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

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 4, 2019

Commission file number 333-184948

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**45-1539785**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076

(Address of Principal Executive Offices, Including Zip Code)

(443) 776-3133

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

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

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

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

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

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

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

Emerging growth company [X]

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

Item 1.01. Entry into a Material Definitive Agreement.

License Agreement

On August 29, 2019, Processa Pharmaceuticals, Inc. ("Processa") entered into a License Agreement with Akashi Therapeutics, Inc. ("Akashi"), pursuant to which Processa obtained an exclusive worldwide license to develop and commercialize products compromising or containing HT-100.

Under the License Agreement, Processa made a nominal upfront payment and has agreed to future Development and Regulatory Milestone, and Sales Milestone payments along with royalties as set forth in the License Agreement.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Exhibit Description
99.1	License Agreement dated 08/29/2019
99.2	Press Release dated 09/03/2019

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized, on September 4, 2019.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ David Young*
David Young
Chief Executive Officer

Confidential

[Execution Copy]

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") dated as of August 29, 2019 (the "**Effective Date**"), is entered into by and between AKASHI THERAPEUTICS, INC., a Delaware corporation ("**Akashi**"), and PROCESSA PHARMACEUTICALS, INC., a Delaware corporation ("**Processa**"). Each of Akashi and Processa may be referred to herein as a "**Party**", or jointly as the "**Parties**".

WHEREAS, Akashi owns or controls rights in and to its proprietary product, known as HT-100, an orally available small molecule drug candidate being developed to reduce fibrosis and inflammation; and

WHEREAS, Processa desires to obtain an exclusive worldwide license to develop and commercialize products comprising or containing HT-100 and Akashi is willing to grant such a license on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

1. DEFINITIONS

1.1 "**Affiliate**" means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

1.2 "**Annual Net Sales**" means aggregate Net Sales of all Licensed Products realized in the Territory in a given calendar year.

1.3 "**Commercially Reasonable Efforts**" means, with respect to the efforts and resources to be expended by a Party, efforts and resources commensurate with the efforts and resources commonly used in the pharmaceutical or biotechnology industry by a company of comparable size in connection with the development or commercialization of pharmaceutical or biotechnology products that are of similar status, taking into account the proprietary position of the product (including intellectual property scope, subject matter and coverage), safety and efficacy, product profile, competitiveness of the marketplace, the regulatory status and approval process, anticipated or approved labeling, present and future market potential, the probable profitability of the applicable product (including pricing and reimbursement status achieved or likely to be achieved) and other relevant factors such as technical, legal, scientific or medical factors. Notwithstanding the foregoing, the factors to be taken into consideration in determining whether Commercially Reasonable Efforts are being or have been used shall not include any obligation to make any payment hereunder or the existence of any of potentially competitive program of such Party or its Affiliates.

1.4 "**Confidential Information**" means, with respect to a Party ("**Discloser**"), all information of any kind whatsoever, and all tangible and intangible embodiments thereof of any kind whatsoever, which is or was disclosed by or on behalf of such Party to the other Party ("**Recipient**") in connection with this Agreement or the Confidentiality Agreement. Notwithstanding the foregoing, Confidential Information of a Party shall not include information which Recipient can establish: (a) to have been publicly known prior to disclosure of such information by Discloser to Recipient; (b) to have become publicly known, without breach of this Agreement or the Confidentiality Agreement on the part of Recipient, subsequent to disclosure of such information by Discloser to Recipient; (c) to have been received by Recipient on a non-confidential basis at any time from a source, other than Discloser, rightfully having possession of and the right to disclose such information without restriction; (d) to have been otherwise known by Recipient prior to disclosure of such information by Discloser to Recipient; or (e) to have been independently developed by or on behalf of Recipient without access to or use of such information disclosed by Discloser to Recipient, as demonstrated by contemporaneous written records.

1.5 "**Confidentiality Agreement**" means the Mutual Confidentiality Agreement between the Parties dated June 13, 2018.

1.6 "**Control**", "**Controls**" or "**Controlled**" means, with respect to any know-how, patents, proprietary information or trade secrets, or other intellectual property rights (collectively, "**Rights**"), the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Rights to the other Party, or to otherwise disclose such proprietary information or trade secrets to the other Party, without breaching the terms of any agreement with a Third Party, misappropriating the proprietary information or trade secrets of a Third Party, or being required to make a payment to a Third Party.

1.7 "**Cover**" means, with respect to a Patent and a product, that such Patent would (absent a license thereunder or ownership thereof) be infringed by the manufacture, use, offer for sale, sale or import of such product, provided, however, that in determining whether a claim of a pending Patent application would be infringed, it shall be treated as if issued in the form then currently being prosecuted. Cognates of the word "Cover" shall have correlative meanings.

1.8 "**Development Plan**" has the meaning set forth in Section 2.1.2.

1.9 "**DMD**" means Duchenne Muscular Dystrophy.

1.10 "**Exploit**" (or "**Exploitation**") means, with respect to HT-100 or Licensed Product (as applicable), to use, have used, manufacture, have manufactured, sell, have sold, offer for sale, have offered for sale, import, and have imported, or otherwise exploit HT-100 or Licensed Product.

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

1.12 "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the rules and regulations promulgated thereunder, and any successor legislation thereto.

1.13 "**Field**" means all therapeutic uses.

1.14 "**First Commercial Sale**" means, with respect to a product in any country, the first sale for end use or consumption by the general public of such product in such country after marketing approval for such product has been granted in such country. First Commercial Sale excludes any sale or other distribution of a product for use in a clinical trial or other development activity, promotional use (including samples) prior to marketing approval or for compassionate use or on a named patient basis.

1.15 "**Foreground IP**" has the meaning set forth in Section 7.1.

1.16 "**Foreground Patent**" has the meaning set forth in Section 7.1.

1.17 "**HT-100**" means the product specified in Exhibit D**.**

1.18 "**IND**" means an investigational new drug application, as defined in the FD&C Act, which is required to be filed with the FDA before beginning clinical testing of a Licensed Product in human subjects, or an equivalent foreign filing.

