Q 2023

*TNX-102 SL has not been approved for any indication.

¹American Chronic Pain Association (www.theacpa.org, 2019)

²Lederman et al., (2023) *Arthritis Care & Research* "Efficacy and Safety of TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia: Results From the RELIEF Trial", doi: 10.1002/acr.25142. Epub ahead of print. PMID: 37165930.

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TNX-102 SL: Phase 3 RESILIENT Study Design



CNS PORTFOLIO

General study characteristics:

- Randomized, double-blind, placebo-controlled study in fibromyalgia
- U.S. sites only, expected to enroll approximately 470 patients

Primary Endpoint:

- Daily diary pain severity score change from baseline to Week 14 (TNX-102 SL vs. placebo)
 - Weekly averages of the daily numerical rating scale scores

Key Secondary Endpoints:

- Fibromyalgia Impact Questionnaire - Revised (FIQ-R) Symptom Domain score
- Patient Global Impression of Change responder analysis
- FIQ-R Function Domain score
- PROMIS Sleep Disturbance instrument
- PROMIS Fatigue instrument
- Weekly average of the daily diary assessment of sleep quality

TNX-102 SL once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets)

Placebo once-daily at bedtime

14 weeks

*Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

ClinicalTrials.gov Identifier: NCT05273749
A Phase 3 Study to Evaluate the Efficacy and Safety of TNX-102 SL Taken Daily in Patients With Fibromyalgia (RESILIENT)

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TNX-102 SL*: Fibromyalgia-Type Long COVID (PASC) Cyclobenzaprine Protectic® Sublingual Tablets

PROFILE

- Occurs in approximately 13% of recovered COVID-19 patients¹
- As many as 40% of Long COVID patients experience multi-site pain, a hallmark of fibromyalgia^{2,3}
- Symptoms of Long COVID, like multi-site pain, fatigue and insomnia, are the hallmarks of chronic pain syndromes like fibromyalgia and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS)
- In August 2022, the HHS released the National Research Action Plan on Long COVID⁴ which endorses the connection between Long COVID and chronic fatigue syndrome

DEVELOPMENT PROGRAM

Market Entry: Fibromyalgia-Type Long COVID (PASC)

Additional Indications: Fibromyalgia, PTSD, Agitation in Alzheimer's, Alcohol Use Disorder

Status: Phase 2 study PREVAIL has completed enrollment of 60 patients

Next Steps: Topline results expected 3Q 2023

Patents Issued

*TNX-102 SL has not been approved for any indication.

¹September 1, 2022- CDC - <https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html>

²Harris, H, et al. Tonix data on file. 2022

³TnNetX Analytics

⁴Department of Health and Human Services, Office of the Assistant Secretary for Health. 2022. National Research Action Plan on Long COVID.

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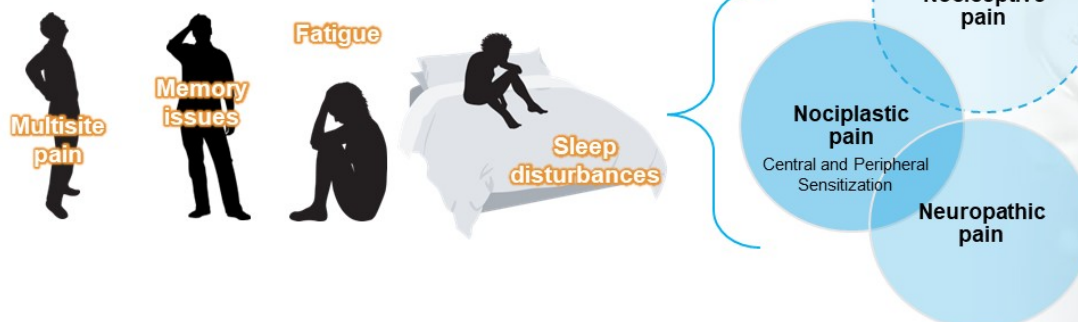
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Fibromyalgia-Type Long COVID

- Long COVID is a heterogeneous condition that displays elements of nociplastic pain in many individuals, who experience otherwise unexplained symptoms¹⁻³



Symptoms (multi-site pain, fatigue, sleep disorders and cognitive dysfunction) overlap with the key symptoms of fibromyalgia

