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

FORM 8-K

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

Date of Report (Date of earliest event report): August 4, 2021

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-31361**	**35-2089858**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4131 ParkLake Ave., Suite 225
Raleigh, NC. 27612
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: 919-582-9050

Not Applicable
(Former name or former address, if changed since last report)

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001	**BDSI**	**The Nasdaq Global Select 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.

On August 3, 2021 (the "**Effective Date**"), BioDelivery Sciences International, Inc. (the "**Company**") and Dr. Reddy's Laboratories Limited, a company incorporated under the laws of India ("**DRL**"), entered into an asset purchase agreement (the "**Asset Purchase Agreement**") for the acquisition by the Company from DRL of certain patents, trademarks, regulatory approvals and other rights related to ELYXYB™ (*celecoxib oral solution*) (the "**Product**") and its commercialization in the United States and Canada (the "**Territory**").

Pursuant to the terms of the Asset Purchase Agreement, and subject to the conditions set forth therein, the Company will pay DRL a $6 million up-front payment to be paid on the date of closing of the transactions contemplated by the Asset Purchase Agreement (the "**Closing**"), $9 million on the twelve-month anniversary of the Effective Date, up to an additional $9 million upon achievement of certain regulatory milestones and quarterly earn-out payments on potential sales of the Product in the Territory that range from high single digits to the low double digits (subject to reduction in certain circumstances) of net sales based on volume of sales. DRL will also be entitled to one-time payments upon the achievement of six escalating sales milestones, which range from $4 million to be paid upon the achievement of $50 million in net sales in a calendar year to $100 million to be paid upon the achievement of $1 billion in net sales in a calendar year, up to a total of $262 million.

The Asset Purchase Agreement contains customary representations, warranties and covenants made by each of Company and DRL, including, among others, covenants by the Company to use certain efforts to pursue achievement of the regulatory and commercialization milestones, to provide period reports on the Company's progress toward achieving such milestones as well as net sales reports, and certain other customary covenants by each of Company and DRL with respect to confidentiality, limitation of liability, indemnification and on certain tax matters.

Upon the Closing, the Company and DRL will enter into a customary transition services agreement under which DRL will provide certain development, regulatory support and intellectual property support activities and services for the Company's benefit for up to three years from the Closing, at a specified hourly rate with reimbursement for certain expenses.

The Closing will occur upon the satisfaction of certain customary closing conditions and the earlier to occur of (i) expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and (ii) sixty-five (65) days after the Effective Date (the "**Outside Date**"). Either party may terminate the Asset Purchase Agreement prior to the Closing if the other party materially breaches or defaults in the performance of its obligations, and, if curable, such material breach remains uncured for thirty (30) days from the date of notice of such breach or default (or remains uncured by the business day immediately preceding the Outside Date).

The foregoing description of the Asset Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the text of the Asset Purchase Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 7.01 Regulation FD Disclosure

On August 4, 2021, BDSI and DRL issued a press release announcing the execution of the Asset Purchase Agreement. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1†	Asset Purchase Agreement, dated August 3, 2021, by and between DRL and the Company.
99.1	Press release, dated August 4, 2021, announcing the Asset Purchase Agreement between the Company and DRL.

† Certain portions of this exhibit have been omitted because they are not material and the registrant customarily and actually treats that information as private or confidential.

SIGNATURES

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

August 4, 2021

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Mary Theresa Coelho

Name: Mary Theresa Coelho

Title: Executive Vice President, Chief Financial Officer and Treasurer

[***] Certain portions of this exhibit have been omitted because they are not material and the registrant customarily and actually treats that information as private or confidential.

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

DR. REDDY'S LABORATORIES LIMITED,

AS SELLER

AND

BIODELIVERY SCIENCES INTERNATIONAL, INC.,

AS PURCHASER

DATED AS OF

August 3, 2021

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ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this "**Agreement**") dated as of August 3, 2021 (the "**Effective Date**") by and between Dr. Reddy's Laboratories Limited, a company incorporated under the laws of India and located 8-2-337, Road No. 3, Banjara Hills, Hyderabad – 500 034, Telangana, India (the "**Seller**") and BioDelivery Sciences International, Inc., a Delaware corporation having its principal place of business located at 4131 ParkLake Ave., Suite 225, Raleigh, NC (the "**Purchaser**"). The Seller and the Purchaser may be collectively referred to herein as the "**Parties**" and each, individually, as a "**Party**".

RECITALS

WHEREAS, the Seller desires to sell, transfer and assign to the Purchaser, and the Purchaser desires to acquire from the Seller, all of the Purchased Assets within the Territory, all as more specifically described herein and subject to the terms and conditions 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 1
DEFINITIONS AND INTERPRETATION

Section 1.1 Defined Terms. Capitalized terms used in this Agreement have the meanings specified in Schedule 1.01 to this Agreement.

Section 1.2 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 assign 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.

(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 Seller 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; LICENSE GRANTS

Section 2.1 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 (and, as applicable, shall cause its applicable Affiliates to) sell, convey, deliver, transfer and assign to the Purchaser, and the Purchaser shall purchase, acquire and assume from the Seller (and its applicable Affiliates), all of the Seller's (and its applicable Affiliates') right, title, and interest in the Purchased Assets in the Territory, 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 (and its applicable Affiliates) is not selling, conveying, transferring, or assigning, any other assets or properties of the Seller (or any of the Seller's Affiliates), 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 or any of the Seller's Affiliates (the "**Excluded Liabilities**"). Without limiting the generality of the foregoing, the Excluded Liabilities shall include any Liability for Excluded Taxes.

(e) **Consents**.

(i) Notwithstanding any other provision of this Agreement, this Agreement does not constitute an agreement to sell, convey, assign, assume, transfer or deliver any interest in any asset that would be a Purchased Asset, or any claim or right of any benefit arising thereunder or resulting therefrom, if an attempted direct or indirect assignment thereof, or agreement to sell, convey, assign, assume, transfer or deliver any such asset, without the Consent of any Third Party, (A) would violate applicable Laws or constitute a breach or other contravention of the rights of such Third Party (including any Governmental Authority), (B) would be ineffective with respect to any Party to an agreement concerning such asset, or (C) would in any way adversely affect the contractual rights of the Seller (and/or the Seller's Affiliates, as applicable), or upon transfer, the Purchaser in connection with such asset. If any direct or indirect transfer or assignment or agreement to do so by the Seller (and/or the Seller's Affiliates, as applicable) of, or any direct or indirect assumption by the Purchaser of, any interest in, or liability, obligation or commitment under, any Purchased Asset requires the Consent of a Third Party, then such transfer, assignment or assumption or agreement to do so shall be made subject to such Consent being obtained.

(ii) The Purchaser acknowledges that certain Consents to the transactions contemplated by this Agreement may be required from counterparties to Contracts and that such Consents may not be obtained prior to Closing. In the event that such required Consent is not obtained, notwithstanding any other provision to the contrary set forth in this Agreement, the Purchaser agrees that the Seller shall not have any Liability whatsoever arising out of or relating to the failure to obtain any Consents that may have been or may be required in connection with the transactions contemplated by this Agreement or because of the default under or acceleration or termination of any Contract as a result thereof. The Purchaser further agrees that no representation, warranty or covenant of the Seller contained herein shall be breached or deemed breached, and no condition to the Purchaser's obligations to close the transactions contemplated by this Agreement shall be deemed not satisfied, as a result of (i) the failure to obtain any such Consent or as a result of any such default, acceleration or termination; or (ii) any Legal Proceeding commenced or threatened by or on behalf of any Person arising out of or relating to the failure to obtain any Consent or any such default, acceleration or termination.

(iii) If any Consent referred to in Section 2.01(e)(i) is not obtained prior to the Closing, the Closing shall nonetheless take place without any adjustment of the Purchase Price on account thereof, and thereafter each of the Seller and the Purchaser shall use commercially reasonable efforts (A) to endeavor to obtain such Consent (provided that neither the Seller nor the Purchaser shall be required to expend money, commence, defend or participate in any litigation or offer or grant any accommodation (financial or otherwise) to any Third Party), and (B) to cooperate, upon written request of the Purchaser, in endeavoring to obtain for the Purchaser, at no cost to the Seller, an arrangement to provide to the Purchaser, in compliance with Law, substantially

comparable benefits thereof; provided that the Purchaser shall indemnify the Seller in respect of all Liabilities of the Seller relating to each such arrangement. Upon obtaining the requisite Consent, such Purchased Asset shall be transferred and assigned to the Purchaser hereunder, for no additional consideration.

(f) **FDA Letters**.

(i) Within five [***] of the Closing, the Seller shall submit the Seller FDA Letter to the FDA, notifying the FDA that the Acquired Regulatory Approvals have been transferred to Purchaser.

(ii) Within [***] of the Closing, the Purchaser shall submit the Purchaser FDA Letter to the FDA, notifying the FDA that the Acquired Regulatory Approvals have been accepted by the Purchaser.

(g) **Transfer of Purchased Assets**. As soon as practicable following the Closing, but in no event more than [***] following the Closing, the Seller shall make available to the Purchaser electronically all Purchased Assets held electronically. Within [***] after the Closing, the Seller shall make available to the Purchaser all tangible Purchased Assets in the Seller's possession, for pick-up at the Seller's facilities, at the Purchaser's sole cost, expense and risk; provided, that if the Seller finds, locates, discovers or otherwise becomes aware that it possesses any Purchased Assets after the Closing, 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.

(h) **Proration Schedule**. Schedule 2.01(h) (the "**Estimated Proration Schedule**") sets forth certain deposits, advances and other prepaid items, which includes certain expenses that Seller or its respective Affiliates have paid or that are required to be paid by the Seller (or their applicable Affiliates) by Law or contractual obligation, and which shall be prorated and estimated as of the projected Closing. [***] prior to the Closing, the Seller shall provide the Purchaser with an updated Estimated Proration Schedule, which shall be deemed the final Proration Schedule (the "**Proration Schedule**"), and which shall be updated and prorated as of the Closing. At the 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.

Section 2.2 License Grants.

(a) **Grants to Purchaser.** Effective as of the Closing, Seller hereby grants to the Purchaser and its Affiliates an irrevocable, royalty-free, exclusive (even as to the Seller and its Affiliates), perpetual, transferable and sublicensable (through multiple tiers) license under the DRL Background Technology solely to Exploit and have Exploited Products solely in or for the Territory, including to manufacture Products for the marketing and sale solely for the Territory, and not for any other use (including any commercialization) in the Retained Territory. For the avoidance of doubt, Purchaser shall not use DRL Background Technology for any product, compounds, assets or any uses other than with respect to Products.

(b) **Grants to Seller.** Effective as of the Closing, Purchaser hereby grants to Seller and its Affiliates an irrevocable, royalty-free, sublicensable (through multiple tiers), transferable, exclusive (even as to the Purchaser and its Affiliates) perpetual (i) license under the Product Intellectual Property (including any Improvements, Improvement Know-How and Improvement Patents) to Exploit and have Exploited Products solely in or for the Retained Territory (except that the grant herein shall not prevent the Seller, its Affiliates or their respective licensees and sublicenses, from manufacturing or having manufactured Product in the Territory for commercial sale in the Retained Territory) and (ii) license and right of reference under the Acquired Regulatory Approvals, all Regulatory Approvals relating to the Products, all Regulatory Documentation relating to the Products, and any other information relating to the Product, with the right to grant sublicenses and further rights of reference, solely to Exploit and have Exploited the Product in, or for, the Retained Territories.

(c) The Parties shall, upon reasonable request from the other Party hereto, provide each other with reasonable assistance and cooperation, including, without limitation, providing copies and reasonable access to documents and information, to enable the other Party to enjoy the rights granted in this Section 2.02.

Section 2.3 Further Expenses and Studies; Post-Approval Commitment Studies; Other Commitments. Upon the Closing, the Purchaser shall be responsible for any and all further developmental activities relating to the Product and Acquired Regulatory Approvals in or for the Territory, including any Post-Approval Commitment Studies and all obligations and expenses relating thereto. Seller shall transfer all related regulatory documentation related to these studies, which shall be deemed Regulatory Documentation.