1.19 "**Indication**" means a separate and distinct disease or medical condition in humans.

1.20 **"Initiation"** of a human clinical trial means, except as otherwise provided in Section 1.31(b), the first dosing of the first subject in such trial.

1.21 "**Know-How**" means all information and data that is not generally known (including, but not limited to, information and data regarding formulae, procedures, protocols, techniques, pharmacological, toxicological and clinical data and results and other results of experimentation and testing), and all rights therein and thereto.

1.22 "**Licensed IP**" means, collectively, the Licensed Patents and the Licensed Know-How.

1.23 "**Licensed Know-How**" means all Know-How which is Controlled by Akashi as of the Effective Date and which is necessary or specifically useful for Processa and its Affiliates and Sublicensees to make, use, develop, sell, or seek regulatory approval to market or otherwise Exploit HT-100, including without limitation the information and data described on Exhibit A attached hereto and any Product Records/Filings provided to Processa in accordance with Section 2.2. Licensed Know-How specifically excludes any Know-How that is owned or licensed by any acquiror or merger partner of Akashi or of any of its Affiliates (other than the Know-How which is Controlled by Akashi as of the Effective Date and is transferred to any such acquiror or merger partner of Akashi or of any of its Affiliates after the Effective Date).

1.24 "**Licensed Patents**" means (a) all Patents listed on Exhibit B; (b) any Patent filed after the Effective Date claiming priority to any Patent set forth in Exhibit B, solely to the extent the claims thereof Cover HT-100 or Licensed Product; and (c) any counterparts of a Patent described in subclause (a) or (b), solely to the extent the claims thereof Cover a Licensed Product. Licensed Patents specifically exclude any Patents that are owned or licensed by any acquiror or

merger partner of Akashi or of any of its Affiliates (other than Patents which are Controlled by Akashi as of the Effective Date and are transferred to any such acquiror or merger partner of Akashi or of any of its Affiliates after the Effective Date).

1.25 "**Licensed Product**" means any product utilizing, containing, comprising or consisting of HT-100 or any derivative, fragment, combination or conjugate thereof.

1.26 "**NDA**" means a new drug application or product license application or its equivalent filed with and accepted by the FDA to obtain marketing approval for any Licensed Product, or any comparable application filed with and accepted by the Regulatory Authority of a country other than the United States.

1.27 "**Net Sales**" means, with respect to any Licensed Product, the gross invoice price of such Licensed Product sold by or on behalf of Processa, its Affiliates or its Sublicensees to Third Parties in bona fide, arms-length transactions after deduction of all of the following (reasonably documented):

(a) normal and customary cash, trade and quantity discounts, actually paid or incurred;

(b) discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances actually made which effectively reduce the net selling price, including any institutional rebate or discount for government subsidy or reimbursement programs such as Medicare or Medicaid provided in the United States or any similar organization elsewhere in the world, and Processa's discount programs;

(c) credits and allowances for returned Licensed Products actually made and actually taken (for financial reporting purposes) and for recalls, retroactive price reductions, and billing corrections;

(d) freight, packing, shipping, handling and insurance fees, but solely to the extent separately stated on the invoice and included in the gross invoice price;

(e) tariffs, duties, exercise taxes and all other taxes, including value added taxes and sales taxes, but excluding taxes based on the Processa's, its Affiliates' or Sublicensees' income; and

(f) amounts actually credited for uncollectible amounts on previously sold Licensed Products;

all as determined in accordance with U.S. generally accepted accounting principles.

Amounts invoiced between Processa and its Affiliates for quantities of the Licensed Products for use in clinical trials or for resale, or by Processa or its Affiliates to permitted Sublicensees for resale, shall not be included in the calculation of Net Sales.

Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to Third Parties shall not be deducted from the invoice price in the calculation of Net Sales.

Net Sales of any Licensed Product sold by or on behalf of Processa, its Affiliates or its Sublicensees as part of a product that, in addition to Licensed Product, contains one or more active pharmaceutical ingredients (a "**Combination Product**"), shall be calculated as follows:

(x) The Net Sales for the purpose of determining royalty payments and sales milestones payments on sales of the Combination Product shall be calculated by multiplying Net Sales of such Combination Product by the fraction A/(A+B) where A is either: (i) the weighted average price (by sales volume) to Third Party end users of the Licensed Product component of the Combination Product when sold separately, should Licensed Products be sold separately in the applicable country; or (ii) the weighted average fair market value (by sales volume) of the portion of the Combination Product containing the Licensed Product included in such Combination Product, as such fair market value is determined in good faith by the Parties, if Licensed Products are not sold separately in the applicable country, and B is either (i) the weighted average price (by sales volume) to Third Party end users of product containing the other active ingredients of the Combination Product when sold separately, should such active ingredients be sold separately in the applicable country; or (ii) the weighted average fair market value (by sales volume) of the portion of the Combination Product containing the other active ingredients, as such fair market value is determined in good faith by the Parties, should such active ingredients not be sold separately in the applicable country.

(y) Regarding prices comprised in the weighted average price when sold separately referred to in paragraph (x) above, if these are available for different dosages of the Licensed Product and the other active ingredients from the dosage that are included in the Combination Product, then Processa shall be entitled to make a proportional adjustment to such prices in calculating the Net Sales of the Combination Product, with written notice of such adjustment to be provided to Akashi.

1.28 "**Patents**" means all patents and provisional and non-provisional patent applications (including inventor's certificates and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations, patent term extensions, patent term adjustments, and supplemental protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.

1.29 "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.30 "**Phase 1 or 2 Trial**" means a human clinical trial of a Licensed Product other than a Pivotal Trial that is designed to demonstrate safety, clinical efficacy or biological activity/proof of concept, and that is generally consistent with 21 CFR 312.21(a) or 21 CFR 312.21(b) for the United States, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

1.31 "**Pivotal Trial**" means:

(a) a Phase 3 clinical trial; or

(b) any other human clinical trial that the applicable Regulatory Authority has agreed, whether before first dosing of the first patient in such trial (e.g., pursuant to a special protocol assessment agreement with the FDA) or after first dosing of the first patient in such trial (e.g., based on an interim data analysis), is sufficient to form the primary basis of an efficacy claim in an NDA submission, regardless of whether the sponsor of such trial characterizes or refers to such trial as a "Phase 3," "Phase 2b" or "Phase 2b/3" trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context. If a human clinical trial does not constitute a Pivotal Trial at the time of first dosing of the first patient in such trial, but is later determined by the applicable Regulatory Authority to be sufficient to form the primary basis of an efficacy claim in an NDA submission, then, for purposes of Section 4.2, "Initiation" of such Pivotal Trial shall be deemed to have occurred on the date of such determination by the applicable Regulatory Authority.