Nociplastic pain⁴: (new term for "Central and Peripheral Sensitization") Pain that arises from altered nociception despite no clear evidence of tissue damage, or for disease or lesion of the somatosensory system causing the pain

¹Bierle et al., 2021. *J Prim Care Community Health*. 12:21501327211030826

²Moghimi et al., 2021. *Curr Neurol Neurosci Rep*. 21(9):44

³Thaweethai T, et al. 2023. *JAMA*. 2023 329(22):1934-1946

⁴Trouvin et al., 2019. *Best Pract Res Clin Rheumatol*. 33(3):101415

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TNX-102 SL: Phase 2 PREVAIL Study Design



CNS PORTFOLIO

Study characteristics:

- Randomized, double-blind, placebo-controlled study of TNX-102 SL in fibromyalgia-type Long COVID
- U.S. sites only, has enrolled approximately 60 patients

Primary Endpoint:

- Daily diary pain severity score change from baseline to Week 14 (TNX-102 SL vs. placebo)
 - Weekly averages of the daily numerical rating scale scores

TNX-102 SL once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets)*

Placebo once-daily at bedtime

Two week run in at 2.8 mg dose at bedtime, followed by 12 weeks at 5.6 mg dose

ClinicalTrials.gov Identifier: NCT05472090

A Phase 2 Study to Evaluate the Efficacy and Safety of TNX-102 SL in Patients With Multi-Site Pain Associated With Post-Acute Sequelae of SARS-CoV-2 Infection (PREVAIL)

14 weeks

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TNX-601 ER*: Depression

Tianeptine Hemioxalate Extended-Release Tablets (39.4 mg)



CNS PORTFOLIO

PROFILE

- A novel, oral, extended-release once-daily tablet
- Treatment effect of tianeptine sodium immediate release *t.i.d.* in depression is well-established
- Tianeptine restores neuroplasticity in animal models
- PPAR- β/δ and PPAR- γ agonist¹

Differentiators:

Relative to tianeptine IR available ex-US:

- Once daily dosing

Relative to traditional antidepressants:

- Unique mechanism of action – beyond neurotransmitter modulation
- Tianeptine sodium IR has similar efficacy but fewer side effects than traditional antidepressants

DEVELOPMENT PROGRAM

Market Entry: Major Depressive Disorder (MDD)

Additional Indications: PTSD, Neurocognitive Disorder From Corticosteroids, Alzheimer's Disease²

Status: Phase 2 MDD study UPLIFT is currently enrolling

Next Steps:

Interim analysis results on first 50% of sample expected 4Q 2023

Topline results expected 1Q 2024 for target enrollment of ~300 patients

Patents Issued

*TNX-601 ER has not been approved for any indication.

¹Sullivan G et al. Poster presentation at the American Society of Clinical Psychopharmacology, June 2023. <https://bit.ly/42a3inV>

²García-Alberca et al., 2022. *J Alzheimers Dis*. 88(2):707-720

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TNX-601 ER - Phase 2 UPLIFT* Study Design

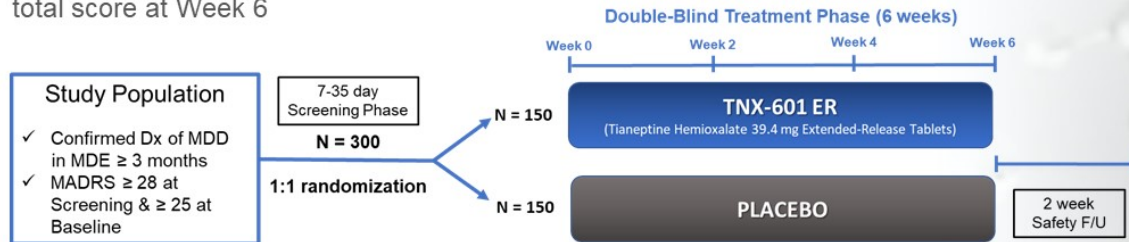
UPLIFT Study

General study characteristics:

- Randomized, double-blind, placebo-controlled study in Major Depressive Disorder to evaluate monotherapy with TNX-601 ER versus placebo
- Parallel design with two arms – treatment with tianeptine hemioxalate 39.4 mg or placebo
- ~30 U.S. sites only, expected to enroll approximately 300 patients
- One unblinded interim analysis based on 50% of randomized participants expected 4Q'23

