Case 23-10937-LSS Doc 696 Filed 05/29/2/1 Page 1 of 90 Docket #0696 Date Filed: 05/29/2024

### IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re: Chapter 11

NVN Liquidation, Inc., *et al.*, f/k/a NOVAN, INC., <sup>1</sup> Case No. 23-10937 (LSS)

(Jointly Administered)

Debtors.

Re: Docket No. 677

# REQUEST FOR ALLOWANCE OF ADMINISTRATIVE CLAIM FILED BY DR. REDDY'S LABORATORIES LTD.

Pursuant to the *Notice of (I) Confirmation Order; (II) Effective Date; (III) Applicable Bar Dates for Filing Certain Claims; and (IV) Related Information* [Docket No. 677], Dr. Reddy's Laboratories Ltd., creditor and party in interest, hereby files this *Request for Allowance of Administrative Claim* related to its postpetition delivery of goods against EPI Health, LLC, Case No. 23-10938, as more fully described in the attached Proof of Claim form and Attachment attached hereto as **Exhibit A**.

Dated: May 29, 2024

Wilmington, Delaware

Respectfully submitted,

COLE SHOTZ P.C.

/s/ Andrew J. Roth-Moore

Justin R. Alberto (No. 5126) Andrew J. Roth-Moore (No. 5988) 500 Delaware Avenue, Suite 1410

Wilmington, DE 19801 Telephone: (302) 652-3131

Facsimile: (302) 652-3117

Email: jalberto@coleschotz.com aroth-moore@coleschotz.com

Counsel to Dr. Reddy's

### EXHIBIT A

Proof of Claim and Rider

United States Bankruptcy Court for the District of Delaware			
Indicate Debtor against which you assert a claim by checking the appropriate box below. (Check only one Debtor per claim form.)			
☐ Novan, Inc. (Case No. 23-10937)	☑ EPI Health, LLC (Case No. 23-10938)		

### Official Form 410

Proof of Claim 04/22

Read the instructions before filling out this form. This form is for making a claim for payment in a bankruptcy case.

Filers must leave out or redact information that is entitled to privacy on this form or on any attached documents. Attach redacted copies or any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements of running accounts, contracts, judgments, mortgages, and security agreements. Do not send original documents; they may be destroyed after scanning. If the documents are not available, explain in an attachment.

A person who files a fraudulent claim could be fined up to \$500,000, imprisoned for up to 5 years, or both. 18 U.S.C. §§ 152, 157, and 3571.

Fill in all the information about the claim as of the date the case was filed.

Pá	Part 1: Identify the Claim				
1.	Who is the current creditor?	Dr. Reddy's Laboratories Ltd.  Name of the current creditor (the person or entity to be paid for this claim)  Other names the creditor used with the debtor			
2.	Has this claim been acquired from someone else?	X No Yes. From whom?			
3.	Where should notices and payments to the creditor be sent?	Where should notices to the creditor be sent? <u>Dr. Reddys Laboratories Ltd., c/o Andrew Roth-Mo</u> ore  Name	Where should payments to the creditor be sent? (if different)  Dr. Reddys Laboratories Ltd.  Name		
	Federal Rule of Bankruptcy Procedure (FRBP) 2002(g)	Cole Schotz P.C., 500 Delaware Avenue, Suite 1410  Number Street  Wilmington, DE 19801  City State ZIP Code  United States  Country  Contact phone Contact email 3026512003  aroth-moore@coleschotz.com	8-2-337, Ro Number S	pad No. 3, Banjara Hills treet Telangana 500034 State	ZIP Code
4.	Does this claim amend one already filed?	Uniform claim identifier for electronic payments in chapter 13 (if you use o	<u></u>	Filed on	
5.	Do you know if anyone else has filed a proof of claim for this claim?	<ul><li>X No</li><li>Yes. Who made the earlier filing?</li></ul>		55 /	

### Case 23-10937-LSS Doc 696 Filed 05/29/24 Page 4 of 90

	art 2: Give information Abo	dut the Claim as of the Date the Case was riled		
6.	Do you have any number you use to identify the debtor?	No  Yes. Last 4 digits of the debtor's account or any number you use to identify the debtor:		
7.	How much is the claim?	\$ 296,029.32  Does this amount include interest or other charges?  No  Yes. Attach statement itemizing interest, fees, expenses, or other charges required by Bankruptcy Rule 3001(c)(2)(A).		
8.	What is the basis of the claim?	Examples: Goods sold, money loaned, lease, services performed, personal injury or wrongful death, or credit card.  Attach redacted copies of any documents supporting the claim required by Bankruptcy Rule 3001(c).  Limit disclosing information that is entitled to privacy, such as health care information.  See Attachment		
9.	Is all or part of the claim secured?	No  Yes. The claim is secured by a lien on property.  Nature of property:  Real estate: If the claim is secured by the debtor's principal residence, file a Mortgage Proof of Claim Attachment (Official Form 410-A) with this Proof of Claim.  Motor vehicle  Other. Describe:  Basis for perfection:  Attach redacted copies of documents, if any, that show evidence of perfection of a security interest (for example, a mortgage, lien, certificate of title, financing statement, or other document that shows the lien has been filed or recorded.)  Value of property:  Amount of the claim that is secured:  Amount of the claim that is unsecured:  \$(The sum of the secured and unsecured amount should match the amount in line 7.)  Amount necessary to cure any default as of the date of the petition:  \$  Annual Interest Rate (when case was filed)%  Fixed  Variable		
10	. Is this claim based on a lease?	<ul> <li>X No</li> <li>Yes. Amount necessary to cure any default as of the date of the petition.</li> </ul>		
11	. Is this claim subject to a right of setoff?	▼ No  Yes. Identify the property:		

12. Is all or part of the claim		No				
entitled to priority under 11 U.S.C. § 507(a)?	X	Yes Che	ck all that apply:			Amount entitled to priority
A claim may be partly	ت	_		alandia ara Para ara ara di alait	d	
priority and partly			estic support obligations (in S.C. § 507(a)(1)(A) or (a)(		d support) under	\$
nonpriority. For example, in some categories, the		Up to		\$3,350* of deposits toward purchase, lease, or rental of property or es for personal, family, or household use. 11 U.S.C. § 507(a)(7).	ental of property or	Ψ
law limits the amount						\$
entitled to priority.		□ Wage	Wages, salaries, or commissions (up to \$15,150*) earned within 180 days before the bankruptcy petition is filed or the debtor's business ends,			
		days			\$	
		which	never is earlier. 11 U.S.C. §	§ 507(a)(4).		
		Taxes	s or penalties owed to gove	ernmental units. 11 U.S.0	C. § 507(a)(8).	\$
		☐ Contr	ibutions to an employee b	enefit plan. 11 U.S.C. §	507(a)(5).	\$
		X Other	. Specify subsection of 11	U.S.C. § 507(a)( 2 ) tha	at applies.	\$296,029.32
						n on or after the date of adjustment.
40. In all any and adding a lating						· · · · · · · · · · · · · · · · · · ·
13. Is all or part of the claim entitled to administrative	X	No				
priority pursuant to 11 U.S.C. § 503(b)(9)?						eived by the debtor within 20 have been sold to the Debtor in
0.0.0. g 000(b)(0):			ary course of such Debtor's			
		\$				
		Ψ	_			
Dont 2: Cirra Dolour						
Part 3: Sign Below						
The person completing	Check	the approp	oriate box:			
this proof of claim must sign and date it.	I am the creditor.					
FRBP 9011(b).						
If you file this claim						
electronically, FRBP 5005(a)(2) authorizes courts	I am the trustee, or the debtor, or their authorized agent. Bankruptcy Rule 3004.					
to establish local rules specifying what a signature		I am a guarantor, surety, endorser, or other codebtor. Bankruptcy Rule 3005.				
is.	I understand that an authorized signature on this <i>Proof of Claim</i> serves as an acknowledgement that when calculating					
A person who files a	the amount of the claim, the creditor gave the debtor credit for any payments received toward the debt.					
fraudulent claim could be fined up to \$500,000,	I have examined the information in this <i>Proof of Claim</i> and have reasonable belief that the information is true and correct.					
imprisoned for up to 5 years, or both.	I declare under penalty of perjury that the foregoing is true and correct.					
18 U.S.C. §§ 152, 157, and	Execu	ted on date	05/29/2024			
3571.	LXCCG	tou on unit	MM / DD / YYYY	•		
	/e/ F	rez Israeli	1			
		ignature				
	Print the name of the person who is completing and signing this claim:					
			a the percent who is com-	proung and organing and		
	Name		Erez Israeli			
			First name	Middle name	Lastı	name
	Title		CEO			
	Compa	ny	Dr. Reddy's Laborato		prizod agont is a sonvicor	
			Identify the corporate servicer as the company if the authorized agent is a servicer.			
	Addres	s	8-2-337, Road No. 3	, Banjara Hills		
			Number Street	500004 ! "		
			Hyderabad, Telangai	na, 500034, India State	ZIP Co	de Country
	Contac	t phone	91-40-4900 2900	23	Email	

## IN THE UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
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NVN Liquidation, Inc., *et al.*, f/k/a NOVAN, INC.,<sup>1</sup>

Case No. 23-10937 (LSS)

Debtors.

(Jointly Administered)

### **ATTACHMENT**

1. Dr. Reddy's Laboratories Ltd. ("<u>Dr. Reddy's Ltd.</u>") submits the following information in support of its request for an administrative expense (the "<u>Claim</u>") against EPI Health, LLC ("EPI") arising from the postpetition transactions.

### **BACKGROUND**

- 2. On July 17, 2023 (the "<u>Petition Date</u>"), EPI filed a voluntary petition or relief under Chapter 11 of Title 11 of the United States Code ("<u>Bankruptcy Code</u>") in the United States Bankruptcy Court for the District of Delaware (the "<u>Court</u>").
- 3. Prior to the Petition Date, EPI and Dr. Reddy's Ltd. entered into to the *Asset Purchase Agreement*, dated August 20, 2018 (the "MinoLira APA"),<sup>2</sup> pursuant to which Dr. Reddy's Ltd. transferred certain rights related to the sale of the pharmaceutical product MinoLira to EPI for an "Upfront Payment" as well as additional, contingent "Milestone Payments" (both terms as defined in the MinoLira APA) based on EPI's future sales of MinoLira. *See* MinoLira APA § 3.01.
- 4. As part of entering into the MinoLira APA, the parties executed a series of related agreements (each as identified in the *Notice of Possible Assumption and Assignment of Certain Executory Contracts and Unexpired Leases* [D.I. 60] as ID # 266 to 271, and collectively with the

<sup>&</sup>lt;sup>1</sup> The Debtors in these chapter 11 cases, along with the last four digitals of the Debtors' federal tax identification number (if applicable), are: NVN Liquidation, Inc., (f/k/a Novan, Inc.) (7682) and EPI Health, LLC (9118). The corporate headquarters and the mailing address for the Debtors is P.O. Box 64, Pittsboro, NC 27312.

<sup>&</sup>lt;sup>2</sup> A copy of the MinoLira APA is enclosed herein as **Exhibit 1**.

MinoLira APA, the "MinoLira Transaction Documents"). The MinoLira Transaction Documents include a *Supply Agreement*, dated August 20, 2018 (the "MinoLira Supply Agreement")<sup>3</sup> pursuant to which Dr. Reddy's Ltd. supplied MinoLira to EPI.

- 5. Under Article VI of the MinoLira Supply Agreement, EPI is obligated to make various taxes, fees, and interest payments ("Fees and Interest"). For example, pursuant to Section 6.4 of the MinoLira Supply Agreement, EPI is obligated to pay for products sold under the agreement within 30 days of invoice. Overdue payments are subject to an additional service charge "equal to lesser of one percent (1%) per month or the highest rate permitted by law of the outstanding amount for each month or portion thereof that such undisputed amount is overdue."
- 6. The MinoLira Supply Agreement expired on its own terms on August 20, 2021. However, Dr. Reddy's Ltd. continued to supply MinoLira to EPI under purchase orders pursuant to the terms of the MinoLira Supply Agreement.
- 7. Prior to the Petition Date, EPI entered two purchase orders with Dr. Reddy's Ltd. for the delivery of MinoLira (together, the "MinoLira PO").<sup>4</sup> As of the Petition Date, Dr. Reddy's Ltd. had not completed the production and packaging required for the MinoLira PO. Following the Petition Date, Representatives of Dr. Reddy's Ltd. contacted EPI and confirmed the order under the MinoLira PO.
- 8. Consistent with those communications, on or about July 19, 2023, Dr. Reddy's Ltd. shipped MinoLira to EPI under the MinoLira PO, for which Dr. Reddy's Ltd. is owed \$296,029.32 plus interest and fees (Invoice No. 9013423923, *i.e.*, the "Claim").<sup>5</sup> Payment for the Claim was due and payable on August 18, 2023. To date, Dr. Reddy's Ltd. has received no payment or compensation on account of the Claim.

<sup>&</sup>lt;sup>3</sup> A copy of the MinoLira Supply Agreement is enclosed herein as **Exhibit 2**.

<sup>&</sup>lt;sup>4</sup> A copy of the MinoLira PO is enclosed herein as **Exhibit 3.** 

<sup>&</sup>lt;sup>5</sup> A copy of Invoice No. 9013423923 is enclosed herein as **Exhibit 4**.

### ADMINISTRATIVE EXPENSE

9. Dr. Reddy's Ltd. asserts an administrative expense for the full amount of the Claim. *In re Harnischfeger Indus., Inc.*, 293 B.R. 650, 659 (Bankr. D. Del. 2003) (quoting *NLRB v. Bildisco & Bildisco*, 465 U.S. 513, 531, 104 S.Ct. 1188, 79 L.Ed.2d 482 (1984)) (Despite the purchase orders being issued pre-petition, "[i]f the debtor-in-possession elects to continue to receive benefits from the other party to an executory contract pending a decision to reject or assume the contract, the debtor-in-possession is obligated to pay for the reasonable value of those services."); *In re Bluestem Brands, Inc.*, 2021 WL 3174911, at \*5 (Bankr. D. Del. July 27, 2021) ("[T]he correct standard for determination of an administrative claim under that section is simply whether the Vendors provided a benefit to the estate post-petition. It does not require that there be a post-petition contract."). Because Dr. Reddy's Ltd. completed and delivered goods to the debtor-in-possession, EPI, the Claim for delivery of those good is entitled to an administrative expense priority.

### RESERVATION

10. This Claim is not, with respect to any entity, including any Debtor, or any of their officers or directors: (a) a waiver or release of the rights of Dr. Reddy's Ltd. against any other entity or person liable for all or any part of the Claim asserted herein; (b) a waiver of any rights or remedies of Dr. Reddy's Ltd. or an election of remedies which waives or otherwise affects any other remedy; (c) consent by Dr. Reddy's Ltd. to the jurisdiction of this Court with respect to any proceeding commenced in this case against or otherwise involving Dr. Reddy's Ltd.; (d) a waiver of the right to move to withdraw the reference with respect to the subject matter of the Claim, any objection or other proceedings commenced with respect thereto or any other proceedings commenced in this case against or otherwise involving Dr. Reddy's Ltd.; (e) a waiver or release by Dr. Reddy's Ltd. of any right to trial by jury, or a consent by Dr. Reddy's Ltd. to a trial by jury,

in this Court or any other court; (f) a waiver of any right to the subordination or recharacterization, in favor of Dr. Reddy's Ltd. of indebtedness or liens held by any creditors of the Debtors or any of their non-Debtor affiliates; (g) a waiver of any past, present or future defaults or events of defaults or other failures to perform; (h) a waiver of any indebtedness owed to or rights held by Dr. Reddy's Ltd. with respect to any Debtor or non-Debtor affiliate or other person or entity; (i) a waiver of any right to fees, indemnities, costs and expenses permitted under any agreements or applicable law; or (j) a waiver of any right to seek and obtain additional interest, including but not limited to the right to recover default interest.

- 11. Dr. Reddy's Ltd. expressly preserves all procedural and substantive defenses with respect to any claim that may be asserted against Dr. Reddy's Ltd. by the Debtor or any of its Debtor or non-Debtor affiliates, or by any trustee or other representative of the Debtors' estates, or by any other person.
- 12. Dr. Reddy's Ltd. expressly reserves its rights to file any separate or additional proofs of claim or requests for administrative expenses with respect to the Claim set forth herein or otherwise (which proofs of claim or requests, if so filed, shall not be deemed to supersede this Claim unless expressly so stated therein), to amend or supplement this Claim in any respect, including with respect to the filing of an additional or amended claim for the purpose of fixing and liquidating any contingent or unliquidated claim, including, without limitation, any Milestone Payments that may come due under the MinoLira APA, or to file additional proofs of claim in respect of additional amounts or for any other reason.

# Exhibit 1

B-743

### ASSET PURCHASE AND LICENSE AGREEMENT

BETWEEN

DR. REDDY'S LABORATORIES LTD.

AND

EPI HEALTH, LLC

DATED AS OF

August 20, 2018

100026099

### List of Exhibits and Schedules

Seller Disclosure Schedule

Exhibit A Knowledge of Purchaser

Exhibit B Knowledge of Seller

Exhibit C List of Assumed Contracts

Exhibit D Trademarks and Domain Names

Exhibit E Patents

Exhibit F Permitted Encumbrances

Schedule 1.01 Definitions

#### ASSET PURCHASE AND LICENSE AGREEMENT

This Asset Purchase and License Agreement (this "Agreement") dated as of August 20, 2018 is made and entered into by and between:

Dr. Reddy's Laboratories, Ltd., an Indian company located at SEZ - Process unit -1, Devunipalavalasa Village, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh, India, Pin-532409 (the "Seller" or "Licensor"); and

EPI Health, LLC, a South Carolina limited liability corporation located at 134 Columbus Street, Charleston, SC 29403(the "Purchaser" or "Licensee");

The Seller and the Purchaser are hereby collectively referred to herein as the "Parties" and each, individually, as a "Party".