1.32 "**Prior IND**" has the meaning set forth in Section 2.2.2.

1.33 "**Product Infringement**" has the meaning set forth in Section 10.2.1.

1.34 "**Product Records/Filing**" means (a) any clinical records (including clinical protocol, study, clinical data or result used in or resulting from any clinical trial) and manufacturing records of HT-100 or Licensed Product, or (b) subject to Section 2.2.2, any IND, application for Regulatory Approval, Regulatory Approval or other regulatory filing regarding HT-100 or Licensed Product and data referenced therein.

1.35 "**Regulatory Approval**" means any license, registration, authorization or approval (including, without limitation, any approval of an NDA, supplement or amendment, pre- and post- approval, pricing approval, or labeling approval) of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of a Licensed Product in a regulatory jurisdiction.

1.36 "**Regulatory Authority**" means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the granting of Regulatory Approval for the Licensed Product.

1.37 "**Right of Reference**" means a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) and any comparable right existing under the laws or regulations of any foreign country.

1.38 "**Rights**" has the meaning set forth in Section 1.6.

1.39 "**Royalty Term**" means, with respect to each Licensed Product in each country, the later of (a) the expiration of the last to expire Valid Claim that Covers such Licensed Product in such country, or (b) ten (10) years from the date of the First Commercial Sale of such Licensed Product in such country.

1.40 "**Sublicensee**" means any Third Party to whom Processa has sublicensed rights with respect to the development, commercialization or other Exploitation of Licensed Product in accordance with Section 3.2.2.

1.41 "**Territory**" means the entire world.

1.42 "**Third Party**" means any Person other than Akashi, Processa and their respective Affiliates.

1.43 "**Valid Claim**" means either (a) a claim of an issued and unexpired Patent within the Licensed Patents, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a claim of a pending Patent application within the Licensed Patents, provided that if such claim shall not have issued within seven (7) years after the earliest filing date from which such claim takes priority, such claim shall not constitute a Valid Claim for the purposes of this Agreement unless and until such claim issues.

2. PRODUCT DEVELOPMENT AND COMMERCIALIZATION

2.1 Research and Development Efforts.

2.1.1 Processa shall use Commercially Reasonable Efforts to research, develop and commercialize Licensed Products in one or more countries in the Territory. The efforts of Processa's Affiliates and Sublicensees shall be treated as the efforts of Processa when evaluating Processa's compliance with the foregoing diligence obligations. Without limiting the generality of the foregoing, Processa will be responsible for conducting all necessary studies, including safety studies and clinical trials that are necessary in connection with seeking Regulatory Approvals to market the Licensed Product in the Territory, at Processa's own cost and discretion.

2.1.2 Development Plan. Processa shall provide to Akashi a written research and development plan (the **"Development Plan"**) setting forth in reasonable detail planned activities to research and develop HT-100 and the Licensed Products and the estimated timelines for such activities. The Development Plan may be amended from time to time by Processa. The initial Development Plan as of the Effective Date will be provided to Akashi and attached as Exhibit C within six (6) months of the Effective Date. As used herein, the term "Development Plan" shall mean the Development Plan as then in effect, including all updates and amendments thereto.

2.1.3 Reporting. Processa shall provide Akashi with written reports detailing the activities of Processa, its Affiliates and Sublicensees with respect to the research and development of and pre-commercial launch activities for Licensed Products in the Field in the Territory, both as to activities conducted during the prior period and planned activities for HT-100 and Licensed Products, in sufficient detail to enable Akashi to reasonably assess Processa's compliance with its diligence obligations hereunder, including compliance with Section 2.5. Such reports shall also include the development funding expended by Processa. Processa shall present such report to Akashi in conjunction with a meeting (either in person or by teleconference, as the Parties may agree) with Processa's personnel responsible for the conduct of such development (and, if applicable, pre-commercial launch activities) which personnel shall include at least one Processa representative responsible for such development (and, if applicable, pre-commercial launch activities) at a level of vice president or higher, and shall provide such additional information to Akashi as Akashi may reasonably request. Such reports shall be made on a calendar quarter basis (within ninety (90) days following the end of each calendar quarter) until the Initiation of a clinical trial for a Licensed Product, and on a semi-annual basis thereafter (within ninety (90) days following January 1 and July 1 of each calendar year).

2.2 Data Sharing and Technology Transfer.

2.2.1 Akashi hereby agrees to provide to Processa, as soon as reasonably practicable following the Effective Date, access to all Product Records/Filings and any other technical data or Licensed Know-How Controlled by Akashi and its Affiliates in connection with and specifically relating to the development of HT-100, and to transfer and deliver to Processa copies of all documents (such as copies of the relevant patent filings, clinical studies, clinical protocols, all IND-related documents, all correspondence with the FDA) included therein that a reasonable person would expect to be material to the exercise of the licenses granted hereunder by Processa or otherwise requested by Processa (either specifically or by category). Processa and its Affiliates and Sublicensees shall have the right to use, without additional payment, any and all such Product Records/Filings and all other CMC, pre-clinical or clinical information and data and/or Licensed Know-How provided to it hereunder to support any regulatory filings for the Licensed Products and to otherwise exercise the license granted to it in accordance with Section 3.1 in accordance with the terms of this Agreement.