ARTICLE III

PURCHASE PRICE

Section 3.1 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) Six Million Dollars ($6,000,000.00) in respect of the Purchased Assets (the "**Upfront Payment**") and the assumption of the Assumed Liabilities;

(ii) the Milestone Payments, as and to the extent provided in Section 3.01(b);

(iii) the Quarterly Earn-Out Payment(s), as and to the extent provided in Section 3.01(c); and

(iv) the Purchaser's Prorated Portion.

(b) Milestone Payments. In addition to the Cash Consideration, the assumption of the Assumed Liabilities and the Quarterly Earn-Out Payments, and subject to this Section 3.01(b), the Purchaser shall pay to the Seller the following non-refundable, non-creditable amounts (each,

a "**Milestone Payment**") upon the achievement by or on behalf of the Purchaser or its Affiliates, licensees, sublicensees or transferees, if any, of the following events (each, a "**Milestone Event**"):

	Table 3.01(b)	
No.	**Milestone Event**	**Milestone Payment**
	Upon the twelve (12) month anniversary of the Effective Date	Nine Million Dollars ($9,000,000.00)
	Upon the acceptance by the FDA of a Regulatory Approval Application with respect to a Product in an Acute Pain Indication	[***]
	Upon the receipt of Regulatory Approval by the FDA of a Product in an Acute Pain Indication	[***]
	Upon the receipt of Regulatory Approval by Health Canada of a Product in the Migraine Indication	[***]
	Upon the receipt of Regulatory Approval by Health Canada of a Product in an Acute Pain Indication	[***]
	Upon the achievement of Net Sales of Fifty Million Dollars ($50,000,000.00) in a Calendar Year	Four Million Dollars ($4,000,000.00)
	Upon the achievement of Net Sales of [***] in a Calendar Year	[***]
	Upon the achievement of Net Sales of [***] in a Calendar Year	[***]
	Upon the achievement of Net Sales of [***] in a Calendar Year	[***]
	Upon the achievement of Net Sales of [***] in a Calendar Year	[***]
	Upon the achievement of Net Sales of One Billion Dollars ($1,000,000,000.00) in a Calendar Year	One Hundred Million Dollars ($100,000,000.00)

Each Milestone Payment set forth in this Section 3.01(b) is payable only once (*i.e.*, the first time the Milestone Event is achieved) and is non-refundable once paid. For the avoidance of doubt, the calculation of Net Sales shall be cumulative of all countries in the Territory.

(c) Quarterly Earn-Out Payments.

(i) In addition to the Cash Consideration, the assumption of the Assumed Liabilities and the Milestone Payments, and subject to this Section 3.01(c), commencing on the Closing, each Quarter and for the duration of the Earn-Out Term, Purchaser shall pay to the Seller non-refundable, non-creditable amounts based upon the cumulative Net Sales of each Product in the Territory in the applicable Calendar Year to which such Quarter relates (together with such amounts payable pursuant to Section 3.01(c), each payment a "**Quarterly Earn-Out Payment**"). Such Quarterly Earn-Out Payment shall be calculated by multiplying the applicable rate set forth in Table 3.01(c) below (the "**Quarterly Earn-Out Rate**") by the aggregate Net Sales of Products in the Territory in an applicable Quarter:

Table 3.01(c)		
No.	**Aggregate Annual Net Sales**	**Quarterly Earn-Out Rate**
1.	For that portion of Net Sales in a Calendar Year up to and including [***]	[***]
2.	For that portion of Net Sales in a Calendar Year that is greater than [***]	[***]

(ii) Quarterly Earn-Out Payments shall be paid pursuant to Section 3.01(c)(i) as from the Closing and until the earlier to occur of, with respect to each Product in each Territory, [***] (the "**Earn-Out Term**"), subject to 3.01(c)(iii) below. For the avoidance of doubt, the Purchaser shall be liable to make Quarterly Earn-Out Payments pursuant to Section 3.01(c)(i) for the Quarter during which such event terminating the obligation to make such Quarterly Earn-Out Payment occurs as long as the Product is sold during such Quarter.

(iii) For the avoidance of doubt, following the Closing, additional strengths of a Product (whether or not such Product is associated with the Acquired Regulatory Approval) shall not be considered an additional "Product" for the purposes of calculating Quarterly Earn-Out Payments, provided, however that (i) the Migraine Indication and Acute Pain Indication shall be considered separate Products, and the Earn-Out Term for each such Product shall run separately and (ii) all indications other than the Migraine Indication and Acute Pain Indication shall only be considered separate Products if marketing of such Product is based on a new Regulatory Approval that is not an amendment or supplement to an existing Regulatory Approval. The Earn-Out Term for Products embodying such additional indications (other than the Acute Pain Indication) or additional strength shall run with the underlying Product from which such additional indication (other than the Acute Pain Indication) or additional strength is derived.

(iv) Blended Rate. The Parties acknowledge and agree that, the Quarterly Earn-Out Rates agreed upon by the Parties for the Product(s) have been blended to take into consideration, the Quarterly Earn-Out Rate that [***]. The Parties recognize that the differing the Quarterly Earn-Out Rate that could apply to such period would last for differing time periods. Therefore the Parties have determined to use the blended Quarterly Earn-Out Rate in this Agreement for reasons of convenience, and the use of such blended rates during a single term is advantageous to both Parties.

(v) For the purposes of calculating Net Sales with respect to Quarterly Earn-Out Payments and Milestone Events in countries and/or jurisdictions within the Territory other than the United States, the rate of exchange to be used in computing the amount of currency equivalent in United States Dollars shall be made at the exchange rate as published by the Wall Street Journal for the last Business Day of such applicable Quarter

period in which such Net Sales occurred, or such other source as the Parties may mutually agree in writing.

Section 3.2 Payment Terms; Transfer Taxes.

(a) Payment of the Purchase Price.

(i) The Purchaser shall pay the Cash Consideration at Closing, by wire transfer of immediately available funds to an account designated in writing by the Seller.

(ii) Each Milestone Payment due and payable under Section 3.01(b) shall be paid by the Purchaser to the Seller promptly (but no more than [***] following the occurrence of the corresponding Milestone Event. The Purchaser shall provide a notice to the Seller of the occurrence of the Milestone Event set forth in Section 3.01(b)(i) prior to, or no later than on, the date of the payment of the corresponding Milestone Payment.

(iii) Each of the Quarterly Earn-Out Payments due and payable under Section 3.01(c) shall be paid by the Purchaser to the Seller promptly, but no more than (A) [***] following the end of the Quarter to which they relate to, other than with respect to any Quarter ending on December 31, and (B) for each Quarter ended December 31, [***] following the end of each such Quarter. The Purchaser shall provide a notice to the Seller prior to, or no later than on, the date such of payment, which notice shall provide sufficient details to permit confirmation by the Seller of the accuracy of the payments made.

(iv) Purchaser shall be entitled to deduct and withhold from the consideration otherwise payable pursuant to this Agreement such amounts that it is required to deduct and withhold with respect to the making of such payment under the Code or any other applicable Law. To the extent that amounts are so withheld, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of which such deduction and withholding was made by Purchaser. If the Seller is eligible for benefits under the Tax Treaty (or any applicable tax treaty), the withholding tax rate applicable will be the withholding tax rate prescribed under such Tax Treaty. The Parties agree that (i) no withholding tax shall apply for Upfront Payment and Milestone No. 1 and (ii) the maximum withholding tax, as of the Closing, is fifteen percent (15%), unless required by a change in applicable Law and provided a W8 BEN claiming such rate is provided. Following the Closing, Seller shall deliver to Purchaser a properly completed and validly executed Internal Revenue Service Form W-8BEN-E. The Parties shall provide each other with any other tax forms that may be reasonably necessary in order for Purchaser not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty (including the Tax Treaty) a reasonable time prior to the date the applicable payment is due. Purchaser shall provide Seller with reasonable assistance to enable the recovery, as permitted by applicable Law, of withholding taxes, value added taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Purchaser.

(b) Mode of Payment. All payments to the Seller under this Agreement shall be made by way of direct wire transfer of immediately available funds, in Dollars, in the requisite amount to such bank account as the Seller may from time to time designate by notice to the Purchaser.

(c) Transfer Taxes. 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, including all recording or filing fees and other similar costs of the Closing, that may be imposed, payable, collectible or incurred, shall be borne by the Purchaser. The Parties hereto agree to reasonably cooperate with each other to claim any applicable exemption from, or reduction of, any applicable Transfer Taxes.

Section 3.3 Additional Covenants relating to the Milestone Payments and Quarterly Earn-Out Payments.

(a) From the Closing and during the applicable Earn-Out Term for the Product in the Migraine Indication, the Purchaser and its Affiliates (or their permitted transferees, licensees or sublicensees) shall use Commercially Reasonable Efforts in order to commercialize the Product in the Migraine Indication in each country within the Territory.

(b) From and after the [***] of the launch of the Product in the Migraine Indication in the United States, Purchaser shall use Commercially Reasonable Efforts to develop, obtain Regulatory Approval, and launch, commercialize, sell and market the Product in the Acute Pain Indication in each country within the Territory during the Earn-Out Term for such Product. Purchaser shall notify Seller promptly, in writing, upon making any determination that it is no longer Commercially Reasonable to develop, obtain Regulatory Approval, launch or commercialize the Product in the Acute Pain Indication in either or both of the United States or Canada. Notwithstanding the foregoing, Purchaser shall use Commercially Reasonable Efforts to launch the Product in the Migraine Indication in the United States on or before [***] anniversary of the Closing.

(c) The Purchaser shall not fail to take, or take, any actions where the primary intent of such action or inaction is to avoid the achievement of any of the Milestone Events or Quarterly Earn-Out Payments or to reduce the amount of any of the Quarterly Earn-Out Payments, including, without limitation, intentionally delaying sales or incentivizing customers to delay placing orders.

(d) The Purchaser shall, and shall cause its Affiliates, permitted transferees, licensees and sublicensees to keep reasonable, correct and complete books, records and documents (whether in hardcopy, electronic or other form) substantiating the achievement (or non-achievement) of the Milestone Event set forth in Section 3.01(b)(i) and the Net Sales amounts recognized in each Calendar Year for the Product in each country of the Territory, as related to the Quarterly Earn-Out Payments (the "**Milestone and Earn-Out Information**") and shall maintain such Milestone and Earn-Out Information until [***] following the end of the Calendar Year to which such Milestone and Earn-Out Information relates.

(e) Until the first Calendar Year following the Calendar Year in which the Earn-Out Term expires, the Purchaser shall provide the Seller, (A) on a Quarterly basis, not later than [***] after the end of each Quarter, an estimate of the aggregate gross sales and Net Sales of the Product in each country of the Territory for such Quarter; and (B) (i) on a Quarterly basis, not later than [***] after the end of each Quarter other than the Quarter ended December 31, and [***] after the end of each Quarter ended December 31, the Quarterly Sales Reports; and (ii) on an annual basis, not later than [***] after the end of each Calendar Year, the annual Sales Report. "**Sales Reports**" shall mean reasonably detailed Quarterly and annual reports of the aggregate gross sales and Net Sales of the Product in each country of the Territory, for such Quarter or Calendar Year, as applicable. All Sales Reports shall also include separate line items for the gross sales and the Net Sales of the Product, in each case per country of the Territory. The expiration of the Purchaser's obligation to provide Sales Reports to the Seller under this Section 3.03(e) shall not be deemed a waiver of any obligation to pay any Milestone Payments if and when they become payable.

(f) From the Closing until the expiration of the Earn-Out Term, Purchaser shall maintain complete and accurate books, records and documents (whether in hardcopy, electronic or other form) in sufficient detail to permit the verification of Purchaser's compliance with its obligations under Section 3.01(b), Section 3.01(c), and Section 3.03(d) and the Sales Reports (the "**Books and Records**"). Once every [***] upon no less than [***] written notice and during normal business hours, the Books and Records shall be open for examination by an independent certified public accountant reasonably acceptable to Purchaser for the sole purpose of verifying Purchaser's compliance with its obligations under Section 3.01(b), Section 3.01(c), and Section 3.03(d) and the Sales Reports. Any such auditor shall not disclose Purchaser's confidential information to Seller, except to the extent such disclosure is necessary to verify Purchaser's compliance with its obligations under Section 3.01(b), Section 3.01(c) and Section 3.03(d) and the Sales Reports. All expenses and costs associated with the review and audit in this Section 3.03(f) shall be borne solely by the Seller; provided that in the event that such review and audit results in a finding and determination that a Milestone Payment or Quarterly Earn-Out Payment payable was not otherwise paid or that the amount paid was lower by more than [***] than the amount that should have been paid, then the expenses and costs of such review and audit (including reasonable attorney's fees) shall be borne and paid by the Purchaser. All amounts due to the Seller as shown by the audit (that have not been previously paid by Purchaser to Seller) shall be paid within [***] following the receipt by Purchaser of a copy of the final audit report. Purchaser will use best efforts to include in all sublicenses granted with respect to the Product, an audit provision substantially similar to the foregoing requiring such sublicensee to keep full and accurate books and records relating to the Product and granting Seller the right to audit the accuracy of the information reported by any sublicensee in connection therewith in accordance with terms and conditions substantially similar to those provided in this Section above.