### RECITALS

WHEREAS, the Seller is engaged in the business of developing, manufacturing, marketing and selling pharmaceutical products;

WHEREAS, the Seller owns the NDA for the Product (as defined herein) for the Product (as defined herein) and related assets;

WHEREAS, the Seller wishes to sell to the Purchaser, and the Purchaser wishes to purchase from the Seller, such NDA for the Product and related assets, as more fully described herein; and

WHEREAS, the Licensor owns or controls certain intellectual property rights with respect to the Purchased Assets (as defined herein) in the Territory (as defined herein); and

WHEREAS, Licensor wishes to grant to Licensee, and Licensee wishes to take, a license under certain intellectual property rights in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and agreements in this Agreement, the Parties hereto agree as follows:

### ARTICLE I DEFINITIONS AND INTERPRETATION

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

### Section 1.02

Other Definitional and Interpretive

Provisions.

- (a) The words "hereof", "herein", "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement.
- (b) The terms defined in the singular shall have a comparable meaning when used in the plural and vice versa.
  - (c) The terms "dollars" and "\$" shall mean United States of America dollars.
- (d) The term "including" (and with correlative meaning "include") shall mean "including, without limitation."
- (e) Reference to any Person includes such Person's successors and assigns but, if applicable, only if such successors and 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 and disclosure schedules attached hereto) and have contributed to its revision; (iii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iv) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

### ARTICLE II PURCHASE AND SALE

### Section 2.01

### Purchase and Sale of Purchased Assets.

(a) <u>Purchased Assets</u>. On the terms and subject to the conditions set forth in this Agreement, at the Closing, the Seller shall, and shall cause its Affiliates to, sell, convey and assign to the Purchaser, and the Purchaser shall purchase, acquire and assume from the Seller or its Affiliates, all of the Seller's and its Affiliates' right, title, and interest in the Purchased Assets, free from any Encumbrances except for Permitted Encumbrances.

- (b) <u>Excluded Assets</u>. The sale and purchase of the Purchased Assets under this Agreement expressly does not include any Excluded Assets.
- (c) <u>Assumed Liabilities</u>. On the terms and subject to the conditions set forth in this Agreement, effective as of the Closing, the Purchaser shall assume and perform the Assumed Liabilities.
- (d) <u>Excluded Liabilities</u>. Except for the Assumed Liabilities, the Purchaser will not purchase the Purchased Assets subject to, and Purchaser shall not acquire any interest in, or obligations in respect of, any liabilities of the Seller or its Affiliates (the "Excluded Liabilities").

### (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, (i) would constitute a breach or other contravention of the rights of such third party (including any Governmental Authority), (ii) would be ineffective with respect to any Party to an agreement concerning such asset or (iii) would in any way adversely affect the contractual rights of the Seller, 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 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. Notwithstanding anything to the contrary set forth in this Agreement, so long as Purchaser has identified the relevant consent on the Seller Disclosure Schedules, the Purchaser agrees that the Seller shall not have any liability whatsoever arising out of or relating to the failure to obtain such consent 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.
- (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, and thereafter each of the Seller and Purchaser shall use commercially reasonable efforts (i) to endeavor to obtain such consent (provided that neither the Seller nor Purchaser shall be required to commence any litigation or offer or grant any accommodation (financial or otherwise) to any third party) until such consent is obtained, and (ii) 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. Upon obtaining the requisite consent, such Purchased Asset shall be transferred and assigned to Purchaser hereunder.

### ARTICLE III PURCHASE PRICE

### Section 3.01

### Purchase Price.

- (a) <u>Amount</u>. The aggregate consideration for the purchase of the Purchased Assets to be paid by the Purchaser shall be:
- (b) One Million Dollars (\$1,000,000USD) upon the execution by the Parties of this Agreement ("Upfront Payment");
- (c) One Million Dollars (\$1,000,000USD) upon the delivery (Ex-Works Seller manufacturing location) of the first commercial batch of the 135 mg. strength Product ("135 Commercial Batch"), provided, at such time, there is no circumstance that is outside of Purchaser's reasonable control that prevents Purchaser from launching the 135 mg. strength Product that arose solely from a breach by Seller of its representations, warranties, or covenants under this Agreement in which case the payment will be made upon launch of the 135 mg. strength Product by Purchaser. This milestone payment is based on the assumption that delivery of 135 Commercial Batch can be accomplished within four (4) months of receipt of active pharmaceutical ingredient ("API") by Seller (such date, the "Expected Delivery Date"). With respect to each week by which the actual date of delivery of 135 Commercial Batch occurs after the Expected Delivery Date, this milestone payment shall be reduced by \$10,000. Without limiting the foregoing, Seller shall use commercially reasonable efforts to accelerate the date of commercial delivery of 135 Commercial Batch;
- (d) One Million Dollars (\$1,000,000USD) upon Purchaser generating cumulative Ten Million Dollars (\$10,000,000USD) in Net Sales of the Product and/or Future Product (based on generally accepted accounting principles "GAAP");
- (e) One Million Dollars (\$1,000,000USD) upon Purchaser generating cumulative Twenty Million Dollars (\$20,000,000USD) in Net Sales of the Product and/or Future Product; and
- (f) One Million Five Hundred Thousand Dollars (\$1,500,000USD) with respect to each additional Twenty Million Dollars (\$20,000,000USD) of Net Sales of the Product and/or Future Product by Purchaser.

Sections 3.01 (b)-(f) collectively, "Milestone Payments," and Upfront Payment and Milestone Payments collectively the "Purchase Price."

### Section 3.02

### Payment Terms.

(a) <u>Payment</u>. The Purchaser shall pay the Upfront Payment at Closing, by wire transfer of immediately available funds into an account or accounts designated by the Seller not less than three Business Days prior to the Closing Date. Purchaser shall pay to Seller (i) the Milestone Payment set forth in Section 3.01 (c) within fifteen (15) days of delivery of the 135 Commercial Batch and (ii) the Milestone Payments set forth in Section 3.01 (d) – (f) within Fifteen (15) days after the end of each calendar quarter in which the relevant milestone event is achieved, all of

which shall be nonrefundable, noncreditable and fully earned upon the achievement of the applicable milestone event.

- (b) <u>Taxes</u>. Notwithstanding any other provisions of this Agreement to the contrary, Seller shall pay all sales (including bulk sales), use, transfer and similar Taxes, if any, required to be paid in connection with the transactions contemplated by this Agreement.
- (c) Allocation of Purchase Price. Within forty-five (45) days after the Closing Date, Seller shall deliver a schedule allocating the Purchase Price (including any Assumed Liabilities treated as consideration for the Purchased Assets for Tax purposes) (the "Allocation Schedule"). The Allocation Schedule shall be prepared in accordance with Section 1060 of the Code. The Allocation Schedule shall be deemed final unless Purchaser notifies Seller in writing that Purchaser objects to one or more items reflected in the Allocation Schedule within forty-five (45) days after delivery of the Allocation Schedule to Purchaser. In the event of any such objection, Seller and Purchaser shall negotiate in good faith to resolve such dispute; provided, however, that if Seller and Purchaser are unable to resolve any dispute with respect to the Allocation Schedule within forty-five (45) days after the delivery of the Allocation Schedule to Purchaser, such dispute shall be resolved by an impartial firm of independent certified public accountants mutually appointed by Purchaser and Seller. The fees and expenses of such accounting firm shall be borne equally by Seller and Purchaser. Seller and Purchaser agree to file their respective IRS Forms 8594 and all federal, state and local Tax Returns in accordance with the Allocation Schedule.
- (d) Reports and Reconciliation. Following the first commercial sale of the Product and/or Future Product by Purchaser following Closing until the payment of all Milestone Payments pursuant to Section 3.01, the Purchaser shall, within forty-five (45) days of the end of each calendar quarter, report to Seller a detailed statement of (i) gross revenue and volumes of sales made for the Product and/or Future Product during the calendar quarter just ended, (ii) Deductions (as defined in the definition of Net Sales) either (A) actually taken during a calendar Quarter that were not accrued during such calendar quarter, or (B) accrued during a calendar quarter but not taken or later subject to a reversal following the end of such calendar quarter (each of (A) and (B), a "Trueup Adjustment"), and (iii) the Net Sales for that calendar quarter. In determining whether a milestone event is triggered pursuant to Section 3.01(d) (f), cumulative Net Sales shall be calculated in a quarter taking into account the True-Up Adjustment in that quarter, however once the milestone event is achieved and the applicable Milestone Payment is made, a subsequent True-Up Adjustment shall not impact the already-paid Milestone Payment but rather shall be applied to the calculation of cumulative Net Sales with respect to the next Milestone Payment.
- (e) Audit. At the request of Seller, Purchaser shall, and shall cause its Affiliates and its and their Sublicensees to, permit Seller or an independent auditor designated by Seller, at reasonable times and upon reasonable written notice, to audit the pertinent books and records directly related to the calculation of the Milestone Payments maintained by Purchaser to ensure the accuracy of all reports and payments made hereunder; provided that this may occur no more than one (1) time per Calendar Year unless Seller has a reasonable belief of a discrepancy between the amounts owed by Purchaser to Seller under this Agreement and the amounts paid, and provided that such independent auditor or any Seller employee or agent conducting such audit shall be subject to confidentiality obligations equivalent or similar to the confidentiality obligations set out in Article 7. Except as provided below, the cost of this audit shall be borne by Seller, unless the audit reveals.

with respect to a period, a variance in favor of Purchaser of more than five percent (5%) from the reported amounts for such period, in which case Purchaser shall bear the cost of the audit. Unless disputed pursuant to Section 3.02 (f) below, if such audit concludes that (a) additional amounts were owed by Purchaser, Purchaser shall pay the additional amounts, with interest from the date originally due as provided in Section 3.01, or (b) excess payments were made by Purchaser, Seller shall reimburse such excess payments, in either case ((a) or (b)), within sixty (60) days after the date on which such audit is completed by Seller, and in the case of (a), of the Purchaser being provided a copy of the audit report by Seller.

(f) Audit Dispute. In the event of a dispute with respect to any audit under Section 3.02 (e), Seller and Purchaser shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "Auditor"). The decision of the Auditor shall be final and the costs of such proceeding as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than ten (10) days after such decision and in accordance with such decision, Purchaser shall pay the additional amounts, with interest from the date originally due as provided in Section 3.01, or Seller shall reimburse the excess payments, as applicable.

### ARTICLE IV CLOSING

Section 4.01 Closing. The transactions contemplated hereby shall be consummated (the "Closing") on the date hereof via the electronic exchange of execution versions of this Agreement and the other transaction documents and the signature pages thereto via facsimile or via email by .pdf (the "Closing Date"). The Closing shall be deemed to occur and be effective as of 12:01 a.m. on the Closing Date.

### Section 4.02

### Closing Deliverables.

- (a) At the Closing, the Seller shall deliver to the Purchaser the following:
- (i) possession and control of the Purchased Assets;
- (ii) the certificates referred to in Section 8.02(a) and Section 8.02(b);
- (iii) a Bill of Sale, duly executed by an authorized officer of the Seller;
- (iv) assignments of Assumed Contracts duly executed by the Seller;
- (v) an agreement for the manufacture and supply of the Product by Seller or its Affiliate for Purchaser (the "Supply Agreement"), duly executed by Seller;

- (vi) a letter from Seller to the applicable Governmental Authority, duly executed by Seller, transferring the rights to the Product Registration to Purchaser in accordance with this Agreement, in a form reasonably satisfactory to Purchaser; <sup>1</sup> and
- (vii) such other documents as the Purchaser may reasonably request to give effect to this Agreement.
  - (b) At the Closing, the Purchaser shall deliver to the Seller the following:
  - (i) the Upfront Payment;
  - (ii) the certificates referred to in Section 8.03(a) and Section 8.03(b);
  - (iii) assignments of Assumed Contracts duly executed by the Purchaser;
- (iv) a letter from Purchaser to the applicable Governmental Authority, duly executed by Purchaser, assuming responsibility for the Product Registration from Seller, in a form reasonably satisfactory to Seller;
  - (v) the Supply Agreement, duly executed by Purchaser; and
- (vi) such other documents as the Seller may reasonably request to give effect to this Agreement.

### ARTICLE V REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the section of the disclosure schedules attached hereto that relates to such Section of this Agreement, (the "Seller Disclosure Schedules"), the Seller represents and warrants to the Purchaser that the statements contained in this ARTICLE V are true and correct as of the date hereof.

Section 5.01 Organization and Authority of the Seller. The Seller is a company duly organized, validly existing and in good standing under the Laws of its jurisdiction of India. The Seller has full corporate power and authority to enter into this Agreement, to carry out its obligations hereunder, and to consummate the transactions contemplated hereby. The execution and delivery by the Seller of this Agreement, the performance by the Seller of its obligations hereunder, and the consummation of the transactions contemplated hereby have been duly authorized by all requisite corporate action. This Agreement has been duly executed and delivered by the Seller, and (assuming due authorization, execution and delivery by each other Party hereto) constitutes a legal, valid and binding obligation of the Seller enforceable against the Seller in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or similar Laws affecting

7

creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a Legal Proceeding in equity or Law) (the "Bankruptcy and Equity Exception").

Section 5.02 Conflicts; Consents of Third Parties. The execution, delivery and performance by the Seller of this Agreement, and the consummation of the transactions contemplated hereby, do not and will not: (a) conflict with or result in a violation or breach of, or default under, any provision of the certificate of incorporation, by-laws or other organizational documents of the Seller; (b) materially conflict with or result in a material violation or material breach of any provision of any Law or any Governmental Order applicable to the Seller; (c) require the consent, notice or other action by any Person under, conflict with, result in a violation or breach of, constitute a default or an event that, with or without notice or lapse of time or both, would constitute a default under, result in the acceleration of or create in any Party the right to accelerate, terminate, modify or cancel any material Contract to which the Seller is a party or is bound, or to which any of their respective properties and assets are subject; or (d) result in the creation or imposition of any Encumbrance, other than Permitted Encumbrances, on the Purchased Assets.

Section 5.03 Purchased Assets. The Seller and its applicable Affiliate is the sole and exclusive owner of all right, title and interest in and to, or have the valid and continuing rights to use, all of the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances; and to Seller's Knowledge, no Person is infringing or otherwise violating any of 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 5.04 Product Registration; Regulatory Compliance.

- (a) The Seller is the sole and exclusive owner of all right, title, and interest in the Product Registration, free and clear of any Encumbrances, other than Permitted Encumbrances.
- (b) Except as set forth in the Seller Disclosure Schedules, (i) the Product Registration is in full force and effect, (ii) all product fees, establishment fees and other fees invoiced by or payable to any Governmental Authority with respect to the Product Registration have been paid (other than the annual program fee due in October 2018, which shall be paid by Purchaser), (iii) Seller has not received any notice of any action initiated by the FDA, or any other Governmental Authority, that could result in the suspension, rejection, or termination of the Product Registration, and (iv) there are no Legal Proceedings pending (or, to the Knowledge of Seller, threatened) which could result in the revocation, cancellation or suspension of the Product Registration, or that challenge the validity or ownership of the Product Registration. Seller has made available to Purchaser a true, correct, and complete copies of the Product Registration.
- (c) No right of reference has been granted to any Person with respect to the Product Registration.
- (d) With respect to the Product Registration, the Seller has not, and to the Knowledge of Seller, none of its officers, employees, agents, or representatives has, made or caused to be made

any untrue statement of material fact or fraudulent statement to the FDA, failed to disclose a material fact required to be disclosed to the FDA, or committed any other act that establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy set forth in the FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09).

(e) Notwithstanding any other provision of this Agreement, this Section 5.04 contains the sole and exclusive representations and warranties of Seller with respect to the Product Registration and the regulatory matters described in this Section 5.04.

### Section 5.05

### **Intellectual Property**

- (a) Seller is the owner of all right, title, and interests in the Trademarks and Licensed Patents. Seller has the right, power, and authority to assign the Trademarks and exclusively license the Licensed Patents to Purchaser in the Territory, and such assignment and license do not violate or breach any contract to which Seller or any of its Affiliates is a party.
- (b) To the Knowledge of Seller, the Product does not infringe or misappropriate any intellectual property owned by any third party in the Territory, subject to the terms of the Settlement Agreement. No Proceeding is pending or, to the Knowledge of Seller, threatened in writing, as of the date of this Agreement, against Seller or any of its Affiliates by any third party claiming that the Product or its use or the use of the Licensed Patents or Trademarks infringes the intellectual property rights of such third party.
- (c) To the Knowledge of Seller, no third party is infringing or misappropriating any Purchased Assets. Neither Seller nor its Affiliates has received any written notice from any third party asserting any position of non-infringement, invalidity, or unenforceability of any of the Licensed Patents.
- (d) To the Knowledge of Seller, Seller and its affiliates have complied with their respective duties of disclosure under 37 CFR Section 1.56 in connection with the Licensed Patents.
- (e) All necessary registration, maintenance and renewal fees due in the Territory in connection with the Intellectual Property Rights have been paid and all documents and certificates necessary in the Territory in connection with such Intellectual Property Rights have been filed with the relevant patent, trademark or other Governmental Authorities for the purposes of maintaining such Intellectual Property Rights .

Section 5.06 No Litigation. No Legal Proceeding by or before any Governmental Authority is pending against or, to the Knowledge of Seller, threatened in writing against the Seller with respect to the Purchased Assets. There are no Legal Proceedings pending or, to Seller's Knowledge, threatened, that are reasonably likely to prohibit or restrain the ability of the Seller to enter into this Agreement or consummate the transactions contemplated

hereby. None of the Seller or any of the Purchased Assets are subject to any Governmental Order or arbitration award related to the Purchased Assets.