2.2.2 To the extent ownership is not otherwise transferred to Processa hereunder and to the extent access thereto is reasonably required in order to seek or obtain Regulatory Approval for the Licensed Products or otherwise in connection with the exercise of the licenses granted herein, Akashi hereby grants to Processa and its Affiliates a Right of Reference to any Product Records/Filing disclosed by Akashi or its Affiliate pursuant to Section 2.2.1 for use in regulatory filings for the Licensed Product by Processa and its Affiliates. Processa may sublicense the Right of Reference set forth in this Section 2.2.2 to its permitted Sublicensees of the Licensed Product as reasonably required. Prior to the Effective Date, Akashi has notified FDA of the withdrawal of the IND filed by Akashi with the FDA with respect to HT-100 (the "**Prior IND**"). The Prior IND will be transferred to Processa if allowed by the FDA and requested by Processa, and Processa is hereby given the Right of Reference and any other right to use such Prior IND for any purpose consistent with applicable laws and Processa's exercise of the licenses granted herein.

2.2.3 Akashi shall promptly, and in any event within sixty (60) days after the Effective Date, conduct a technology transfer of all Licensed Know-How in Akashi's possession and Control in accordance with Section 2.2.1. Akashi shall pay for all reasonable expenses and out-of-pocket costs incurred in connection with the technology transfer activities set forth in Section 2.2.1.

2.3 Regulatory Approvals and Regulatory Reporting. From and after the Effective Date, Processa will be responsible for the preparation and filing of all applications for Regulatory Approvals for the Licensed Products with the applicable Regulatory Authorities in the Territory, including the filing of an IND under which all relevant activities hereunder shall be conducted. Processa shall prepare and file the IND and any applications for Regulatory Approval for the Licensed Products with the Regulatory Authorities in its name and at its cost. Processa shall file, in its own name and at its own expense, all other applications for any approvals required for any clinical study or other study or action necessary or desirable to obtain such Regulatory Approval. Processa shall have the sole responsibility for communicating with any Regulatory Authority regarding any applications for Regulatory Approval or any Regulatory Approval for the Licensed Products once granted or any such other applications. Processa shall be responsible for filing, at its own expense, all reports required to be filed in order to maintain any Regulatory Approvals granted for the Licensed Products. The efforts of Processa's Affiliates and Sublicensees shall be treated as the efforts of Processa when evaluating Processa's compliance with this Section 2.3.

2.4 Licensed Product Labeling. Processa shall be solely responsible for the administrative aspects of preparing, updating and maintaining product labeling in connection with commercialization of the Licensed Products. Such labeling may include but is not limited to text and graphical contents of printed labels and labeling components, including but not necessarily limited to healthcare professional leaflets or inserts, patient leaflets or inserts, and cartons. The efforts of Processa's Affiliates and Sublicensees shall be treated as the efforts of Processa when evaluating Processa's compliance with this Section 2.4.

2.5 Specific Diligence Obligations. Without limiting the generality of Processa's obligations under this Section 2, including Section 2.1, Processa agrees to the following:

2.5.1 The Parties have agreed that the financial consideration to be paid to Akashi in exchange for the rights granted and materials transferred hereunder will be largely deferred until such time as Processa has substantially advanced the development of HT-100 and Licensed Products and commenced commercialization of Licensed Products, such that Akashi is reliant on Processa's diligent development of HT-100 and Licensed Products and commercialization of the Licensed Products to fully receive the benefit of its bargain. Further, Processa acknowledges that the diligent conduct of such development requires the commitment by Processa of an appropriate level of funding directed to such development. Accordingly, and without limiting the generality of Section 2.1.1:

Diligence Milestones	Date (On or Before)
1. FDA Meeting Request for 1st Indication	18 Months after Effective Date
2. IND submission for DMD or any Indication	6/30/22
3. Initiation of Phase 1 or 2 Trial for DMD or any other Indication	12/30/22

2.5.2 Processa shall promptly provide written notice to Akashi if at any time during the term of this Agreement: (i) Processa, its Affiliates, or Sublicensees are not actively pursuing development of the Licensed Products for a period of twelve (12) consecutive months at any time following the Effective Date and prior to the first NDA submission; or (ii) prior to such time as Regulatory Approval of a Licensed Product has been achieved Processa decides to suspend the further development of Licensed Products. Such notice shall be deemed a termination of this Agreement by Processa pursuant to Section 11.2.

2.6 Compliance. Processa, its Affiliates, and its Sublicensees shall comply with all applicable rules, laws and regulations in connection with their performance under this Agreement.

3. LICENSE GRANT

3.1 License. Subject to the terms and conditions of this Agreement, Akashi hereby grants and agrees to grant to Processa an exclusive license under the Licensed Products, Licensed IP, and Product Records/Filings, to research, develop, manufacture, make, have made, use, import, export, sell, offer to sell, have sold, commercialize, supply, and sublicense across multiple levels, the Licensed Products within the Field in the Territory.

3.2 Sublicenses.

3.2.1 Processa shall have the right to grant sublicenses under the licenses granted in Section 3.1 to its Affiliates, subject to Section 13.16, and provided that Processa provides Akashi with written notice of each such sublicense within sixty (60) days of granting such sublicense.

3.2.2 Processa may grant sublicenses under the license in Section 3.1 to Third Parties, subject to the remainder of this Section 3.2.2 and subject to Akashi's prior written consent to such sublicense, which consent shall not be unreasonably withheld or delayed by Akashi. Processa shall, within sixty (60) days after granting any sublicense to a Third Party, provide Akashi with a true, complete and legible copy of such sublicense agreement and each amendment thereto, provided that Processa may redact from such agreement or amendment any financial terms that are unrelated to this Agreement. Processa shall remain directly responsible for each of its Sublicensees' compliance with this Agreement.

4. ROYALTIES AND OTHER PAYMENTS

4.1 Upfront Payment. As partial consideration for the licenses granted to Processa under this Agreement, Processa shall pay an upfront payment of ten thousand U.S. dollars (US$10,000) to Akashi within five (5) business days of the full execution of this Agreement.