Primary Endpoint:

- Mean change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6



*ClinicalTrials.gov Identifier: NCT05686408

Abbreviations: Dx, diagnosis; ER, extended-release; F/U, follow-up; MDD, major depressive disorder; MDE, major depressive episode; N, number

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TNX-601 ER – Racemic Tianeptine – Composed of Two Isomers

Racemic tianeptine:

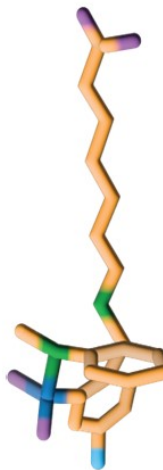
- Approved in Europe and ex-US
- 1:1 mixture of 2 mirror-image isomers^{1,2}
- Weak μ -opioid receptor agonism²
 - Risk of abuse or diversion for euphoric effects³

(S)-Tianeptine: PPAR- β/δ agonist, no opiate liability⁴

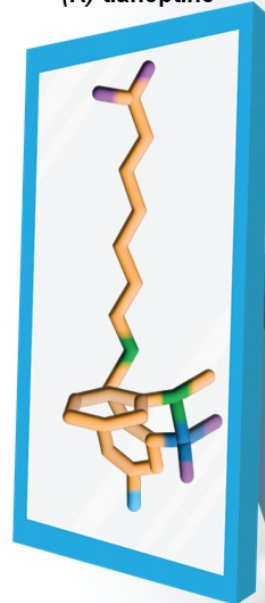
- Both (S)- and (R)-tianeptine are agonists of PPAR- γ
- New mechanism of action for treating depression

	Racemic-Tianeptine	(S)-Tianeptine TNX-4300	(R)-Tianeptine
μ -Opioid Receptor	+	-	+
PPAR- β/δ	+	+	-
PPAR- γ	+	+	+

(S)-tianeptine



(R)-tianeptine



¹Stablon. Summary of product characteristics. Les Laboratoires Servier Industrie; 2014.

²PubChem. Accessed November 10, 2022. <https://pubchem.ncbi.nlm.nih.gov/compound/Tianeptine>

³Drug Enforcement Administration. May 2019. Accessed November 11, 2022. https://www.deadiversion.usdoj.gov/drug_chem_info/tianeptine.pdf

⁴Sullivan G et al. Poster presentation at the American Society of Clinical Psychopharmacology, June 2023. <https://bit.ly/42o3inV>

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TNX-4300*: Depression, Alzheimer's & Parkinson's diseases

Estianeptine (Single (S)-isomer of Tianeptine)

PROFILE

- Single isomer, oral treatment
- Proposed mechanism of action from lab studies indicates estianeptine is the active ingredient of TNX-601 ER¹
 - PPAR- β/δ and PPAR- γ agonist
 - Free of μ -opioid receptor activity
- Estianeptine restores neuroplasticity in tissue culture

Differentiators:

Relative to racemic tianeptine IR or TNX-601 ER:

- Lack of opioid liability

Relative to traditional antidepressants:

- Unique mechanism of action – beyond neurotransmitter modulation
- Racemic tianeptine sodium IR has similar efficacy but fewer side effects than traditional antidepressants

DEVELOPMENT PROGRAM

Market Entry: Major Depressive Disorder (MDD)

Additional Indications: PTSD, Neurocognitive Disorder From Corticosteroids, Alzheimer's Disease²

Status: Pre-clinical

Next Steps: Expect IND can be supported by pre-clinical and clinical data from TNX-601 (racemic tianeptine) development

Patents Issued

*TNX-4300 has not been approved for any indication.

