

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

)	Chapter 11
In re:)	
)	Case No. 20-11177 (KBO)
AKORN, INC., et al.,)	(Jointly Administered)
)	
Debtors.)	Objections due: August 14, 2020
)	Hearing Date: August 20, 2020 @ 1:00 p.m.

**OBJECTION OF PRIMAPHARMA, INC. TO THE MOTION OF DEBTORS FOR
THE ASSUMPTION AND ASSIGNMENT OF CERTAIN EXECUTORY
CONTRACTS AND LEASES**

PrimaPharma, Inc. (õPrimaPharmaö) hereby submits this objection to the Motion of Debtors for the Assumption and Assignment of the õPrimaPharm contractö between Akorn, Inc. and PrimaPharm, Inc. (õPrimaPharmö). In Support of this Objection, PrimaPharma states as follows:

BACKGROUND

1. On May 20, 2020 (the õPetition Dateö), Akorn, Inc. (õAkornö) and certain of its affiliates (together, the õDebtorsö) filed voluntary petitions for relief under chapter 11 of Title 11 of the United States Code.

2. Prior to the Petition Date, Akorn and PrimaPharm entered into that certain Asset Purchase Agreement dated as of June 16, 2011 (the õAPAö). PrimaPharma subsequently acquired the contract rights is now the owner of PrimaPharm's contract rights under the APA.

3. On June 15, 2020, the Court entered the *Order (A) Authorizing and*



Approving Bidding Procedures, (B) Scheduling an Auction and a Sale Hearing, (C) Approving the Form and Manner of Notice Thereof, (D) Establishing Notice and Procedures for the Assumption and Assignment of Certain Executive Contracts and Leases, and (E) Granting Related Relief [Docket No. 181) (the "Bidding Procedures Order"), authorizing the Debtors to conduct an auction (the "Auction") to select the party to purchase the Debtors' assets. The Auction will be governed by the bidding procedures approved pursuant to the Bidding Procedures Order (the "Bidding Procedures").

4. Pursuant to the Bidding Procedures and the terms of any Successful Bid, the Debtors may assume and assign to the Successful Bidder the APA upon approval of the Sale. The Debtors have conducted a review of their books and records and have determined that the cure amount for unpaid monetary obligations under the APA is \$0.00.

OBJECTION

5. PrimaPharma objects to the extent that the Debtors propose to pay less than the full cure amounts owed to PrimaPharma and fail to provide additional information regarding adequate assurance of future performance and clarification regarding the counterparties being added to the assumed contracts.

6. In order for the Debtors to assume the contracts, Section 365 of the Bankruptcy Code requires this Court's approval and imposes certain obligations upon the Debtors, including:

(b)(1) If there has been a default in an executory contract or unexpired lease of the debtor, the trustee may not assume such contract or lease unless, at the time of assumption of such contract or lease, the trustee

(A) cures, or provides adequate assurance that the trustee will promptly cure, such default other than a default that is a breach of a provision relating to the satisfaction of any provision (other than a penalty rate or penalty provision) relating to a default arising from any failure to perform nonmonetary obligations under an unexpired lease of real property, if it is impossible for the trustee to cure such default by performing nonmonetary acts at and after the time of assumption, except that if such default arises from a failure to operate in accordance with a nonresidential real property lease, then such default shall be cured by performance at and after the time of assumption in accordance with such lease, and pecuniary losses resulting from such default shall be compensated in accordance with the provisions of this paragraph;

(B) compensates, or provides adequate assurance that the trustee will promptly compensate, a party other than the debtor to such contract or lease, for any actual pecuniary loss to such party resulting from such default; and

(C) provides adequate assurance of future performance under such contract or lease. 11 U.S.C. § 365(b) (emphasis added).

The Proposed Cure Amounts

7. Pursuant to Section 365's requirements, the Debtors propose to cure the defaults in the APA by paying PrimaPharma the proposed Cure Amount. At the time of the filing of this Objection, PrimaPharma is owed significant additional amounts not reflected in the proposed Cure Amount. The Debtors have listed a proposed Cure Amount of zero with respect to the APA with PrimaPharma when the actual cure amounts owed to PrimaPharma, as of the date of this Objection, is approximately \$160,000. See Declaration of Mark Livingston filed concurrently herewith.

8. Furthermore, the cure amount owed to PrimaPharma under the APA will likely increase by the date of assumption or the effective date for determining cure costs

under Section 365. To the extent that any such amounts become due and payable prior to assumption date, the Debtors will be required to cure such amounts. PrimaPharma hereby objects to the Motion as it fails to provide for the cure of all amounts currently due and for any additional amounts existing and owing at the time of the actual assumption of the Contracts as required under 11 U.S.C. § 365(b). See Krikor Dulgarian Trust v. Unified Mgmt. Corp (In re Peaberryø), 205 B.R. 6, 9 (1st Cir. BAP 1997); In re F.W. Restaurants Associates, Inc., 190 B.R. 143, 147-48 (Bankr. D. Conn. 1995); see also In re Entertainment, Inc., 223 B.R. 141, 151 (Bankr. N.D. Ill. 1998), quoting In re Diamond Head Emporium, Inc., 69 B.R. 487, 495 (Bankr. D. Hawaii 1987) (öOne of the purposes of Section 365 is to permit the debtor to continue in a beneficial contract, provided, however, that the other party to the contract is made whole at the time of the debtorø assumption of the contract.ö).

**Adequate Assurance and Clarification Regarding Additional Counterparties
under the Assumed Contracts and their Respective Obligations**

9. In order to obtain the relief requested in the Motion, the Debtors and the additional counterparties to the assumed contracts must demonstrate adequate assurance of future performance. See 11 U.S.C. § 365(b). öAdequate assurance of future performance are not words of art, but are to be given practical, pragmatic construction.ö In re U. L. Radio Corp., 19 B.R. 537, 542 (Bankr. S.D. N.Y. 1982). Thus, the question of adequate assurance öis to be determined by factual conditions.ö Id.

10. Furthermore, pursuant to its terms, the APA is not assumable or amendable

without PrimaPharma's consent. See In re Village Rathskeller, Inc., 147 B.R. 665, 671-672 (Bankr. S.D.N.Y. 1992); Kopel v. Campanile (In re Kopel), 232 B.R. 57, 63664 (Bankr. E.D.N.Y. 1999) (A debtor cannot simply retain the favorable and excise the burdensome provisions of an agreement.)

11. Without additional information and further clarification regarding the actual proposed, additional counterparties to the APA, as well as a more detailed demonstration of adequate assurance of performance, it is impossible for PrimaPharma to make an informed decision regarding the propriety of consenting to the assumption and assignment of the APA. PrimaPharma objects to the proposed relief to the extent that the Debtors fail to provide this information to PrimaPharma.

RESERVATION OF RIGHTS

12. PrimaPharma hereby reserves the right to amend, modify or supplement this Objection and to raise any additional arguments and objections to the Motion on all grounds available under applicable law. Additionally, PrimaPharma reserves its rights to comment upon and object to the form of order presented to the Court in connection with the Motion.

WHEREFORE, PrimaPharma requests that the Court enter an order: (I) sustaining this Objection and denying the Motion, except to the extent that the Debtors: a) pay the correct cure amount of \$160,000 and any and all additional amounts incurred as of the date of assumption as a prerequisite to the APAs' assumption, and b) provide specific information to demonstrate sufficient adequate assurance of future performance under the

APA with respect to each additional counterparty; and (ii) providing for such other relief the Court deems just and proper.

Dated: August 13, 2020

BODELL BOVE LLC

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- and -

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

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In re:)	Chapter 11	
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AKORN, INC., et al.,)	Case No. 20-11177 (KBO)	
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Debtors.)	(Jointly Administered)	
)		

Objections due by: August 14, 2020
Hearing Date:

**DECLARATION OF MARK T. LIVINGSTON IN SUPPORT OF OBJECTION OF
PRIMAPHARMA, INC. TO THE MOTION OF DEBTORS FOR THE
ASSUMPTION AND ASSIGNMENT OF CERTAIN EXECUTORY CONTRACTS
AND LEASES**

I, Mark T. Livingston, declare as follows:

I make the following declaration of facts based upon my own knowledge and, if called upon, can testify competently thereto except where the same are stated upon my information and belief, as to which facts I believe them to be true.