4.2 Development and Regulatory Milestone Payments.

4.2.1 As additional consideration for the licenses granted to Processa under this Agreement, Processa shall pay Akashi development and regulatory milestone payments as set forth below. Each milestone payment owed by Processa to Akashi pursuant to this Section 4.2.1 shall be payable by Processa within sixty (60) days following the first achievement of the corresponding milestone event by Processa or a Processa Affiliate. For clarity, in the event that any such milestone event is achieved by a Sublicensee, no payment under this Section 4.2.1 shall be due. For the avoidance of doubt, each milestone payment is only payable once, regardless of the number of times such milestone may be achieved by Processa, or its Affiliates, and shall be non-refundable and non-creditable. In addition, if a given clinical or Regulatory Approval milestone event is achieved by Processa or a Processa Affiliate for a Licensed Product in the second Indication without one or more preceding clinical milestone events for the relevant Indication having been achieved by Processa or its Affiliate with respect to such Licensed Product, then the milestone payments corresponding to such skipped clinical milestone events shall be made simultaneously upon achievement of such clinical or Regulatory Approval milestone event by such Licensed Product and for such Indication.

Milestone Event	**Amount If Processa or a Processa Affiliate Achieves Event**
1. Initiation of 1st Pivotal Trial for 1st Indication	US$200,000
2. 1st Indication approved by Regulatory Authority in the US	US$3 Million
3. 1st Indication approved by Regulatory Authority outside US	US$3 Million
4. Initiation of 1st Phase 1 or 2 Trial in Patients for 2nd Indication	US$50,000
5. Initiation of 1st Pivotal Trial for 2nd Indication	US$100,000
6. 2nd Indication approved by Regulatory Authority in the US	US$3 Million
7. 2nd indication approved by Regulatory Authority outside US	US$3 Million

4.2.2 As additional consideration for the licenses granted to Processa under this Agreement, in the event that Processa or its Affiliate grants sublicenses under the licenses granted in Section 3.1 and in the event that Processa or its Affiliate receives any milestone payment from any Sublicensee for any event relating to the clinical development, Regulatory Approval or First Commercial Sale of a Licensed Product for a first or second Indication that is achieved by or on behalf of such Sublicensee (and for clarity not by Processa or its Affiliate),

whether or not such event is listed in items 1-7 above, Processa shall pay Akashi fifty percent (50%) of any such milestone payment paid to Processa or its Affiliate by the relevant Sublicensee within sixty (60) days of receipt of the relevant amount by Processa or its Affiliate. For clarity, the milestone payments set forth in Section 4.2.1 shall not apply with respect to events achieved by Sublicensees.

4.3 Sales Milestone Payments.

4.3.1 As additional consideration for the licenses granted to Processa under this Agreement, Processa shall pay Akashi one-time, non-refundable, non-creditable annual net sales milestone payments based on the achievement during a calendar year of one or more thresholds for Annual Net Sales. The annual net sales milestone payments shall be paid within sixty (60) days after the end of the first calendar quarter within the relevant calendar year in which the Annual Net Sales of all Licensed Products in the Territory first reach the relevant threshold for Annual Net Sales. For clarity, an annual net sales milestone payment for a given threshold for Annual Net Sales listed in Section 4.3.2 (or a pro-rata portion thereof as determined in accordance with Section 4.3.4) will be due once and only once during the term of this Agreement, at the time the threshold is first achieved by Processa and/or its Affiliates, alone or in combination with Sublicensees. Thereafter, the threshold for Annual Net Sales and the corresponding annual net sales milestone payment in Section 4.3.2 will no longer apply. The determination of the amount of any annual net sales milestone payments will be based on whether sales of Licensed Products during the pertinent calendar year are made only by Processa and/or its Affiliates (Section 4.3.2), only by Sublicensees (Section 4.3.3), or by Processa and/or its Affiliates and by Sublicensees (Section 4.3.4).

4.3.2 In the event that Licensed Products are sold only by Processa and/or its Affiliates (i.e., no sales by Sublicensees) during a pertinent calendar year and Processa and/or its Affiliates are the first to achieve one or more of the Annual Net Sales thresholds set forth in the table below, the annual net sales milestone payment from Processa to Akashi shall be in the corresponding amount set forth in the table below.

Annual Net Sales Threshold	**Annual Net Sales Milestone Payment**
US$50 Million	US$5 Million
US$250 Million	US$15 Million
US$500 Million	US$20 Million
US$750 Million	US$30 Million
US$1 Billion	US$40 Million

4.3.3 In the event that Licensed Products are sold only by one or more Sublicensees (i.e., no sales by Processa and/or its Affiliates) during a pertinent calendar year and in the event that Processa or its Affiliate receives any milestone payment from any Sublicensee based on achievement of any Annual Net Sales (or substantially equivalent) threshold in such calendar year, Processa shall pay Akashi fifty percent (50%) of any such annual net sales milestone payments paid by Sublicensees to Processa or its Affiliate. For clarity, the annual net sales milestone payments set forth in Section 4.3.2 for any achieved Annual Net Sales (or

substantially equivalent) threshold shall not apply if Licensed Products are sold only by one or more Sublicensees (i.e., no sales by Processa and/or its Affiliates) during the pertinent calendar year.

4.3.4 In the event that Licensed Products are sold by Processa and/or its Affiliates and by one or more Sublicensees during a pertinent calendar year and they collectively are the first to achieve one or more of the Annual Net Sales thresholds set forth in the table in Section 4.3.2, the amount of the corresponding annual net sales milestone payments due to Akashi for such calendar year shall be determined on the following basis (and except to the extent specifically referenced below, the annual net sales milestone payments set forth in Section 4.3.2 for each such achieved Annual Net Sales threshold shall no longer apply):

1) The total Annual Net Sales (C) for determination of threshold achievement shall be determined by adding the Annual Net Sales as of the relevant date by Processa and/or its Affiliates (A) and the Annual Net Sales as of the relevant date by Sublicensee(s) (B) (i.e., C = A+B).

2) The total Annual Net Sales (C) as of the relevant time shall be used to determine whether or not the achievement of any relevant threshold for Annual Net Sales in the table in Section 4.3.2 has occurred.

3) The annual net sales milestone payment corresponding to the achieved Annual Net Sales threshold due based on Net Sales by Processa and its Affiliates shall be determined by determining the percentage of the total Annual Net Sales (C) attributable to Annual Net Sales by Processa and/or its Affiliates (A), and multiplying that percentage by the annual net sales milestone payment in the table in Section 4.3.2 corresponding to the achieved Annual Net Sales threshold.