¹TNX-4300 is in the pre-IND stage of development and has not been approved for any indication

¹Sullivan G et al. Poster presentation at the American Society of Clinical Psychopharmacology, June 2023. <https://bit.ly/42o3inV>

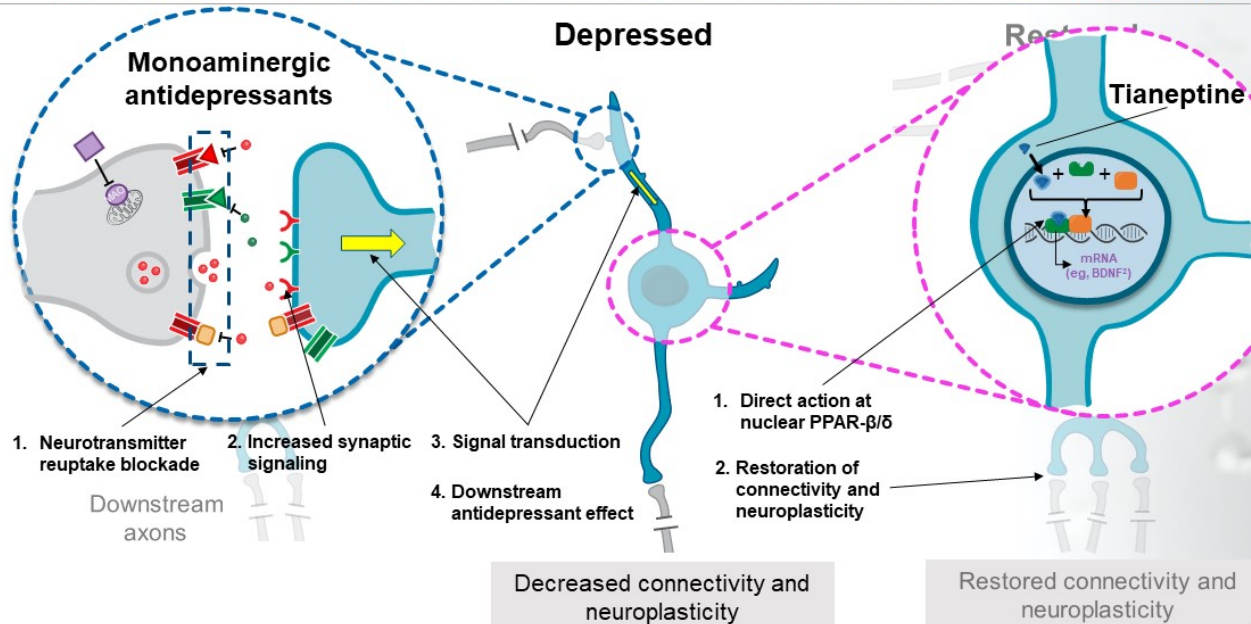
²García-Alberca et al., 2022. J Alzheimers Dis. 88(2):707-720

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While Monoaminergic Antidepressants Work at the Synapse, (S)-Tianeptine “Cuts in Line” to More Directly Affect Neuroplasticity¹



¹Sullivan G et al. Poster presentation at the American Society of Clinical Psychopharmacology, June 2023. <https://bit.ly/42o3inV>

²BDNF=brain-derived neurotrophic factor.

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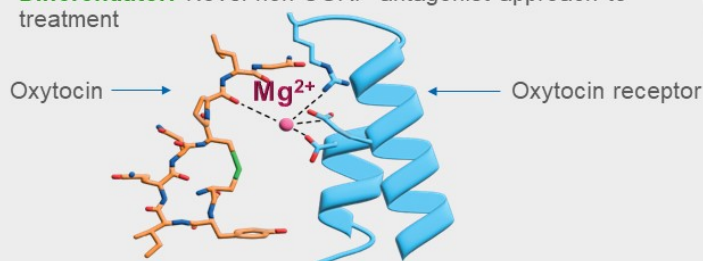
TNX-1900*: Migraine Intranasal Potentiated Oxytocin (OT) with Magnesium



PROFILE

- Intranasal OT has potential utility in treating migraine¹
- Magnesium is known to potentiate the binding of OT to its receptor^{2,3}
- One billion individuals worldwide suffer from migraines

Differentiator: Novel non-CGRP antagonist approach to treatment



Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Chronic Migraine

Additional Indications: Acute Migraine, Craniofacial Pain, Insulin Resistance, Binge Eating Disorder

Status: Phase 2 study PREVENTION is currently enrolling⁴

Next Steps: Topline results expected 4Q 2023

Investigator initiated Phase 2 trial in obesity-associated binge eating disorder 2Q 2023

*TNX-1900 has not been approved for any indication. CGRP = calcitonin gene-related peptide.



¹Tzabazie et al., 2017. *Headache*. 57 Suppl 2:64-75

²Antoni et al., 1989. *Biochem J*. 257(2):611-4

³Meyerowitz et al., 2022. *Nat Struct Mol Biol*. (3):274-281

⁴A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900 © 2023 Tonix Pharmaceuticals Holding Corp.