(g) From the Closing until the Seller has received all Milestone Payments and Quarterly Earn-Out Payments, the Purchaser and its Affiliates shall not without the prior written consent of the Seller, sell, assign, exclusively license or otherwise transfer ownership of any of the Purchased Assets to any Person; provided that, (i) such consent shall not be unreasonably withheld, conditioned or delayed (provided, that all transferees of any such rights and/or

Purchased Assets shall assume all of the obligations of Purchaser and its Affiliates under this Agreement as applicable to such rights and/or Purchased Assets being transferred to such Person, including, but not limited to, obligations under Section 3.01, Section 3.02, the license set forth in Section 2.02(b), Section 7.01, ARTICLE IX) and (ii) no such consent shall be required for such sale, license, assignment, or transfer to any Person who agrees in writing to be bound by the terms of, and to assume all obligations of Purchaser and its Affiliates under this Agreement and the other Transaction Documents, including obligations under ARTICLE III and the license set forth in Section 2.02(b). Nothing contained herein shall release the Purchaser from its obligations under this Agreement or any other Transaction Document after any sale, exclusive license, assignment or transfer of ownership of any Purchased Assets or Assumed Liabilities and Purchaser hereby expressly agrees that it shall remain liable under this Agreement and the other Transaction Documents following any assignment or exclusive license for the full and complete performance of all obligations arising hereunder or thereunder.

(h) During the Earn-Out Term, once annually until all Approval Milestones have been achieved, Purchaser shall meet and confer with Seller and update Seller on the status of the Approval Milestones. Prior to such meeting, Purchaser shall deliver to Seller a written report in reasonable detail setting forth for the efforts undertaken with respect to such Approval Milestones and an update on the status of all Approval Milestones.

ARTICLE IV

CLOSING

Section 4.1 Closing. 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, at such time and place as the Parties mutually agree, orally or in writing, which shall not be later than [***] following satisfaction of the conditions set forth in Section 4.02. The Closing shall be deemed to be effective as of 12:00:01 a.m. eastern time on the date of the Closing (the "**Closing Date**").

Section 4.2 Closing Deliverables.

(a) The obligations of Purchaser to consummate the transactions contemplated hereby at Closing are subject to the fulfillment, on or before the Closing, of each of the following conditions unless waived by the Purchaser:

(i) Solely during the period beginning on the Effective Date and ending on the Outside Date, the waiting period (and any extension thereof) applicable to the consummation of the transactions contemplated by this Agreement under the HSR Act shall have expired or otherwise been terminated;

(ii) The Seller shall have delivered the Bill of Sale & Assignment and Assumption Agreement, duly executed by an authorized officer of the Seller;

(iii) The Seller shall have delivered the Transition Services Agreement, duly executed by an authorized officer of the Seller;

(iv) The Seller shall have delivered (or caused to be delivered) each of the Intellectual Property Assignment Agreements, duly executed by an authorized officer of the Seller or Dr. Reddy's Laboratories, Inc., as applicable; and

(v) The Seller shall have delivered such other documents as the Purchaser may reasonably request to give effect to this Agreement.

(b) The obligations of Seller to consummate the transactions contemplated hereby at Closing are subject to the fulfillment, on or before the Closing, of each of the following conditions unless waived by the Seller:

(i) Solely during the period beginning on the Effective Date and ending on the Outside Date, the waiting period (and any extension thereof) applicable to the consummation of the transactions contemplated by this Agreement under the HSR Act shall have expired or otherwise been terminated;

(ii) Purchaser shall have delivered the payment of the Cash Consideration in accordance with Section 3.02(b);

(iii) Purchaser shall have delivered the Bill of Sale & Assignment and Assumption Agreement, duly executed by an authorized officer of the Purchaser;

(iv) Purchaser shall have delivered the Transition Services Agreement, duly executed by an authorized officer of the Seller;

(v) Purchaser shall have delivered each of the Intellectual Property Assignment Agreement, duly executed by an authorized officer of the Purchaser;

(vi) Purchaser shall have delivered such other documents as the Seller may reasonably request to give effect to this Agreement.

(c) At least [***] prior to the Closing, the Purchaser shall have delivered a purchase order to the Seller pursuant to which the Seller shall transfer, effective as of and subject to the Closing, such identified engineering batches of Product that are and located at the Seller's contract manufacturing organization in consideration of Purchaser's fulfillment of its obligations at Closing pursuant to this Agreement, duly executed by an authorized officer of the Purchaser.

ARTICLE V

REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the disclosure schedules attached hereto (the "**Seller Disclosure Schedules**"), but subject to the immediately following sentence, 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 (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). Notwithstanding the foregoing, it is expressly understood and acknowledged that any information disclosed in the

Seller Disclosure Schedule under any numbered or lettered schedule, section, or subsection shall be deemed to relate to and qualify such schedule, section or subsection, as well as any other schedule, sections or subsections of the Seller Disclosure Schedule, but only where the relevance of such disclosure to such other schedule, section or subsection is reasonably apparent from the text of such disclosure.

Section 5.1 Organization. The Seller is a company duly organized, validly existing and in good standing under the Laws of India. The Seller has the requisite power and authority to own and operate the Purchased Assets. The Seller is duly qualified to do business and in good standing in each jurisdiction where the ownership of the Purchased Assets requires such qualification, except where such failure to qualify would not result in Material Adverse Effect.

Section 5.2 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 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) This Agreement and the other Transaction Documents to which the Seller is a Party have been duly executed and delivered by the Seller, and each constitutes a legal, valid and binding obligation of the Seller, enforceable against it in accordance with its respective terms, 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 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) constitute a material breach, materially violate the terms, conditions or provisions of, or result in a material default under, or give to others any rights of termination, amendment, acceleration or cancellation of, or notice with regard to, any agreement to which the Seller is a party or is otherwise bound, (iii) result in the creation of any Encumbrance (except for Permitted Encumbrances) upon the Purchased Assets or (iv) violate any provision of any Laws; except in the cases of clause (ii), where the violation, breach, default, grants to others of any rights of termination, amendment, acceleration or cancellation of, or notice would not have a Material Adverse Effect, individually or in the aggregate.

(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 Seller is required in connection with the execution or delivery by the Seller of this

Agreement as of the Closing, or the consummation of the transactions contemplated hereby, other than (i) the FDA Letters and (ii) compliance with and filings under the HSR Act.

Section 5.3 Purchased Assets. The Seller (and its applicable Affiliates) are 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; and to the Knowledge of the Seller, no Person is infringing or otherwise violating any of the Purchased Assets. Upon Closing, good and marketable title to the Purchased Assets will pass to Purchaser, free and clear of all Encumbrances other than Permitted Encumbrances.

Section 5.4 Acquired Contracts.

(a) Each Acquired Contract is a valid and binding obligation of the Seller who is a party thereto and, to the Knowledge of the Seller, each other party thereto, and is enforceable against the Seller who is a party thereto 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) 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. 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.

(c) All Consents required for the sale, conveyance, transfer and delivery of the Acquired Contracts to Purchaser pursuant to this Agreement have been obtained.

Section 5.5 Compliance with Law; Permits; Regulatory Matters.

(a) The Acquired Regulatory Approvals are in full force and effect. All maintenance, fees under the Prescription Drug User Fee Act (as amended), and other fees related to the Acquired Regulatory Approvals occurring or accruing prior to the Closing Date have been paid. All Acquired Regulatory Approvals and all related records have been maintained in accordance with all applicable Laws.

(b) The Business and the Seller's use of the Purchased Assets is being, and has been, conducted in compliance with the Acquired Regulatory Approvals and all applicable Laws, except where the failure to be in compliance would not have a Material Adverse Effect. No loss, revocation, termination, suspension, material modification 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.

(c) The Existing Product is being and has been developed, tested, manufactured and stored, as applicable, in material compliance with applicable Law, including those requirements relating to good manufacturing practice, good laboratory practice and good clinical practice. Neither the Seller nor any of its Affiliates 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, any attorney general of any jurisdiction, alleging that the Seller has been or is in violation of any healthcare or regulatory Law, the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Act (42 U.S.C. § 1320a-7b(a)) or false claims acts under comparable foreign, supranational, state or local Law, or commencing or indicating an intention to conduct an investigation, audit, or review; (ii) written notice of inspectional observation (including those recorded on FDA Form 483), warning letter, penalty, fine, sanction, request for recall or other written request for remedial action in connection with the Purchased Assets; (iii) other written documents issued by the FDA or any other Governmental Authority alleging lack of compliance with any healthcare of regulatory Law by the Seller or any Person engaged by the Seller to provide any service with respect to the Existing Product or (iv) written notice from the FDA recommending or requiring the submission of a 505(b)(2) NDA with respect to the Existing Product. Solely with respect to the Existing Product, the Seller has not, either voluntarily or involuntarily, initiated, conducted or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of the Existing Product or any alleged product defect or violation and, to the Knowledge of the Seller, no Third Party has initiated or conducted any such notice or action.

(d) The Existing Product has not been sold, advertised for sale or distributed for commercial purposes by or on behalf of the Seller or its Affiliates in the Territory.

(e) All reports, documents, claims and notices required to be filed, maintained, or furnished to the FDA or any other Regulatory Authority by the Seller with respect to the Existing Product 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 or made available to Purchaser 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 or Seller's Affiliates from the FDA or similar foreign Governmental Authorities which relate to the Seller's compliance with regulatory requirements of the FDA or similar state, local or foreign Governmental Authorities.

(f) Neither the Seller nor, to the Knowledge of the Seller, any director, officer, employee or agent of the Seller (including, without limitation, any Person engaged by the Seller to provide any service with respect to the Existing 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 director, officer, employee or agent of the Seller (including, without limitation, any Person engaged by the Seller to provide any service with respect to the Existing Product) has (i) been excluded, suspended, debarred or disqualified by any Governmental Authority, (ii) 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 (iii) 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.

(g) Neither the Seller, nor, to the Knowledge of the Seller, any Affiliate, director, manager, officer, equityholder, 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.

(h) The Seller and its applicable Affiliate(s), if any, have, with respect to the Existing Product, complied in all material respects with all applicable marketing codes of conduct, including federal, state, local and foreign Laws and marketing codes of conduct and the PhRMA Code on Interactions with Health Care Professionals in the [***] prior to the Closing.

(i) Seller has all applicable Permits necessary for the ownership of the Existing Product and the operation of the Business, as currently conducted, except where the failure to possess any such Permit, individually or in the aggregate, would not have a Material Adverse Effect. No proceeding is pending or, to the Knowledge of the Seller, (i) threatened regarding the withdrawal, material modification or revocation of any such Permit. And (ii) Seller has not received any written communication from any Governmental Authority threatening to withdraw, materially modify or suspend any Permit. Seller is not in violation of the terms of any Permit in any material respect.

(j) Seller is not party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders or similar agreements with or imposed by any Governmental Authority relating specifically to the Existing Product.

Section 5.6 Brokers. The Seller has not incurred, nor will it incur, directly or indirectly, any Liability for brokers' or finders' fees or agents' commissions or any similar charges in connection with this Agreement or the consummation of the transactions contemplated hereby.

Section 5.7 Litigation.

(a) There is no action, claim, demand, suit or other assertion by any Person pending or, to the Knowledge of the Seller, threatened in writing against or by the Seller relating to or affecting the Business, the Purchased Assets or the Assumed Liabilities, which if determined adversely to the Seller would result in a Material Adverse Effect. There is no Legal Proceeding pending or, to the Knowledge of the Seller, threatened that is reasonably likely to prohibit or restrain the ability of the Seller to enter into this Agreement or consummate the transactions contemplated hereby.