4) In addition to any amount payable based on Annual Net Sales of Processa and its Affiliates in the pertinent calendar year as determined in 3) above, Processa shall pay to Akashi fifty percent of any amount that Processa or its Affiliate receives as milestone payments from Sublicensees based on achievement of any Annual Net Sales (or substantially equivalent) threshold during the pertinent calendar year.

4.4 Royalties.

4.4.1 As additional consideration for the licenses granted to Processa under this Agreement, during the Royalty Term for each Licensed Product and country, Processa shall pay royalties on Net Sales of Licensed Products to Akashi based on total Annual Net Sales by Processa, its Affiliates, and Sublicensees of Licensed Products in the Territory in accordance with this Section 4.4. The determination of the royalties to be paid by Processa to Akashi shall

be based on whether sales of Licensed Products during the pertinent year are made only by Processa and/or its Affiliates (Section 4.4.2), only by Sublicensees (Section 4.4.3), or by Processa and/or its Affiliates and by Sublicensees (Section 4.4.4). Royalties will be payable on a calendar quarter basis. Within sixty (60) days after the end of each calendar quarter following the First Commercial Sale of the first Licensed Product, Processa shall deliver to Akashi a report containing the following information for the prior calendar quarter on a Licensed Product-by-Licensed Product and country-by-country basis, and reported separately for Net Sales by Processa and its Affiliates and for Net Sales of its Sublicensees: (a) the gross sales associated with each Licensed Product sold by Processa and its Affiliates and, separately, Sublicensees; (b) a calculation of Net Sales of each Licensed Product that is sold by Processa, its Affiliates and, separately, its Sublicensees; and (c) a calculation of payments due to Akashi with respect to the foregoing. Concurrently with such report, Processa shall remit to Akashi any payment due for the applicable calendar quarter. At Akashi's request, Processa shall also provide to Akashi reasonable supporting documentation. If no royalties are due to Akashi for any such reporting period, the report shall so state. The method of payment shall be by check or wire transfer to an address or account specified in writing by Akashi.

4.4.2 In the event that Licensed Products are sold only by Processa and/or its Affiliates (i.e., no sales by Sublicensees) during the pertinent calendar quarter, the applicable royalty rate shall be determined as follows:

On that Portion of Annual Net Sales	**Royalty Rate If Processa or its Affiliate Sells the Product**
≤ US$250 Million	8%
>US$250 Million	12%

4.4.3 In the event that Licensed Products are sold only by one or more Sublicensees (no sales by Processa and/or its Affiliates) during the pertinent calendar quarter, Processa shall pay Akashi fifty percent (50%) of any royalties paid by such Sublicensees to Processa for such calendar quarter, and the table set forth in Section 4.4.2 shall not apply to such calendar quarter.

4.4.4 In the event that Licensed Products are sold by Processa and/or its Affiliates and by one or more Sublicensees during the pertinent calendar quarter, the royalties to be paid by Processa to Akashi shall be determined on the following basis (and except to the extent specifically referenced below, the table set forth in Section 4.4.2 shall not apply to such calendar quarter):

1) The total Annual Net Sales (C) as of the end of the relevant calendar quarter shall be determined by adding the Annual Net Sales achieved by Processa and/or its Affiliates (A) and the Annual Net Sales by Sublicensee(s) (B), in each case as of the end of the relevant calendar quarter (i.e., C = A+B).

2) The total Annual Net Sales (C) as of the end of the relevant calendar quarter shall be used to determine the corresponding royalty rate in the table in Section 4.4.2.

3) The royalty to be paid by Processa to Akashi on Net Sales by Processa and its Affiliates shall be the royalty rate indicated in the table in Section 4.4.2 for that portion the Annual Net Sales (C), except as otherwise provide below. For clarity, if C as of the end of the relevant calendar quarter is less than or equal to US$250 Million, royalties payable on Net Sales by Processa and its Affiliates in the relevant calendar quarter shall be 8%, and if C as of the end of the prior calendar quarter is greater than US$250 Million, royalties payable on Net Sales by Processa and its Affiliates in the relevant calendar quarter shall be 12%. In the event that the US$250 Million threshold is reached during the relevant calendar quarter, royalties payable on Net Sales by Processa and its Affiliates in the relevant calendar quarter shall be 10%.

4) The royalty to be paid by Processa to Akashi on Net Sales by Sublicensees shall be fifty percent of any royalties that Processa receives from Sublicensees for Net Sales by or on behalf of Sublicensees in the relevant calendar quarter.

4.5 Upfront Sublicense Payments. As additional consideration for the licenses granted to Processa under this Agreement, (a) if Processa grants or agrees in writing to grant one or more sublicenses with respect to any Licensed Product prior to the first FDA meeting with respect to Licensed Product held with the FDA after the Effective Date, or prior to starting the first pre-clinical study with respect to Licensed Product after the Effective Date, whichever comes first (such earlier date, the "**Start Point**"), then Processa shall pay Akashi seventy-five percent (75%) of any upfront sublicense fee and/or upfront Sublicensee equity, and of any related option fee and/or option equity, received from such Sublicensee and not required to be used by Processa for the development of the Licensed Product, and (b) if Processa grants or agrees in writing to grant one or more sublicenses with respect to any Licensed Product after the Start Point, then Processa shall no longer pay Akashi seventy-five percent (75%) as provided above but instead shall pay Akashi forty percent (40%) of any upfront Sublicensee fee and/or upfront Sublicensee equity, and of any related option fee and/or option equity, received from such Sublicensee and not required to be used by Processa for the development of the Licensed Product. Any payment due to Akashi in accordance with this Section 4.5 shall be made within sixty (60) days of receipt of the relevant amount by Processa or its Affiliate. For clarity, all milestone payment obligations and royalty payment obligations from Processa to Akashi specified in other sections of this Section 4 are not affected by this Section 4.5.