Section 5.07 Compliance with Laws. The Seller is and has been in compliance in all material respects with all Laws and any Governmental Order applicable to the Purchased Assets and the Assumed Liabilities. Seller has not received any written notice of or been charged with the violation of any Laws applicable to the Purchased Assets or the Assumed Liabilities.

Section 5.08 Contracts. The Seller has made available to the Purchaser true, complete and correct copies of all Assumed Contracts including any and all amendments, supplements or modifications thereto, to which it is a party. Each such Assumed Contract is a legal, valid and binding obligation enforceable against the Seller and, to the Knowledge of Seller, the other party thereto, and is in full force and effect, subject to the Bankruptcy and Equity Exception. Neither the Seller nor, to the Knowledge of Seller, any other party thereto (i) is in breach or violation of, or default under, or has delivered a notice of termination of, any such Assumed Contract and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a breach or default of any such Assumed Contract, (ii) has not communicated any intention or threat to the Seller to terminate or to cancel any such Assumed Contract or has failed to renew or extend the term of any such Assumed Contract upon the expiration of any such term.

Section 5.09 Brokers. Except for Triad Securities, 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 Seller. The Seller is solely responsible for the fees and expenses of Triad Securities.

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.

Section 6.01 Organization and Authority of the Purchaser. The Purchaser is a limited liability company duly organized, validly existing and in good standing under the Laws of its jurisdiction of organization. The Purchaser has full corporate power and authority to enter into this Agreement, to carry out its obligations hereunder, and to consummate the transactions contemplated hereby. The execution and delivery by the Purchaser of this Agreement, the performance by the Purchaser of its obligations hereunder, and the consummation

of the transactions contemplated hereby have been duly authorized by all requisite limited liability company action. This Agreement has been duly executed and delivered by the Purchaser, and (assuming due authorization, execution and delivery by each other party hereto) constitutes a legal, valid and binding obligation of the Purchaser enforceable against the Purchaser in accordance with its terms, subject to the Bankruptcy and Equity Exception.

Section 6.02 Conflicts; Consents of Third Parties. The execution, delivery and performance by the Purchaser of this Agreement, and the consummation of the transactions contemplated hereby, do not and will not (a) conflict with or result in a violation or breach of, or default under, any provision of the certificate of incorporation, by-laws or other organizational documents of the Purchaser, (b) conflict with or result in a violation or breach of any provision of any Law or Governmental Order applicable to the Purchaser, and (c) require the consent, notice or other action by any Person under any Contract to which the Purchaser is a party or is bound.

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

Section 6.04 Sufficiency of Funds. The Purchaser has or will have prior to the Closing sufficient cash, available lines of credit or other sources of immediately available funds to enable them to make payment of the Upfront.

**Section 6.05 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 6.06 Solvency. Immediately after the Closing, the Purchaser will be Solvent.

Section 6.07 No Other Representations and Warranties.

The Purchaser acknowledges and agrees that: (i) the only representations, warranties, and covenants made by the Seller are the representations, warranties, and covenants expressly set forth in this Agreement and the certificates and documents delivered hereunder; (ii) in making their decision to enter into this Agreement and to consummate the transactions contemplated hereby, they have relied solely upon their own investigation and the express representations and warranties of the Seller set forth in this Agreement; and (iii) they have not relied upon any other representations or other information made or supplied by or on behalf of the Seller (including any information provided by their advisors or in management presentations) and they 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 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 noninfringement. Except for the representations and warranties contained in this Article VI, the Purchaser has not made any other express or implied representation or warranty, either written or oral, on behalf of

the Purchaser, including any representation or warranty as to the accuracy or completeness of any information regarding the Purchaser furnished or made available to the Seller or its representatives

### ARTICLE VII COVENANTS

### Section 7.01

### Information and Documents.

From and after the date hereof and pending Closing, upon reasonable advance notice, to the extent permitted by applicable Law, the Seller shall permit the Purchaser and its representatives to have reasonable access, during regular business hours to all books, records, agreements, documents, data, files and personnel of, and such other information relating to the Seller's Purchased Assets (including the Books and Records); provided, however, that no such access shall unreasonably interfere in any material respect with the Seller's operation of business; and provided further that the Seller may restrict the foregoing access to the extent that (A) in the reasonable judgment of the Seller, any applicable Law requires the Seller to restrict or prohibit access to any information, (B) in the reasonable judgment of the Seller, the information is subject to confidentiality obligations to a third party, or (C) disclosure of any such information or document could result in the loss or waiver of the attorney-client or other applicable privilege. It is further agreed that, prior to Closing, the Purchaser and its representatives shall not make any announcements or statements targeted at, or otherwise communicate directly with, any of the customers, manufacturers or suppliers of any Seller, in connection with the transactions contemplated by this Agreement, whether in person or by telephone, mail or other means of communication, without the specific prior authorization by Sellers, which authorization shall not be unreasonably withheld, conditioned or delayed.

### Section 7.02

**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 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. Seller shall not use the Confidential Information of Purchaser for any purpose except for the benefit of Purchaser, unless expressly permitted by this Agreement.
- (c) The Purchaser shall treat as confidential and shall safeguard any and all Confidential Information of Seller relating to the business 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 7.02(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 or desirable 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 7.02(c).

- (d) The Purchaser and Seller acknowledge that the confidentiality obligations set forth herein shall not extend to information, knowledge and data that is publicly available or becomes publicly available through no act or omission of the Party owing a duty of confidentiality, or becomes available on a non-confidential basis from a source other than the Party owing a duty of confidentiality so long as such source is not known by such Party to be bound by a confidentiality agreement with or other obligations of secrecy to the other Party.
- (e) In the event that the party receiving Confidential Information from the other party is required by law or legal process to disclose any such Confidential Information, such party agrees to give prompt written notice thereof to the disclosing party to allow the disclosing party an opportunity, at its sole cost and expense, to seek an appropriate protective order with respect to such Confidential Information. If the disclosing party fails to obtain a protective order, the receiving party may disclose only that portion of any Confidential Information which the receiving party is compelled to disclose pursuant to applicable law.
- (f) In the event of a breach of the obligations hereunder by the Purchaser or Seller, the non-breaching party, in addition to all other available remedies, will be entitled to injunctive relief to enforce the provisions of this Section 7.02 in any court of competent jurisdiction.

### Section 7.03

### Preservation of Books and Records.

- (a) The Seller shall have the right to retain copies of all books and relating to the Purchased Assets relating to periods ending on or prior to the Closing Date, provided that such books and records are kept confidential in accordance with the Seller's normal confidentiality procedures.
- (b) The Purchaser shall preserve and keep, or cause to be preserved and keept, the books and records relating to the Purchased Assets in the possession of the Purchaser or their Affiliates for the longer of: (i) any applicable statute of limitations; and (ii) a period of seven (7) years from the Closing Date.
  - (c) During such retention period:
- (i) the Seller, their Affiliates and their respective representatives shall, upon reasonable notice and for any reasonable business purpose, have access during normal business hours to examine, inspect and copy such books and records; and
- (ii) the Purchaser shall provide, or cause to be provided to, the Seller, their Affiliates and their respective representatives, access to such books and records relating to the Purchased Assets as they shall reasonably request in connection with any Legal Proceeding to which any of them 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 7.03 where such access would violate any Law.

# Section 7.04 Transfer of Product Registration, Related Applications and Dossiers; Other Information.

- (a) On the Closing Date, the Seller shall deliver a letter to the FDA transferring the rights to the Product Registration to the Purchaser (or its designee). On the Closing Date, Purchaser shall deliver a letter to the FDA assuming responsibility for the Product Registration from the Seller. As soon as practical after the Closing Date and in no event more than twenty-one (21) calendar days following the Closing Date, the Seller shall deliver to the Purchaser in electronic form, the regulatory documentation in the possession or control of the Seller related to such Product Registration.
- (b) Without limiting the Parties' respective obligations under Section 7.04(a), (i) the Seller shall use commercially reasonable efforts to complete the transfer of the corresponding Product Registration as promptly as practicable after the Closing Date to the benefit of the Purchaser or its Affiliates as directed by Purchaser in accordance with this Section 7.04(b) and (ii) the Purchaser or its Affiliates shall use commercially reasonable efforts to assist the Seller in the transfer of such Product Registrations, accept the transfer of the corresponding Product Registration and formalize with the Seller and any applicable Governmental Authority, as promptly as practicable after the Closing Date, all necessary documents.
- (c) Seller will reasonably cooperate with 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 Product Registration and coordinating with Purchaser to make an orderly and prompt transition of the Purchased Assets as soon as practicable after Closing.

Section 7.05 Public Announcements. Neither the Seller nor the Purchaser shall, and the Seller and Purchaser shall cause their respective Affiliates not to, issue any press release or public announcement concerning this Agreement or the transactions contemplated hereby without the prior written approval of the other Party (which approval will not be unreasonably withheld or delayed), unless disclosure is required by Law or the rules of a stock exchange on which the Purchaser or Seller, as applicable, list securities, in which case the Party required to make such disclosure shall allow the other Party a reasonable opportunity to review and comment on such press release or public announcement in advance of such disclosure.

Section 7.06 Non-Competition. During the period from the Closing Date until the fifth (5<sup>th</sup>) anniversary from the Closing Date, Seller and its Affiliates shall not, in any capacity, whether directly or indirectly, for their own account or for the benefit of any Person, engage in the development, manufacture, supply, promotion, sale, distribution, or commercialization of the Product and/or Future Product provided, however, that nothing herein shall restrict Seller and its Affiliates from developing, manufacturing, supplying, promoting, selling, distributing, or commercializing the Product and/or Future Product and/or a product that is not the Product and/or Future Product outside the Territory; and/or a product that is not the Product and/or Future Product inside the Territory. The Parties hereto agree that any breach by Seller or its Affiliates of the covenants in this Section 7.06 may result in irreparable injury to Purchaser and its Affiliates for which money damages could not adequately compensate it or its Affiliates and, therefore, in the event of any such breach, Purchaser or its Affiliates shall be entitled (in addition to any other rights and remedies which it or they may have at law or in

equity) to seek an injunction from any competent court of equity to enjoin and restrain Seller and any other person or entity involved therein from continuing such breach.

Section 7.07 Further Assurances. Following the Closing, each of the Parties hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents and instruments and take such further actions, as may be reasonably required to carry out the provisions of and give effect to the transactions contemplated by this Agreement.

### ARTICLE VIII CONDITIONS TO CLOSING

### Section 8.01

### Conditions to Obligations of All Parties.

- (a) No Governmental Authority shall have enacted, issued, promulgated, enforced or entered any Governmental Order which is in effect and has the effect of making the transactions contemplated by this Agreement illegal, otherwise restraining or prohibiting consummation of such transactions, or causing any of the transactions contemplated hereunder to be rescinded following completion thereof.
- (b) No Legal Proceedings shall have been instituted or threatened, or claim or demand made, against the Seller or the Purchaser seeking to restrain or prohibit, or to obtain material damages with respect, to the consummation of the transactions contemplated in this Agreement.

Section 8.02

Intentionally omitted.

Section 8.03

Intentionally omitted.

### ARTICLE IX LICENSE GRANT AND INTELLECTUAL PROPERTY

#### Section 9.01

#### License Grants

- (a) <u>License Grant by Seller</u>. Seller hereby grants to Purchaser, and Purchaser hereby accepts, a perpetual, irrevocable, exclusive, royalty-free license under (i) any of the Seller Intellectual Property Rights not assigned to Purchaser hereunder, including Licensed Patents, to develop, manufacture, have manufactured, market, offer to sell, sell, use, import, export, distribute or otherwise commercialize the Product and/or Future Product in the Territory, and (ii) any Grantback Patents solely to the extent necessary to sublicense such Grantback Patents as required pursuant to the Settlement Agreement ("**License Grant**"). For the avoidance of doubt, the License Grant does not include a license to Intellectual Property Rights that extend beyond the Product and/or Future Product in the Territory.
- (b) Purchaser may grant sublicenses under the Seller Intellectual Property Rights, subject to Seller's consent, which will not be unreasonably withheld or unduly delayed, to develop,

manufacture, have manufactured, market, offer to sell, sell, use, import, export, distribute or otherwise commercialize the Product and/or Future Product in the Territory. Seller hereby grants a non-exclusive license under the Know-How and patent rights owned by or licensed to Seller to manufacture the Product and/or Future Product outside the Territory solely for importation, offer for sale, sale, and use in the Territory.

(c) Regulatory Documentation Grant. As of the Closing Date, Purchaser hereby grants to Seller, and shall procure that each of its relevant Affiliates shall grant, to Seller or its Affiliates (i) a non-exclusive license and right of reference under the Product Registration and/or Regulatory Documentation, with the right to grant sublicenses and further rights of reference in accordance with this Section for the purposes of obtaining or maintaining Regulatory Approvals for the Product, Future Product, or a product that is not the Product and/or Future Product outside the Territory; and (ii) a Right of Reference under the Product Registration for purposes of obtaining or maintaining regulatory approval inside the Territory for anything that is not the Product and/or Future Product. In each case, Purchaser shall provide the applicable Regulatory Authorities a letter confirming such Right of Reference within fifteen (15) business days of request from Seller or its Affiliate and shall take such other actions and execute such other documents as Seller or its Affiliates may reasonably request to further confirm and give effect to this Right of Reference. "Right of Reference" shall have the meaning ascribed in 21 C.F.R. § 314.3.

### Section 9.02. Ownership of Intellectual Property

- (a) Ownership of Technology Other Than Purchased Assets. Except as otherwise provided by this Agreement (such as the Purchased Assets), each Party shall own and retain all right, title and interest in and to any and all Know-How and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party or its Affiliates or its or their (sub)licensees (or Sublicensee(s)), as applicable, whether or not patented or patentable, and any and all patents and other intellectual property rights with respect thereto.
- (b) <u>Ownership of Corporate Names</u>. As between the Parties, Seller shall retain all right, title and interest in and to its Corporate Names and Purchaser shall retain all right, title and interest in and to its Corporate Names.

### Section 9.03 Maintenance and Prosecution of Patents

- (a) Seller shall have the first right, but not the obligation, to prepare, file, and prosecute the Licensed Patents through counsel of its choice. Should Seller elect to prepare, file and prosecute the Licensed Patents, Seller will use best efforts to obtain a U.S. patent which can be listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book) for the Product within two years from the Effective Date. Seller will use best efforts to prosecute the currently pending U.S. patent application no. 15/093,673 to obtain a patent covering the Product.
- (b) Seller will initially cover the costs and expenses incurred after the Effective Date for preparing, filing and prosecuting Licensed Patents. Upon issuance of a Licensed Patent, Purchaser will reimburse Seller for part of the third party costs, including fees paid to the United States Patent

and Trademark Office, and expenses incurred after the Effective Date for prosecuting the Licensed Patent as follows.

- (1) For any issued Licensed Patent claiming (A) the Product and/or Future Product and (B) a product that is not the Product or Future Product (a "Second Product") (the Licensed Patent hereafter referred to as a "Two Product Patent"), Seller will have 30 days from the date of patent issuance to provide written notice to Purchaser if Seller has commercial interest in the claimed Second Product. If Seller does not provide such written notice, the issued patent will be considered a Single Product Patent. Subject to section 9.03(b)(3), for any Two Product Patent, Purchaser will, after receiving written evidence of the third party costs and expenses incurred, reimburse Seller for fifty percent (50%) of the third party costs and expenses incurred after the Effective Date for preparing, filing and prosecuting such Two Product Patent.
- (2) Subject to section 9.03(b)(3), for any issued Licensed Patent claiming the Product and/or Future Product exclusively and not claiming a Second Product (hereafter "a Single Product Patent"), Purchaser will, after receiving written evidence of the third party costs and expenses incurred, reimburse Seller for seventy-five percent (75%) of the third party costs and expenses incurred after the Effective Date for preparing, filing and prosecuting such Single Product Patent.
- (3) In no event will Purchaser be responsible for third party costs and expenses under this Section 9.03(b) totaling in excess of \$100,000, unless Purchaser specifically requests in writing the filing, preparation, and prosecution of the Two Product Patent or the Single Product Patent after the third party costs and expenses total \$100,000.
- (c) Seller will (i) provide Purchaser with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Licensed Patent reasonably promptly, and in any event within 10 business days, after making such filing or receiving such document, including a copy of each application for each Licensed Patent as filed together with notice of its filing date and application number; (ii) keep Purchaser advised of the status of all material communications, actual and prospective filings or submissions regarding the Licensed Patents, and will give Purchaser copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body at least 10 business days before any deadline or other suitable time period if the deadline is shorter; and (iii) consider in good faith Purchaser's comments on the communications, filings and submissions for the Licensed Patents.

### Section 9.04 Enforcement of Patents

(a) Notice. Each Party shall promptly notify the other Party in writing of (i) any alleged or threatened infringement of any Licensed Patent in the Territory or (ii) any certification filed under the FFDCA claiming that any Licensed Patent is invalid or unenforceable or claiming that any Licensed Patent would not be infringed by the making, having made, use, offer for sale, sale or import of a product for which an application under the FFDCA is filed, in each case ((i) and (ii)) of which such Party becomes aware (an "Infringement").