(b) The Seller is not a party or subject to the provisions of any Governmental Order that is unsatisfied or that affects the Business or Purchased Assets which has or would reasonably be expected to have a Material Adverse Effect.

Section 5.8 Intellectual Property.

(a) The Exploitation of the Existing Product and practice of (i) the Product Know-How does not misappropriate, and, (ii) to the Knowledge of the Seller, neither the Patents nor the registered trademarks, service marks, logos, slogans and trade names that comprise the Product Intellectual Property do not, infringe, in each case (i) and (ii), any intellectual property rights owned by any Third Party in the Territory.

(b) No action, claim, demand, suit or other assertion by any Person is pending, or to the Knowledge of the Seller, has been threatened in writing as of the Effective Date against the Seller or any of its Affiliates by any Third Party claiming that the (i) Product Intellectual Property, or (ii) the Exploitation of the Product infringes or misappropriates the Intellectual Property rights of such Third Party in the Territory. To the Knowledge of the Seller, no Third Party is infringing or misappropriating any of the Purchased Assets.

(c) The Seller exclusively owns the Product Intellectual Property free and clear of all Encumbrances except for Permitted Encumbrances. Other than the grant of rights to manufacture or have manufactured Product in the Territory for commercial sale in the Retained Territory, the Seller has not granted, directly or indirectly, to any Third Party any current or contingent right, license or interest to Exploit the Product or otherwise use or reference any of the Product Intellectual Property in the Territory, nor is the Seller obligated to pay any royalties, licensing fees or other amounts to any Third Party in connection with the use of the Product Intellectual Property or the Exploitation of the Product in or for the Territory. There are no settlements, covenants not to sue, consents, judgments, or orders or similar obligations in the Territory that: (i) restrict the use of any Product Intellectual Property, (ii) restrict the operation of the Business, in order to accommodate a Third Party's Intellectual Property, or (iii) permit Third Parties to use or reference any Product Intellectual Property.

(d) All Product Patents and Product Trademarks that have been issued by, or registered with, or the subject of an application filed with, as applicable, the U.S. Patent and Trademark Office, the U.S. Copyright Office or any similar office or agency anywhere in Canada have been duly maintained (including the payment of maintenance fees) and are not expired, cancelled or abandoned; and, to the Knowledge of the Seller, all Product Patents and Product

Trademarks are valid and enforceable. None of the Product Intellectual Property is subject to any maintenance fees or actions falling due within [***] of the Effective Date.

(e) Seller has not received any written notice stating that any Product Patent has been or is now involved in any reissue, reexamination, inter-partes review, post-grant review, or opposition proceeding; all Products made, used or sold under the Product Patents have been marked with the proper patent notice.

(f) Seller and its Affiliates have taken reasonable security measures to protect the confidentiality of all DRL Background Know-How and Product Know-How, including, without limitation, requiring all employees and consultants and all other Persons with access to DRL Background Know-How and Product Know-How to execute a confidentiality agreement and, to the Knowledge of the Seller, there has not been any breach by any party to any such confidentiality agreement.

(g) The Product Patents are the only Patents Controlled by the Seller or its Affiliates that Cover the Exploitation of the Product in or for the Territory.

Section 5.9 Taxes.

(a) There are no liens for Taxes (other than liens for Taxes not yet due and payable) on any of the Purchased Assets.

(b) None of the Purchased Assets consists of an equity interest in any entity treated as a partnership or corporation for U.S. federal income Tax purposes.

(c) None of the Purchased Assets is a "United States real property interest" within the meaning of Section 897(c)(1) of the Code.

Section 5.10 No Other Representations and Warranties. Except for the representations and warranties contained in this ARTICLE V, the Seller has not made 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 or the Purchased Assets furnished or made available to the Purchaser or its representatives.

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 date hereof.

Section 6.1 Organization and Authority of the Purchaser. 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. 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 Purchaser to consummate the transactions contemplated by this Agreement and the other Transaction Documents.

Section 6.2 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, 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 breach, violate the terms, conditions or provisions of, or result in a default under, or give to others 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.

(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 compliance with and filings under the HSR Act.

Section 6.3 Legal Proceedings. There are no Legal Proceedings pending or, to the Knowledge of the Purchaser, threatened against or by Purchaser or any Affiliate of 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 6.4 Sufficiency of Funds. The Purchaser has sufficient cash, available lines of credit or other sources of immediately available funds to enable it to timely make payment of the Purchase Price and consummate the transactions contemplated by this Agreement.

Section 6.5 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 6.6 Financial Statements. Complete copies of the Purchaser's audited financial statements consisting of the balance sheet of the Purchaser as at December 31, 2020 and as at December 31, 2019 and the related statements of income, stockholders' equity and cash flow for the years then ended (the "**Audited Financial Statements**"), and unaudited financial statements consisting of the balance sheet of the Purchaser as at March 31, 2021 and the related statements of income and cash flow for the three-month period then ended (the "**Interim Financial Statements**" and together with the Audited Financial Statements, the "**Financial Statements**") have been made available to the Seller by way of the SEC's Electronic Data Gathering Analysis and Retrieval (EDGAR) system. The Audited Financial Statements have been prepared in accordance with GAAP and the Interim Financial Statements have been prepared in accordance with GAAP, both as applied on a consistent basis throughout the period involved, subject, in the case of the Interim Financial Statements, to normal and recurring year-end adjustments (the effect of which will not be materially adverse) and the absence of notes (that, if presented, would not differ materially from those presented in the Audited Financial Statements). The Financial Statements are based on the books and records of the Purchaser, and fairly present the financial condition of the Purchaser as of the respective dates they were prepared and the results of the operations of the Purchaser for the periods indicated. The Purchaser maintains a standard system of accounting established and administered in accordance with GAAP. The Purchaser acknowledges that, in making their decision to enter into this Agreement and the Transaction Documents and to consummate the transactions contemplated hereby and thereby, the Seller is expressly relying on the Purchasers' representations and warranties in this Section 6.06 and that, without such representations and warranties, the Seller would not have entered into this Agreement and the other Transaction Documents or consented to the transactions contemplated hereby and thereby.

Section 6.7 Solvency. Immediately after the Closing, and after giving effect to the transactions contemplated by this Agreement, the Purchaser will be Solvent.

Section 6.8 Status of NDA. Purchaser acknowledges that NDA number 212157 is in a "discontinued" status as of the Effective Date.

Section 6.9 Independent Investigation; No Other Warranties. The Purchaser acknowledges that (a) they have conducted their own independent investigation, review and analysis of the Purchased Assets and have formed an independent judgment concerning the Purchased Assets, the Assumed Liabilities and the other rights or obligations to be transferred under this Agreement, and (b) they have been provided adequate access to the personnel, properties, assets, premises, books and records, and other documents and information of the Seller. The Purchaser further 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 its own investigation and 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 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, the sale of the Purchased Assets is "as is" and "where is," and 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.

ARTICLE VII

COVENANTS

Section 7.1 Confidentiality. From and after the Closing:

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

(b) The Seller shall treat as confidential and shall safeguard any and all Confidential Information of the Purchaser (which shall include information, knowledge, and data regarding the Product, 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 or its Affiliates used with respect thereto prior to the execution of this Agreement. The Seller shall not use the Confidential Information of the Purchaser for any purpose except for the benefit of the Purchaser, unless expressly permitted by this Agreement.

(c) The Purchaser shall treat as confidential and shall safeguard any and all Confidential Information of the Seller relating to the businesses of the Seller, other than the Product, the Purchased Assets, or the Assumed Liabilities, and except as otherwise agreed to by the Seller in writing; provided, however, that nothing in this Section 7.01(c) shall prevent the disclosure of any such Confidential Information to any directors, officers, employees, 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 7.01(c).

(d) 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 7.01 in any court of competent jurisdiction, without the necessity of posting a bond and the burden of proving actual damages.

(e) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws reference to, or a copy of this Agreement with the SEC or other Governmental

Authorities. Each Party may make such a required filing and shall use reasonable efforts to request confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party under applicable Law. In the event of any such filing, each Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent (i) consistent with the legal requirements governing disclosure of material agreements and material information that must be publicly filed, and (ii) provided within [***] after provision of such copy (or such shorter period of time as may be required to comply with applicable Law).

(f) The Parties agree that the existence and terms of this Agreement are the Confidential Information of both Parties.

Section 7.2 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, provided that such books and records are kept confidential in accordance with the Seller's normal confidentiality procedures and the provisions of Section 7.01.

(b) Without prejudice to the provisions of Section 3.03, 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 its Affiliates for the longer of: (i) any applicable statute of limitations; and (ii) a period of [***] from the Closing.

(c) Without prejudice to the provisions of Section 3.03, during such retention period:

(i) the Purchaser shall permit representatives of an applicable Regulatory Authority to have access to and inspect such books and records at Purchaser's place of business, upon reasonable written notice from the Seller to Purchaser reasonably in advance of such inspection, and only in connection with any regulatory examination, quality related inquiry, Legal Proceeding or bona-fide compliance matter, in each case, with respect to the Product outside of the Territory; and

(ii) the Purchaser shall use Commercially Reasonable Efforts, at the Seller's expense, to provide, or cause to be provided to, the Seller with an electronic copy of any such books and records to extent included in the Purchased Assets as of the Closing as the Seller shall reasonably request in connection with any Legal Proceeding to which the Seller or its Affiliates are parties or in connection with the requirements of any Law applicable to them.

(d) No Party shall be obligated to provide the other Party with access to any books or records pursuant to this Section 7.02 where such access would violate any Law or any agreement.

Section 7.3 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 in accordance with Section 2.01(f) and Section 2.01(g). 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 and its Affiliates 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. Each of the Parties shall each make an appropriate filing pursuant to the HSR Act with respect to the transactions contemplated by this Agreement promptly (and in any event, within [***] after the Effective Date and shall supply as promptly as practicable to the appropriate Governmental Authorities any additional information and documentary material that may be requested pursuant to the HSR Act or other applicable antitrust laws.

(c) Notwithstanding anything in this Agreement to the contrary, Purchaser shall take, or cause to be taken, all actions and shall do, or cause to be done, all things necessary, proper or advisable to eliminate each and every impediment under the HSR Act or any other antitrust law that is asserted by any Governmental Authority to permit the Closing to occur as promptly as reasonably practicable and in any event prior to the date that is [***] after the Effective Date or such other date as mutually agreed to by the Parties in writing (such date, the "**Outside Date**"), including: (i) proposing, negotiating, committing to, effecting and agreeing to, by consent decree, hold separate order, or otherwise, the sale, divestiture, license, holding separate, and other disposition of or restrictions on the businesses, assets, properties, product lines, and equity or other business interests of, or changes to the conduct of business of the Purchaser (ii) creating, terminating, unwinding, divesting or assigning, subcontracting or otherwise securing substitute parties for relationships, ventures, and contractual or commercial rights or obligations of the Purchaser and (iii) otherwise taking or committing to take any action that would limit Purchaser's freedom of action with respect to, or its ability to retain, hold or continue, directly or indirectly, any businesses, assets, properties, product lines, and equity or other business interests, relationships, ventures or contractual rights and obligations of the Purchaser. The Purchaser shall

not be required to agree to take or enter into any such action described in clauses (i) through (iii) that is not conditioned upon, or that becomes effective prior to, the Closing.

(d) 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.

(e) Following the Closing, upon request by Purchaser, the Seller will reasonably cooperate with the Purchaser and applicable Regulatory Authorities to enable the Purchaser to effectuate a conversion of NDA number 212157 from "discontinued" status to active or "prescription" marketing status with the FDA in order to effectuate First Commercial Sale by the Purchaser in the United States. All fees and expenses associated with the conversion of NDA number 212157 from "discontinued" status to active or "prescription" marketing status with the FDA, including all fees that were deferred during such discontinued status, shall be borne by the Purchaser.