1. I am the President and Chief Executive Officer of PrimaPharma, Inc., a California corporation (“PrimaPharma”). I make this declaration in support of PrimaPharma’s objection to the Motion of Debtors for the Assumption and Assignment of the “PrimaPharm contract” between Akorn, Inc. (“Akorn”) and PrimaPharm, Inc. (“PrimaPharm”).

2. I am a custodian of records of PrimaPharma. Attached to my declaration as exhibits is a true and correct copy of various documents that I either obtained from the

public record, documents that were sent to PrimaPharma or documents that were prepared in the regular course of business of PrimaPharma. The documents were made at or near the time of the act, condition, or event described in the documents. The documents were prepared from information transmitted by a person with knowledge of the act, condition or event described therein or were prepared by a person with knowledge of the act, condition or event described therein. At the time the documents were prepared it was a regular practice of the business to prepare documents in connection with the business activity.

3. On or about July 1, 2015, PrimaPharma acquired certain contract rights of PrimaPharm.

4. I am informed and believe that on May 20, 2020 (the "Petition Date"), Akorn, Inc. ("Akorn") and certain of its affiliates (together, the "Debtors") filed voluntary petitions for relief under chapter 11 of Title 11 of the United States Code.

5. Prior to the Petition Date, Akorn and PrimaPharm entered into that certain Asset Purchase Agreement dated as of June 16, 2011 (the "APA"). PrimaPharma subsequently acquired the contract rights and is now the owner of PrimaPharm's contract rights under the APA. A true and correct copy of the APA is attached hereto as Exhibit A and is incorporated herein by this reference.

6. Pursuant to the APA, PrimaPharm transferred to Akorn the Marketing Authorization which transferred to Akorn the right to make, use and sell Hydase (TM)

(Hyaluronidase Injection, USP) 150 unites/mL in the United States of America, including all of its territories and possessions, including Puerto Rico, for diagnostic, therapeutic and over the counter products for ophthalmic use. PrimaPharma retains all other rights.

7. Paragraph 6.3 of the APA provides:

From and after the Effective Date, Akorn shall be responsible for and shall satisfy all obligations and liabilities arising from or relating to the Marketing Authorization, including, without limitation, all applicable regulatory obligations regarding the sale of the Product within the Field of Use and in the Territory under the Marketing Authorization.

8. By invoice dated August 15, 2011, number PAB121689R, the U.S. Food and Drug Administration billed PrimaPharm \$98,970.00 for fiscal year 2012 PDUFA Fees, which fees covered from October 1, 2011 to September 30, 2012. A true and correct copy of the invoice is attached hereto as Exhibit B and is incorporated herein by this reference.

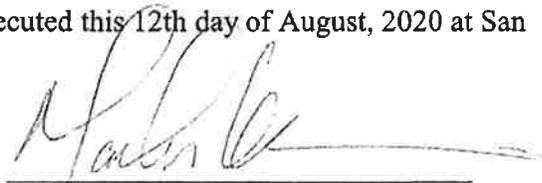
9. By notice dated March 15, 2019, the Department of Health & Human Services Debt Collection Center informed PrimaPharma that it was indebted to the United States government in the amount of \$116,725.62, consisting of principal of \$98,970.00, interest of \$2,910.11 which accrued at the rate of 10.125% and a penalty of \$14,845.51. A true and correct copy of the Notice is attached hereto as Exhibit C and is incorporated herein by this reference. However, this amount consists of the PDUFA fees rightfully owed by Akorn plus interest and penalties.

10. As of the date of this declaration, the amount owed by Akorn under the

ADA is approximately \$160,000.00. This amount consists of the PDUFA fees, interest, penalties and fees and costs incurred by PrimaPharma in connection with the government's collection efforts. Furthermore, the cure amount owed to PrimaPharma under the APA will likely increase by the date of assumption as amounts continue to accrue.

11. Furthermore, pursuant to its terms, the APA is not assumable or amendable without PrimaPharma's consent.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 12th day of August, 2020 at San Diego, California.



MARK T. LIVINGSTON

EXHIBIT A

ASSET PURCHASE AGREEMENT

THIS AGREEMENT is dated as of June 16, 2011 (the "Effective Date"), by and between Akorn Inc., a corporation incorporated under the laws of Louisiana, USA ("Akorn"), and PRIMAPHARM, a corporation incorporated under the laws of California, USA ("PrimaPharm").

WHEREAS:

- A. Akorn is engaged in the business of developing, manufacturing, commercializing and selling pharmaceutical products;
- B. PrimaPharm is engaged in the business of developing, manufacturing, commercializing and selling pharmaceutical products;
- C. PrimaPharm is the holder of the Marketing Authorization for the Product in the Territory; and
- D. PrimaPharm desires to sell to Akorn and Akorn desires to purchase the Marketing Authorization from PrimaPharm upon the terms and subject to the conditions hereinafter set forth.

NOW THEREFORE, the parties agree as follows:

1. **Definitions**

In addition to any terms defined elsewhere in this Agreement, the terms set forth below shall be defined in this Agreement (including the recitals) as follows:

- 1.1 "Affiliate" with respect to a party means any corporation or business entity that directly or indirectly controls, is controlled by or is under common control with the applicable party. The term "control" means the beneficial (direct or indirect) ownership of more than fifty percent (50%) of the voting or equity interests of such corporation or business entity or the power or right to direct the management and affairs of its business, whether through the ownership of voting securities, by contract or otherwise;
- 1.2 "Agreement" means this Asset Purchase Agreement, including all schedules attached hereto, and all instruments supplemental or ancillary hereto;
- 1.3 "API" means Active Pharmaceutical Ingredient or drug substance
- 1.4 "Field of Use" means diagnostic, therapeutic and over the counter products for ophthalmic use.

- 1.5 “**Intellectual Property**” shall mean, collectively, (i) the Licensed Trademark Rights, (ii) the licensed Product Technology (Knowhow); and (iii) the Licensed Marketing Authorization.
- 1.6 “**Marketing Authorization**” means the approval granted by the Regulatory Authorities authorizing PrimaPharm to promote, market, distribute, and sell the Product in the Territory, being the new drug application (NDA#021716) described in **Schedule A** hereto and covered by the package insert for the HYDASE product as attached in **Schedule B**;
- 1.7 “**Product**” means the finished pharmaceutical product set forth in **Schedule A**;
- 1.8 “**Product Technology (Knowhow)**” means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) relating to the research and development, manufacture, validation, packaging, release, testing, stability and shelf life of the Product in existence and in the possession of PrimaPharm as of the Effective Date. The Product Technology includes, without limitation, the following information relating to the Product: product formulations and processes; product specifications; product designs and plans; manufacturing, engineering and other manuals and drawings; standard operating procedures; flow diagrams; chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, efficacy, bio-equivalency, quality assurance, quality control and clinical data, studies and reports; research records; compositions; annual product reviews; process validation reports; analytical method validation reports; specifications for stability trending and process controls; testing and reference standards for impurities in and degradation of Product; technical data packages; chemical and physical characterizations; dissolution test methods and results; formulations for administration; labeling specifications; supplier lists; and all other information related to the manufacturing process for the Product;
- 1.9 “**Regulatory Authorities**” means the governmental regulatory health authorities in the Territory responsible for regulating the manufacture, distribution and sale of pharmaceutical products, being the Food and Drug Administration or any successor thereto;
- 1.10 “**Licensed Trademark Rights**” shall mean all proprietary names or designations, registered and unregistered trademarks, service marks, trade names, brand names, certification marks, and trade dress, and any applications for registration therefor, (and all renewals, modifications, and extensions thereof) associated with the Product. Specifically, the trademark, HYDASE, is hereby licensed to Akorn in the Field of Use and in the Territory.
- 1.11 “**Territory**” means the United States of America, including all of its territories and possessions, including Puerto Rico.