TNX-1900: Phase 2 PREVENTION Study Design

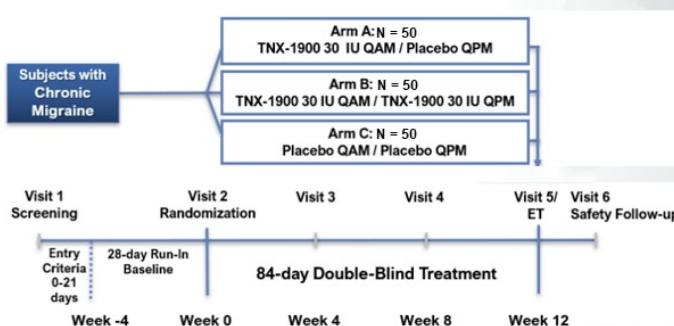


General study characteristics:

- Randomized, double-blind, placebo-controlled study (three arms— two treatment regimens and one placebo) in chronic migraine
- U.S. sites only, expected to enroll approximately 150 patients
- Topline results expected 4Q'23

Primary Endpoint:

- Mean change in the number of migraine headache days between the 28-day Run-In phase and the last 28-days of the Treatment phase (TNX-1900 vs. placebo)



ClinicalTrials.gov Identifier: NCT05679908
A Study to Evaluate the Efficacy and Safety of TNX-1900 in Patients With Chronic Migraine (PREVENTION)



TNX-1300*: Cocaine Intoxication

Cocaine Esterase (CocE)



PROFILE

Cocaine is the main cause for drug-related ED visits¹

CocE is a recombinant protein that degrades cocaine in the bloodstream

- Rapidly reverses physiologic effects of cocaine
- Drops plasma exposure by 90% in 2 minutes

Differentiators: Rapidly metabolizes cocaine in the bloodstream; no other product currently on the market for this indication



Patents Issued

DEVELOPMENT PROGRAM

Market Entry: Cocaine Intoxication

Status: Mid-Phase 2

Next Steps: Initiate new Phase 2 trial 3Q 2023

- Single-blind, placebo (+ usual care) controlled, randomized, potentially pivotal study
- Expected to enroll approximately 60 emergency department patients at sites in the US

FDA Breakthrough Therapy Designation

Awarded Cooperative Agreement Grant from National Institute on Drug Abuse (NIDA)

¹Havakuk et al., 2017. J Am Coll Cardiol. 70:101-113
ED = emergency department.

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IMMUNOLOGY: KEY CANDIDATES

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TNX-1500*

Next Generation α -CD40 Ligand (CD40L) Antibody

The CD40-CD40L pathway is a pivotal immune system modulator and a well-established and promising treatment target

Differentiators: Expected to deliver efficacy without compromising safety

First Generation: Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (Fc γ R)

Second Generation: Eliminated the Fc γ R TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of Fc γ R.



*TNX-1500 has not been approved for any indication. Patents filed.

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Prevention of Allograft Rejection

Status: Phase 1 ready – IND cleared

- Collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

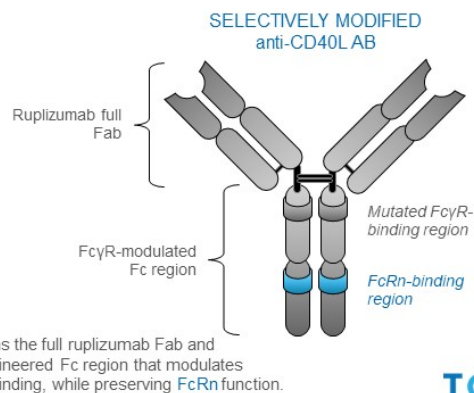
Next Steps: Initiate Phase 1 study 3Q 2023

Autoimmune Diseases

Status: Potential future indications include:

Sjögren's Syndrome, Systemic Lupus Erythematosus

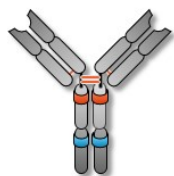
- These indications require large studies, but represent large target markets



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Third-Generation α -CD40L Engineered to Decrease Risk of Thrombosis