Section 7.4 Public Announcements. Neither the Seller, the Purchaser nor any of their respective Affiliates 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, including any federal, state or local securities law (including stock exchange rules and regulations) upon the advice of counsel, and only if the disclosing Party (a) provides the non-disclosing Party with an opportunity to first review the release or other public announcement, (b) 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 and (c) after its release, shall provide the non-disclosing Party with a copy thereof. 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 Party and its counsel with a redacted version of this Agreement which it intends to file and any draft correspondence with the SEC requesting the confidential treatment by the SEC of those redacted sections of this Agreement, and will give due consideration to any comments provided by such other Party or its counsel and use commercially reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by such other Party or its counsel. Following the Closing, the Purchaser shall be entitled to make such public announcements as it deems appropriate related to the Product; provided however that except as otherwise provided above, without the Seller's prior written consent, no such announcement shall contain any reference to this Agreement or the terms set forth therein or the Seller, its Affiliates or actions taken with respect to the Product prior to the Closing other than references consistent with those previously approved by the Seller.

Section 7.5 Further Assurances. Except as otherwise set forth in Section 7.03, subject to the terms and conditions set forth herein and to applicable legal requirements, each of the Parties hereto shall, and shall cause its respective Affiliates to, 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, 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. Purchaser shall provide Seller with reasonable assistance and cooperation to enable Seller to respond to any request by any Regulatory Authority in the Retained Territory with respect to the Products.

Section 7.6 Certain Intellectual Property Matters.

(a) The Purchaser shall use Commercially Reasonable Efforts to file, prosecute and maintain the Product Patents in the Territory. The Purchaser shall periodically inform the Seller of all material steps with regard to the preparation, filing, prosecution and maintenance of the Product Patents (including any pending applications included in a Product Patent) in the Territory, including by providing the Seller with a copy of material communications to and from any patent authority regarding such Product Patents and by providing the Seller drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the Seller to review and comment thereon. The Purchaser shall consider in good faith the requests and suggestions of the Seller with respect to such drafts and with respect to strategies for filing and prosecuting such Product Patents.

(b) Any recovery realized because of litigation of the Product Patents or Product (whether by way of settlement or otherwise) shall be first allocated to reimburse Purchaser and Seller for their direct and out of pocket costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by Purchaser and deemed Net Sales for purposes of calculating Quarterly Earn-Out Payments and Milestone Events.

(c) Seller hereby assigns to Purchaser the right solely to file non-provisional applications in the Territory claiming priority to the US Provisional Patent Application No. US63/131,172, and hereby assigns all right, title and interest in all such non-provisional applications in the Territory and all patents issuing therefrom in the Territory. The Parties agree that the Seller retains title and ownership of US Provisional Patent Application No. US63/131,172 for the sole purpose of filing non-provisional applications in the Retained Territory claiming priority to the US Provisional Patent Application No. US63/131,172, and that the Seller retains all right, title and interest in all such non-provisional applications in the Retained Territory and all patents issuing therefrom in the Retained Territory. Seller shall not, directly or indirectly, use or practice US Provisional Patent Application No. US63/131,172 or the subject matter thereof in or for the Territory (except that the grant herein shall not prevent the Seller, its Affiliates or their respective licensees and sublicenses, from manufacturing or having manufactured Product in the Territory for commercial sale in the Retained Territory). The Parties agree to cooperate to take reasonable actions (including executing any relevant documents or notices) in order to enable Purchaser to file any such applications in the Territory and to enable Seller to file any such applications in the Retained Territory.

(d) Each Party shall periodically inform the other Party hereto of all material steps with regard to the preparation, filing, prosecution and maintenance of non-provisional applications filed by or on behalf of such Party based on US Provisional Patent Application No. US63/131,172 in its respective territories, including by providing such other Party with a copy of material communications to and from any patent authority regarding such non-provisional applications filed based on US Provisional Patent Application No. US63/131,172 and by providing the other Party drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for such other Party to review and comment thereon. The filing Party shall consider in good faith the requests and suggestions of the other Party with respect to such drafts and with respect to strategies for filing and prosecuting such non-provisional applications filed based on US Provisional Patent Application No. US63/131,172.

Section 7.7 Pharmacovigilance Agreement; Global Safety Database. Within [***] after the Closing, the Parties shall enter into a separate written pharmacovigilance agreement providing details related to safety and reporting practices and procedures in compliance with all applicable Laws in relation to the Product. Each Party shall, at its sole cost, establish, hold and maintain the safety database for Product in its respective territory. Each Party shall provide the other Party with information in the possession and control of such Party as necessary for the other Party to comply with its pharmacovigilance responsibilities in respect of the Product, in each case, in the form reasonably requested by the other Party. In the event of any inconsistency between the provisions of the pharmacovigilance agreement and the provisions of this Agreement, the wording of the pharmacovigilance agreement shall govern any and all patient safety matters, and this Agreement shall govern all other matters.

Section 7.8 Conduct of Business Pending Closing.

(a) The Seller shall direct [***] to perform the validation activities with respect to the Product for the United States in accordance with Issued [***] issued in favor of [***]. Purchaser will reimburse Seller for its out of pocket costs incurred in performing such validation services from the Effective Date until the Closing Date, and such amounts shall be payable at the Closing or upon the termination of this Agreement, whichever is earlier.

(b) Except for (i) matters set forth in Section 7.08(b) of the Seller Disclosure Schedule, (ii) as consented to by Purchaser (such consent not to be unreasonably withheld, conditioned or delayed) and which consent shall be deemed to be given if, within [***] after the Seller has provided to Purchaser a written request for consent, Purchaser has not rejected such request in writing, (iii) any actions or omissions taken reasonably and in good faith in response to the COVID-19 virus (SARS-COV-2) (or related strains, variations, and sequences) or related Governmental Order or action by a Governmental Authority in relation thereto, (iv) as required by applicable Laws, or (v) as otherwise contemplated by the terms of the Transaction Documents, from the Effective Date until the Closing or earlier termination of this Agreement, Seller shall: (a) conduct its business with respect to the Purchased Assets in the ordinary course of business consistent with past practice; and (b) not sell, transfer, license, permit to lapse or otherwise dispose of any Purchased Assets.

(c) Other than as expressly contemplated by this Agreement, during the period from the Effective Date until the earlier of (a) the date this Agreement is terminated in accordance with its terms and (b) the Closing, the Seller shall not, and shall cause its directors, officers, employees, founders, agents and advisors not to, directly or indirectly, solicit, knowingly encourage or accept any offers for the purchase, license or acquisition of any of the Purchased Assets (other than as expressly contemplated by this Agreement and such activities that are otherwise immaterial).

ARTICLE VIII

RESERVED

ARTICLE IX

INDEMNIFICATION

Section 9.1 Survival. The representations and warranties contained in ARTICLE V and ARTICLE VI of this Agreement shall survive the Closing until the close of business on the [***]. All covenants and agreements contained in this Agreement, whether of the Purchaser or the Seller, shall survive the Effective Date [***] or until [***]. Any claims for Losses arising out of or caused by or relating to fraud shall survive indefinitely. The representations and warranties of the Seller are bargained for assurances. 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, warranties, covenants and agreements, as applicable, 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 9.2 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, directors, officers, stockholders, 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 based upon or arising out of:

(a) any inaccuracy in or breach of any of the representations or warranties of the Seller contained in this Agreement, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Effective Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

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

(c) any Excluded Asset or Excluded Liability.

Section 9.3 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, directors, officers, stockholders, 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 based upon or arising out of:

(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, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Effective Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

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

(c) any Assumed Liability; or

(d) the Exploitation, development, manufacture, supply, marketing or distribution of the Product following the Closing.

Section 9.4 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 Purchaser shall provide notice and an opportunity to comment to the Seller before the Purchaser 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. In the event the Purchaser is required to file such a report, notification or filing immediately, the Purchaser shall provide simultaneous notice to the Seller when it submits such report, notification or filing to the applicable Governmental Authority.

Section 9.5 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. 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 [***] after receipt of any notice issued pursuant to Section 9.05(a), 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 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 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 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 9.6 Limitations on Indemnification; Limitations on Liability.

(a) 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 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 [***] (the "**Indemnity Threshold**"), and then the Seller shall only be liable to provide indemnification to the extent exceeding the Indemnity Threshold. No Losses shall be included in determining whether the 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) 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 [***] (the "**Cap**") that has been actually paid by the Purchaser to the Seller pursuant to this Agreement. Notwithstanding anything to the contrary herein, with respect to breaches by Seller of Section 5.01 [***] the Cap shall be an amount [***].

Section 9.7 Exclusion of Certain Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, NO INDEMNIFYING 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, PROFITS 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 OF ANY LIABILITY RETAINED OR ASSUMED HEREUNDER, PROVIDED, HOWEVER THAT THE FOREGOING WAIVER DOES NOT APPLY TO ANY RIGHT TO INDEMNITY FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT OR PUNITIVE DAMAGES, LOST PROFITS, DIMINUTION IN VALUE OR SIMILAR ITEMS PAYABLE TO THIRD PARTIES PURSUANT TO A THIRD PARTY CLAIM THAT HAVE BEEN AWARDED TO SUCH THIRD PARTY.

Section 9.8 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 Effective Date all written materials furnished or made available, as the case may be, to the Purchaser on or prior to the Effective Date in connection with the transactions contemplated by this Agreement. The Purchaser acknowledges that it and its Affiliates and representatives have been permitted full and complete access to the books and records, and other assets related to the Purchased Assets that it and its representatives have desired or requested to see or review and that it and its representatives have had a full opportunity to meet with the officers and employees of the Seller to discuss the Purchased Assets and the Assumed Liabilities. The Purchaser further acknowledges and agrees that (i) other than the representations and warranties of the Seller specifically contained in ARTICLE V of this Agreement, 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 ARTICLE V of this Agreement 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, other than claims for Losses arising out of, or caused by or relating to fraud, to the Purchaser Group (or any Person who is part of such group) or any other Person, in each case, with respect to any information, documents or materials furnished by the Seller or any of its 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 ARTICLE V of this Agreement). 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 it shall obtain rights in the Purchased Asset in their present condition and state of repair, "as is" and "where is".

Section 9.9 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 under this Agreement as

adjustments to the Purchase Price for Tax purposes to the extent permitted under applicable tax Law.

Section 9.10 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 9.11 Losses Net of Insurance and Tax Benefits. In determining the amount of Losses in respect of a claim under this ARTICLE IX, there shall be deducted an amount equal to any Tax benefit realized or reasonably expected to be realized as a result of such Loss by the Indemnified Party and 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 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 the Indemnifying Party in accordance with the provisions of Section 9.10 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 9.10 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 9.12 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 or any of its Affiliates may have against any other Person with respect to any Losses to which such indemnification payment is directly related.

Section 9.13 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 Product, 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 the knowing and intentional 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 9.13.

ARTICLE X

TERMINATION

Section10.1 Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by mutual written consent of Seller and Purchaser;

(b) by Purchaser, if Seller shall have breached or failed to perform in any material respect any of its representations, warranties, covenants or other agreements contained in this Agreement, and such breach or failure to perform (A) is incapable of being cured prior to the Outside Date or (B) if capable of being cured prior to the Outside Date, has not been cured prior to the date that is the earlier of (x) the Business Day immediately preceding the Outside Date and (y) [***] from the date that Seller is notified in writing by Purchaser of such breach or failure to perform, provided, however, that Purchaser shall not have the right to terminate this Agreement pursuant to this Section 10.01(b) if Purchaser is then in breach of its obligations under Section 7.03(b) or Section 7.03(c); or

(c) by Seller, if Purchaser shall have breached or failed to perform in any material respect any of its representations, warranties, covenants or other agreements contained in this Agreement, and such breach or failure to perform (A) is incapable of being cured prior to the Outside Date or (B) if capable of being cured prior to the Outside Date, has not been cured prior to the date that is the earlier of (x) the Business Day immediately preceding the Outside Date and (y) [***] from the date that Purchaser is notified in writing by Seller of such breach or failure to perform.

Section10.2 Notice of Termination. In the event of termination of this Agreement by either or both of Seller and Purchaser pursuant to Section 10.01, written notice of such termination shall be given by the terminating Party to the other Party.

Section10.3 Effect of Termination. In the event of termination of this Agreement by either or both of Seller and Purchaser pursuant to Section 10.01, this Agreement shall terminate and become void and have no effect. Notwithstanding anything to the contrary contained herein, the provisions of Section 7.01, Section 7.04, Section 7.08(a), ARTICLE IX, and this Section 10.03 shall survive any termination of this Agreement. For the avoidance of doubt, following any termination of this Agreement, Seller shall provide Purchaser with an invoice with respect to its costs incurred in connection with Section 7.08(a), and Purchaser shall pay such invoice within [***] of receipt thereof.