2. **Transfer of the Marketing Authorization**

2.1 Transfer of the Marketing Authorization. Upon the terms and subject to the conditions of this Agreement, PrimaPharm hereby transfers to Akorn the right to make, use, and sell the Product in the Territory for the stated Field of Use. The following assets ("Acquired Assets") are included as part of the Marketing Authorization purchase:

- (a) the Marketing Authorization;
- (b) the Intellectual Property;
- (c) any correspondence with the Regulatory Authorities in PrimaPharm's files with respect to the Marketing Authorization; and
- (d) except as otherwise set forth in **Section 2.2**, all regulatory reports relating to the Product that have been filed with the Regulatory Authorities by PrimaPharm in connection with the Marketing Authorization including, without limitation, all adverse event reports, history and statistics pertaining to the Product as reported by PrimaPharm to the Regulatory Authorities.

2.2 Excluded Assets. PrimaPharm and Akorn expressly acknowledge and agree that the Acquired Assets do not include any of the following (the "**Excluded Assets**"):

- (a) the name "PrimaPharm" and any and all variations, formatives and derivatives thereof, all composite marks including such names or any such formatives or derivatives and any colorable imitation of any of the foregoing, and all trademarks, trade names, brand names, logotypes, symbols, service marks, and the goodwill of the business symbolized thereby, including registrations and applications for registrations thereof and all renewals, modifications and extensions thereof, currently used or proposed to be used by PrimaPharm or any of its Affiliates in connection with the manufacture, marketing, sale and distribution of either the Product or any other product;
- (b) any administrative, financial and accounting records of PrimaPharm unrelated to the Product and the Acquired Assets; and
- (c) any other assets that are not specifically included within the definition of the Field of Use.

2.3 Assumption of Obligations. Akorn shall not assume any liabilities or obligations of PrimaPharm whatsoever, and specifically Akorn will not assume and will not be liable for, and PrimaPharm will indemnify Akorn from and against, all obligations, commitments and liabilities of and claims against PrimaPharm (whether absolute, accrued, or contingent) relating to the Product and the Acquired Assets during the period prior to the Effective Date. Without limiting the generality of the foregoing, it is agreed that Akorn will have no liability for any of the following obligations or liabilities of PrimaPharm (the "**Excluded Obligations**"):

- (a) all liabilities in respect of all indebtedness of PrimaPharm;

- (b) all product liability claims and liabilities for warranty or product return claims relating to any product or service of PrimaPharm and any Product produced, sold, or delivered prior to the Effective Date;
- (c) all liabilities for all taxes, duties, levies, assessments and other such charges, including any penalties, interests and fines with respect thereto, payable by PrimaPharm to any federal, provincial, municipal or other government or governmental agency, authority, board, bureau or commission, domestic or foreign, including, without limitation, any taxes in respect of or measured by the sale, consumption or performance by PrimaPharm of any product or service prior to the Effective Date, and any tax in respect of all remuneration payable to all persons employed by PrimaPharm prior to the Effective Date; and
- (d) all liabilities for salary, bonus, vacation pay and other compensation, and all liabilities under employee benefit plans of PrimaPharm relating to employment of any and all persons in PrimaPharm.

2.4 License to Product Technology.

- (a) PrimaPharm hereby grants to Akorn, subject to the terms and conditions hereof, an exclusive right and license to use the Product Technology for the sole purpose of manufacturing the Product for marketing and sale by Akorn and Akorn's distributors within the Territory for use in the field of ophthalmics.
- (b) If Akorn grants to any Authorized Manufacturer a sublicense to use the Product Technology in accordance with the provisions hereof, then Akorn shall cause and obligate the Authorized manufacturer to comply with all covenants and restrictions herein applicable to the use of the Product Technology.

2.5 Retention of Rights to Reference Marketing Authorization. PrimaPharm retains the right to reference the Marketing Authorization, Akorn also agrees that PrimaPharm shall retain the right to separately file a Marketing Authorization (NDA or IND) using Product Technology, provided that PrimaPharm is prohibited from developing ophthalmic products related to clinical indications within the Territory for the Field of Use. For purposes of clarity, PrimaPharm may pursue the development of products for any indication fully outside the Field of Use.

2.6 API Supply. Akorn has the right to order and PrimaPharm shall supply API to Akorn for the Field of Use in the Territory and Akorn on the terms set forth in Schedule C. Notwithstanding the foregoing, Akorn has the right to qualify a second API supplier from which Akorn may procure API, provided that Akorn uses the API solely in the manufacture of the Product and not for any for resale, distribution or use in the manufacture of any other pharmaceutical product.

2.7 Marketing Authorization Acquisition Fee. In consideration of the rights granted to Akorn hereunder, Akorn shall pay to PrimaPharm the sum of One Million Five Hundred

Thousand (\$1,500,000) United States Dollars subject to the conditions set forth herein and in accordance with the terms set forth in Section 3 below.

- 2.8 Transfer Taxes. All transfer, sales, value-added, stamp, duty, and any other taxes payable in connection with the transactions contemplated hereby, if any, will be borne by Akorn.

3. Closing

- 3.1 Closing. Closing shall take place and be effective upon the Effective Date.

3.2 Payment of License Price and Delivery of Licensed Assets.

- (a) Delivery and Evaluation of Acquired Assets. On the Effective Date, PrimaPharm shall deliver or otherwise make available to Akorn the Acquired Assets for purposes of Akorn's evaluation of the Acquired Assets, in its sole discretion, and shall thereafter provide written notice to PrimaPharma of its acceptance or rejection of the Acquired Assets.
- (b) Acceptance or Rejection of Acquired Assets. Should Akorn provide notice of its acceptance of the Acquired Assets, then the remaining obligations of this Agreement shall remain in full force and effect. Should Akorn provide notice of rejection of the Acquired Assets, it shall then immediately return all Acquired Assets and any related files or documentation to PrimaPharma, and all remaining obligations under this agreement shall terminate, except for those provisions which are intended to survive termination. Should Akorn provide notice of rejection of the Acquired Assets, Akorn warrants that it will not attempt to file its own NDA for Hyaluronidase for a period of three years from the Effective Date nor will Akorn use any of the information provided for any purpose.
- (c) Initial Payment. Within seven (7) business days of the Effective Date, provided PrimaPharm's delivery and Akorn's acceptance of the Acquired Assets has occurred, Akorn will deliver or cause to be delivered to PrimaPharm payment of One Million Three Hundred Twenty-five Dollars (\$1,375,000) by wire transfer in immediately available funds to such account as PrimaPharm may designate in writing, and PrimaPharm shall transfer and deliver to Akorn all right, title and interest in and to the Product Registration, the Licensed Assets and the Product Technology
- (d) Upon the Effective Date PrimaPharm shall send a letter to the respective FDA Division informing them of the Marketing Authorization (NDA) transfer to Akorn. Akorn will send acceptance of NDA letter to the Division to complete the transfer of the Marketing Authorization.
- (e) Second Payment. A second and final payment in the amount of Three Hundred Seventy-Five Thousand Dollars (\$375,000) will be delivered to PrimaPharm on

the six (6) month anniversary of commercialization of the Product by Akorn. Commercialization of the Product shall mean the initial introduction of Akorn labeled Product within the Territory and whose supply is not interrupted due to API supply issues by PrimaPharm.

3.2 Technical Transfer Services to Akorn by PrimaPharm.

- (a) Upon request of Akorn and as close as possible to the Effective Date, the Parties shall form a technical transfer team (the "Technical Team"), which shall coordinate and oversee the transfer of the Product, and all technical information and support reasonably necessary to enable Akorn to assume responsibility for the technical transfer, testing, and manufacture of the Product as of the Effective Date. The Technical Team shall consist of representatives from each of Akorn and PrimaPharm or their designees.
- (b) Promptly following the Effective Date, PrimaPharm, with input from the Technical Team, shall, or shall cause the Product to, commence the transfer of all technical information and support reasonably necessary to enable Akorn to assume responsibility for the testing and manufacture of the Product, and will provide:
 - (i) The reasonable assistance of its then current employees and reasonable access to its other internal resources to provide Akorn with a reasonable level of technical assistance and consultation in connection with the transfer of the Product to Akorn; and
 - (ii) copies of the comprehensive dossier, including manufacturing process production outlines, standard testing requirements, standard operating procedures, technology, documents, data, or other information that constitutes the Product Technology.