- (b) Purchaser, at its own expense, shall have the sole right, but not the obligation, to (i) institute, prosecute and control any action or proceeding for Infringement of a Single Product Patent or (ii) defend against an invalidity or unenforceability proceeding (such as an inter partes review) regarding a Single Product Patent. In the event Purchaser initates a lawsuit under this section 9.04(b), Seller agrees to be joined as a party and to give Purchaser reasonable assistance and authority to file, prosecute, and defend any of the aforementioned actions or proceedings at Purchaser's expense. Purchaser shall consult Seller in good faith on an infringement strategy, including defense or counterclaim strategy in connection with any action or proceeding initatied under this section.
- Seller shall have the first right, but not the obligation, to (i) institute, prosecute and (c) control any action or proceeding for Infringement of a Two Product Patent due to the filing of an abbreviated application pursuant to 21 U.S.C. §355(b)(2) or (j) (i.e., an 505(b)(2) application or ANDA) based on the NDA, such as an abbreviated application including a paragraph IV certification with respect to the Two Product Patent, or (ii) defend against an invalidity or unenforceability proceeding (such as an inter partes review) regarding a Two Product Patent. Seller shall use Commercially Reasonable Efforts to prosecute the lawsuit and seek an injunction against the marketing of the product that is the subject of the abbreviated application. In the event Seller initiates a lawsuit under this section 9.04(c), (i) Seller and Purchaser will each pay 50% of the costs and expenses for the lawsuit, and (ii) Purchaser shall have the right to join as a party to the lawsuit. Seller shall consult Purchaser in good faith on an infringement strategy, including defense or counterclaim strategy in connection with any action or proceeding initiated under this section. If Seller does not file a lawsuit within 20 days of receipt of a notice letter sent pursuant to 21 U.S.C. §355(b)(3) or (j)(2)(B) ("Paragraph IV Notice Letter") or otherwise of learning of the Infringement, Purchaser shall have the right at its own expense, but not the obligation, to institute, prosecute and control any action or proceeding for Infringement with respect to such Two Product Patent.
- (d) Purchaser shall have the right to settle any disputes over Single Product Patents and Two Product Patents with respect to Infringement by an abbreviated application pursuant to 21 U.S.C. §355(b)(2) or (j) based on the NDA with Seller's consent, which will not be unreasonably withheld or unduly delayed.
- (e) Cooperation. Each Party shall cooperate fully in any Infringement action pursuant to this section, including by making the inventors (to the extent the inventors are available to a Party), applicable records, and documents (including laboratory notebooks) with respect to the relevant Licensed Patents available to the other party.
- (f) Recovery. Any recovery realized as a result of litigation described in this section 9.04 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their 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.
- (g) Abandonment. If the Seller decides to abandon or allow to lapse, or otherwise decides not to prosecute, enforce, or defend, any of the Licensed Patents, the Seller shall inform the Purchaser of such decision promptly and, in any event, so as to provide the Purchaser a reasonable amount of time to meet any applicable deadline to establish or preserve such Licensed

Patents. Should Purchaser decide to continue to prosecute, enforce, or defend such Licensed Patents, Seller shall assign and transfer such Licensed Patents to Purchaser.

### ARTICLE X INDEMNIFICATION

Section 10.01

Survival. The representations and warranties of the Seller contained in ARTICLE V of this Agreement shall survive the Closing until the close of business on the eighteen (18) month anniversary of the Closing Date, provided that the Excluded Representations shall survive until sixty (60) days after the expiration of the applicable statute of limitations for the applicable underlying claim, including any extensions or waivers thereof (Survival Period). All covenants and agreements contained in this Agreement, whether of the Purchaser or the Seller, shall survive the Closing Date until the applicable statute of limitations has expired or until the expiration date for such covenant or agreement specified in this Agreement, if sooner. Any claims for Losses arising out of, or caused by or relating to fraud, willful misconduct, or intentional misrepresentation shall survive indefinitely. The representations and warranties of Seller are bargained for assurances.

Section 10.02 Indemnification by Seller. Subject to the terms and conditions of this ARTICLE X, the Seller shall indemnify and defend the Purchaser, its Affiliates, and each of their respective employees, directors, managers, officers, members, 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 Seller contained in this Agreement or in any certificate or instrument delivered by or on behalf of the Seller pursuant to this Agreement;
- (b) any breach or non-fulfillment of any covenant, agreement, or obligation to be performed by Seller pursuant to this Agreement; or
- (c) the ownership and operation of the Purchased Assets before Closing including any Proceeding against the Purchaser by any Person arising out of or caused by any act or omission of Seller occurring at any time before the Closing Date; or
  - (d) any Excluded Asset or Excluded Liability.

Section 10.03 Indemnification by Purchaser. Subject to the terms and conditions of this ARTICLE X, from and after the Closing, the Purchaser shall indemnify and defend the Seller, their 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;
- (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; provided, however, that this shall not limit the representations and warranties made by Seller pursuant to this Agreement as limited by the Survival Period.

### Section 10.04

### Notice of Direct Claims.

Party") has suffered or incurred any Loss subject to indemnification under this Article X 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 10.04(a) shall not limit the obligation of the Indemnifying Party under this Article X, except (i) to the extent such Indemnifying Party is prejudiced thereby, or (ii) as provided by Section 10.01.

### Section 10.05

### Third Party Claims.

- (a) If any Legal Proceeding is instituted by or against a third party with respect to which the Indemnified Party intends to seek indemnity under this Article X (a "Third Party Claim"), the Indemnified Party shall promptly notify the Indemnifying Party of such 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 and to tender the conduct or defense of the Third Party Claim in a timely manner pursuant to this Section 10.04(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, (ii) to the extent expenses are incurred during the period in which notice was not provided, and (iii) as provided by Section 10.01.
- (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, 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 10.04(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 10.04(b), and the Indemnified Party shall bear its own costs and expenses with respect to such participation.

- If the Indemnifying Party does not notify the Indemnified Party that the Indemnifying Party elects to defend the Indemnified Party pursuant to Section 10.04(b) within sixty (60) Business Days after receipt of any Claim Notice, then the Indemnified Party shall defend, and be reimbursed for its reasonable cost and expense (but only if the Indemnified Party is actually entitled to indemnification hereunder) in regard to the Third Party Claim with counsel selected by the Indemnified Party, in all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnified Party. In such circumstances, the Indemnified Party shall defend any such Third Party Claim in good faith and have full control of such defense and proceedings; provided, however, that the Indemnified Party may not enter into any compromise or settlement of such Third Party Claim if indemnification is to be sought hereunder, without the Indemnifying Party's consent (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party may participate in, but not control, any defense or settlement controlled by the Indemnified Party pursuant to this Section 10.04(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 VIII, the Indemnifying Party shall be entitled to assume the defense of such Third Party Claim in accordance with Section 10.04(b), though the costs and expenses of the Indemnified Party incurred up until such notice shall be reimbursed by the Indemnifying Party in accordance with this Section 10.04(c).
- (d) If requested by the Indemnifying Party, the Indemnified Party agrees, at the sole cost and expense of the Indemnifying Party, 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 10.06

#### Limitations on Indemnification.

(a) Threshold. Notwithstanding the other provisions of this Article X, other than claims for Losses arising out of, or caused by or relating to fraud, willful misconduct, or intentional misrepresentation, Seller shall not be liable to provide indemnification for any Losses arising from or in connection with Section 10.02 suffered by any Indemnified Party unless and until the

aggregate amount of all Losses suffered by the Indemnified Parties exceeds, on a cumulative basis, an amount equal to Fifty Thousand Dollars (\$50,000) (the "Indemnity Threshold"), and then Seller shall only be liable to provide indemnification to the extent of any such excess.

- (b) Representations Cap. Other than claims for Losses arising out of, or caused by or relating to (i) inaccuracy in or breach of the Excluded Representations, or (ii) fraud, willful misconduct, or intentional misrepresentation, in no event shall Seller be liable to provide indemnification pursuant to Article X for Losses arising from or in connection with Section 10.02(a) in the aggregate in excess of an amount equal to twenty-five percent (25%) of the Purchase Price (the "Representations Cap").
- (c) <u>Cap</u>. Subject to Section 10.06(b), other than claims for Losses arising out of, or caused by or relating to (i) inaccuracy in or breach of the Excluded Representations, (ii) fraud, willful misconduct, or intentional misrepresentation, or (iii) any Excluded Liability, in no event shall Seller be liable to provide indemnification pursuant to Article X for Losses under Section 10.02 in the aggregate in excess of an amount equal to the Purchase Price (the "Overall Cap").

Section 10.07 Exclusion of Certain Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, NO INDEMNIFIED PARTY SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, TREBLE, REMOTE, SPECIAL, EXEMPLARY, OPPORTUNITY COST, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR, MEASURED BY OR BASED ON LOST PROFITS, LOSS OF REVENUE OR INCOME, DIMINUTION IN VALUE, MULTIPLE OF EARNINGS, 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.

Section 10.08 Adjustment to Purchase Price. The Seller and 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 10.09 Losses Net of Insurance, Etc. In determining the amount of Losses in respect of a claim under this Article X, there shall be deducted an amount equal to the amount of any third-party insurance proceeds actually received (net of direct collection expenses) by an Indemnified Party making such claim with respect to such Losses, provided that the foregoing shall not (i) require an Indemnified Party to proceed or seek action or recovery from any such third-party as a requirement hereunder or as a condition to seeking or recovering indemnification from any Indemnitor hereunder, or (ii) be construed or interpreted as a guaranty of any level or amount of insurance recovery 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 10.10 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 X, the Indemnified Party shall promptly remit to the Indemnifying Party the amount received from the third party in respect thereof.

Sole Remedy/Waiver. Should the Closing occur, the remedies provided for in this Article X shall be the sole and exclusive remedies of any Indemnified Party in respect of this Agreement, other than (i) for actions for specific performance or other equitable remedies or (ii) 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 10.11, and each Party hereby waives (on behalf of itself and the relevant Indemnified Parties) for periods following the Closing any and all other rights, claims or causes of action it or its Affiliates or relevant Indemnified Parties may have against the other Party or its Affiliates or Representatives now or in the future arising under or based upon this Agreement, except for the remedies provided for in this Article X.

### ARTICLE XI MISCELLANEOUS

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

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

### (a) if to the Seller:

DR. REDDY'S LABORATORIES LTD. 8-2-337, Banjara Hills, Hyderabad-500034, India Attention: Head of Proprietary Products

With a copy to:

DR. REDDY'S LABORATORIES LTD. 8-2-337, Banjara Hills,

Hyderabad-500034, India Attention: Legal Counsel

(b) if to the Purchaser:

EPI Health 134 Columbus Street Charleston, SC 29403 Facsimile: [FAX NUMBER]

Email: <u>rowens@epihealth.com</u> Attention: Ron Owens, President

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

Section 11.04 Entire Agreement. This Agreement constitutes the entire agreement, and supersedes all prior agreements and understandings (both written and oral), among the parties regarding the subject matter hereof.

Section 11.05

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. Neither party may assign its rights or obligations hereunder without the prior written consent of the other party.

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

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

### Section 11.08

### Governing Law; Jurisdiction.

(a) This Agreement and its negotiation, execution, performance or non-performance, interpretation, termination, construction and all claims or causes of action (whether in contract, in tort, at Law or otherwise) that may be based upon, arise out of, or relate to this Agreement, or the

transactions contemplated hereby (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in connection with this Agreement or as an inducement to enter this Agreement), shall be exclusively governed by, and construed in accordance with, the Laws of the State of Delaware regardless of Laws that might otherwise govern under any applicable conflict of laws principles.

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 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.

Section 11.09 WAIVER OF JURY TRIAL. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HERETO HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY 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.

Section 11.10 Specific Performance. The Seller, on the one hand, and the Purchaser, on the other hand, acknowledge and agree that the breach of this Agreement or other failure to perform any provision of this Agreement would cause irreparable damage to the other and such other parties 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.

Section 11.11 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.

[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.

DR. REDDY'S LABORATORIES LTD.

**EPI HEALTH LLC** 

Ву

Ву\_\_\_\_

Name: SHANAVAS ALIKUNJU

VICE PRESIDENT

Name: Title:



[Signature Page - Asset Purchase and License Agreement]

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.

DR. REDDY'S LABORATORIES LTD.	EPI HEALTH LLC
Ву	By (1) (5)
Name:	Name: Ronald C. Ower:
Title:	Title: President

[Signature Page - Asset Purchase and License Agreement]

#### **SCHEDULE 1.01**

#### DEFINITIONS

Affiliate of a Person or a Party means 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") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

Agreement has the meaning set forth in the preamble.

Assumed Contracts has the meaning set forth in the definition of Purchased Assets.

Assumed Liabilities means those liabilities arising after Closing out of or in connection with the Assumed Contracts, but only to the extent such liabilities arise in the ordinary course of performing such Assumed Contracts, in accordance with their respective terms, after the Closing Date and are not due to any breach or default by Seller under such Assumed Contracts (including any that result from or are triggered by the Closing), and provided that the incurrence or existence of any such liability does not constitute a breach or failure of, or default under, any representation, warranty, covenant, or other provision of this Agreement.

Bankruptcy and Equity Exception has the meaning set forth in Section 5.02.

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

Cap has the meaning set forth in Section 10.06(b).

Closing has the meaning set forth in Section 4.01.

Closing Date means the day on which the Closing takes place.

Confidential Information means, 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 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** means the Confidentiality Agreement between the Seller (or its Affiliate) and the Purchaser, dated September 15, 2017, as amended or supplemented from time to time.

**Contracts** means all contracts, leases, deeds, mortgages, licenses, instruments, notes, commitments, undertakings, indentures, joint ventures and all other agreements, commitments and legally binding arrangements, whether written or oral.

Corporate Names means, (a) with respect to Seller, the trademarks, names and logos identified on Schedule 9.02 (a) and such other trademarks, names and logos as Seller may designate in writing from time to time, and (b) with respect to Purchaser, the trademarks, names and logos identified on Schedule 9.02 (b) and such other trademarks, names and logos as Purchaser may designate in writing from time to time.

**Domain Names** means the domain names listed on Exhibit D.

Encumbrances means 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.

Excluded Assets means those assets that are not expressly include within the definition of Purchased Assets.

Excluded Liabilities has the meaning set forth in Section 2.01(d).

**Excluded Representations** means those representations and warranties set forth in Sections 5.01 (Organization and Authority), 5.02 (Conflicts; Consents of Third Parties), 5.03 (Title to Purchased Assets), and 5.09 (Brokers).

**FDA** means the United States Food and Drug Administration and any successor agency thereto.

FFDCA means the Federal Food, Drug and Cosmetic Act of 1938, as amended.

**Future Product** means the biphasic minocycline hydrochloride immediate release/extended release tablets having the other dosage strengths (otherthan the Product) approved for Solodyn (NDA 050808), namely, 45, 55, 65, 80, 90, and/or 115 mg for treating inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Governmental Authority means any federal, state, local or foreign government, or political subdivision thereof or 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 means any order, writ, judgment, injunction, decree, stipulation, determination, or award entered by or with any Governmental Authority.

Grantback Patents shall have the meaning given to such term in the Settlement Agreement.

**IND** means (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions and (b) all supplements and amendments that may be filed with respect to the foregoing.

**Indemnified Party** has the meaning set forth in Section 10.04(a).

Indemnifying Party has the meaning set forth in Section 10.04(a).

**Indemnity Threshold** has the meaning set forth in Section 10.06(a).

Intellectual Property Rights means all: (a) rights in Licensed Patents; (b) rights in Know-How; (c) rights in Copyrights; (d) rights in Trademarks and internet Domain Names; and (e) rights or forms of protection, having equivalent or similar effect to the rights referred to in paragraphs (a) through (d) above, in each case, whether registered or unregistered and including applications for registration of any of the foregoing to the extent such rights relate to the Product and/or Future Product in the Territory.

Know-How means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed. For the avoidance of doubt, Know-How does not include Licensed Patents (as defined below).

Knowledge of Purchaser means the current knowledge following due inquiry of any of the individuals listed on Exhibit A.

**Knowledge of Seller** means the current knowledge following due inquiry of any of the individuals listed on Exhibit B.

Law means any statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority.

**Legal Proceeding** means any judicial, administrative or arbitral action, suit, proceeding (public or private), investigation, hearing, or any other claim or proceeding by or before a Governmental Authority.

**Licensed Patents** means (i) the U.S. patents and patent applications listed in <u>Exhibit E</u>; (ii) any U.S. non-provisional patent applications that claim priority to any provisional patent applications listed in <u>Exhibit E</u>; (iii) any and all divisionals, continuations, continuation-in-part applications, reissues, re-examinations, renewals, substitutions, and extensions of the foregoing; and (iv) any and all patents issuing from the foregoing to the extent that the patent or application claims the Product and/or Future Product in the Territory. For the avoidance of doubt, Licenced Patents does not include any patent or application that does not claim the Product and/or Future Product in the Territory.

Losses means losses, obligations, damages, liabilities, costs or expenses, including reasonable attorneys' fees.

**Net Sales** means the aggregate gross sales (to the extent recognized as gross revenue by Purchaser on an accrual basis in accordance with the GAAP) resulting from Purchaser's sales of the Product, and/or Future Product, less the following deductions (the "**Deductions**") accrued or actually taken:

- a) Trade, quantity and cash discounts or rebates accrued or actually taken;
- b) Credits, refunds, allowances, volumes rebates, charge backs, direct and indirect rebates, distribution fee, wholesaler fees for service and other third party administrative and marketing 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;
- c) Any adjustments on account of price adjustments, shelf stock or floor stock adjustments, billing errors, rejected goods, damaged goods, product recall and sales returns;
- d) Patient co-pay assistance benefits, rebates and coupon or voucher redemptions provided specifically to the licensed product;
- e) the amount of any penalty payments that Purchaser has paid to third party customers for undelivered quantities of the Product as a result of Purchaser's failure to fulfill its contractual obligations to its customers due to Seller's failure to timely deliver Product under the terms of the Supply Agreement;
- f) Rebates paid or other price reductions provided in connection with sale of product to any government or regulatory authority in respect of any state or federal Medicare, Medicaid, or similar programs; and
- g) Any freight, shipping, insurance costs, fees paid to third party logistics providers, and any duties, taxes, or excises paid by Purchaser upon sale of the Product and/or Future Product into the territory to the extent they are included in the gross sales.

Purchaser shall be responsible for payment of rebates or other price reductions provided in connection with sales of product to any Governmental Authority or Regulatory Authority in respect of any state or federal Medicare, Medicaid or similar program (provided such amounts are considered Deductions in calculating Net Sales).