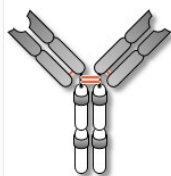
First-generation anti-CD40L mAbs



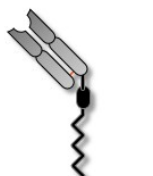
Ruplizumab

Constant fragment (Fc) domain interacted with Fc γ RIIA (CD32A), which suggested a mechanism for the increased risk of thrombosis.^{1,2}

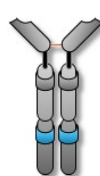
Second-generation anti-CD40L proteins



Aglycosyl Ruplizumab



Dapirolizumab



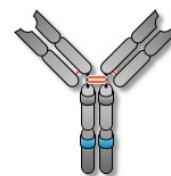
Letolizumab



Dazodalibep

Second-generation anti-CD40L proteins exhibited dramatically reduced binding to Fc γ RIIA³⁻⁶ but had other issues, including decreased efficacy, shortened half-life, or engendering of anti-drug antibodies (ADAs).⁷⁻⁹

Third-generation anti-CD40L mAbs*



TNX-1500

TNX-1500 is engineered to target CD40L therapeutically while reducing Fc γ RIIA binding and thereby lowering the potential for thrombosis.¹⁻⁹

*Sanofi's frexalimab (formerly SAR441344) and Eledon's tegoprubart (formerly AT-1501) also are Fc modified

¹Inwald et al., 2003. *Circ Res*. 92(9):1041-1048

²Robles-Carrillo et al., 2010. *J Immunol*. 185(3):1577-1583

³Shock et al., 2015. *Arthritis Res Ther*. 17(1):234

⁴Xie et al., 2014. *J Immunol*. 192(9):4083-4092

⁵Ferranti et al., 2004. *Int Immunol*. 16(11):1583-1594

⁶Karnell et al., 2019. *Sci Transl Med*. 11(489):eaar6584

⁷ClinicalTrials.gov identifier: NCT02273960. Updated July 16, 2019. Accessed June 1, 2021. <https://clinicaltrials.gov/ct2/show/results/NCT02273960?view=results>

⁸Waters, 2018. *BioCentury*.

⁹Company data

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IMMUNOLOGY PORTFOLIO



Other anti-CD40L Monoclonal Antibodies in Development

UCB (Co-developed with Biogen) – Systemic Lupus Erythematosus (SLE)

- Phase 3 Trial Currently Enrolling (NCT04294667)
 - Topline results expected 1H 2024¹
- Dapirolizumab pegol (pegylated Fab)

Horizon (being acquired by Amgen) – Sjögren's Syndrome (SjS)

- Two Positive Phase 2 studies reported^{2,3}
- Dazodalibep (tn03 fusion protein)

Sanofi – Sjögren's Syndrome (SjS), Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE)

- Phase 2 Trial Currently Enrolling in SjS (NCT04572841) and SLE (NCT05039840)
- Active Phase 2 Trial in Relapsing MS (NCT04879628)
- Frexalimab, f.k.a. SAR441344 (Fc-modified)

Eledon – Amyotrophic Lateral Sclerosis (ALS) and Kidney Transplant

- Phase 2 Trial Completed in ALS (NCT04322149)
- Phase 1/2 Trial Currently Enrolling in Kidney Transplant (NCT05027906)
- Tegoprubart, f.k.a. AT-1501 (Fc-modified)

Lundbeck and AprilBio – Neurology

- Phase 1 Trial Currently Enrolling in Healthy Adults (NCT05136053)
- APB-A1 or Lu AG22515 (HAS fusion protein)

¹<https://www.ucb.com/our-science/pipeline>

²<https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating>

³<https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-0>

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Milestones: Recently Completed and Upcoming

- ✓ 2nd Quarter 2022 Phase 3 RESILIENT study start of TNX-102 SL for the management of fibromyalgia
- ✓ 3rd Quarter 2022 Phase 2 PREVAIL study start of TNX-102 SL for the treatment of fibromyalgia-type Long COVID
- ✓ 1st Quarter 2023 Phase 2 PREVENTION study start of TNX-1900 for the treatment of migraine
- ✓ 1st Quarter 2023 Phase 2 UPLIFT study start of TNX-601 ER for major depressive disorder