3.3 Support Services to PrimaPharm by Akorn

- (a) PrimaPharm retains the right to amend the NDA for uses outside Akorn's Field of Use and Territory as defined herein. Upon request of PrimaPharm, Akorn agrees to execute any necessary documents to support PrimaPharm's filing for such uses.
- (b) All related costs of preparation of any amendment application by PrimaPharm shall be absorbed by PrimaPharm.

4. **Representations and Warranties of PrimaPharm**

PrimaPharm hereby represents and warrants to Akorn as follows:

- 4.1 Organization; Good Standing; Power. PrimaPharm is a corporation duly organized, validly existing and in good standing under the laws of the United States. PrimaPharm has the corporate power and authority to conduct any lawful business activity.

PrimaPharm has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement.

- 4.2 Authority; Validity. The execution and delivery by PrimaPharm of this Agreement, the performance by PrimaPharm of its obligations hereunder and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of PrimaPharm. This Agreement has been duly executed and delivered by PrimaPharm and constitutes the valid and binding obligation of PrimaPharm, enforceable against PrimaPharm in accordance with its terms, except to the extent that enforceability hereof may be limited by general equitable principles or the operation of bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting the rights of creditors generally, and by general principles of equity.
- 4.3 Agreement Will Not Cause Breach. To the best of its knowledge, the execution, delivery, and performance of this Agreement will not result in any violation of or default under, or create a conflict with the terms, conditions, or provisions of the articles and by-laws of PrimaPharm or any material agreement or instrument by which PrimaPharm is bound.
- 4.4 Litigation. There are no suits, actions, disputes, claims, litigation, arbitrations, legal, administrative or other proceedings or governmental investigations, including appeals and applications for review, at law or in equity before any court or any federal, provincial, municipal or other governmental department, commission, tribunal, board, agency or arbitrator that is in progress, pending, or, to the knowledge of PrimaPharm, threatened or anticipated against PrimaPharm in relation to the Product or the Marketing Authorization. There are no outstanding judgments, orders, injunctions, decrees or awards against PrimaPharm in connection with the Product, the Marketing Authorization, this Agreement or the transactions contemplated hereby that have not been satisfied in all material respects.
- 4.5 Title to Purchased Assets. PrimaPharm has good and marketable title to the Acquired Assets, free and clear of all mortgages, security interests, charges, encumbrances, liens, assessments, covenants, claims, title defects, pledges, encroachments, and burdens of every kind or nature other than existing UCC-1's file as a part of prior financings.
- 4.6 Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Section 4, PrimaPharm does not make, and hereby expressly disclaims, any and all other representations or warranties, express or implied, including any warranties of non-infringement, merchantability, or fitness for a particular purpose, with respect to the Product or the Marketing Authorization. It is expressly understood by each party hereto that any cost estimates, projections, or other predictions contained or referred to in any financial information or other materials that have been provided to Akorn are not and shall not be deemed to be representations or warranties of PrimaPharm.
5. **Representations and Warranties of Akorn**

Akorn hereby represents and warrants to PrimaPharm as follows:

5.1 Organization; Good Standing; Power. Akorn is a corporation duly incorporated, validly existing and in good standing under the laws of the jurisdiction described on the first page hereof. Akorn has the corporate power and authority to conduct any lawful business activity. Akorn has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement.

5.2 Authority; Validity. The execution and delivery by Akorn of this Agreement, the performance by Akorn of its obligations hereunder and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of Akorn. This Agreement has been duly executed and delivered by Akorn and constitutes the valid and binding obligation of Akorn, enforceable against it in accordance with its terms, except to the extent that enforceability hereof may be limited by general equitable principles or the operation of bankruptcy, insolvency, reorganization, moratorium, or similar laws relating to or affecting the rights of creditors generally, and by general principles of equity.

5.3 Agreement Will Not Cause Breach. The execution, delivery and performance of this Agreement will not result in any violation of or default under or create a conflict with the terms, conditions or provisions of the articles and by-laws of Akorn or any material agreement or instrument by which Akorn is bound.

5.4 Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Section 5, Akorn does not make any other representations or warranties, express or implied.

6. Covenants of the Parties

6.1 Confidentiality.

(a) Akorn acknowledges that the Product Technology constitutes valuable and proprietary information that is the property of PrimaPharm. Akorn shall keep confidential all information disclosed by PrimaPharm relating to the Product Technology (the “Confidential Information”), shall not disclose any Confidential Information to any person except as authorized herein, and shall not use any Confidential Information except for the purposes expressly contemplated herein. Akorn shall ensure that any person to whom it discloses the Confidential Information is informed of the confidential nature of and duty not to disclose the information, and is obligated to maintain the confidentiality thereof. For greater certainty, the confidentiality obligations set forth herein shall survive Closing.

(b) “Confidential Information” shall not include information that: (i) is or becomes a matter of public knowledge through no breach by Akorn or any of its Affiliates or representatives, (ii) is lawfully acquired from a third party without restrictions of

confidentiality, (iii) is independently developed by Akorn without reliance on Confidential Information supplied by PrimaPharm, (iv) constitutes the general business or industry expertise of any employee of Akorn or its Affiliates, so long as such general business knowledge or industry expertise is not derived from information that would otherwise be deemed to be confidential and proprietary information hereunder, or (v) is required to be disclosed by applicable law, provided that prior to any such disclosure Akorn shall, if possible, notify PrimaPharm and provide PrimaPharm with a reasonable opportunity to contest or limit the scope of the required disclosure and obtain any protective orders as may be appropriate.

- (c) Akorn acknowledges and agrees that: (i) PrimaPharm would be irreparably injured in the event of a breach by Akorn of any of its obligations under this **Section 6.1**; (ii) monetary damages would not be an adequate remedy for such breach; and (iii) PrimaPharm shall be entitled to injunctive relief, in addition to any other remedy that it may have, in the event of any such breach.

- 6.2 Records. Akorn will preserve all books and records included within the Acquired Assets for a period of at least five (5) years from the date hereof and make such books and records (including reports required by Regulatory Authorities) available for inspection and copying by PrimaPharm upon reasonable request and upon reasonable notice. Thereafter, Akorn will not dispose of or destroy any of such books or records without giving thirty (30) days' prior written notice to PrimaPharm to permit PrimaPharm to duplicate or take possession of any such books and records.
- 6.3 Assumption of Product Obligations. From and after the Effective Date, Akorn shall be responsible for and shall satisfy all obligations and liabilities arising from or relating to the Marketing Authorization, including, without limitation, all applicable regulatory obligations regarding the sale of the Product within the Field of Use and in the Territory under the Marketing Authorization.
- 6.4 Response to Medical Inquiries and Product Complaints. Akorn shall be responsible for responding to any medical inquiries or complaints about the Product in the Territory sold under the NDC numbers of Akorn or its distributors. PrimaPharm shall be responsible for responding to any medical inquiries or complaints about the Product in the Territory sold under PrimaPharm NDC numbers.
- 6.5 Representations to Customers. From and after the Effective Date, Akorn will not make any false or misleading representations to customers or others regarding Akorn, PrimaPharm or its Affiliates, or the Product, and will not make any representations, warranties, or guarantees with respect to the specifications, features, or capabilities of the Product that are not consistent with the applicable current labeling and package insert or other documentation accompanying or describing such Product as approved by the Regulatory Authorities.

6.6 Use of Purchased Assets. Akorn acknowledges and agrees that this License Agreement does not convey any right to Akorn to use the Purchased Assets outside the Licensed Field of Use or to sell the Product outside of the Territory.

7. **Indemnification**

7.1 By PrimaPharm. PrimaPharm shall indemnify, defend and hold harmless Akorn, its Affiliates, subsidiaries, officers, directors and agents from any and all liabilities, demands, obligations, assessments, judgments, levies, losses, fines, penalties, damages (including compensatory damages), costs and expenses, including reasonable attorneys', accountants', investigators' and experts' fees and expenses (collectively, "Losses") which Akorn (or any Akorn indemnitee) may suffer or incur resulting from any third party demand, claim, action, or cause of action (a "Third Party Claim") arising from or in connection with:

- (a) the breach by PrimaPharm of any of its representations, warranties, covenants or other obligations hereunder; and
- (b) the Excluded Obligations.