In the event the Purchaser sells Product and/or Future Product as part of a bundle or group sale with other products not covered by this Agreement, and Purchaser provides discounts, allowance or rebate to the purchaser of the Product and/or Future Product based on the invoiced price for all the products sold, such discount must be allocated pro rata based on the selling prices of such products before taking into account the discount, allowance or rebate on product provided as part of such bundle.

The foregoing deductions from gross sales shall only be deducted only once and to the extent not otherwise deducted from the gross sales and net sales cannot be negative. All deductions provided above shall be based on accrual or actual basis without any retroactive adjustments relating to any previous years.

NDA means a new drug application as defined in the FFDCA.

Party or Parties has the meaning set forth in the introductory paragraph hereto.

**Permitted Encumbrances** means: (a) liens for Taxes not yet due and payable or being contested in good faith by appropriate procedures; and (b) mechanics', carriers', workmen's, repairmen's or other like liens arising or incurred in the ordinary course of business, in each case set forth on Exhibit F.

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

**Product** means biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets for treating inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older, including but not limited to NDA 209269.

Product Registration means the new drug application NDA No. 209269 submitted to the FDA.

**Purchased Assets** means: (a) the Product Registration and IND 120026, (b) Regulatory Documentation in Seller's possession or control with respect to the Product; (c) Trademarks; (d) Domain Names; and (f) the Contracts relating to the Product set forth on <u>Exhibit C</u> hereto (the "Assumed Contracts").

**Purchase Price** has the meaning set forth in Section 3.01(a).

Purchaser has the meaning set forth in the preamble.

Purchaser Group has the meaning set forth in Section 10.02.

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

Regulatory Documentation" means: all (a) applications (including all INDs and Product Registration), 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 with respect to the Product; and (e) clinical and other data contained or relied upon in any of the foregoing; in each case relating to the Product.

**Seller** has the meaning set forth in the preamble.

**Seller Disclosure Schedules** has the meaning set forth in the introductory sentence to ARTICLE V.

**Seller Group** has the meaning set forth in Section 10.03.

**Settlement Agreement** means the License and Settlement Agreement, dated March 17, 2017, by and between Medicis Pharmaceutical Corporation and Seller.

**Solvent** when used with respect to any Person, means that, as of any date of determination, (a) the amount of the "fair saleable value" of the assets of such Person on a going concern basis will, as

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

Taxes means 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** means the United States of America and its territories, possessions, districts, protectorates and commonwealths.

Third Party Claim has the meaning set forth in Section 10.05(a).

**Trademarks** means all trademarks, service marks, trade names, brand names, trade dress rights, logos, and slogans set forth on Exhibit D.

Valid Patent Claim means a claim of an issued and unexpired patent included within the Seller Licensed Patents, within the Territory that, unless licensed would be infringed by the manufacture, use, importation or sale of such Product in the Territory, which claim has not been held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction, which decision is an unappealable or unappealed decision within the time allowed for appeal, and which is not lost in an interference proceeding or through disclaimer or otherwise not admitted to be invalid.

DRL DRAFT DATED 10/24/17

# **EXHIBIT A**

# KNOWLEDGE OF PURCHASER

Ronald C. Owens, President, EPI Health, LLC

# **EXHIBIT B**

# KNOWLEDGE OF SELLER

Vice President, Sales & Marketing Head – Promius Pharma, LLC; or Senior Director & Head – IP, Intellectual Property Management; or Vice President & Head of Regulatory Affairs

## **EXHIBIT C**

# ASSUMED CONTRACTS

License and Settlement Agreement, dated as of March 17, 2017, by and between Medicis Pharmaceutical Corporation ("Medicis") and Seller, including the obligation to pay to Medicis the royalty required under such Agreement.

### **EXHIBIT D**

### DOMAIN NAMES AND TRADEMARKS

#### **US TM REGISTRATIONS**

US TM application 87126356 for MINOLIRA

## **COMMON LAW USAGE**

The following common law trademark:



## **DOMAINS**

MINOLIRA.COM

MINOLIRA.NET

# EXHIBIT E PATENTS

U.S. Patent Application No. 15/093,673

# Seller Disclosure Schedule 5.04 (b)

Annual program fee due in October 2018 for Product Registration

Quarterly Periodic Adverse Drug Experience Reports (PADERs) to FDA for Product Registration were delayed in submission.

Schedule 9.02 (a)

Dr. Reddy's Laboratories Ltd.

Promius Pharma LLC

Schedule 9.02 (b)

EPI Health, LLC

# Exhibit 2

# Case 23-10937-LSS Doc 696 Filed 05/29/24 Page 56 of 90

# **Execution Version**

# **SUPPLY AGREEMENT**

**BETWEEN** 

DR. REDDY'S LABORATORIES LTD.

**AND** 

EPI HEALTH, LLC

**DATED AS OF** 

**AUGUST 20, 2018** 

# Case 23-10937-LSS Doc 696 Filed 05/29/24 Page 57 of 90

# **Execution Version**

# **Exhibits and Schedules**

Schedule 1.1 Definitions

Schedule 6.1 Products, Transfer Prices and Batch

Quantities

### **EXECUTION VERSION**

### **SUPPLY AGREEMENT**

This Supply Agreement (this "Supply Agreement"), dated as of August 20, 2018 ("Effective Date"), by and between:

Dr. Reddy's Laboratories Ltd., a company established under the laws of India through its FTO Division have developed an Unit approved in the SEZ sector located at and having address as "SEZ - Process unit – 1, Devunipalavalasa Village, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh, India, Pin-532409. (the "Manufacturer"); and

EPI Health, LLC, a South Carolina Limited Liability corporation located at 134 Columbus Street, Charleston, SC 29403 (the "**Purchaser**");

### WITNESSETH:

WHEREAS, pursuant to that certain Asset Purchase Agreement, dated as of the date hereof, by and between the Purchaser and the Manufacturer (the "<u>Asset Purchase Agreement</u>"), the Purchaser purchased certain assets relating to the Products (the "<u>Acquisition</u>");

WHEREAS, the Purchaser desires to engage the Manufacturer to manufacture and/or supply the Products to the Purchaser; and

WHEREAS, the Manufacturer wishes to manufacture and/or supply the Products to the Purchaser upon the terms and subject to the conditions set forth herein;

Now, THEREFORE, in consideration of the premises and mutual covenants contained herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereto agree as follows:

#### **ARTICLE I**

## **DEFINITIONS**

Section 1.1 <u>Definitions</u>. Capitalized terms used in this Supply Agreement have the meanings specified in Schedule 1.1 to this Supply Agreement. As used herein the words "including" or "includes" shall be deemed to mean "including, without limitation," or "includes, without limitation".

#### **ARTICLE II**

#### MANUFACTURE AND SALE OF PRODUCTS

Section 2.1 <u>Engagement</u>. During the Term and upon the terms and subject to the conditions set forth herein, the Purchaser hereby agrees to purchase from Manufacturer and the Manufacturer agrees to supply the Products exclusively to Purchaser for sale by Purchaser in the Territory. The Manufacturer shall have the right to subcontract its obligations under this Supply Agreement to a third party that has been approved in advance by Purchaser; provided, however that the Manufacturer shall be responsible for all the acts and omissions of the subcontractor and no subcontract shall release the Manufacturer from its responsibility for its obligations under this Agreement. Manufacturer shall not, directly or indirectly, manufacture or sell (or cause its

Affiliates to manufacture or sell) the Products to any third party during the Term for sale in the Territory.

- Section 2.2 <u>Sale and Distribution</u>. The Purchaser will sell the Products only in the Territory and will not directly or indirectly sell or otherwise distribute the Products outside of the Territory. The Purchaser shall have the sole and exclusive right to determine all terms and conditions of sale by it of the Products.
- Section 2.3 Packaging and Labeling. Manufacturer shall ensure that the Products and all labeling and packaging used in connection therewith shall include the appropriate product trademarks associated with any specific Product, in the manner and to the extent specified in the Specifications. The Purchaser will be responsible for ensuring the accuracy of all information contained on Products with Purchaser's labels for Products and for the compliance of all such labels with applicable Governmental Rules. The Manufacturer will, or will cause its contractors to, supply all packaging and labels for Products under this Supply Agreement. Such packaging and labels will be in accordance with the Specifications. The Manufacturer will make any changes to labeling and packaging Specifications required in writing by the Purchaser, at the Purchaser's sole cost and expense, within a reasonable timeframe to be agreed upon in writing by both Parties. The Purchaser will be responsible for submitting any such changes to all applicable Governmental Entities for approval, if required the Manufacturer shall provide all support and documents reasonably necessary in this regard.

# Section 2.4 Facility Maintenance; Inspection; Reports.

- The Manufacturer shall, at all times, maintain and operate, or cause its (a) contractors to maintain and operate, all facilities where Products are Manufactured, packaged, tested, stored, warehoused or shipped in compliance with cGMP and applicable Laws, and implement such quality control procedures, as is reasonably required so as to be able to perform its obligations hereunder in accordance with all applicable Governmental Rules, including without limitation, the cGMP Requirements. Not more than once every twelve (12) months (or more often for follow-up audits or inspections directed at significant or critical quality issues observed during the regular audit or brought to the Purchaser's attention through customer complaints or claims or by Governmental Entities), the Manufacturer shall permit, or cause its contractors to permit, quality assurance representatives of the Purchaser or designated third parties (subject to appropriate confidentiality obligations) to inspect such facilities, operations, documents, and records related to the handling, manufacture, testing, inspection, packaging, storage, disposal and transportation of the Products by the Manufacturer or the applicable contractor upon reasonable notice (which shall not be less than ten (10) days), during normal business hours and on a confidential basis. The Manufacturer shall also permit, and cause its contractors to permit, representatives of the FDA to inspect such facilities as requested by the FDA.
- (b) The Manufacturer shall maintain adequate and accurate records consistent with the applicable Specifications, including records covering quality control testing and release of the Products and all other Manufacturing services provided hereunder in material compliance with the cGMP Requirements and any other relevant Governmental Rules, at all times during the performance of the Manufacturing services and for a period as required by Governmental Rules.

- (c) The Manufacturer shall notify Purchaser as soon as reasonably practicable and in any event within five (5) business days following receipt of notice of any FDA or other regulatory authority inspection of the Manufacturing facilities if such inspection pertains to any Product
- Section 2.5 <u>Adverse Events</u>. Prior to the Effective Date the Parties shall each assign a representative to negotiate in good faith and agree on a process and procedure for sharing adverse event information which shall be documented in a safety data exchange (SDEA) agreement which the Parties shall use commercially reasonable efforts to agree upon and execute prior to commercialization of the Product.

## **ARTICLE III**

## FORECASTS, ORDERS AND SHIPMENT

Forecasts. In order to assist in the planning of production runs for the Section 3.1 Products, the Purchaser will, within thirty (30) days following the execution of this Supply Agreement, provide the Manufacturer with a non-binding written forecast of estimated quantities of Product that the Purchaser anticipates ordering from the Manufacturer during the next twentyfour (24) month period (the "Forecast"). This initial Forecast will be updated at least five business days before each following calendar quarter and such updated Forecast will be promptly delivered to the Manufacturer by the Purchaser. The first three (3) months of each such Forecast (the "Firm Order Period") shall be binding on Purchaser. The remaining twenty-one (21) months of each such forecast shall be non-binding estimates for planning purposes. No Forecast shall be required for any period of time that extends beyond the Term (as in effect at the time of such Forecast). The Purchaser will forecast in amounts comprising full batch and in multiples of batch quantities, as such quantities are set forth on Schedule 6.1. Each Forecast will be made by the Purchaser in good faith, taking into account reasonable projections of demand for the Products including, without limitation, demand in line with prescription trends, and allowing for reasonable safety stock. The Manufacturer shall use its commercially reasonable efforts to ensure sufficient Manufacturing The Manufacturer shall purchase raw materials (e.g. API, capacity to meet the Forecast. excipients, and packaging material) upon receipt of Product quantities set forth in the Firm Order Period or procure such items in advance to support delivery of the Products within One Hundred and Twenty (120) days from the date of receipt of Firm Orders from Purchaser. Upon receipt of a Firm Order, Manufacturer shall invoice Purchaser fifty (50%) percent of the value of the Firm Order as an advance towards procurement of raw materials (e.g. API, excipients, packaging material), payment to be made by Purchaser in accordance with the payment terms set forth in Section 6.4. The amount paid as advance shall be deducted from the invoice issued by Manufacturer to Purchaser for the Product in accordance with the terms of this Agreement. For clarity, title and risk of loss with respect to the materials purchased shall remain with Manufacturer despite payment of the advance on total order amount.

# Section 3.2 Orders.

(a) The Purchaser will place firm purchase orders ("<u>Firm Orders</u>") for Products in writing for delivery at least one hundred and twenty (120) days after the Purchase Order Date. The Manufacturer shall accept or reject each Firm Order in writing within seven (7) Business Days

after its receipt of each order, and may only reject a Firm Order that fails to meet the requirements specified below. Each Firm Order will specify the quantity and description of each Product ordered, the requested delivery date (which delivery dates will not be on a Saturday, Sunday or holiday), the delivery address, the transportation method and carrier and any special instructions requested; provided that no Firm Order shall include a quantity of a Product that is greater than the quantity of such Product set forth in the Firm Order Period of the most recent Forecast delivered to the Manufacturer by the Purchaser. The minimum size of any order placed by the Purchaser will be a full batch (or multiples of a full batch) in accordance with Schedule 6.1 hereto, except with the prior approval of the Manufacturer and payment of any additional expenses or fees that are required for split batches. The Products set forth in Firm Orders will be delivered to such location as the Purchaser designates in writing to the Manufacturer from time to time. The date an order will be deemed placed (the "Purchase Order Date") will be the date that the Manufacturer actually receives the purchase order form. The Purchaser will be fully responsible for any changes to a Firm Order. Orders will be deemed accepted by the Manufacturer unless the Manufacturer provides notification of rejection to the Purchaser within seven (7) Business Days of receipt of the Firm Order. In the event that a Firm Order is rejected, the Manufacturer shall provide to Purchaser the reasons for rejection in writing and the Manufacturer and the Purchaser will cooperate in good faith to promptly resolve any issues raised by such order. The Manufacturer shall use commercially reasonable efforts to timely supply any Products in accordance with the resolution of a rejected Firm Order.

- (b) The Manufacturer will supply the Products in accordance with each Firm Order placed pursuant to the terms of this Supply Agreement by the Purchaser and accepted by the Manufacturer including the quantities and delivery dates requested in each Firm Order. Each Firm Order will set forth a delivery date, not less than one hundred and twenty (120) days after the date of such order.
- (c) No later than six (6) months after delivery of the first binding Forecast, and thereafter at all times during the Term, Manufacturer shall, at Purchaser's expense and advance payment, maintain an amount of inventory of raw materials (API, excipients, and packaging) necessary to manufacture the amount of Product set forth in Purchaser's last Firm Order, updated on a rolling basis based on the last Firm Order (the "Safety Stock"). The Safety Stock shall be maintained for the sole benefit of Purchaser, shall not be subject to allocation, and shall be stored at a secure facility in compliance with applicable Laws, and other requirements and any of Purchaser's specific reasonable demands in order to maintain the quality of the Safety Stock. Manufacturer shall rotate the Safety Stock on a "First Expiry-First Out" basis for routine fulfillment of Purchaser's orders. At the end of the Term or upon earlier termination all Safety Stock that remains in inventory will be promptly delivered to Purchaser or otherwise disposed of by agreement between the Parties.
- (d) In the event that at any time Manufacturer foresees that it will be unable to supply to Purchaser (or its nominee) in whole or in part an ordered or forecasted quantity of Product by the delivery date for any reason, including a Force Majeure event, Manufacturer shall notify Purchaser of such inability as soon as possible, the reasons therefor and the date such inability is expected to end, the quantities of Product available during such period and the proposed

amount of the raw materials and/or resources prioritized to Purchaser in the event such inability is caused by a shortage of raw materials and/or resources required for the Manufacture of Product.

- (e) At any time during the Term, Purchaser shall have the right to qualify one or more third parties ("<u>Alternative Manufacturers</u>") to Manufacture and supply the Product to Purchaser for sale in the Territory. Manufacturer will assist as necessary with technology transfer to such Alternative Manufacturer. Purchaser will pay for actual costs and any reasonable out of pocket expenses for the Technology Transfer, such costs and expenses to be agreed upon by the Parties prior to initiation of Technology Transfer.
- (f) The initial Firm Order is attached as <u>Schedule 3.2(d)</u> hereto. The Manufacturer will deliver the Products subject to the initial Firm Order no later than 30<sup>th</sup> November 2018.
- (g) Manufacture shall deliver the Products to Purchaser with at least 85% (eighty five percent) of remaining shelf life at the shipment date in accordance with Section 3.2(b).
- (h) The terms of this Supply Agreement shall prevail over any conflicting, inconsistent or additional terms set forth in any Firm Order, invoice, or acceptance form.

## Section 3.3 Delivery.

- (a) All Products shipped under this Supply Agreement will be shipped FCA Hyderbad airport or such other location reasonably requested by Purchaser. The Purchaser shall make necessary arrangements to pick up the shipment and will pay all freight, insurance charges, taxes, import and export duties, inspection fees and other charges applicable to the sale and transport of Products purchased by the Purchaser. Title and risk of loss and damages to Products purchased by the Purchaser will pass to the Purchaser upon delivery to the carrier. In the event of damage or loss to the Products after delivery to the carrier, the Purchaser will be responsible to file claims with the carrier. The Manufacturer shall notify Purchaser of the following information concurrently with each shipment of Product: (i) date of shipment, (ii) quantity and type of Product shipped, and (iii) order number or other identifying information.
- (b) Manufacturer shall perform quality assurance testing with respect to the Products sold hereunder, including stability testing, so that the Products conform with the Specifications. Manufacturer shall provide Purchaser with a Certificate of Analysis ("COA") and a Certificate of Compliance ("COC") confirming that the Products in such shipment have been tested in accordance with the NDAs and meet the Specifications via facsimile transmission. Any deviations and investigations related to such Products shall be completed in compliance with applicable NDA, cGMP Requirements and the Quality Agreement (as defined in Section 5.6 hereof).