4.6 Anti-Stacking. If Processa and/or its Affiliate is obligated to take a royalty-bearing license under intellectual property rights owned by a Third Party in order to research,

develop, manufacture, make, have made, use, import, export, sell, offer to sell, have sold, commercialize, supply, and sublicense across multiple levels the Licensed Products within the Field in the Territory for any Licensed Product, then Processa may deduct fifty percent (50%) of any royalties actually paid to such Third Party based on sales of the relevant Licensed Product from royalties owed to Akashi under this Agreement for such Licensed Product; provided, however, that in no event will the royalties owed to Akashi for the relevant Licensed Product in any royalty reporting period be reduced to less than twenty-five percent (25%) of the total royalties otherwise due on Net Sales.

5. ROYALTY REPORTS AND ACCOUNTING

5.1 Royalty Reports. During the term of this Agreement, Processa shall timely furnish to Akashi written royalty reports as specified in Section 4.4 for each royalty reporting period, as well as reports showing the calculation of any payments due to Akashi with respect to any milestones achieved by Processa, its Affiliates or Sublicensees and/or sublicenses granted by Processa.

5.2 Audits.

5.2.1 Upon the written request of Akashi and not more than once in each calendar year, Processa shall permit an independent certified public accounting firm selected by Akashi and reasonably acceptable to Processa, at Akashi's expense, to have access during normal business hours to such of the records of Processa as may be reasonably necessary to verify the accuracy of the amounts paid to Akashi and reports provided to Akashi hereunder. The accounting firm shall disclose to Akashi only whether or not the payments and reports are correct and the amount of any discrepancies. No other information shall be shared.

5.2.2 If such accounting firm concludes that additional payments were owed during the relevant period, Processa shall make such additional payments, along with any corresponding interest payments, within sixty (60) days of the date Akashi delivers to Processa such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by Akashi; provided, if the audit correctly discloses that the amounts payable by Processa for the audited period are five percent (5%) or more than the amounts actually paid for such period, then Processa shall pay the reasonable fees and expenses charged by such accounting firm.

5.2.3 Akashi shall treat all financial information subject to review under this Section 5 as confidential, and shall cause its accounting firm to retain all such financial information in confidence under Section 9 below.

6. PAYMENTS

6.1 Payment Terms. Royalties, and any payments based on the achievement of milestones or sublicensing, shown to have accrued by each report provided for under Section 5.1 above, shall be due as specified in Section 4. Payment in whole or in part may be made in advance of the relevant due date.

6.2 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all royalties with respect to any country in the Territory where the Licensed Product is sold, Processa shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to Akashi's account in a bank or other depository institution in such country. If the royalty rate specified in this Agreement exceeds the permissible rate established in any country, the royalty rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

6.3 Withholding Taxes. Processa shall be entitled to deduct the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Processa, its Affiliates or Sublicensees, or any taxes required to be withheld by Processa, its Affiliates or Sublicensees, to the extent Processa, its Affiliates or Sublicensees pay to the appropriate governmental authority on behalf of Akashi such taxes, levies or charges. Processa shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of Akashi by Processa, its Affiliates or Sublicensees. Processa promptly shall deliver to Akashi proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

6.4 Interest. Without limiting any other rights or remedies available to Akashi, Processa shall pay Akashi interest on any payments that are not paid on or before the date such payments are due under this Agreement at an annual rate of one percent (1%) above the prime rate as published by *The Wall Street Journal, Eastern Edition,* on the date such payments first became due, or the maximum applicable legal rate, if less, calculated based on the total number of days payment is delinquent.

7. Foreground IP Ownership

7.1 Foreground IP. Processa shall own all inventions (whether patentable or not), improvements, and Know-How that are conceived, discovered, developed, or otherwise made by or on behalf of Processa or its Affiliates, or their respective employees, agents or subcontractors in the course of performing activities under this Agreement that are reasonably necessary or useful for the Exploitation of HT-100 or Licensed Products in the Field, and whether or not patentable (collectively, "**Foreground IP**"), and any and all Patents claiming such Foreground IP ("**Foreground Patents**"). Processa shall own all Product Records/Filings with respect to the Licensed Products made by or on behalf of Processa or its Affiliates, or their respective employees, agents or subcontractors in the course of performing activities under this Agreement.

7.2 No Other Rights. Except as expressly set forth in this Agreement, neither Party grants to the other Party any right or license, express or implied, under any of such Party's Rights.

8. REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows as of the Effective Date:

8.1.1 Corporate Existence. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated or organized.

8.1.2 Authorization and Enforcement of Obligations. Such Party (a) has the organizational power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

8.1.3 No Consents. All necessary consents, approvals, and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained.

8.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations, and (b) do not conflict with, or constitute a default under, any contractual obligation of it.

8.2 Additional Akashi Representations and Warranties. In addition, Akashi hereby represents and warrants to Processa that, as of the Effective Date:

8.2.1 Each item of the Licensed Patents set forth in Exhibit B (a) Akashi has the right to license, (b) to Akashi's knowledge, if issued, is valid, subsisting and in full force and effect, (c) has not been abandoned or passed into the public domain, and (d) is free and clear of any liens or encumbrances.

8.2.2 Akashi has not transferred ownership of, or granted any license of or right to use, or authorized the retention of any rights to use or joint ownership of, any Licensed IP to any Person in any manner that would conflict with the license granted to Processa in Section 3.1.

8.2.3 To Akashi's knowledge, no claim or litigation has been brought or threatened by any Third Party alleging that (a) the Licensed Patents are invalid or unenforceable or (b) the Exploitation of HT-100 and/or any subject matter covered by the Licensed IP infringe or misappropriate or would infringe or misappropriate any right of any Third Party.

8.2.4 The Licensed IP and the Product Records/Filings and other Licensed Know-How to be provided to Processa in accordance with Section 2.2 include all of the Patents, Know-How, and Products Records/Filings that are Controlled by Akashi that are reasonably necessary for Processa to research, develop, manufacture, make, have made, use, import, export, sell, offer to sell, have sold, commercialize and supply the Licensed Products within the Field in the Territory.