7.2 By Akorn. Akorn shall indemnify, defend and hold harmless PrimaPharm, its Affiliates, subsidiaries, officers, directors and agents from any and all Losses which PrimaPharm (or any PrimaPharm indemnitee) may suffer or incur resulting from any Third Party Claim arising from or in connection with:

- (a) the breach of Akorn's representations, warranties, covenants or other obligations hereunder;
- (b) any product liability claim to the extent it relates to any Product sold in the Territory by or on behalf of Akorn on or after the Effective Date;
- (c) any claims by the Regulatory Authorities or any other governmental entity in relation to the Product sold in the Territory by or on behalf of Akorn arising on or after the Effective Date; and
- (d) patent, trademark, or other intellectual property infringement claims in relation to the manufacture, marketing and/or sale of the Product in the Territory arising on or after the Effective Date.

7.3 Procedure.

- (a) In order for an indemnified party under this Section 7 (an "Indemnified Party") to be entitled to any indemnification provided for under this Agreement, such Indemnified Party shall, promptly following the discovery of the matters giving rise to any actual or potential Losses, notify the indemnifying party under this Section 7 (the "Indemnifying Party") in writing of its claim for indemnification for such Losses, specifying in reasonable detail the nature of such Losses and the

amount of the liability estimated to accrue therefrom; *provided, however*, that failure to give such prompt notification will not affect the indemnification provided hereunder, except to the extent the Indemnifying Party will have been actually prejudiced as a result of such failure (except that the Indemnifying Party will not be liable for any expenses incurred during the period in which the Indemnified Party failed to give such notice).

- (b) Upon receipt of notice from the Indemnified Party, the Indemnifying Party shall assume the defense of the Third Party Claim. The Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof (other than during any period in which the Indemnified Party will have failed to give notice of the Third Party Claim as provided above). The Indemnified Party will cooperate in the defense of the Third Party Claim. Such cooperation will include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. The Indemnified Party will agree to any settlement, compromise, or discharge of such Third Party Claim that the Indemnifying Party may recommend and that, by its terms, obligates the Indemnifying Party to pay the full amount of the liability in connection with such Third Party Claim. The Indemnifying Party shall not otherwise settle or consent to judgment without the Indemnified Party's approval, which approval shall not to be unreasonably withheld. Provided that the Indemnifying Party assumes control of the defense of the Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnifying Party's prior written consent. If the Indemnifying Party fails to assume control of the defense of any Third Party Claim, or, having elected to assume control, thereafter fails to diligently defend the claim, the Indemnified Party shall, without limitation to the Indemnifying Party's obligations hereunder, be entitled to contest, settle or pay the amount of the Third Party Claim, and the Indemnifying Party shall be bound by the results obtained by the Indemnified Party with respect to the Third Party Claim.

8. **Dispute Resolution**

- 8.1 Relationship of Parties. Neither Party is the agent nor legal representative of the other Party, and neither Party has the right or authority to bind the other Party in any way. This Agreement creates no relationship as partners or a joint venture, and creates no pooling arrangement.

- 8.2 Governing Law and Venue. This Agreement is governed by and shall be construed in accordance with the law of the State of Illinois, USA excluding any conflict-of-laws rule or principle that might refer the governance or the construction of this Agreement to the law of another jurisdiction. Each Party hereby consents to the exclusive jurisdiction of the state and federal courts sitting in Illinois in any action on a claim arising out of, under or in connection with this Agreement or the transactions contemplated by this Agreement, provided such claim is not required to be arbitrated. Each Party further agrees that personal jurisdiction over it may be effected by service of process by registered or certified mail addressed as provided in Section 9.5 of this Agreement, and that when so made shall be as if served upon it personally within the State of Illinois.
- 8.3 Notice of Dispute. In the event of a dispute between the Parties which may arise under, out of, in connection with or in relation to this Agreement (a "Dispute"), either Party may at any time provide the other Party with written notice of its intention to formally invoke the dispute resolution provisions of this Section (a "Notice of Dispute").
- 8.4 Negotiated Settlement. Neither Party will commence any proceedings against the other Party in respect of a Dispute unless it has first used commercially reasonable efforts to resolve the Dispute by good faith discussions between the respective designated representatives of the parties or, if such discussions are not successful in resolving the Dispute, by good faith discussions between the parties' senior executives. Each of the parties will provide full, candid and timely disclosure of all relevant facts, information and documents to facilitate any such discussions.
- 8.5 Mediation. In the event of a Dispute that has not been resolved to the satisfaction of the parties under Section 8.4, either Party may, at any time after 14 days following the date that a Notice of Dispute is given in respect of the Dispute, refer the Dispute, including a Dispute which is under review or subject to a recommendation under Section, to mediation which, unless otherwise agreed between the parties, will be commenced and carried out in accordance with the mediation rules of procedures of JAMS in effect at the time of the mediation.
- 8.6 Binding Arbitration. If the parties are unable to resolve their dispute using Mediation they agree to go to Binding Arbitration under rules and procedures of JAMS before a single arbitrator in Illinois.
9. Miscellaneous Provisions
- 9.1 Fees and Disbursements. Except as otherwise expressly provided herein, each party shall bear its own costs and expenses, including attorney, accountant and consultant fees, incurred in connection with the negotiation and execution of this Agreement, any related agreements and the consummation of the transactions contemplated hereby and thereby.
- 9.2 Press Releases and Other Announcements. No press releases or other public announcements related to this Agreement or the transactions contemplated hereby will be issued without the prior written approval of both parties, except for any public disclosure that PrimaPharm or Akorn in good faith believes is required by applicable law.

9.3 Amendments and Waivers. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the parties hereto. No failure or delay on the part of any party hereto in exercising any right, power, or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power, or remedy preclude any other or further exercise thereof or the exercise of any other right, power, or remedy. No waiver by a party hereto of a default hereunder shall operate against such party as a waiver of such default unless made in writing and signed by an authorized officer of such party.

9.4 Further Assurances. Each of the parties hereto, upon the request of the other party hereto, without further consideration, will do, execute, acknowledge and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement. Each party agrees to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

9.5 Notices. 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 electronically or by telecopier (if transmitted before 5:00 p.m. local time on a business day, or if not, on the following business day) 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 recognized overnight courier service which utilizes a written form of receipt for next day or next business day delivery, or (d) three (3) business days after mailing, if mailed by postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable party at the address set forth below (provided, however, that a party may change its address for receiving notice by the proper giving of notice hereunder):

(i) If to Akorn:

Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Attn: Legal Department
Facsimile: 866-468-0750
E-Mail: sean.brynjelsen@akorn.com

Copy: Sean Brynjelsen

(ii) If to PrimaPharm:

PrimaPharm Inc.
3443 Tripp Court
San Diego, CA 92121
Attention: Mark T. Livingston
Facsimile: 858-259-8268
E-mail: mark@primapharm.net

- 9.6 Assignment. This Agreement is binding on, and shall inure to the benefit of, the parties hereto and their successors and permitted assigns. This Agreement (including any rights hereunder) may not be assigned and no obligations hereunder may be delegated by any party without the prior written consent of the other party, which consent shall not be unreasonably withheld, and any attempted assignment in contravention hereof shall be deemed void.
- 9.7 Governing Law. This contract shall be governed by, and construed in accordance with, the laws of the State of Illinois applicable to contracts entered into and performed wholly within such state. The parties hereby agree that service of process delivered by certified mail, return receipt requested in accordance with the provisions of Section 8.5 hereof shall constitute personal service for all purposes hereof.
- 9.8 Waiver of Jury Trial. Each party hereto waives, to the extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this agreement.
- 9.9 Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability, and without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any one jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.
- 9.10 Certain Rules of Construction. As used in this Agreement, unless the context otherwise requires: words describing the singular number include the plural, and vice versa; words denoting any gender include all genders; the word "including" means "including, without limitation"; and the words "hereof," "herein" and "hereunder," and words of similar import, refer to this Agreement as a whole and not to any particular provision of this Agreement. The headings contained herein are for the sole purpose of convenience of reference, and do not in any way limit or affect the meaning or interpretation of any of the provisions of this Agreement.
- 9.11 Entire Agreement. This Agreement, which includes all schedules attached hereto, and all other documents which may be delivered at Closing constitutes the entire agreement among the parties and contain all of the covenants, representations and warranties of the respective parties with respect to the subject matter hereof. There are no oral representations or warranties among the parties of any kind.