#### **ARTICLE IV**

### REPRESENTATIONS AND WARRANTIES

Section 4.1 Representations and Warranties of the Manufacturer.

The Manufacturer hereby represents and warrants to the Purchaser as follows:

- (a) Product Compliance. All Products delivered pursuant to this Agreement by the Manufacturer (or any sub-contractor thereof) to the Purchaser or its designee during the Term will at shipment be in compliance in all material respects with this Supply Agreement, the Specifications, the Quality Agreement and applicable Governmental Rules, including the cGMP Requirements and DSDCA serialization requirements, and the Manufacturing of such Products will have been in accordance with the cGMP Requirements. At the time Manufacturer makes each shipment of Product available for pick-up by Purchaser (or Purchaser's carrier), the Products shall: (i) not be adulterated or misbranded within the meaning of the FFDCA or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the FFDCA, as such FFDCA and such laws are constituted and in effect at the time of delivery; (ii) be free of any lien or other encumbrance; and (iii) not be an article that may not be introduced into interstate commerce under the provisions of Sections 404 and 505 of the FFDCA.
- (b) <u>Authorization</u>. This Supply Agreement has been duly executed and delivered by the Manufacturer and, assuming due execution and delivery by the Purchaser, constitutes a valid and binding obligation, enforceable against the Manufacturer in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Supply Agreement have been duly authorized by all necessary action on the part of the Manufacturer and its respective officers and directors.
- (c) <u>Absence of Conflicts</u>. The execution, delivery and performance of this Supply Agreement by the Manufacturer does not conflict with or constitute a default under any agreement, instrument or understanding, oral or written to which it is a party or by which it may be bound, does not conflict with any provision of any of its organizational documents and does not conflict with or violate any Governmental Rule or court order or decree.
- (d) <u>Organization and Standing</u>. The Manufacturer is a corporation, duly organized, validly existing and in good standing under the laws of India.
- (e) <u>Power and Authority</u>. The Manufacturer has the corporate power and authority to execute, deliver and perform this Supply Agreement and to consummate the transactions contemplated hereby.
- (f) <u>Compliance With Law</u>. Manufacturer has and will maintain throughout the Term of this Agreement all permits, licenses, registrations and other forms of governmental

authorization and approval as required by law in order for Manufacturer to execute and deliver this Agreement and to perform its obligations hereunder in accordance with all applicable laws.

(g) <u>No Debarment</u>. Manufacturer is not debarred and has not and will not use in any capacity the services of any person debarred under subsection 306(a) or (b) of the Generic Drug Enforcement Act of 1992. If at any time this representation and warranty is no longer accurate, Manufacturer shall promptly notify Purchaser of such fact.

## Section 4.2 Representations and Warranties of the Purchaser.

The Purchaser hereby represents and warrants to the Manufacturer as follows:

- (a) <u>Authorization</u>. This Supply Agreement has been duly executed and delivered by the Purchaser and, assuming due execution and delivery by the Manufacturer, constitutes a valid and binding obligation, enforceable against the Purchaser in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Supply Agreement have been duly authorized by all necessary action on the part of the Purchaser and its respective officers and directors.
- (b) <u>Absence of Conflicts</u>. The execution, delivery and performance of this Supply Agreement by the Purchaser does not conflict with or constitute a default under any agreement, instrument or understanding, oral or written to which it is a party or by which it may be bound, does not conflict with any provision of any organizational documents of the Purchaser and does not conflict with or violate any Governmental Rule or court order or decree.
- (c) <u>Organization and Standing</u>. The Purchaser is a corporation, duly organized, validly existing and in good standing under the laws of the State of South Carolina.
- (d) <u>Power and Authority</u>. The Purchaser has the corporate power and authority to execute, deliver and perform this Supply Agreement and to consummate the transactions contemplated hereby.
- Section 4.3 Disclaimer. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT ARE THE PARTIES' ONLY WARRANTIES AND NO OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, WILL APPLY. EACH PARTY EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FOR THE AVOIDANCE OF DOUBT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF NON-INFRINGEMENT THAT ARE NOT EXPRESSLY SET FORTH IN THIS AGREEMENT.

# ARTICLE V QUALITY ASSURANCE

# Section 5.1 <u>The Manufacturer's Covenants.</u>

The Manufacturer hereby covenants during the Term that it will:

- (a) manufacture, fill, package, test, handle, store, warehouse and ship the Products in conformity with this Supply Agreement, Quality Agreement, Governmental Rules, applicable requirements of DSCSA, and cGMP Requirements and the Specifications;
- (b) promptly (but in any event no later than five (5) Business Days after becoming aware) inform Purchaser of any adverse events related to the Products and any inspections, communications, or material issues raised by the FDA in connection with the Manufacturing of the Products, and shall provide Purchaser with copies of any correspondence (including emails) relating thereto;
- (c) obtain and maintain all permits reasonably necessary to Manufacture and supply Product subject to an FDA approved NDA in accordance with the Specifications, applicable Governmental Rules and this Supply Agreement; and
- (d) if Manufacturer becomes aware of any Products that have not been Manufactured in accordance with the Specifications and that have been supplied, promptly take such corrective action as shall be reasonably necessary to correct such nonconformity and inform Purchaser in writing.

### Section 5.2 The Purchaser's Covenants

The Purchaser hereby covenants during the Term that it will:

- (a) hold, store, handle, ship, deliver, distribute and/or sell the Products (i) in accordance with applicable cGMP Requirements and Governmental Rules, including but not limited to any risk management programs required by the FDA; and (ii) in compliance with the Specifications;
- (b) enter into all necessary compliance agreements with the Manufacturer, including but not limited to agreements to cover quality assurance and adverse incident reporting; and
- (c) except as set forth herein or in the Quality Agreement between the Parties, upon delivery of the Products to the Purchaser, the Purchaser will be solely responsible for compliance with all quality control testing and other testing requirements set forth in this Supply Agreement and all related Governmental Rules with respect to such Products.
- Section 5.3 <u>Rejection of Delivered Products</u>. Within 30 days of receipt of any shipment of Product and applicable COA and COC by the Purchaser at its applicable warehouse, the Purchaser will inspect the Product, COA and COC and advise the Manufacturer of any defect

revealed from such inspection whereby the Product does not conform to the Specifications. Any Product not refused within 30 days will be deemed accepted. If the Purchaser wishes to refuse acceptance, the Purchaser will, within such 30-day period, provide written notice to the Manufacturer of its refusal to accept the defective Product and the reason(s) therefor. In the event a hidden defect (i.e., one which could not have been reasonably identified during the initial 30-day Purchaser inspection period) is discovered at a later date whereby the Product does not conform to the Specifications, the Purchaser shall inform the Manufacturer within fifteen days after Purchaser becomes aware of the alleged hidden defect. In the event that the Purchaser refuses acceptance or rejects the Product due to a hidden defect, the Manufacturer, upon confirmation of the reasons for refusal or rejection of the Product, will replace within ninety (90) days or as soon as reasonably practicable the defective Product at the Manufacturer's sole cost and expense (including the cost of shipping) or refund the Transfer Price and reimburse the shipping expense, at the Purchaser's option. If the Manufacturer and the Purchaser do not agree on the refusal or rejection of Products, then either Party may refer the matter for final analysis to a specialized laboratory of national reputation acceptable to both Parties for the purpose of determining the results. Any determination by such laboratory will be final and binding upon the Parties. The cost of any such review by a laboratory shall be borne by the Purchaser if it is determined that the Product conforms to the Specifications, and by the Manufacturer if determined that it does not. Except as set out in this Section 5.3 and Section 10.1, the Manufacturer shall have no liability to Purchaser for any defect for which it has not received notice from the Purchaser as specified herein.

Section 5.4 Recall. Manufacturer shall maintain traceability records in accordance with the applicable Governmental Rules, including cGMP Requirements, DSCSA requirements, and in accordance with any written instructions or guidelines provided to Manufacturer by the Purchaser, necessary to permit a recall, field correction or other notification to the field, of the Products. Purchaser, in consultation with Manufacturer, shall have the exclusive right to institute a recall and shall be responsible for managing the recall and communications with customers and Governmental Entities. The Parties shall cooperate with each other in connection with any such efforts. In the event that any Product is quarantined or recalled by Purchaser, or is subject to stopsale action, whether voluntary or by governmental action, it is agreed and understood that any reasonable and documented expenses, including any out-of-pocket administrative costs and reasonable and documented fees of any experts or attorneys that may be utilized by either Party, government fines or penalties, related to such recall, quarantine or stop-sale, will be borne by the Purchaser unless it is determined that the reason for the quarantine, recall or stop-sale action is the result of the breach by the Manufacturer of its obligations under this Supply Agreement, and in such case such expenses will be the responsibility of Manufacturer. If the Parties do not mutually agree on which Party is responsible for the recall or other field action, the responsibility for the recall or field action shall be determined by a mutually acceptable independent qualified third party whose fees shall be shared equally by the Parties.

Section 5.5 <u>Quality Procedures</u>. Manufacturer and Purchaser shall comply with the terms of the quality requirements set forth in a quality agreement to be negotiated in good faith by the Parties and entered into by the Parties as soon as practicable after the date hereof (the "<u>Quality Agreement</u>") with respect to the manufacture of the Products. To the extent that any inconsistencies or conflicts exist between the Quality Agreement and this Supply Agreement with

regard to quality requirements and compliance with Governmental Rules, the provisions in the Quality Agreement shall prevail.

Section 5.6 <u>Regulatory Communications</u>. Purchaser shall be responsible for communicating with the FDA regarding the Products and the Manufacturing performed by Manufacturer hereunder and Manufacturer shall not initiate contact with the FDA or such other regulatory authority regarding the Products or the Manufacturing without Purchaser's prior written consent, except when required by the terms of this Supply Agreement or by applicable Governmental Rules. Each Party shall provide reasonable assistance to the other Party upon such Party's reasonable request, and at the requesting Party's sole cost and expense, with respect to such regulatory communications.

#### **ARTICLE VI**

#### PRICE AND PAYMENTS

Section 6.1 <u>Prices</u>. The prices payable by the Purchaser for Products will be the prices set forth on Schedule 6.1, and will be adjusted pursuant to Section 6.3 (the "<u>Transfer Price</u>"). The prices for the Products set forth on Schedule 6.1 shall be equal to the Manufacturing Costs of the Manufacturer. The method for calculation of the Transfer Price set forth in this Section 6.1 shall be valid for the Initial Term only, Transfer Price of any agreed upon Extended Term shall be subject to negotiate between the Parties.

Section 6.2 Any additional costs such as stability costs, scale-up expenses, and additional analytical or testing expenses that may be specifically incurred at the request of Purchaser or as required for the Manufacture of the Product in accordance with the Specifications and/or cGMP compliance; and any Initial Batch Failure Costs will be charged at actual cost to the Purchaser. Manufacturer will provide prior information to the Purchaser before incurring any such costs and/or expenses. A separate invoice will be issued to Purchaser for such costs and/or expenses. For purposes of this Section 6.2, "Initial Batch Failure Costs" means, with respect to the batches of Product to be manufactured pursuant to Purchaser's initial Purchase Order placed hereunder, the actual direct costs incurred by Manufacturer to manufacture a replacement batch where a batch fails other than due to the gross negligence or willful misconduct of Manufacturer.

Section 6.3 <u>Adjustment</u>. On the first and each subsequent anniversary of the date Manufacturer fulfills an initial Firm Order with respect to Product, Manufacturer shall increase the Transfer Price of Product to the extent of any actual increase in the Manufacturing Costs. However, if the cost increase is more than ten percent (10%) of the Transfer Price, then the Manufacturer will share the full details of cost of production to justify any such increase applicable to the immediately preceding contract year.

Section 6.4 <u>Invoices</u>. The Manufacturer will send all invoices in respect of any Products to a single address specified in writing by the Purchaser to the Manufacturer following the date that such Products subject to any Firm Order shall have been made available to the Purchaser under Section 3.3(a). Payments for Product sold hereunder will be made by the Purchaser to the Manufacturer within thirty (30) days after the date of the invoice by electronic funds transmission in United States dollars as specified in any invoice, without any offset or deduction of any nature

whatsoever. All payments will be made to such account as the Manufacturer will have specified in writing to the Purchaser with written confirmation of payment sent by email or facsimile to such address as the Manufacturer will have specified in writing to the Purchaser. Purchaser shall advise Manufacturer within ten (10) calendar days of any disputed invoice. If the Purchaser fails to pay any undisputed invoiced amount when due, a service charge will be imposed by the Manufacturer equal to the lesser of one percent (1%) per month or the highest rate permitted by law of the outstanding amount for each month or portion thereof that such undisputed amount is overdue.

Section 6.5 <u>Taxes, etc.</u> The Purchaser will bear solely the cost of any taxes, levies, duties or fees of any kind, nature or description whatsoever applicable to the sale and transportation of Product sold by the Manufacturer to the Purchaser ("<u>Purchaser Taxes</u>"), and the Purchaser will forthwith pay to the Manufacturer all such sums upon demand. Manufacturer and Purchaser shall cooperate with each other and use their commercially reasonable efforts to obtain any certificate or other document from any person as may be necessary to mitigate, reduce or eliminate any such Purchaser Taxes.

Section 6.6 <u>Separate Sale</u>. Each shipment of Product to the Purchaser will constitute a separate sale, obligating the Purchaser to pay therefor, whether said shipment is in whole or only partial fulfillment of any order or confirmation issued in connection therewith.

Section 6.7 <u>Deductions</u>. Except as otherwise required by applicable law, the Purchaser agrees not to make any deductions of any kind from any payments becoming due to the Manufacturer unless the Purchaser will have received prior written authorization from the Manufacturer authorizing such deduction.

Section 6.8 Audits. Upon sixty (60) days prior written notice, Manufacturer will permit its books and records related to the calculation of the Transfer Price to be examined for a particular calendar year, no more than once annually, during normal business hours, by an independent auditor appointed by the other Party and reasonably acceptable to the audited Party, and at the auditing Party's expense, to verify the accuracy of the Transfer Price calculation in accordance with the terms of this Agreement. Any information received as a result of such inspection will be maintained as the audited Party's Confidential Information. In the event that an examining auditor concludes that an underpayment or overpayment was made, the auditor will specify such underor over-payment in a written report, along with the information on which such conclusion is based. This report will be shared promptly with the audited Party. The amount of any such underpayment or the reimbursement of any such overpayment will be due and payable by the audited Party within sixty (60) days of the date of such report. If the underpayment by the audited Party or the overpayment by the auditing Party differs by greater than ten percent (10%) from the amount that was otherwise due, the audited Party will pay all of the costs of such review.

## **ARTICLE VII**

### TERM AND TERMINATION

Section 7.1 <u>Term</u>. The provisions of this Supply Agreement will commence on the date hereof and will expire in three (3) years from the Effective Date, unless earlier terminated in accordance with this Article VII (the "<u>Initial Term</u>"). This Supply Agreement may be extended

for an additional two (2) year term at least ninety (90) days prior to the end of the Initial Term, subject to a mutually agreed upon price increase at the time of the extension, (the "Extended Term" and together with the Initial Term, the "Term").

- Section 7.2 <u>Termination</u>. Either the Manufacturer, on the one hand, or the Purchaser, on the other hand, as applicable, will have the right to terminate this Supply Agreement with immediate effect (except as otherwise stated below) upon written notice to the other upon the occurrence of the following:
- (a) the Manufacturer, on the one hand, or the Purchaser, on the other hand, files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency Law; or
- (b) the Manufacturer, on the one hand, or the Purchaser, on the other hand, fails to cure any non-compliance with any of the terms and conditions hereof within the time period specified in any prior written notice (which will be at least thirty (30) days) delivered to the non-compliant Party by another Party; provided; however, that the Manufacturer shall be permitted to terminate immediately upon delivery of written notice to Purchaser in the event that Purchaser has failed at least three (3) times in any twelve (12) month period to pay to Manufacturer any amount invoiced hereunder when such amount is due, other than where such failure is due to a good faith dispute over the amount owed.

# Section 7.3 Effects of Termination.

If this Supply Agreement is terminated pursuant to Section 7.2:

- (a) The Purchaser acknowledges and agrees that the Manufacturer will be entitled to cancel any Firm Order accepted prior to the date of termination, and will not be obligated to supply any Products ordered by the Purchaser pursuant to such Firm Order, with respect to any Products to be delivered after the effective date of the termination. In addition, Manufacturer shall deliver in accordance with the shipping terms of this Agreement all quantities of components, materials, APIs and work-in-progress, and finished product in the Manufacturer's or its Affiliates' possession, and to the extent such components, materials, API, work-in-progress, and finished product have not already been paid for by Purchaser and are not reasonably allocable to or usable for other activities being carried out by the Manufacturer or its Affiliates, then the Purchaser shall purchase them from the Manufacturer at Manufacturer's actual cost, which amount shall be payable no later than thirty (30) days after receipt thereof by the Purchaser.
- (b) Subject to Section 7.3(a) and (b) hereof, termination or expiration of this Supply Agreement for any reason will not relieve the Parties of any obligation accruing prior to such termination or expiration (including in respect of any Firm Orders). The rights and obligations of the Parties under Sections 5.4, 5.5, 7.3, Article IX, Article X, Article XI and Article XII of this Supply Agreement will survive the expiration or termination of this Supply Agreement.