Section10.4 Extension; Waiver. At any time prior to the Closing, either Seller, on the one hand, or Purchaser, on the other hand, may (a) extend the time for performance of any of the obligations or other acts of the other, (b) waive any inaccuracies in the representations and warranties of the other contained in this Agreement or in any document delivered pursuant to this Agreement or (c) waive compliance with any of the agreements or covenants of the other, or conditions for such Party's benefit, contained in this Agreement. Any such extension or waiver

shall be valid only if set forth in an instrument in writing signed by the Party granting such extension or waiver.

ARTICLE XI

MISCELLANEOUS

Section11.1 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.

Section11.2 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 facsimile (with verification of transmission) or email (with confirmation of receipt of the email and any attachments); or (iv) on the [***] 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):

(a) if to the Seller:

Dr. Reddy's Laboratories Limited
8-2-337, Road No. 3
Banjara Hills, Hyderabad – 500 034, Telangana, India
Email: [***]
Attention: Head of Business Development, Proprietary Products

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

Dr. Reddy's Laboratories Limited
8-2-337, Road No. 3
Banjara Hills, Hyderabad – 500 034, Telangana, India
Email: [***]
Attention: General Counsel

Dr. Reddy's Laboratories, Inc.
107 College Road East
Princeton, New Jersey 08540
[***]
Attention: Legal Affairs

Reed Smith LLP
506 Carnegie Center
Suite 300
Princeton, New Jersey 08540
[***]

(b) if to the Purchaser:

BioDelivery Sciences International, Inc.
4131 ParkLake Ave., Suite 225
Raleigh, NC
[***]
Attention: [***], General Counsel

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

BioDelivery Sciences International, Inc.
4131 ParkLake Avenue, Suite #225
Raleigh, NC 27612
Attn: [***], Business Development
Email: [***]

And

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attn: Robert M. Crawford; Robert E. Puopolo
Email: RCrawford@goodwinlaw.com; RPuopolo@goodwinlaw.com

Section11.3 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.

Section11.4 Entire Agreement. This Agreement, together with the Exhibits hereto, the Seller Disclosure Schedule, the other Transaction Documents and the Transition Services Agreement, constitute the entire agreement, and supersedes all prior agreements and understandings (both written and oral), among the Parties regarding the subject matter hereof.

Section11.5 Successors and Assigns. 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 their rights or obligations hereunder without the prior written consent of the Purchaser. Purchaser may not assign any of its rights, interests or obligations without the prior written consent of the Seller. Any assignee hereunder shall agree in writing to assume all obligations and Liabilities of the assignor 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*.

Section11.6 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.

Section11.7 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.

Section11.8 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 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.

Section11.9 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 WITHOUT LIMITATION, 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.

Section11.10 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 specific performance of the terms of this Agreement in addition to any other remedy to which they are entitled at Law or in equity.

Section11.11 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.

Section11.12 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.

Section11.13 Bulk Transfer Laws. The Purchaser hereby waives compliance by the Seller and its Affiliates with any applicable provisions of any so-called “bulk transfer law” of any jurisdiction in connection with the transactions contemplated under this Agreement.

Section11.14 Setoff Rights. Neither Party shall have any right of setoff against any amounts due and payable by the other Party, or any Liabilities arising for which the other Party is responsible, under any Transaction Document.

Section11.15 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. In the event that any signature to this Agreement or any agreement or certificate delivered pursuant hereto, or any amendment thereof, is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof. No Party shall raise the use of a facsimile machine or e-mail delivery of a ".pdf" format data file to deliver any such signature page or the fact that such signature was transmitted or communicated through the use of a facsimile machine or e-mail delivery of a ".pdf" format data file as a defense to the formation or enforceability of a contract and each Party forever waives any such defense.

[*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.

Seller:

DR. REDDY'S LABORATORIES LIMITED

By: /s/ Erez Israeli

Name: Erez Israeli

Title: Chief Executive Officer

Purchaser:

BIODELIVERY SCIENCES INTERNATIONAL, INC.

By: /s/ Jeffrey A. Bailey

Name: Jeffrey A. Bailey

Title: Chief Executive Officer

Schedule 1.01
Definitions

"**Acquired Contracts**" shall mean all Contracts specifically listed on Exhibit A, including the purchase orders set forth in Exhibit A.

"**Acquired Regulatory Approvals**" shall mean the US NDA number 212157, Investigational New Drug (IND) Application 125585 and Investigational New Drug (IND) Application 138593, and all amendments and supplements thereto filed with the FDA as of the Closing.

"**Acute Pain Indication**" shall mean, other than the Migraine Indication, an indication for the prevention, treatment, control, mitigation and/or palliation of pain and/or acute pain.

"**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.

"**Approval Milestones**" means Milestone Nos. 2, 3, 4 and 5 as set forth in Section 3.01(b).

"**Assumed Liabilities**" shall mean:

a) Liabilities arising under or relating to the Acquired Regulatory Approvals on or after the Closing, including any and all Post-Approval Commitment Studies and all costs and expenses relating thereto;

b) all Liabilities arising out of or relating to the ownership or operation of the Business and the Purchased Assets on or after the Closing;

c) 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, which result from the use or misuse of the Product or otherwise related to the Product (including all Legal Proceedings relating to any such liabilities), in each case, only to the extent related to Product sold by or on behalf of the Purchaser following the Closing;

d) all Liabilities, obligations and commitments arising out of or relating to any Product recall in the Territory which such recall was instituted on or after the Closing and relates to Product manufactured or sold by the Purchaser (or any of its Affiliates, representatives, licensees or sublicensees);

e) all Liabilities, obligations and commitments arising out of or relating to any chargebacks related to any Product manufactured sold by Purchaser (or any of its Affiliates, representatives, licensees, sublicensees or transferees) on or after the Closing;

f) any Liabilities, obligations or commitments arising out of or relating to any Acquired Contract to the extent incurred on or after the Closing;

g) all Liabilities, obligations and commitments arising out of or relating to the return of, or warranty claims relating to any Product sold on or after the Closing;

h) any Liability, amount payable to Contract Pharmaceuticals Limited, after Closing relating to any stability studies, engineering or process validation batches or any new studies required to ensure the Product commercial batches are manufactured;

i) any 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 on or after the Closing;

j) 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, the Product, the Purchased Assets, the Business or the ownership, sale or lease of any of the Purchased Assets in the Territory to the extent arising on or after the Closing.

"**Audited Financial Statements**" shall have the meaning set forth in Section 6.06.

"**Authorized Generic**" means, with respect to the Product on a country-by-country basis in the Territory, any product containing the same active ingredient, same mode of administration and dosage strength as the Product (or otherwise matching the label and indications for the Product) and that is marketed or sold by or on behalf of a Purchaser, its Affiliates, licensees, sublicensees or transferees as a generic version of such a Product in the Territory under NDA No. 212157 or any other similar Regulatory Approval owned by Purchaser, its Affiliates, licensees, sublicensees or transferees in the Territory (including any Regulatory Approval relating to a Product that is owned or otherwise controlled by the Purchaser, its Affiliates, licensees, sublicensees or transferees).

"**Bill of Sale & Assignment and Assumption Agreement**" shall mean the certain Assignment and Assumption Agreement, to be entered into on the date of the Closing by and between the Purchaser and the Seller in the form attached hereto as Exhibit B.

"**Business**" shall mean the development of the Product (as such Product exists as of the Effective Date) and the non-commercial manufacture of Product as part of such development, in or for the United States.

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

"**Calendar Year**" shall mean each respective period of twelve (12) consecutive months ending on December 31.

"**Canada**" means the country of Canada, any province or territory thereof, and possessions.

"**Cap**" shall have the meaning set forth in Section 9.06(b).

"**Cash Consideration**" shall mean the Upfront Payment, plus the Purchaser's Prorated Portion.

"**Closing**" shall have the meaning set forth in Section 4.01.

"**Closing Date**" shall have the meaning set forth in Section 4.01.

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

"**Commercially Reasonable Efforts**" shall mean, with respect to a Party fulfilling its obligations under this Agreement, the efforts [***], including with respect to use and expenditure of resources, in connection with a comparable project of similar nature, value and status, with respect to the Product or potential product at a similar stage in its development or product life, taking into account product labeling, market and commercial potential, medical and clinical considerations, the regulatory environment, patent and other proprietary position and competitive market conditions in the therapeutic area, all as measured by the facts and circumstances at the time such efforts are due. "**Commercially Reasonable**" as applied to a Party fulfilling such Party's obligation under this Agreement will be similarly construed.

"**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, together with the terms and conditions or other facts relating to the transactions contemplated hereby, including, without limitation, 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 terms and conditions of this Agreement shall be deemed the Confidential Information of both Parties. 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 Parties dated March 22, 2021.

"**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, purchase order, statement of work, instruments, notes, commitments, undertakings, indentures, joint ventures and all other agreements, commitments and legally binding arrangements, whether written or oral.

"**Controlled**" means, with respect to any material, Information, Patent or other intellectual property right, that a Party (a) owns or (b) has a license or other right to such material, Information or intellectual property right, and, in each case ((a) and (b)), has the ability to grant a

Person access, a license or a sublicense (as applicable) to the foregoing without violating the terms of any then-existing agreement or other arrangement with any Third Party.

"**Cover**" means, as used in relation to a Patent and a product or invention, and in connection with a duty, obligation or performance of a Party, that such Patent would be infringed by the manufacture, use, offer for sale, sale or import of, or other Exploitation of, such product or invention by such Party, but for this Agreement, including infringement of patent claims claiming compositions of matter as well as methods of manufacture or use. "**Covering**" and "**Covered**" shall have a correlative meaning.

[***]

"**DRL Background Know-How**" means all Information (whether or not such Information is Confidential Information, patentable or not patentable) Controlled by Seller or any of its Affiliates before or on the Closing or at any time during the Earn-Out Term, in each case, that is (a) is generally not known, (b) related to the Product, and (c) necessary or used to Exploit the Products in or for the Territory, but excluding any Product Know-How.

"**DRL Background Patents**" means any Patent Controlled by Seller or any of its Affiliates issued or filed before or on the Closing or at any time during the Earn-Out Term that is (a) related to the Product, and (b) necessary or used to Exploit the Products in or for the Territory, but excluding any Product Patent.

"**DRL Background Technology**" means the DRL Background Know-How and the DRL Background Patents.

"**Earn-Out Term**" shall have the meaning set forth in Section 3.01(c)(iii).

"**Effective Date**" shall have the meaning set forth in the preamble.

"**Encumbrances**" shall mean any charge, claim, community property interest, pledge, condition, equitable interest, lien (statutory or other), option, 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 Proration Schedule**" shall have the meaning set forth in Section 2.01(h).

"**Excluded Assets**" shall have the meaning set forth in Section 2.01(b).

"**Excluded Liabilities**" shall have the meaning set forth in Section 2.01(d).

"**Excluded Taxes**" shall mean (i) all Taxes incurred by the Seller or its Affiliates, or for which the Seller or its Affiliates are liable, for any Tax period, including any Taxes that arise as a result of the transactions contemplated by this Agreement (which does not include Transfer Taxes which the Purchaser is responsible pursuant to Section 3.02(c)), (ii) all Taxes related to any asset of the Seller (other than the Purchased Assets) or Excluded Liabilities for any Tax period, (iii) all Taxes relating to the Purchased Assets or Assumed Liabilities for any Pre-Closing Tax Period and, with respect to any Straddle Period, for the portion of such taxable period ending on the Closing, apportioned as provided in the definition of "Pre-Closing Tax Period" hereof, and (iv) any Transfer Taxes for which the Seller is responsible for as set forth in Section 3.02(c).

Excluded Taxes shall not include any Taxes which the Purchaser is responsible for as a result of the assumption of the Assumed Liabilities.

"**Existing Product**" means the pharmaceutical product that is approved pursuant to a Regulatory Approval by the FDA under NDA No. 212157 as of the Effective Date.