9.12 Counterparts. This Agreement may be executed in counterparts, each of which shall constitute an original but all of which, when taken together, shall constitute but one Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PRIMAPHARM INC.

By: 
Name: MARK T. LIVINGSTON
Title: PRESIDENT

PRIMAPHARM INC.

By: 
Name: ANTHONY D'ZIABO
Title: Vice President

AKORN, INC.

By: 
Name: Raj Rai
Title: Chief Executive Officer

AKORN, INC.

By: 
Name: Joe Bonaccorsi
Title: Sr. Vice President, General Counsel

SCHEDULE A
PRODUCT & MARKETING AUTHORIZATION

<u>Product</u>	<u>Description of Marketing Authorization</u>
HYDASE TM (hyaluronidase injection) 150 UNITS/ML	NDA Application # 21-716

SCHEDULE B

Hydase Package Insert

Hydase™

(hyaluronidase injection)

DESCRIPTION

Hydase™, is a preparation of purified bovine testicular hyaluronidase, a protein enzyme. The exact chemical structure of this enzyme is unknown. However, the amino acid sequence for the primary structure of the enzyme has been deduced from the sequence of purified peptides.

Hydase™ (hyaluronidase injection) is supplied as a sterile, colorless, odorless, ready for use solution. Each vial contains 150 USP units of hyaluronidase per ml, with 0.5 mg sodium chloride, 1 mg edetate disodium, 0.4 mg calcium chloride, monobasic sodium phosphate buffer, sodium hydroxide to adjust the pH, and sterile water.

Hydase™ has an approximate pH of 6.9 and an osmolality of 275 to 305 mOsm.

CLINICAL PHARMACOLOGY

Hyaluronidase is a spreading or diffusing substance which modifies the permeability of connective tissue through the hydrolysis of hyaluronic acid, a polysaccharide found in the intercellular ground substance of connective tissue, and of certain specialized tissues, such as the umbilical cord and vitreous humor. Hyaluronic acid is also present in the capsules of type A and C hemolytic streptococci. Hyaluronidase hydrolyzes hyaluronic acid by splitting the glucosaminic bond between C1 of the glucosamine moiety and C4 of glucuronic acid. This temporarily decreases the viscosity of the cellular content and promotes diffusion of injected fluids or of localized transudates or exudates, thus facilitating their absorption.

Hyaluronidase cleaves glycosidic bonds of hyaluronic acid and, to a variable degree, some other acid mucopolysaccharides of the connective tissue. The activity is measured *in vitro* by monitoring the decrease in the amount of an insoluble serum albumon-hyaluronic acid complex as the enzyme cleaves the hyaluronic acid component.

When no spreading factor is present, material injected subcutaneously spreads very slowly, but hyaluronidase causes rapid spreading, provided local interstitial pressure is adequate to furnish the necessary mechanical impulse. Such an impulse is normally initiated by injected solutions. The rate of diffusion is proportionate to the amount of enzyme, and the extent is proportionate to the volume of solution.

Knowledge of the mechanisms involved in the disappearance of injected hyaluronidase is limited. It is known, however, that the blood of a number of mammalian species brings about the inactivation of hyaluronidase. Studies have demonstrated that hyaluronidase is antigenic; repeated injections of relatively large amounts of this enzyme may result in the formation of neutralizing antibodies. The reconstitution of the dermal barrier removed by intradermal injection of hyaluronidase (20, 2, 0.2, 0.02, and 0 (0.02 Unit)) to adult humans indicated that at 24 hours the restoration of the barrier is incomplete and inversely related to the dosage of enzyme; at 48 hours the barrier is completely restored in all treated areas.

Results from an experimental study, in humans, on the influence of hyaluronidase in bone repair support the conclusion that this enzyme alone, in the usual clinical dosage, does not deter bone healing.

INDICATIONS AND USAGE

Hydase™ is indicated as an adjunct to increase the absorption and dispersion of other injected drugs, for hypodermoclysis, and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

CONTRAINDICATIONS

Hypersensitivity to hyaluronidase or any other ingredient in the formulation is a contraindication to the use of this product.

WARNINGS

Discontinue Hydase™ (hyaluronidase injection) if sensitization occurs.

Hyaluronidase should not be used to enhance the absorption and dispersion of depanamine and/or alpha agonist drugs.

Hyaluronidase should not be injected into or around an infected or acutely inflamed area because of the danger of spreading a localized infection.

Hyaluronidase should not be used to reduce the swelling of bites or stings.

Hyaluronidase should not be applied directly to the cornea.

Hyaluronidase should not be used for intravenous injection, because the enzyme is rapidly inactivated.

PRECAUTIONS

General

Furosemide, the benzothiazepines and phenytoin have been found to be incompatible with hyaluronidase.

When considering the administration of any other drug with hyaluronidase, it is recommended that appropriate references first be consulted to determine the usual precautions for the use of the other drug; e.g., when epinephrine is injected along with hyaluronidase, the precautions for the use of epinephrine in cardiovascular disease, thyroid disease, diabetes, digitalis block, ischemia of the fingers and toes, etc., should be observed.

Laboratory tests

A preliminary skin test for sensitivity to Hydase™ can be performed. The skin test is made by an intradermal injection of approximately 0.02 ml (3 Units) of a 150 Unit/ml solution (See "Dosage and Administration"). A positive reaction consists of a wheal with pseudopods appearing within five minutes and persisting for 20 to 30 minutes and accompanied by localized itching. Transient vasodilation at the site of the test, i.e., erythema, is not a positive reaction.

Drug Interactions

When hyaluronidase is added to a local anesthetic agent, it hastens the onset of analgesia and tends to reduce the swelling caused by local infiltration, but the wider spread of the local anesthetic solution increases its absorbability; this shortens its duration of action and tends to increase the incidence of systemic reactions.

Patients receiving large doses of salicylates, cortisone, ACTH, estrogens or antiandrogens may require larger amounts of hyaluronidase for equivalent dispersing effect, since these drugs apparently render tissues partly resistant to the action of hyaluronidase.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to assess the carcinogenic or mutagenic potential of hyaluronidase. Hyaluronidase is found in most tissues of the body.

Long-term animal studies have not been performed to assess whether hyaluronidase impairs fertility; however, it has been reported that testicular degeneration may occur with the production of organ-specific antibodies against this enzyme following repeated injections. Human studies on the effect of intravaginal hyaluronidase in sterility due to oligospermia indicated that hyaluronidase may have aided conception. Thus, it appears that hyaluronidase may not have adversely affected fertility in females.

Pregnancy

Teratogenic Effects—Pregnancy Category C

No adequate and well controlled animal studies have been conducted with Hydase™ to determine reproductive effects.

No adequate and well controlled studies have been conducted with Hydase™ in pregnant women.

Hydase™ should be used during pregnancy only if clearly needed.

Labor and Delivery

Administration of hyaluronidase during labor was reported to cause no complications; no increase in blood loss or differences in cervical trauma were observed. It is not known whether hyaluronidase has an effect on the later growth, development, and functional maturation of the infant.

Nursing Mothers

It is not known whether hyaluronidase is excreted in human milk, because many drugs are excreted in human milk, caution should be exercised when hyaluronidase is administered to a nursing woman.

Pediatric Use

Hyaluronidase may be added to small volumes of solution (up to 200 ml), such as small clysts for infants or solutions of drugs for subcutaneous injection. The potential for chemical or physical incompatibilities should be kept in mind (See "Dosage and Administration").

For infants and children less than 3 years old, the volume of a single clyst should be limited to 200 ml; and in premature infants or during the neonatal period, the daily dosage should not exceed 25 ml/kg of body weight; the rate of administration should not be greater than 2 ml per minute. For older patients, the rate and volume of administration should not exceed those employed for intravenous infusion.