#### ARTICLE VIII

### **FORCE MAJEURE**

Section 8.1 Force Majeure. Neither Party will be deemed to have defaulted under or breached this Supply Agreement for failure or delay in fulfilling or performing any term or provision of this Supply Agreement (other than the payment of money) when such failure or delay will be caused (directly or indirectly) by a circumstance beyond the reasonable control of the affected Party, including, without limitation, fire; flood; accident; explosion; terrorism, sabotage; strike, or any labor disturbance (regardless of the reasonableness of the demands of labor); civil commotions; riots; invasions; wars (present or future); acts, restraints, requisitions, regulations, or directions of any Governmental Entity, except where such acts, restraints, requisitions, regulations or directions are the result of a Party's violation of applicable Law; voluntary or mandatory compliance by the Manufacturer with any request for material represented to be for purposes of (directly or indirectly) producing articles for national defense or national defense facilities; shortage of labor, fuel, or power; industry wide shortage of raw materials;; inability to obtain supplies or failures of normal sources of supplies where the relevant supplier is unable to supply as a result of a force majeure event applicable to such supplier; inability to obtain or delays of transportation facilities; any act of God; any act of the other Party or any cause (whether similar or dissimilar to the foregoing) beyond the reasonable control of such Party (each a "Force Majeure"). Any Party asserting its inability to perform any obligation hereunder for any such contingency shall promptly notify the other Party of the existence of any such contingency and shall use commercially reasonable efforts to mitigate such contingency and re-commence its performance of such obligation as soon as commercially practicable. Subject to this Section 8.1, if the Manufacturer is unable to supply the Purchaser with its requirements of Products by reason of Force Majeure, Force Majeure shall excuse the Manufacturer's performance until the Force Majeure has ceased and for a reasonable period of time thereafter, to allow the Manufacturer to restore itself to the position it was in with respect to the Products immediately prior to the Force Majeure. Within thirty (30) days of notification by the Manufacturer that it is able to resume the necessary supply of the Products to the Purchaser, in respect of any Firm Orders for the Products the delivery of which was during such Force Majeure period, the Parties shall discuss in good faith the requirements of Purchaser and delivery of such Products. Neither Party shall suffer penalty or incur any liability for its inability to perform hereunder by reason of Force Majeure. If a Party fails to perform any of its obligations under this Agreement by reason of Force Majeure and such non-performance continues for a period of one hundred and eighty (180) days from the first occurrence of the event of Force Majeure, the other Party may terminate this Agreement by providing written notice to that effect to the non-performing Party. In the event of such termination, both Parties' respective rights and obligations under this Agreement shall terminate except for any amounts previously due and owing by one Party to the other and except for any other obligations which this Agreement expressly provides shall survive termination.

#### **ARTICLE IX**

### CONFIDENTIALITY

Section 9.1 Non-disclosure and Non-use Obligation. Each Party or its Affiliates or contractors may, from time to time, prior to or after the date hereof, disclose to the other Party information of a technical or non-technical nature that is not generally known to the trade or public. Each Party agrees that it will not, and will cause its Affiliates, and will use reasonable best efforts to cause its contractors, not to, use for any purpose other than as necessary to perform its obligations under this Supply Agreement, and will not disclose to anyone in any manner whatsoever, any such information including, without limitation, information relating in any way to the products, processes, and services of each Party or its Affiliates or contractors, which becomes known to the other Party on or prior to the date of the termination or expiration of this Supply Agreement. The obligations of this Section 9.1 will not apply to information (i) that is known to a Party as shown by written records prior to its disclosure by the Manufacturer or its contractors; (ii) that becomes public information or is generally available to the public other than by an unauthorized act or omission of the other Party; or (iii) that is received by a Party from third parties who are in rightful possession of such information and who are lawfully entitled to disclose such information and did not receive such information from the other Party. Upon the termination or expiration of this Supply Agreement, each Party will return or destroy (with written confirmation thereof) to the other Party all documents that include confidential information of each Party or its contractors including all copies of such documents or extracts therefrom, if any, and will make no further use of such information. This Agreement shall not be deemed to restrict the receiving Party from complying with a lawfully issued governmental order or any other requirement of applicable Law to produce or disclose confidential information of the other Party; provided that the receiving Party shall have complied with the requirements of this Section 9.1. With respect to any such governmental order or requirement of applicable Law, the receiving Party shall promptly notify the disclosing Party of such order so that the disclosing Party may seek to quash such order or to obtain an appropriate protective order requiring that the confidential information that is the subject of such order or requirement of applicable Law be held in confidence or, if disclosed, be used only for the purposes for which such order was issued or such requirement of applicable Law covers. The receiving Party shall reasonably cooperate with the disclosing Party in any such proceeding. With respect to any such order that is not quashed or any other requirement of applicable Law to disclose confidential information of the disclosing Party, the receiving Party shall furnish only that portion of such confidential information that the receiving Party is advised by counsel is legally required to be disclosed and the receiving Party shall, at the disclosing Party's cost, exercise its reasonable efforts, in its sole discretion, to obtain a protective order or other reliable assurance that confidential treatment shall be accorded to the confidential information so disclosed. The receiving Party's obligations shall be qualified to the extent it is reasonably able to comply with the terms of this Section 9.1 depending upon the order or other legal requirement and the timing within which the receiving Party is obligated to comply therewith.

#### **ARTICLE X**

### **INDEMNIFICATION**

Section 10.1 <u>By the Manufacturer</u>. From and after the Effective Date, the Manufacturer will indemnify, defend and hold harmless, and pay and reimburse, the Purchaser, its Affiliates and their respective officers, directors, employees, agents, advisors, and shareholders from and against any and all liabilities, losses, claims, damages, costs, and expenses (including reasonable attorneys' fees) ("*Losses*") resulting from or relating to any claim by a Third Party resulting from, arising out of, or in connection with: (i) Manufacturer's or its contractors' or Affiliate's negligence or willful misconduct, or (ii) any breach by Manufacturer of any of its representations and warranties, covenants, agreements or obligations contained in this Agreement; except to the extent such Losses arise as a result of the breach of this Agreement, or the negligence, willful misconduct, or breach of this Agreement by Purchaser or its contractors or Affiliates.

Section 10.2 By the Purchaser. From and after the Effective Date, the Purchaser will indemnify, defend and hold harmless, and pay and reimburse, the Manufacturer and its Affiliates and their respective officers, directors, employees, agents, advisors and shareholders from and against any and all Losses resulting from or relating to any claim by a Third Party resulting from, arising out of, or in connection with: (a) the Purchaser's negligence or willful misconduct, or (b) breach of any of its representations and warranties, covenants, agreements or obligations contained in this Supply Agreement; or (c) regarding any Product sold by Purchaser or its Affiliates from and after the Effective Date, including but not limited to (i) any claim for patent infringement, personal injury, death or property damage or (ii) the use of the Products by any person; provided, however, that the Purchaser shall not be liable for any Losses to the extent (A) arising from the Manufacturer's or it contractors' negligence, willful misconduct, or breach of its representations and warranties, covenants, agreements or obligations contained in this Agreement or (B) to the extent the Loss falls within the scope of Manufacturer's indemnification obligations under the Asset Purchase Agreement.

Section 10.3 Procedures. If Purchaser, Manufacturer or their respective Affiliates, employees or agents (in each case an "Indemnified Party"), receive any written claim which such Indemnified Party believes is the subject of indemnity hereunder by another Party hereto (an "Indemnifying Party"), the Indemnified Party shall, as soon as reasonably practicable after forming such belief, give notice thereof to the Indemnifying Party, provided that the failure to give timely notice to the Indemnifying Party as contemplated hereby shall not release the Indemnifying Party from any liability to the Indemnified Party unless the Indemnifying Party demonstrates that the defense of such claim is materially prejudiced by such failure. The Indemnifying Party shall have the right, by prompt written notice to the Indemnified Party to assume the defense of such claim at its cost, with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not so assume the defense of such claim or, having done so, does not diligently pursue such defense, the Indemnified Party may assume the defense, with counsel of its choice, but at the cost of the Indemnifying Party. If the Indemnifying Party so assumes the defense, it shall have absolute control of the litigation; provided that the Indemnified Party may, nevertheless, participate therein through counsel of its choice and at its cost. The involved Party not assuming the defense of any such claim shall render all reasonable assistance to the Party assuming such

defense, and out-of-pocket costs of such assistance shall be for the account of the Indemnifying Party. No such claim shall be settled other than by the Party defending the same, and then only with the consent of the other involved Party, which consent shall not be unreasonably withheld; provided that the Indemnified Party shall have no obligation to consent to any settlement of any such claim which (i) imposes on the Indemnified Party any liability or obligation which cannot be assumed or performed in full by the Indemnifying Party, (ii) does not unconditionally release the Indemnified Party, (iii) requires a statement as to or an admission of fault, culpability or failure to act by or on behalf of Indemnified Party or (iv) imposes any restrictions on the conduct of business by the Indemnified Party..

Section 10.4 <u>Insurance</u>. At all times from the Effective Date through that date which is three (3) years after the termination or expiration of this Supply Agreement, each of the Purchaser and the Manufacturer will maintain general liability insurance in the amount of not less than USD \$5,000,000 per occurrence and USD \$5,000,000 in aggregate and product liability insurance (or self-insurance), which is reasonable and customary in the USA pharmaceutical industry for companies of comparable size, provided that in no event shall the product liability insurance amounts be less than USD \$5,000,000 per occurrence and USD \$5,000,000 in the aggregate limit of liability per year. Each of the Purchaser and the Manufacturer shall add the other party as additional insured in their general liability and product liability policy and provide written proof of such insurance to the other Party upon request.

### Section 10.5 Limitations.

- (a) In no event shall either Party be liable by reason of any breach of any representation, warranty, condition or other term of this Agreement or any duty of common law, for any consequential, special, indirect or incidental or punitive loss or damage (whether for loss of current or future profits, loss of enterprise value or otherwise) and each Party agrees that it shall not make any such claim; provided, however, that the foregoing does not limit any of the obligations or liability of either Party or its Affiliates under Sections 10.1 and 10.2 with respect to claims of unrelated third parties or liability arising from fraud or willful misconduct of a Party or its Affiliates or contractors.
- (b) Notwithstanding any other provision of this Agreement, in the event that the Purchaser asserts or claims that the Manufacturer has breached any of its obligations hereunder or that the Manufacturer is liable pursuant to Section 10.1, the Manufacturer's maximum liability under or in connection with any such claim herein shall be limited to Two Million Dollars (\$2,000,000); provided, however, that the foregoing shall not limit any liability arising from (a) fraud or willful misconduct of Manufacturer or its Affiliates or contractors.

### ARTICLE XI

### INTELLECTUAL PROPERTY RIGHTS

Section 11.1 <u>License</u>. The Purchaser hereby grants to the Manufacturer for the Term of this Supply Agreement, a royalty-free, non-exclusive, non-transferable, right and license under the Purchased Assets, as applicable in the Territory to manufacture and supply the Products for the Purchaser. This license is sublicenseable by the Manufacturer to contractors which the

Manufacturer may cause to manufacture and supply the Products with the prior approval of Purchaser.

To the extent that any of the Products are marketed under a trademark or housemark of the Purchaser ("<u>Purchaser Trademark</u>"), Purchaser hereby grants to the Manufacturer a revocable, non-assignable and non-exclusive license to apply and affix the Purchaser Trademark on or in relation to the Products Manufactured for the Purchaser hereunder; provided, however that nothing herein contained shall give or be deemed to give or shall be intended to give the Manufacturer any right, title, interest or claim in or to the Purchaser Trademark.

#### **ARTICLE XII**

### **MISCELLANEOUS**

Section 12.1 <u>Assignment</u>. Neither Party may assign its rights or obligations under this Supply Agreement without the prior written consent of the other Party; provided, however either Party may assign its rights and obligations under this Supply Agreement, without the prior written consent of the other Party, to an Affiliate or to a successor of the assigning Party by reason of merger, sale of all or substantially all of its assets or the portion of its business which relates to a Product or any number of the Products, or any similar transaction. Any permitted assignee or successor-in-interest will assume all obligations of its assignor under this Supply Agreement. No assignment will relieve either Party of its responsibility for the performance of any obligation. This Supply Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

Section 12.2 <u>Severability</u>. If any provision of this Supply Agreement is held to be illegal, invalid or unenforceable by any Law or public policy, the remaining provisions of this Supply Agreement will nevertheless remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom as long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to either Party. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties will negotiate reasonably and in good faith to modify this Supply Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

Section 12.3 <u>Notices</u>. All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given (a) on the date delivered, if personally delivered, (b) on the date sent by telecopier with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (c) on the Business Day after being sent by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next Business Day delivery or (d) two (2) Business Days after mailing, if mailed by United States postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable Party at the address set forth below; provided that a Party may change its address for receiving notice by the proper giving of notice hereunder:

(a) if to the Purchaser, to:

EPI Health, LLC134 Columbus Street, Charleston, SC 29403

Attn: Ronald C. Owens

Facsimile No.: rowens@epihealth.com

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

Blank Rome LLP 405 Lexington Avenue New York, NY 10174

Attn: Jennifer DanielsEmail: daniels@blankrome.com

Facsimile No.: 917.332.3075

(b) if to the Manufacturer, to:

Dr. Reddy's Laboratories, Ltd. SEZ - Process unit – 1, Devunipalavalasa Village Ranasthalam Mandal, Srikakulam District Andhra Pradesh, India, Pin-532409 Attention: PPG Business Head

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

Dr. Reddy's Laboratories, Ltd.
SEZ - Process unit – 1,
Devunipalavalasa Village
Ranasthalam Mandal, Srikakulam District
Andhra Pradesh, India, Pin-532409Attn: PPG Legal Counsel

It is understood and agreed that this Section 12.3 is not intended to govern the ordinary course business communications necessary between the Parties in performing their duties, in due course, under the terms of this Supply Agreement, including the placement of orders and the delivery of Forecasts.

Section 12.4 <u>Applicable Law.</u> 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.

### Section 12.5 Jurisdiction, Venue, Service of Process, WAIVER OF JURY TRIAL.

- Any Legal Proceeding based upon, arising out of, or related to this (a) 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 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 12.5 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 12.03. 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.
- (b) THE PURCHASER AND THE MANUFACTURER HEREBY WAIVE, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION (I) ARISING UNDER THIS AGREEMENT OR (II) IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE PARTIES HERETO IN RESPECT OF THIS AGREEMENT OR ANY OF THE TRANSACTIONS RELATED HERETO, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER IN CONTRACT, TORT, EQUITY, OR OTHERWISE. THE PARTIES TO THIS AGREEMENT EACH HEREBY AGREES AND CONSENTS THAT ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY AND THAT THE PARTIES TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OF A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

Section 12.6 <u>Entire Agreement</u>. This Supply Agreement and the attached Schedules, which are incorporated herein, along with the Asset Purchase Agreement and the Schedules and Exhibits thereto, constitute the entire agreement between the Parties with respect to the subject matter hereof and all prior agreements with respect hereto are superseded. Each Party confirms that no representations, warranties, covenants or understandings of any kind, nature or description whatsoever are being made or relied upon by any Party, except such as are as specifically set forth herein or in the Asset Purchase Agreement. No amendment or modifications hereof will be binding upon the Parties unless set forth in a writing specified to be an explicit amendment to this Supply

Agreement duly executed by authorized representatives of each of the Parties. The Parties recognize that, during the Term of this Supply Agreement, a purchase order, acknowledgement form or similar routine document (collectively "Forms") may be used to implement or administer provisions of this Supply Agreement. Therefore, the Parties agree that the terms of this Supply Agreement, as it may be amended, will prevail in the event of any conflict between this Supply Agreement and the printed provision of such Forms, or typed provisions of Forms that add to, vary, modify or are in conflict with the provisions of this Supply Agreement with respect to the Products sold during the Term of this Supply Agreement. Nothing in this Agreement is intended to increase or limit either Party rights, remedies, or responsibilities under the Asset Purchase Agreement.

Section 12.7 <u>Headings</u>. The headings used in this Supply Agreement are intended for convenience only and will not be considered part of the written understanding among the Parties and will not affect the construction of this Supply Agreement.

Section 12.8 <u>Independent Contractors</u>. The relationship between the Manufacturer, on the one hand, and the Purchaser, on the other hand, is solely that of Purchaser and seller. It is expressly agreed that the Manufacturer, on the one hand, and the Purchaser, on the other hand, will be independent contractors and that neither the relationship among the Parties nor this Supply Agreement will be construed as creating a partnership, joint venture or agency. Neither the Manufacturer, on the one hand, nor the Purchaser, on the other hand, will have the authority to make any statements, representations or commitments of any kind, or to take any action or to incur any liability or obligation which will be binding on the other, without the prior consent of the other Party to do so. All persons employed by a Party will be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment will be for the account and expense of such Party.

Section 12.9 <u>Waiver</u>. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other or subsequent breach or failure by said other Party whether of a similar nature or otherwise.

Section 12.10 <u>Counterparts</u>. This Supply Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will constitute one and the same instrument.

Section 12.11 <u>No Benefit to Third Parties</u>. The representations, warranties, covenants and agreements set forth in this Supply Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and nothing herein, express or implied, is intended to or will confer upon any person or entity any legal or equitable rights, benefits or remedies, other than to the extent set forth in Sections 10.1 and 10.2.

### [signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Supply Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date first written above.

DR. REDDY'S LABORATORIES LTD.