Expected Data

- 3rd Quarter 2023 Topline results of Phase 2 PREVAIL study of TNX-102 SL for fibromyalgia-type Long COVID
- 4th Quarter 2023 Topline results of Phase 2 PREVENTION study of TNX-1900 for chronic migraine
- 4th Quarter 2023 Interim Analysis results of Phase 2 UPLIFT study of TNX-601 ER for major depressive disorder
- 4th Quarter 2023 Topline results of Phase 3 RESILIENT study of TNX-102 SL for fibromyalgia
- 1st Quarter 2024 Topline results of Phase 2 UPLIFT study of TNX-601 ER for major depressive disorder*

Expected Clinical Trial Initiations

- 3rd Quarter 2023 Phase 1 study start of TNX-1500 for prevention of allograft rejection
- 3rd Quarter 2023 Phase 2 study start of TNX-1300 for the treatment of cocaine intoxication
- 1st Quarter 2024 Phase 1 study start of TNX-801 for prevention of mpox and smallpox

*For target enrollment of ~300 patients



THANK YOU

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Zembrace® IMPORTANT SAFETY INFORMATION (1 of 2)

Zembrace Sym Touch (Zembrace) can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- Discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw or stomach; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; feeling lightheaded

Zembrace is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace if you have:

- History of heart problems; narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease); uncontrolled high blood pressure; hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; severe liver problems; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, dihydroergotamine; are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- An allergy to sumatriptan or any of the components of Zembrace

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.



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Zembrace® IMPORTANT SAFETY INFORMATION (2 of 2)

Zembrace may cause serious side effects including:

- Changes in color or sensation in your fingers and toes; sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever; cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet; increased blood pressure including a sudden severe increase even if you have no history of high blood pressure; medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- Serotonin syndrome, a rare but serious problem that can happen in people using Zembrace, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- Hives (itchy bumps); swelling of your tongue, mouth, or throat
- Seizures even in people who have never had seizures before

The most common side effects of Zembrace include: pain and redness at injection site; tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace. For more information, ask your provider.

This is the most important information to know about Zembrace but is not comprehensive. For more information, talk to your provider and read the [Patient Information](#) and [Instructions for Use](#). You can also visit www.upsher-smith.com or call 1-888-650-3789. For full Prescribing Information, visit: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e5b104f-2b9e-416e-92fb-ef1bdaea867d>

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Zembrace is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.

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Tosymra® IMPORTANT SAFETY INFORMATION (1 of 2)

Tosymra® can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop Tosymra and get emergency medical help if you have any signs of heart attack:

- Discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw, or stomach; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; feeling lightheaded

Tosymra is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Do not use Tosymra if you have:

- History of heart problems; narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease); uncontrolled high blood pressure; severe liver problems; hemiplegic or basilar migraines. If you are not sure if you have these, ask your healthcare provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider if you are not sure if your medicine is listed above
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure
- An allergy to sumatriptan or any ingredient in Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements. Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

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Tosymra® IMPORTANT SAFETY INFORMATION (2 of 2)

Tosymra may cause serious side effects including:

- Changes in color or sensation in your fingers and toes; sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever; cramping and pain in your legs or hips, feeling of heaviness or tightness in your leg muscles, burning or aching pain in your feet or toes while resting, numbness, tingling, or weakness in your legs, cold feeling or color changes in one or both legs or feet; increased blood pressure including a sudden severe increase even if you have no history of high blood pressure; medication overuse headaches from using migraine medicine for 10 or more days each month. **If your headaches get worse, call your provider.**
- Serotonin syndrome, a rare but serious problem that can happen in people using Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. **Call your provider right away if you have:** mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- Seizures even in people who have never had seizures before

The most common side effects of Tosymra include: tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Tosymra. For more information, ask your provider.

This is the most important information to know about Tosymra but is not comprehensive. For more information, talk to your provider and read the [Patient Information and Instructions for Use](#). You can also visit www.upsher-smith.com or call 1-888-650-3789. For full Prescribing Information, visit: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=015a5cf9-f246-48bc-b91e-cd730a53d8aa>

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Tosymra is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

Tosymra is not used to treat other types of headaches such as hemiplegic or basilar migraines or cluster headaches.

Tosymra is not used to prevent migraines. It is not known if Tosymra is safe and effective in children under 18 years of age.

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