"**Exploit**" means to make, have made, import, use, sell, or offer for sale, including to research, develop, commercialize, register, modify, enhance, improve, manufacture, have manufactured, hold or keep (whether for disposal or otherwise), formulate, optimize, have used, export, transport, distribute, promote, market, have sold or otherwise dispose of, and otherwise exploit. "**Exploitation**" shall have a correlative meaning.

"**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.

"**Financial Statements**" shall have the meaning set forth in Section 6.06.

"**First Commercial Sale**" means the first sale of the Product by Purchaser or its Affiliate, licensee, sublicensee or transferee for monetary value to a Third Party in the Territory. For clarity, sales prior to receipt of Regulatory Approval for the Product, if any, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale with respect to the Product.

"**GAAP**" shall mean generally accepted accounting principles in the United States, consistently applied.

"**Generic Entry**" means with respect to the Product for a particular indication in each country in the Territory, the [***] following the occurrence of both of the following (i) the date that the first sale of a Generic Version of the Product is sold by a Third Party in such Territory, and (ii) [***]

"**Generic Version**" means, with respect to the Product, any other prescription pharmaceutical product that (i) has the same mode of administration and dosage strength as the Product, (ii) contains the same active ingredient as the Product, (iii) is A/B Rated with respect to the Product, including by mode of administration and dosage strength of the Product, (iv) is marketed for the same indication as the Product and (v) is sold in such jurisdiction by a Third Party that is not a licensee, sublicensee or transferee, and did not purchase the product from Purchaser or its Affiliates or licensee, sublicensee or transferee. For purposes of this definition, "**A/B Rated**" means, for the U.S., "therapeutically equivalent" as determined by the FDA, applying the definition of "therapeutically equivalent" set forth in the preface to the then-current edition of the FDA publication "Approved Drug Licensed Products With Therapeutic Equivalence Evaluations" and, for outside the United States, such equivalent determination by the applicable Regulatory Authority. For the avoidance of doubt, an Authorized Generic of a Product shall not constitute a Generic Version.

"**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.

"**Health Canada**" means the Canadian federal Department of Health and any successor thereof.

"**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

"**Improvement**" means any invention, discovery, development or modification (whether or not patented or patentable) made, created, conceived or developed, in each case, for or in relation to the Product, by Purchaser, Seller or their respective Affiliates or its or their licensees, sublicensees or transferees after the Closing, including any enhancement in the efficiency, operation, manufacture, ingredients, preparation, packaging, presentation, formulation, means of delivery or dosage of the Product.

"**Improvement Know-How**" means any Improvement to any Know-How made by or under authority of Purchaser or Seller in connection with the further research, development and/or commercialization of the Product.

"**Improvement Patents**" means any Improvement to any Product Patent and any patent rights in inventions made by or under authority of Purchaser or Seller in connection with the further research, development and/or commercialization of the Product.

"**IND**" means an Investigational New Drug Application filed with the FDA pursuant to 21 C.F.R. Part 312 (or its successor regulation) with respect to a product, or the equivalent application or filing filed with any equivalent agency or Governmental Authority outside the United States of America, and all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

"**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).

"**Indemnity Threshold**" shall have the meaning set forth in Section 9.06(a).

"**Information**" means any technical, scientific and other data, in written, electronic or other form, including results, approvals, technology, trade secrets, practices, techniques, methods, processes, inventions, ideas, drawings, study designs, protocols, assays and biological methodology, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (whether or not patentable), software, algorithms, marketing reports, expertise, technology, test data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical test data and data resulting from pre-clinical and clinical studies), manufacturing and quality control data, and safety data.

"**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, service marks, trade dress, logos, trade names, and corporate names, together with translations, adaptations, derivations and combinations thereof and including goodwill associated therewith, and applications, registrations, and renewals in

connection therewith, (iv) domain names and URLs, (v) copyrights, mask works, works of authorship, and applications, registrations, and renewals in connection therewith, (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 (a) the certain Assignment of Patents to be entered into on the Closing by and between the Purchaser and the Seller in the form attached hereto as Exhibit C-1, (b) the certain Assignment of Trademarks to be entered into on the Closing by and between the Purchaser and the Seller in the form attached hereto as Exhibit C-2, (c) the certain Assignment of Patent Rights to be entered into on the Closing by and between the Purchaser and the Seller in the form attached hereto as Exhibit C-3, and (d) the certain Assignment of Domain Names to be entered into on the Closing by and between the Purchaser and Dr. Reddy's Laboratories, Inc. in the form attached hereto as Exhibit C-4.

"**Interim Financial Statements**" shall have the meaning set forth in Section 6.06.

"**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, preclinical, 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 Purchaser**" shall mean the actual knowledge after due inquiry of any of the individuals listed on Exhibit D.

"**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, Governmental Order, constitution, treaty, common law, judgment, decree, guidance, 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.

"**Loss**" or "**Losses**" shall mean actual out-of-pocket losses, damages, liabilities, costs or expenses, including reasonable attorneys' fees.

"**Material Adverse Effect**" means any effect that is materially adverse to the Exploitation of the Product in any indication or any country in the Territory; 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 Product 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 Product 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 (such as the COVID-19 virus (SARS-COV-2) (or related strains, variations, and sequences)) or related Governmental Order or action by a Governmental Authority in relation thereto; (h) changes or effects that arise out of or are attributable to the Excluded Assets or Excluded Liabilities; (i) any action taken by the Seller as contemplated or permitted by this Agreement or with the Purchaser's consent; or (j) any matter disclosed in the Seller Disclosure Schedules to this Agreement, including in each case, any adverse effect that occurs after the Effective Date but that arises out of or results from any such matter; or (k) any existing event or occurrence or circumstance to the Knowledge of the Purchaser as of the date hereof.

"**Migraine Indication**" shall mean an indication for the acute treatment of migraine with or without aura in adults.

"**Milestone and Earn-Out Information**" shall have the meaning set forth in Section 3.03(d).

"**Milestone Event**" shall have the meaning set forth in Section 3.01(b).

"**Milestone Payment**" shall have the meaning set forth in Section 3.01(b).

"**NDA**" means a New Drug Application for a drug filed submitted in accordance with 21 C.F.R. Part 314, and all supplements filed submitted pursuant to the requirements of the FDA, including all documents, data and other information concerning the applicable drug which are necessary for FDA approval to market such drug in the United States, and any equivalent application submitted to any other health authority.

"**Net Sales**" shall mean the aggregate gross amounts invoiced or otherwise received for all of the Purchaser's, its Affiliates', licensees', sub-licensees' and transferees' sales or other commercial distribution of the Product (including any Authorized Generic) in the Territory, for any indication, during the applicable period in the considered territory less the sum of the following, to the extent related to the sale or commercial distribution of the Product and otherwise included in such gross amounts (but only to the extent accrued or actually taken, but only to the extent not previously deducted from gross sales): (1) trade, quantity and cash discounts in amounts reasonable or customary in the trade and to extent accrued or actually taken; (2) credits, refunds, allowances, volumes rebates, direct and indirect rebates, distribution fees, reimbursements, or similar payments granted or given to wholesalers and other distributors, managed care and pharmacy benefit management companies, but only to the extent not previously deducted from gross sales; (3) rejected goods, damaged goods, product recall and sales returns; (4) patient co-pay assistance benefits, rebates and coupon or voucher redemptions provided specifically to the concerned Product; (5) reasonable rebates paid or other price reductions provided in connection with sale of the concerned Product to any government or regulatory authority in respect of any state or federal Medicare, Medicaid, or similar programs available under or required by applicable Law; (6) sales and excise taxes or customs duties invoices and any other governmental charges imposed to the selling party upon the sale of the Product (but solely to the extent such amounts are actually included in gross sales); In the event the Purchaser (and/or any its Affiliates, licensees, sublicensees, and transferees) sells the considered Product as part of a bundle or group sale with other products, (i) the Net Sales shall be adjusted to be proportional to the ratio of the individual selling price of the concerned Product to the aggregate of the individual selling prices of each other product included as part of such bundle or group sale, and (ii) to the extent the Purchaser (and/or any its Affiliates, licensees, sublicensees, and transferees) provides discounts, allowance or rebate to the purchaser of the concerned Product based on the invoiced price for the products sold as a bundle or group sale, such discount must be allocated pro rata based on the selling prices of such products sold individually before taking into account the discount, allowance or rebate on product provided as part of such bundle. The foregoing deductions from gross sales shall be deducted only once and only to the extent not otherwise deducted from the gross sales. All deductions provided above shall be based on accrual or actual basis shall be based on Generally Accepted Accounting Principles regularly and consistently employed by the Purchaser with respect to the transactions in question.

"**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, without limitation, 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.

"**Outside Date**" shall have the meaning set forth in Section 7.03(c).

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

"**Patents**" means any and all (a) patent applications and issued patents, including, all national, regional, and international patent applications of any type including provisional applications; continuations; divisionals; continuations-in-part; continued prosecution applications; (b) patents

that have issued or in the future issue from any patent applications, including utility models, petty patents and design patents and certificates of invention; (c) reissues, renewals, substitutions, additions, reexaminations, corrections, revivals and/or any similar modifications of any such patents; and (d) extensions (including pediatric exclusivity, patent term extension, and supplementary patent certificate extensions), and/or restorations of patents.

"**Permits**" shall mean all certifications (including those of standards-setting organizations), licenses, permits, franchises, approvals, authorizations, exemptions, notices to, consents, orders or similar authorizations of, or filings with, any trade association, any standards-setting organization, or any Governmental Authority.

"**Permitted Encumbrances**" shall mean: (a) liens for Taxes not yet due and payable or being contested in good faith by appropriate procedures; (b) mechanics', carriers', workmen's, repairmen's or other like liens arising or incurred in the ordinary course of business; (c) liens arising under original purchase price conditional sales contracts and equipment leases with Third Parties entered into in the ordinary course of business; and (d) other imperfections of title or Encumbrances, if any, that have not had, and would reasonably not be expected to have, a Material Adverse Effect.

"**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.

"**Post-Approval Commitment Studies**" means clinical studies either mandated by the FDA (or other Regulatory Authorities) to be performed after approval of the Product, committed to be done during the NDA review for NDA number 212157, included in the NDA approval letter, or otherwise required to be completed as a condition of such approval. Post-Approval Commitment Studies related to the Product as of the Effective Date are set forth on Exhibit J.

"**Pre-Closing Tax Period**" means any taxable period (or portion thereof) ending on or before the Closing. In the case of any taxable period that includes (but does not end on) the Closing (a "**Straddle Period**"), the amount of any Taxes based on or measured by income, receipts, sales, use or payroll of the Seller that relates to the Pre-Closing Tax Period shall be determined based on an interim closing of the books as of the close of business on the Closing (and for such purpose, the taxable period of any partnership or other pass-through entity or non-U.S. entity in which the Seller holds a beneficial interest shall be deemed to terminate at such time), and the amount of other Taxes of the Seller for a Straddle Period that relates to the Pre-Closing Tax Period shall be deemed to be the amount of such Tax for the entire taxable period multiplied by a fraction the numerator of which is the number of days in the taxable period ending on and including the Closing and the denominator of which is the number of days in such Straddle Period.

"**Product**" means the non-steroidal anti-inflammatory drug product that contains celecoxib as the sole active pharmaceutical ingredient in an oral solution form (a) based on self-micro emulsifying drug delivery system (SMEDDS) technology, and (b) whose manufacture, use, or sale is Covered by a Valid Claim of any Product Patent or Improvement Patent, and shall include any such celecoxib product identified in the Acquired Regulatory Approvals, the Regulatory Approvals with respect to the Acute Pain Indication, and any future Regulatory Approvals for

other indications of such celecoxib products in the Territory, as each may be amended or supplemented.

"**Product Domains**" shall mean the internet domains set forth in Exhibit G.

"**Product Intellectual Property**" shall mean collectively the Product Patents, Product Domains, Product Know-How and Product Trademarks in the Territory.

"**Product Know-How**" means all Know-How Controlled by the Seller or any of its Affiliates that is (a) solely and exclusively related to the Product, and (b) necessary or used to Exploit the Product in or for the Territory as of the Closing.

"**Product Patent(s)**" means the Patents set forth in Exhibit F, which are the only Patents Controlled by the Seller or its Affiliates as of the Closing Date that are (a) solely and exclusively related to the Product, and (b) necessary to Exploit the Product, in each case, in the Territory.