During hypodermoclysis, special care must be taken in pediatric patients to avoid overdilatation by controlling the rate and total volume of the clyst (See "Dosage and Administration, Hypodermoclysis").

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

ADVERSE REACTIONS

The most frequently reported adverse experiences have been local injection site reactions. Hyaluronidase has been reported to enhance the adverse events associated with co-administered drug products. Edema has been reported most frequently in association with hypodermoclysis. Allergic reactions (urticaria, angioedema) have been reported in less than 0.1% of patients receiving hyaluronidase. Anaphylactic-like reactions following retrobulbar block or intramuscular injections have occurred, rarely.

OVERDOSAGE

Symptoms of toxicity consist of local edema or urticaria, erythema, chill, nausea, vomiting, dizziness, tachycardia, and hypotension. The enzyme should be discontinued and supportive measures initiated immediately.

DOSAGE AND ADMINISTRATION

Hydase™ (hyaluronidase injection) should be administered only as discussed below, since its effects related to absorption and dispersion of other drugs are not produced when it is administered intravenously.

Absorption and Dispersion of Injected Drugs

Absorption and dispersion of other injected drugs may be enhanced by adding 50-300 Units, most typically 150 U hyaluronidase, to the injection solution.

It is recommended that appropriate references be consulted regarding physical or chemical incompatibilities before adding Hydase™ to a solution containing another drug.

Hypodermoclysis

Insert needles with aseptic precautions. With lip tying free and movable between skin and muscle, begin clyst; fluid should start in readily without pain or lump. Then inject Hydase™ (hyaluronidase injection) into rubber tubing close to needle.

An alternate method is to inject Hydase™ under skin prior to clyst. 150 U will facilitate absorption of 1,000 ml or more of solution. As with all parenteral fluid therapy, observe effect closely, with same precautions for restoring fluid and electrolyte balance as in intravenous injections. The dose, the rate of injection, and the type of solution (saline, glucose, longer, etc.) must be adjusted carefully to the individual patient. When solutions devoid of inorganic electrolytes are given by hypodermoclysis, hypovolemia may occur. This may be prevented by using solutions containing adequate amounts of inorganic electrolytes and/or controlling the volume and speed of administration.

Hydase™ may be added to small volumes of solution (up to 200 ml), such as small clysts for infants or solutions of drugs for subcutaneous injection. For infants and children less than 3 years old, the volume of a single clyst should be limited to 200 ml; and in premature infants or during the neonatal period, the daily dosage should not exceed 25 ml/kg of body weight; the rate of administration should not be greater than 2 ml per minute. For older patients, the rate and volume of administration should not exceed those employed for intravenous infusion.

Subcutaneous Urography

The subcutaneous route of administration of radiographic contrast media is indicated when intravenous administration cannot be successfully accomplished, particularly in infants and small children. With the patient prone, 75 U of Hydase™ (hyaluronidase) is injected subcutaneously over each scapula, followed by injection of the contrast medium at the same sites.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Hydase™ (hyaluronidase injection) is supplied sterile as 150 USP units of hyaluronidase per ml in a 2 ml glass vial.

NDC 059650-019-01, 1 ml, in a 2ml vial, as single use vials

NDC 059650-019-09, 6 X 1 ml in a 2ml vial, as single use vials

NDC 059650-019-24, 24 X 1 ml in a 2ml vial, as single use vials

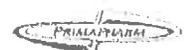
Not recommended for IV use.

Store in a refrigerator at 2-8°C (36° to 46°F).

DO NOT FREEZE

Rx Only

Manufactured by



Primapharm, Inc.
3443 Tripp Court
San Diego, CA 92121 USA
1-866-399-6569
www.primapharm.net

LAB 62 Rec Group

SCHEDULE C

API Supply Pricing from PrimaPharm

<u>Product</u>	<u>Pricing</u>
Hyaluronidase (as approved in NDA Application # 21-716)	COGS+20%

**FIRST AMENDMENT TO
ASSET PURCHASE AGREEMENT**

This First Amendment to the Asset Purchase Agreement ("First Amendment") is dated as of July 8th 2011 (the "Effective Date"), by and between Akorn Inc., a corporation incorporated under the laws of Louisiana, USA ("Akorn"), and PRIMAPHARM, a corporation incorporated under the laws of California, USA ("PrimaPharm").

WHEREAS:

- A. Akorn and PrimaPharm entered into the Asset Purchase Agreement as of June 16, 2011 ("Agreement");
- B. PrimaPharma delivered to Akorn the Acquired Assets, and thereafter, pursuant to its rights under the Agreement, Akorn conducted an evaluation of the Acquired Assets and subsequently provided notice of its rejection of the Acquired Assets to PrimaPharm; and
- C. The parties now desire to amend the Agreement as follows.

NOW THEREFORE, the parties agree as follows:

1. Incorporation of the Agreement

Except as specifically set forth herein, the Agreement shall remain in full force and effect and its provisions shall be binding on the parties hereto. To the extent any terms and provisions of the Agreement are inconsistent with the amendments set forth below, such terms and provisions shall be deemed superseded hereby.

2. Amendments to the Agreement

- a. Section 3.2 of the Agreement shall be deleted in its entirety and replace with the following:

3.2 Payment of License Price and Delivery of Licensed Assets.

- (a) **Initial Payment.** PrimaPharm having transferred and delivered to Akorn all right, title and interest in and to the Product Registration, the Licensed Assets and the Product Technology, upon the Effective Date of this First Amendment, Akorn will deliver or cause to be delivered to PrimaPharm payment of Eight Hundred Seventy Five Thousand dollars (\$875,000) by wire transfer in immediately available funds to such account as PrimaPharm may designate in writing.

AB HK MR

- (b) **Marketing Authorization.** Upon the Effective Date, PrimaPharm shall send a letter to the respective FDA Division informing them of the Marketing Authorization (NDA) transfer to Akorn. PrimaPharm shall send a hardcopy of the complete NDA to Akorn. Akorn will send acceptance of NDA letter to the Division to complete the transfer of the Marketing Authorization.
- (c) **Second Payment.** Akorn will deliver a second payment in the amount of Four Hundred Thirty Seven Thousand Five Hundred Dollars (\$437,500) to PrimaPharm upon Akorn's production of a stability batch of the product.
- (d) **Third Payment.** Akorn will deliver a third and final payment in the amount of Four Hundred Thirty Seven Thousand Five Hundred Dollars (\$437,500) to PrimaPharm upon Akorn's receipt of FDA approval of the Product site transfer.

b. Section 2.6 of the Agreement shall be deleted in its entirety and replace with the following:

2.6. API Supply. Akorn has the right, but not the obligation to order from PrimaPharm and PrimaPharm shall supply API to Akorn for the Field of Use in the Territory on the terms set forth in Schedule C. Notwithstanding the foregoing, Akorn has the right to qualify other API suppliers from which Akorn may procure API, provided that Akorn uses the API solely in the manufacture of the Product and not for any for resale, distribution or use in the manufacture of any other pharmaceutical product. Furthermore, PrimaPharm agrees to provide such technical support necessary to effect transfer of the API manufacturing process as described in the Marketing Authorization.

4. **Counterparts**

This First Amendment may be executed in counterparts, each of which shall constitute an original but all of which, when taken together, shall constitute but one agreement.

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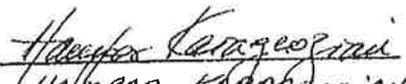
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IN WITNESS WHEREOF, the parties hereto have executed this First Amendment as of the date first above written.

PRIMAPHARM INC.

By: 
Name: MARK T. LIVINGSTON
Title: PRESIDENT CEO

PRIMAPHARM INC.

By: 
Name: HAYKHAR KARAGEORGIAN
Title: Chairman of the Board.

AKORN, INC.