Name:

Title: VICE PRESIDENT

EPI HEALTHLLC

Title:

# Schedule 1.1 DEFINITIONS

As used in this Supply Agreement, the following terms will have the meanings ascribed to them below:

- (a) "API" means the active pharmaceutical ingredient for Product.
- (b) "Acquisition" has the meaning set forth in the recitals.
- (c) "Affiliate" of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.
  - (d) "Asset Purchase Agreement" has the meaning set forth in the recitals.
- (e) "<u>cGMP Requirements</u>" means the FDA's current good manufacturing practice requirements as promulgated under the FFDCA at 21 C.F.R. (parts 11, 210 and 211), and as further defined by FDA guidance documents, as such may be amended from time to time.
  - (f) "COA" has the meaning set forth in Section 3.3(b).
  - (g) "COC" has the meaning set forth in Section 3.3(b).
  - (h) "DSCSA" means the Drug Supply Chain Security Act.
  - (i) "Extended Term" has the meaning set forth in Section 7.1.
- (j) "FDA" means the United States Food and Drug Administration and any successor agency thereto
- (k) "FFDCA" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as amended.
  - (l) "Firm Order" has the meaning set forth in Section 3.2.
  - (m) "<u>Firm Order Period</u>" has the meaning set forth in Section 3.1.
  - (n) "Force Majeure" has the meaning set forth in Section 8.1.
  - (o) "Forecast" has the meaning set forth in Section 3.1.
  - (p) "Forms" has the meaning set forth in Section 12.6.

- (q) "<u>Governmental Entity(ies)</u>" means any federal, state, local or foreign government, or political subdivision thereof or 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.
- (r) <u>"Governmental Rule"</u> means any Law, judgment, order, decree, statute, ordinance, rule or regulation enacted, issued or promulgated by any Governmental Entity.
  - (s) "<u>Initial Term</u>" has the meaning set forth in Section 7.1.
- (t) "<u>Law</u>" means each federal, state, provincial, municipal, local, or foreign law, statute, ordinance, order, determination, judgment, common law, code, rule, official standard, or regulation, enacted, enforced, entered, promulgated, or issued by any Governmental Entity.
  - (u) "<u>Manufacturer</u>" has the meaning set forth in the preamble.
- (v) "<u>Manufacturing</u>" or "<u>Manufactured</u>" means the manufacture and packaging of Products, including, without limitation, mix, fill and finish.
- (w) "<u>Manufacturing Costs</u>" means, with respect to a Product, the actual cost of Manufacturing the Product (expressed on a per unit manufactured basis), which consists of (i) actual direct cost of any raw materials, intermediates, packaging materials and labor utilized in such Manufacturing, (ii) an appropriate share of factory overhead costs allocated to Manufacture of the Product, but excluding any costs related to under-utilized capacity, all calculated in accordance with. GAAP, and (iii) any transportation, freight expenses actually incurred by the Manufacturer to ship the material.
  - (x) "NDA" means the new drug application for Product as approved by the FDA.
  - (y) "Party" or "Parties" means the Manufacturer and/or the Purchaser, as applicable.
- (z) "<u>Person</u>" means any individual, corporation, partnership, limited liability company, limited liability partnership, syndicate, person, trust, association, organization or other entity, and including and successor, by merger or otherwise, of any of the foregoing.
- (aa) "Products" means the pharmaceutical Products on Schedule 6.1 that are to be supplied by the Manufacturer to the Purchaser hereunder.
  - (bb) "Purchase Order Date" has the meaning set forth in Section 3.2(a).
  - (cc) "Purchased Assets" has the meaning set forth in the Asset Purchase Agreement.
  - (dd) <u>Purchaser</u>" has the meaning set forth in the preamble.
  - (ee) "Purchaser Taxes" has the meaning set forth in Section 6.4.

- (ff) "Purchaser Trademark" has the meaning set forth in Section 11.1.
- (gg) "Quality Agreement" has the meaning set forth in Section 5.6.
- (hh) "<u>Specifications</u>" means the requirements and standards for the Products set forth in the Quality Agreement, as amended or supplemented in accordance with this Supply Agreement.
  - (ii) "Supply Agreement" has the meaning set forth in the preamble.
  - (jj) "<u>Term</u>" has the meaning set forth in Section 7.1.
- (kk) "<u>Territory</u>" means the United States of America and its territories, possessions, districts, protectorates and commonwealths.
- (ll) "<u>Third Party</u>" means any Person, other than Purchaser and its Affiliates, and other than Manufacturer and its Affiliates.
- (mm) "<u>Transfer Prices</u>" means the amount(s) to be paid by the Purchaser to the Manufacturer pursuant to Section 6.1 and as may be adjusted from time to time pursuant to Section 6.2.

# SCHEDULE 6.1 PRODUCTS, TRANSFER PRICES AND BATCH QUANTITIES

PRODUCT: NDA No. 209269 for Minocycline hydrochloride extended release tablets,  $105~\mathrm{mg}$  and  $135~\mathrm{mg}$ .

TRANSFER PRICES AND BATCH QUANTITIES FOR DOSAGES AS OF EFFECTIVE DATE:

PRODUCT	SKU	THEORETICAL BATCH SIZE (IN TABLETS)	THEORETICAL UNITS PER BATCH (PACK OF TABLET)	RATE \$ PER PACK	RATE \$ PER TABLET
MINOCYCLINE HYDROCHLORIDE ER TABLETS 30CT	135 MG	175,000	5833	29.70	\$0.99
MINOCYCLINE HYDROCHLORIDE ER TABLETS 30CT	105 MG	175,000	5833	25.48	\$0.849
MINOCYCLINE HYDROCHLORIDE ER TABLETS 5CT	135 MG	175000	35000	6.25	\$1.25
MINOCYCLINE HYDROCHLORIDE ER TABLETS 5CT	105 MG	175000	35000	6.00	\$1.20

# Exhibit 3

### EPI HEALTH, LLC

### **PURCHASE ORDER**

Date: 06-Feb-2023

PO #: Revised 629

<u>Vendor:</u> <u>Ships To:</u>

Dr. Reddy's Labs ICS

Ltd, FTO SEZ-PU01 420 International Srikakulam, Blvd. Suite 500 532409, India Brooks, KY 40109

Terms: Net 30

Shipping Method	Shipping Terms	Delivery Date
Air	FCA	14-Feb-23

Quantity	Item #	Description	Unit Price	Line Total
5833	SKU: 71403-101-30	Minolira (Minocycline	\$25.48	\$148,624.84
		Hydrochloride) 105mg		
*Note- Revised fron	n AG dress to trade Dr	ess- revised NDC to reflect trade o	ress.	
_		TOTAL	\$148	,624.84

- 1. **Shipping Requirements:** Ensure finished product is maintained, packed and shipped per the label claim storage requirements of USP controlled room temperature (20c to 25c). Ship per approved LRG. Shipment shall not be released to the originating carrier if they do not meet the temperature and handling requirements. The originating carrier is responsible for conveying said written shipping instructions to all connecting carriers.
- 2. Enter this order with the prices, terms, delivery method, and specifications listed above.
- 3. Please notify us immediately if you are unable to ship as specified.
- 4. Send all correspondence to:

Cindy Adams at cadams@epihealth.com

Phone: (985) 859-7494 Fax: (843) 737-8746

Authorized By Date

<u>Cindy Adams</u> 9/13/22

M. Goodhead 2.6.23

### EPI HEALTH, LCC

### **PURCHASE ORDER**

Date: 06-Feb-2023

PO #: Revised 630

Vendor:Ships To:Dr. Reddy's LabsICS

Ltd, FTO SEZ-PU01 420 International Srikakulam, Blvd. Suite 500 532409, India Brooks, KY 40109

Terms: 30 days

Shipping Method	Shipping Terms	Delivery Date
Air/Sea	FCA	10-Feb-23

Quantity	Item #	Description	Unit Price	Line Total
5833	SKU: 71403-105-30	Minolira (Minocycline	\$29.70	\$173,240.10
		Hydrochloride) 135mg		
*Note- Revised from	AG dress to trade Dre	ss- revised NDC to reflect trade o	ress.	
		TOTAL	\$173	,240.10

- 1. **Shipping Requirements:** Ensure finished product is maintained, packed and shipped per the label claim storage requirements of USP controlled room temperature (20c to 25c). Ship per approved LRG. Shipment shall not be released to the originating carrier if they do not meet the temperature and handling requirements. The originating carrier is responsible for conveying said written shipping instructions to all connecting carriers.
- 2. Enter this order with the prices, terms, delivery method, and specifications listed above.
- 3. Please notify us immediately if you are unable to ship as specified.
- 4. Send all correspondence to:

Cindy Adams at cadams@epihealth.com

Phone: (985) 859-7494 Fax: (843) 737-8746

Authorized By Date

<u>Cindy Adams</u> 9/13/22

M. Goodhead 2.6.23

# Exhibit 4

### Case 23-10937-LSS Doc 696 Filed 05/29/24 Page 87 of 90

INVOICE

			INVOI	CE		Page no:1 of 3
	exporter		A CONTRACTOR OF THE REAL PROPERTY.	No: 9013423		0.07.2023
Dr. Reddy's Laboratories Ltd, FT0-SEZ-ProcessUnit-01, SyNo.57-59,60,62,72 SecNo9-14,17-20, DevunipalavalasaVillage Ranasthalam(M), Srikakulam Dt, AP - 532409 CINNo.L85195AP1984PLC004507, GSTIN NO.37AAACD7999Q2ZI Consignee ICS [EPI Health 1402] 420 International Blvd Kentucky 40109 USA		Buyer's Order No. & Date IE Code 1			1E Code No 098800283	
		Buyer (If other than Consignee) EPI HEALTH ,LLC Charleston 174 Meeting St. Ste.200 Charleston-29403 USA				
Pre Carriage by Air	Place of Receipt by Pr DRL SSSEZ, SRIKA		Country INDIA	of Origin of C	Gds Count USA	try of Final Dest.
Vessle / Flight No.  Port of Loading HYDERABAD			Terms of Within FCA B	of Delivery Pay 30 days from It Y AIR	ment nv. date	
Port of Discharge CHICAGO	Final Destination CHICAGO		•			
S. Descript	ion of Goods	Batel		Quantity	Unit Price	Amount

S. No	Description of Goods	Batch No. Mfg/Exp Date	Quantity GW/NW	Unit Price USD	Amount USD
1	300030414 Minolira 105mg Tablets 30's US HSN Code: 30042049 NDC Code No:7140310130 ANDA Code:209269	T2302943 09.06.2023 31.05.2026	5424 SU 429.000 KG 146.550 KG	25.48 Per 1 SU	138,203.52
2	300030415 Minolira 135mg Tablets 30's US HSN Code: 30042049 NDC Code No:7140310230 ANDA Code:209269	T2302944 09.06.2023 31.05.2026	5314 SU 478.000 KG 185.990 KG	29.70 Per 1 SU	157,825.80

Bank Address: DRL Ltd-FTO-SEZ-Process Unit-01, Account No.: 520761322, Citibank, India Bank Swift Code:

CITIINBXCorrespondent Bank: Citibank, NewyorkCorrespondent Bank Swift code:CITIUS33

**Delivery Nos:** 0090049433

Advance License:

### Case 23-10937-LSS Doc 696 Filed 05/29/24 Page 88 of 90

INVOICE

Page no:2 of 3

		INVOICE	1 age	110.2 01 3	
Dr. Reddy's Laboratories Ltd, FTO-SEZ-ProcessUnit-01, SyNo.57-59,60,62,72 SecNo9-14,17-20, DevunipalavalasaVillage Ranasthalam(M),Srikakulam Dt, AP - 532409 CINNo.L85195AP1984PLC004507, GSTIN NO.37AAACD7999Q2ZI Consignee ICS [EPI Health 1402] 420 International Blvd Kentucky 40109 USA		Invoice No: 9013423923 I GST Inv No: OS371241004			
		Buyer's Order No. & Date IE Code No 640 13.09.2022 0988002833  Other Reference(s) FTOSEZPU1/EXP/196/2023-24			
		Buyer (If other than Consignee) EPI HEALTH ,LLC Charleston 174 Meeting St. Ste.200 Charleston-29403 USA  Date: April 2000 USS  Devumpolavalor			
Pre Carriage by Air	Place of Receipt by Pre-Carrier DRL SSSEZ, SRIKAKULAM	Country of Origin of Gds INDIA	Country of Fina USA	al Dest.	
Vessle / Flight No.  Port of Loading HYDERABAD		Terms of Delivery Payment Within 30 days from Inv. da FCA BY AIR	ite		
Port of Discharge CHICAGO	Final Destination CHICAGO				

We intend to claim Benefit of RoDTEP schme if applicable to SEZ Units and subject to such conditions as prescribed including the product coverage

### **USDA Declaration:**

Minolira (Minocycline Hydrochloride Extended Release Tablets) 105 mg ,135 mg contains no ingredient of animal origine

### Storage Condition:

Temperature +15° C to +25° C Must be Maintained in Transit

### Marks & Nos:

448 Boxes

Packed on 04 wooden

Pallets

### Logger Details:

Datalogger S123031545-16, Make:tempmate-S1 are placed in Batch

## Case 23-10937-LSS Doc 696 Filed 05/29/24 Page 89 of 90

INVOICE

Page no:3 of 3

Dr. Reddy's Laboratories Ltd, FTO-SEZ-ProcessUnit-01, SyNo.57-59,60,62,72 SecNo9-14,17-20, DevunipalavalasaVillage Ranasthalam(M),Srikakulam Dt, AP - 532409 CIN No.L85195AP1984PLC004507, GSTIN NO.37AAACD7999Q2ZI Consignee ICS [EPI Health 1402] 420 International Blvd Kentucky 40109 USA		Invoice No: 9013423923 D GST Inv No: OS371241004 Buyer's Order No. & Date 640 13.09.2022 Other Reference(s) FTOSEZPU1/EXP/196/2023 Buyer (If other than Consign EPI HEALTH ,LLC Charleston 174 Meeting St. Ste.200 Charleston-29403 USA	6 IE Code No 0988002833
Pre Carriage by Air	Place of Receipt by Pre-Carrier DRL SSSEZ, SRIKAKULAM	Country of Origin of Gds INDIA	Country of Final Dest. USA
Vessle / Flight No.	Port of Loading HYDERABAD	Terms of Delivery Payment Within 30 days from Inv. dat FCA BY AIR	re
Port of Discharge CHICAGO	Final Destination CHICAGO		
x			>
Exporter's Ref: 000194143  Amount Chargable (in wor		TOTAL	296,029.32
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Gross Weight: 907. Net Weight: 332 Volume Weight:	0004 000 KG 540 KG this invoice shows the actual price of	Signature & Dat	ddy's Laboratories Ltd., SEZ Process Unit-01
	all particulars are true and correct.	<u> </u>	(M. VAMSI) utorized Signatory

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Dr.	Reddy's	Exporter				
- , -		Dr. Reddy's Laboratories Ltd, FTO-SEZ-ProcessUnit-01, SyNo,57-59,60,62,72		GST InvNo: OS3712410046		10 07 2022
		SecNo9-14,17-20, DevunipalavalasaVillage		Billing No.	9013423923/	19.07.2023
		Ranasthalam(M),Srikakulam Dt, AP - 532409		Buyer's Order No.	640/13/09/2022	
		CIN No. L85195AP1984PLC004507				
		GSTIN NO. 37AAACD7999Q2ZI				
				Other Def. F	TOSEZDIII/RV	D/10 c/mmax a c
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	ucky 40109			EPI HEALTH ,LLC	action promise	SIL
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Pre-Ca	rriage by	Place of Receipt by pre-carriage		Port of Discharge		
AIR	Flight No.	DRL SSSEZ, SRIKAKULAM Port of Loading		CHICAGO		
r Canel 7	angue au.	HYDERABAD		Final Destination CHICAGO		
S.No.		Description of goods	Marks & Nos	No & kind	Quantity	Remarks
1	300030414 Minolli	ra (Minocycline Hydrochlorlde Extended Release Tablets )	DRL-EXPORT	of packages		03410551
1	105mg US (30's Pac	k)	196	Packed on 04 wooden		Pallet dimentions: 1.=122 W = 102 H = 132 cm =1
	Batch No: T230294		1/4 to 4/4	Pallets		1.=122 W =102 H = 65 cm =1
	NDC Code No's, 7	1403-101-30	, , , , ,			1.=122 W =102 H= 116 cm -1
	ANDA Code: 209269					L=122 W=102 H = 103 cm -1
	Outbound Dely.No:					
	IISN code:-3004204 GROSS WEIGHT :-					
	NET WEIGHT :- 146	5.55 KG				
2	300030415 Minolir 135mg US (30's Pac	a (Minocycline Hydrochloride Extended Release Tablets )	W2202043		0040	100 04
	Batch No: T230294		T2302943	1 of 4 2 of 4		160 x 24 (66 x 24)
	NDC Code No's, 71	1403-102-30		TOTAL	5424	4.
	ANDA Code: 209269		T2302944	3 of 4	3072	(128 x 24)
	Outbound Dely,No:			4 of 4		(93x 24)+(1x10)
	HSN code:-3004204 GROSS WEIGHT:-			TOTAL	5314	
	NET WEIGHT :- 185					
		Mfg.Dt. Exp.Dt.				
	The state of the s	06/2023				
	1	00/2025 03/2020				
	Minolira ( Minocy	cline Hydrochloride Extended Release Tablets) 105 mg,135 m	g contains no ing	redient of animal origine		(1)
	Temperature -	+15° C to +25° C Must be Maintained in Transit				
	We intend to claim I	Benefit of RoDTEP schme if applicable to SEZ Units and subject to suc 123031545-16, Make:tempmate-S1 are placed in Batch no:	ch conditions as prese	ribed including the product cov	erage	ATT.
	Datalogger 3		re during transit.	no.4/4 Snipper code.A411	NQDEWSINL	III for monitoring the
	Gross Weight: 907 K	g				
	Net Weight: 332.54 I Total Pallets =04	og.		0 10		
			14	For Dr. Red	dy's Tor	offatories Talimited
				FTO S	E7 Proces	ss Unit-01
				110-5	LL Proce	ss Unit-UI
				Lim		
				7011	22	Authorised Signatory

(M. VAMSI)
Autorized Signatory