"**Product Trademarks**" shall mean, as Controlled by the Seller or any of its Affiliates, and to the extent exclusively related to the Exploitation of the Product in or for the Territory, 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, and which are listed on Exhibit H.

"**Proration Schedule**" shall have the meaning set forth in Section 2.01(h).

"**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, and (D) the Acquired Contracts**.**

"**Purchaser**" shall have the meaning set forth in the preamble.

"**Purchaser FDA Letter**" shall mean the letters from the Purchaser to the FDA, duly executed by 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 Section 9.02.

"**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. "**Quarterly**" shall have a correlative meaning.

"**Quarterly Earn-Out Payments**" shall have the meaning set forth in Section 3.01(c).

"**Quarterly Earn-Out Rate**" shall have the meaning set forth in Section 3.01(c).

"**Regulatory Approval**" means any and all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations or authorizations of any Regulatory Authority, national, supra-national, regional, state or local regulatory agency, department, bureau,

commission, council or other governmental entity, that are necessary to commercialize a product in a regulatory jurisdiction in the Territory.

"Regulatory Approval Application" means an application to the applicable Regulatory Authority for approval to commercialize a product in a particular country or other jurisdiction.

"**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 Product thereto in the Territory, including the FDA and Health Canada.

"**Regulatory Documentation**" shall mean all (a) applications (including all 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 Product, 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.

"**Retained Territory**" shall mean the entire world, except for the Territory.

"**Sales Reports**" shall have the meaning set forth in Section 3.03(e).

"**SEC**" shall have the meaning set forth in Section 7.04.

"**Seller**" shall have the meaning set forth in the preamble.

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

"**Seller FDA Letter**" shall mean the letters from the Seller to the FDA, 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 Group**" shall have the meaning set forth in Section 9.03.

"**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.

"**Tax Treaty**" shall mean the Convention and Protocol between the United States of America and the Republic of India signed on September 12, 1989.

"**Taxes**" shall mean all federal, state, local, foreign and other income, gross receipts, sales, use, production, ad valorem, transfer, franchise, registration, profits, license, lease, service, service use, withholding, payroll, employment, unemployment, estimated, excise, severance, environmental, stamp, occupation, premium, property (real or personal), real property gains, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatsoever, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties.

"**Territory**" shall mean the United States and Canada.

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

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

"**Transaction Documents**" shall mean this Agreement, the Bill of Sale & Assignment and Assumption Agreement and the Intellectual Property Assignment Agreements.

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

"**Transition Services Agreement**" means the Transition Services Agreement attached hereto as Exhibit I.

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

"**Upfront Payment**" shall have the meaning set forth in Section 3.01(a)(i).

"**Valid Claim**" shall mean (i) any claim of a Patent or any other patent Covering the considered Product (including if filed after the date hereof and including all reissues, reexaminations, revisions, divisionals, continuations, continuations-in-part, provisional and continued examinations, extensions, restorations or renewals of such patents to the extent they relate to the Product) that has been granted by a patent granting authority, that is in force, and that has not been surrendered, abandoned, revoked or held invalid or unenforceable by a decision taken by an administrative or civil court in a jurisdiction, or (ii) a pending claim in an application for a Patent or any other patent set forth under (i), provided that under this clause (ii) such claim has not been pending for more than [***] from the date of the first substantive office action considering patentability of such claim (for claims filed in the United States) or the date of the first regional or national phase examiner's report considering patentability of such claim (for claims filed outside of the United States), [***].

Schedule 2.01(h)
Estimated Proration Schedule

[***]

SELLER'S DISCLOSURE SCHEDULE

TO THE ASSET PURCHASE AGREEMENT

[***]

[***]

[***]

[***]

Exhibit A
Acquired Contracts

[***]

Exhibit B
Bill of Sale & Assignment and Assumption Agreement

[***]

Schedule 1.01 2

Exhibit C-1
Assignment of Patents

[***]

Exhibit C-2
Assignment of Trademarks

[***]

Exhibit C-3
Assignment of Patent Rights

[***]

Exhibit C-4
Assignment of Domain Names

[***]

Exhibit D
Knowledge of the Purchaser

[***]

Exhibit E
Knowledge of the Seller

[***]

Exhibit F
Product Patents

[***]

Exhibit G
Product Domains

Domains owned by Dr. Reddy’s Laboratories, Inc.

Domain name	Expiration Date
https://www.myelyxyb.info	02/07/2024
https://www.elyxybrx.net	02/07/2024
https://www.myelyxyb.org	02/07/2024
https://www.elyxyb.net	02/07/2024
https://www.elyxyb.com	02/07/2024
https://www.myelyxyb.com	02/07/2024
https://www.elyxybrx.org	02/07/2024
https://www.elyxybrx.info	02/07/2024
https://www.elyxyb.org	02/07/2024
https://www.elyxybrx.com	02/07/2024
https://www.myelyxyb.info	02/07/2024

Exhibit H
Product Trademarks

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

Exhibit I
Transition Services Agreement

[***]

Exhibit J
Post-Approval Commitment Studies

[***]

BioDelivery Sciences Announces Agreement to Acquire U.S. and Canadian Rights to FDA-approved ELYXYB™ for the Acute Treatment of Migraine

The only FDA-approved, ready-to-use oral solution for the acute treatment of migraine with or without aura in adults

First step to building a growth platform in Neurology

Patent protection until 2036

RALEIGH, N.C., August 4, 2021 - BioDelivery Sciences International, Inc. (NASDAQ: BDSI), a growing specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions, announced today that it entered into an agreement on August 3, 2021 with Dr. Reddy's Laboratories Limited to acquire the U.S. and Canadian rights to ELYXYB (celecoxib oral solution), the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults.

"ELYXYB represents an excellent strategic fit for BDSI and a very attractive opportunity to diversify our product portfolio by expanding into the dynamic migraine market, deepening our presence in Neurology, a logical adjacency to our pain franchise," stated Jeff Bailey, CEO of BDSI.

"ELYXYB will contribute nicely to the Company's revenue growth and profitability over time. This transaction leverages our commercial expertise and much of our existing infrastructure. We see this acquisition as establishing a great growth platform in Neurology. Further, the deal structure is attractive, allowing us to maintain our strong balance sheet and position us to pursue additional value-enhancing business development opportunities," Bailey concluded.

ELYXYB is an oral solution of celecoxib, formulated using a self-micro emulsifying drug delivery system that improves solubility and bioavailability of the drug leading to better absorption[1]. This allows for the administration of a lower dose of drug to achieve therapeutic effect relative to a conventional oral solid dosage form. In pivotal studies, ELYXYB demonstrated a rapid onset of action which is critically important to patients suffering from acute migraine attacks. The results from pivotal studies established the efficacy of ELYXYB in the treatment of acute migraine. For adult patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. ELYXYB's unit-dose oral solution makes it convenient for patients to take it immediately upon emergence of acute migraine attacks.

With over 13 million migraine patients receiving prescription drug treatment in the U.S. in 2020, the dynamic migraine market continues to grow and evolve, including with new product introductions. BDSI will be conducting an ELYXYB pediatric study which has the potential to address the significant unmet need in the pediatric patient population.

Under the terms of the agreement, ELYXYB will be acquired for an upfront payment of $6 million, plus an additional $9 million on August 3, 2022. BDSI will make tiered quarterly earn-out payments on potential net sales ranging from the high single digits to the low double digits. Additional payments will be made contingent upon the achievement of certain regulatory and sales milestones. The impact of the acquisition is estimated to be cash flow accretive within approximately 24 months of commercial launch, currently planned for Q1 2022. The closing of the transaction is subject to satisfactory completion of

customary closing conditions, including the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act).

“We are excited to acquire ELYXYB,” said Thomas Smith, MD, Chief Medical Officer at BDSI, and a former thought leader in the migraine space with over 30 years of experience both as a physician and with multiple migraine product developments and launches. The clinical data are quite compelling, including a meaningful speed of onset with Tmax achieved in approximately 60 minutes. Additionally, in the two pivotal studies conducted, the percentage of patients achieving Most Bothersome Symptom (MBS) freedom at two hours post-dose was significantly greater among patients receiving ELYXYB, compared to those receiving placebo. In Study 2, the percentage of patients achieving headache pain freedom two hours post-dose was significantly greater among patients receiving ELYXYB, compared to those receiving placebo. We believe that this profile, coupled with the ready-to-use oral solution, make ELYXYB an attractive option for the acute treatment of migraine in adults.”

The Company plans to conduct a BDSI investor day early in the fourth quarter, where further details regarding ELYXYB will be shared.

Please see Important Safety Information about ELYXYB below.

ABOUT BIODELIVERY SCIENCES INTERNATIONAL, INC.

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a commercial-stage specialty pharmaceutical company dedicated to patients living with serious and complex chronic conditions. BDSI has built a portfolio of products that includes utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs. BDSI's marketed products address serious and debilitating conditions, including chronic pain and opioid-induced constipation.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This press release and any statements of employees, representatives, and partners of BioDelivery Sciences International, Inc. (“BDSI”) related thereto contain, or may contain, among other things, certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to BDSI’s plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential” or similar expressions. These statements are based upon the current beliefs and expectations of BDSI’s management and are subject to significant risks and uncertainties, including those detailed in BDSI’s filings with the Securities and Exchange Commission. Actual results (including, without limitation, the closing of the acquisition of ELYXYB, the contribution of ELYXYB to the Company’s revenue growth and shareholder value, the timing of commercial launch of ELYXYB, the Company’s expansion into neurology, the growth of the migraine market and the significant unmet need in pediatric migraine patients may differ materially from those set forth or implied in the forward-looking statements. These

forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond BDSI's control), including those set forth in our 2020 annual report on Form 10-K filed with the US Securities and Exchange Commission and subsequent filings. BDSI undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

ELYXYB INDICATION AND USAGE

ELYXYB is indicated in adults for the acute treatment of migraine with or without aura.

Limitations of Use: ELYXYB is not indicated for the preventive treatment of migraine.

ELYXYB IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use *[see Warnings and Precautions (5.1)].*
- ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see Contraindications (4) and Warnings and Precautions (5.1)].*

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events *[see Warnings and Precautions (5.2)].*

ELYXB is contraindicated in patients with:

- Known hypersensitivity to celecoxib, any components of the drug product, or sulfonamides (4)
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (4)
- In the setting of CABG surgery (4)

To minimize the potential risk for an adverse cardiovascular (CV) event in NSAID-treated patients, use ELYXYB for the fewest number of days per month as needed, based on individual treatment goals. Physicians and patients should remain alert for the development of such events, throughout the entire treatment course, even in the absence of previous CV symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

Avoid the use of ELYXYB in patients with a recent myocardial infarction (MI) unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

NSAIDs, including ELYXYB, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with celecoxib. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occurred in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for one year. However, even short-term NSAID therapy is not without risk.

Avoid the use of ELYXYB in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ELYXYB is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Elevations of ALT or AST (less than three times ULN) may occur in up to 15% of patients treated with NSAIDs, including ELYXYB.

Long-term administration of NSAIDs, including celecoxib, the active ingredient in ELYXYB, has resulted in renal papillary necrosis and other renal injury.

No information is available from controlled clinical studies regarding the use of celecoxib in patients with severe renal impairment. The renal effects of celecoxib may hasten the progression of renal dysfunction in patients with preexisting renal disease.

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, nonsteroidal anti-inflammatory drugs or combination of these drugs for 10 or more days per month), including ELYXYB, may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

NSAIDs, including ELYXYB, may increase the risk of bleeding events. Co-morbid conditions such as coagulation disorders or concomitant use of warfarin, other anticoagulants, antiplatelet drugs (e.g., aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors (SNRIs) may increase this risk.

Most common adverse reaction (at least 3% and greater than placebo) is dysgeusia.

These are not all the side effects associated with ELYXYB.

Please see Patient Information, Instructions For Use, Medication Guide and Full Prescribing Information for ELYXYB

(https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212157s000lbl.pdf)

[1] Arindam Pal, Srinivas Shenoy, Anirudh Gautam, Sagar Munjal, Jing Niu, Mathangi Gopalakrishnan & Joga Gobburru, Clinical Drug Investigation volume 37, pages 937–946(2017)

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