By: 
Name: Sean Brynjelsen
Title: Vice President

MSV

SCHEDULE A
PRODUCT & MARKETING AUTHORIZATION

<u>Product</u>	<u>Description of Marketing Authorization</u>
HYDASE™ (hyaluronidase injection) 150 UNITS/ML	NDA Application # 21-716

AB HE MV

SCHEDULE B

Hydase Package Insert

AB HC
MP

SCHEDULE C

API Supply Pricing from PrimaPharm

<u>Product</u>	<u>Pricing</u>
Hyaluronidase (as approved in NDA Application # 21-716)	COGS+20%

AB HK
MM

EXHIBIT B



Attachment A

FY 2012 PDUFA INVOICE	Invoice Date	15-AUG-2011	Invoice Number	PAB121689R
	Due Date	01-OCT-2011	Invoice Amount	\$98,970.00
PRIMAPHARMA INC Attention: ANTHONY DZIABO 3443 TRIPP COURT SAN DIEGO, CA 92121 UNITED STATES				

Type of Fee (Product or Establishment)	Number of Products or Establishments	Unit Fee	Total
PRODUCT	1	\$98,970.00	\$98,970.00
ESTABLISHMENT	0	\$520,100.00	\$0.00

Total Fee:	\$98,970.00
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Payment Information

Online payments:

The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Credit Card payments (Discover, VISA, MasterCard, American Express) are acceptable for amounts less than \$25,000.

Make an online payment at <http://users.fda.gov/pay>. (Note: only full payments are accepted. No partial payments can be made online.)

Alternative Payment Options

Checks:

Mail payment and copy of your invoice to:
 Food and Drug Administration
 P.O. Box 979 107
 St. Louis, MO 63197-9000

For overnight courier use only:
 U.S. Bank
 ATTN: Government Lockbox 979107
 1005 Convention Plaza
 St. Louis, MO 63101

If a phone number is also required for courier delivery, use
 314-418-4013.

Wire Transfers:

US Department of the Treasury
 TREAS NYC
 33 Liberty Street
 New York, NY 10045

FDA Deposit Account Number: 75050099
 Routing/Transit Number: 021030004
 SWIFT Number: FRNY1533
 Reference - Cite Invoice #

Payments should include the invoice number with the payment. All fees assessed by your financial institution for wire transfers should be added to your payment to ensure that the full invoice amount is received.

Payment must be received by the U.S. Food and Drug Administration by the due date. Any check or bank draft should be drawn on or payable through U.S. financial institutions located in the United States. All payments should include the invoice number with the payment. Bank fees assessed for eChecks, credit cards, wire transfers or currency exchanges are the responsibility of the firm and should not be deducted from the payment amount.

If full payment is not received by 01-OCT-2011, an interest rate will be charged as set by the U.S. Department of the Treasury. Information regarding current interest rates on overdue and delinquent debt may be found at <http://www.fhs.gov/sirt/ef/finpollibrary/chronology.html>. In addition, delinquent invoices will have a \$20 administrative fee assessed for each 30-day period that the invoice remains outstanding. A penalty of 5% per year will be assessed also on any invoices delinquent for more than 90 days in accordance with 45 CFR Subpart B, Section 30.18.

This invoice will not be considered paid until payment has been cleared and the amount received by the U.S. Food and Drug Administration.

For further information concerning this invoice, please contact the Prescription Drug User Fee Staff at 301-796-7900.

EXHIBIT C



DEPARTMENT OF HEALTH & HUMAN SERVICES

PROGRAM SUPPORT CENTER
DEBT COLLECTION CENTER
7700 WISCONSIN AVE.
MAILSTOP 10230B
SUITE 8-8110D
BETHESDA, MD 20857

Date: 3/15/2019

CLAIM NUMBER: 738005811
TYPE OF DEBT: FDA
INTEREST RATE: 10.125
PRINCIPAL DUE: \$ 98,970.00
INTEREST DUE: \$ 2,910.11
PENALTY/ADM DUE: \$ 14,845.51
TOTAL DUE: \$ 116,725.62
DUE DATE: 01/12/2019

PRIMAPHARMA INC
3443 TRIPP COURT
SAN DIEGO, CA 92121

Please be advised that you are indebted to the United States government and that this account is seriously delinquent.

This notice is to inform you of our intent to refer this debt to other federal agencies for the purpose of administrative offset under the Debt Collection Improvement Act Of 1996, Section 31001 of public law 104-134 as revised. Administrative offset includes but is not limited to the following actions: Federal tax refund offset, Salary offset, Wage garnishment and other Federal and/or State agencies' payments.

You have the right to inspect and copy the agency's records relating to the debt. You have the right to present evidence that all or part of your debt is not past due or legally enforceable. In order to exercise these rights, the agency must receive in writing, at the address below, your request of intent and evidence within 60 days from this letter.

Payment in full or an executed repayment agreement will terminate administrative offset action.

To avert administrative offset under the Debt Collection Improvement Act Of 1996, Section 31001 of public law 104-134 as revised, please submit payment in full or a request to enter into a repayment agreement to the following address.

HHS/PROGRAM SUPPORT CENTER
DEBT COLLECTION CENTER
7700 WISCONSIN AVE., SUITE 8-8110D
BETHESDA, MD 20857

A good faith payment must accompany your proposed monthly payment amount. If you have any questions, you may contact the Debt Collection Center at (301) 492-4664 or email to PSCDebtServicing@psc.hhs.gov.

Sincerely,

Debt Collection Center

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

In re : **Chapter 11**
: **AKORN, INC., et al.** : **Case No. 20-11177 (KBO)**
: **Debtors.** : **(Jointly Administered)**

CERTIFICATE OF SERVICE

I, BRUCE W. McCULLOUGH, hereby certify that on this date a copy of the foregoing OBJECTION OF PRIMAPHARMA, INC. TO THE MOTION OF DEBTORS FOR THE ASSUMPTION AND ASSIGNMENT OF CERTAIN EXECUTORY CONTRACTS AND LEASES and DECLARATION OF MARK T. LINGSTON IN SUPPORT OF OBJECTION OF PRIMAPHARMA, INC. TO THE MOTION OF DEBTORS FOR THE ASSUMPTION AND ASSIGNMENT OF CERTAIN EXECUTORY CONTRACTS AND LEASES was served via CM/ECF on the following:

Counsel to the Debtors:

Kirkland & Ellis LLP
300 North LaSalle Street
Chicago, Illinois 60654
Attn.: Patrick J. Nash, Jr
Gregory F. Pesce
Christopher M. Hayes

Kirkland & Ellis LLP
601 Lexington Ave
New York, New York 10022
Attn. Nicole L. Greenblatt

Counsel to the Committee:

Jenner & Block LLP
353 N. Clark St.
Chicago, IL 60654
Attn: Catherine Steege
Landon Raiford
William Williams

Co-Counsel to the Debtors:

Richards, Layton, & Finger, P.A.
920 N. King Street
Wilmington, Delaware 19801
Attn.: Paul N. Heath
Paul N. Heath
Amanda R. Steele
Zachary I. Shapiro
Brett M. Haywood

The United States Trustee

Office of the United States Trustee
for the District of Delaware
844 King Street, Suite 2207, Lockbox 35,
Wilmington, Delaware 19801
Attn.: Jane M. Leamy

and

Saul Ewing Arnstein & Lehr
1201 North Market Street, Suite 2300
Wilmington, DE 19801
Attn: Mark Minuti
Luke Murley

Counsel to the Stalking Horse Bidder

Gibson Dunn & Crutcher
200 Park Avenue,
New York, New York 10166
Attn.: Scott J Greenberg
Michael J. Cohen

Co-Counsel to the Stalking Horse Bidder

Young Conaway Stargatt & Taylor
1000 North King Street
Wilmington, DE 19801
Attn: Robert S. Brady

Counsel to the Ad Hoc Group

Gibson Dunn & Crutcher
200 Park Avenue,
New York, New York 10166
Attn.: Scott J Greenberg
Michael J. Cohen

Co-Counsel to the Ad Hoc Group

Young Conaway Stargatt & Taylor
1000 North King Street
Wilmington, DE 19801
Attn: Robert S. Brady

Counsel to the Term Loan Agent under the Debtors' Term Loan Agreement

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center,
250 Greenwich Street,
New York, NY 10007
Attn: Andrew Goldman

Dated: August 13, 2020

/s/ Bruce W. McCullough
Bruce W. McCullough (Del. ID #3112)