9. CONFIDENTIALITY

9.1 Confidentiality Obligations. Confidential Information shall be governed by the terms of this Agreement, which supersedes the prior Confidentiality Agreement. Recipient shall keep and hold Confidential Information of Discloser in strictest confidence, and shall not use such Confidential Information for any purpose, other than as may be reasonably necessary for the performance of its duties or the exercise of its rights under this Agreement, without Discloser's prior written consent. Recipient shall not disclose any such Confidential Information to any person or entity without Discloser's prior written consent, except to its and its Affiliates' employees, consultants and agents, as necessary for purposes of performing Recipient's duties hereunder, under the terms and conditions no less protective of the Confidential Information than the terms and conditions of this Section 9. The obligations of confidentiality under this Section 9 shall last with respect to each item of Confidential Information until one of the exceptions in Section 1.4 applies to such Confidential Information.

9.2 Permitted Disclosures. Notwithstanding anything herein to the contrary, Recipient may disclose Confidential Information of Discloser to the extent necessary to: (a) comply with an applicable law, regulation of a governmental agency or order of a court of competent jurisdiction, (b) to disclose information to any governmental agency for purposes of obtaining approval to test or market a Licensed Product, or (c) prosecute or defend litigation; provided that if Recipient is required by law or regulation to make any such disclosure of Discloser's Confidential Information, it will give reasonable advance notice to Discloser of such disclosure requirement and will use commercially reasonable efforts to assist such Discloser to secure a protective order or confidential treatment of the Confidential Information required to be disclosed. In addition, notwithstanding anything herein to the contrary, Recipient may disclose Discloser's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances: (i) in order for it to reasonably fulfill its obligations herein and to conduct its ordinary course of business, to its subcontractors, vendors, outside legal counsel, accountants and auditors under obligations of confidentiality substantially similar in scope to the confidentiality obligations herein; (ii) in connection with prosecuting and enforcing intellectual property rights in connection with Recipient's rights and obligations pursuant to this Agreement; and (iii) in connection with exercising its rights hereunder, to its Affiliates, potential and future bona fide collaborators (including Sublicensees, potential and permitted acquirers or assignees and potential investment bankers, investors and lenders);

9.3 Confidential Terms. Each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to advisors (including financial advisors, attorneys and accountants), potential and existing bona fide investors, financing sources, merger or other business partners and acquirers, and others on a need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof, or to the extent required by applicable law.

9.4 SEC or Similar Filings. Either Party may disclose the terms of this Agreement and events related to the development or commercialization of Licensed Products (including the receipt of milestone payments) to the extent reasonably required to comply with applicable laws, rules and regulations, including, without limitation, the rules and regulations promulgated by the United States Securities and Exchange Commission comparable foreign

regulator and self-regulatory organizations (such as securities exchanges). Subject to the foregoing, before disclosing this Agreement or any of the terms hereof or other events pursuant to this Section 9.4, the Parties will reasonably consult with one another on the terms of this Agreement to be redacted in making any such disclosure and the scope of such disclosure. The disclosing Party agrees, at its own expense, to seek confidential treatment of portions of this Agreement, or such terms, as may be reasonably and timely requested by the other Party.

9.5 Injunctive Relief Authorized. Each Party as a Recipient acknowledges and agrees that (a) the Confidential Information of Discloser is of a special, unique, unusual, extraordinary and intellectual character; (b) the unauthorized use or disclosure of any Confidential Information of Discloser would constitute a material breach of this Agreement; (c) the interests of Discloser in and to the Confidential Information would be irreparably injured by the unauthorized use or disclosure of such information; and (d) money damages would not be sufficient to compensate Discloser for any such unauthorized use or disclosure. Accordingly, Recipient agrees that, in addition to any other remedies available to Discloser at law, in equity or under this Agreement, Discloser shall be entitled to seek specific performance, injunctive relief and other equitable relief to prevent any actual or threatened use or disclosure of the Confidential Information of Discloser without obligation to post any bond.

10. PATENTS

10.1 Prosecution and Maintenance.

10.1.1 Licensed Patents. From and after the Effective Date, Processa shall be responsible for and shall control, in its sole discretion, the filing, prosecution, and maintenance of the Licensed Patents. In connection with such activities, Processa shall have the right to transfer the responsibility for such filing, prosecution and maintenance of the Licensed Patents to patent counsel (outside or internal) selected by Processa and reasonably acceptable to Akashi, and Akashi shall cooperate with Processa as reasonably requested by Processa, and at Processa's expense, to facilitate control of such filing, prosecution and maintenance by Processa. In any event, Processa shall pay for all costs and expenses incurred during the term of this Agreement in preparing, filing, prosecuting, and maintaining the Licensed Patents as set forth herein. In the event that Processa decides not to continue the prosecution or maintenance of any Licensed Patent in any country, Processa shall provide Akashi with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof and will allow Akashi to assume responsibility therefor. In the event that Akashi elects to assume responsibility for such prosecution or maintenance, Akashi shall have the right to transfer the responsibility for such filing, prosecution and maintenance of such Licensed Patent(s) to patent counsel (outside or internal) selected by Akashi, and Processa shall cooperate with Akashi as reasonably requested by Akashi, and at Akashi's expense, to facilitate control of such prosecution and maintenance by Akashi. Akashi shall pay for all costs and expenses incurred by it in preparing, filing, prosecuting, and maintaining any patents and patent applications for which Akashi has elected to assume responsibility for prosecution or maintenance.

10.1.2 Foreground Patents. Processa shall be responsible for and shall control, in its sole discretion, the preparation, filing, prosecution, and maintenance of the

Foreground Patents. Processa shall pay for all costs and expenses incurred in preparing, filing, prosecuting, and maintaining the Foreground Patents.

10.2 Enforcement.

10.2.1 Generally. Each Party shall notify the other Party of any infringement known to such Party of any Licensed Patent or Foreground Patent by a Third Party that is manufacturing, using, offering for sale, selling or importing a product that is utilizing, comprises, contains or constitutes HT-100 or a Licensed Product (each, a "**Product Infringement**") and shall provide the other Party with the available evidence, if any, of such infringement.

10.2.2 Licensed Patents.

(a) With respect to any Product Infringement that occurs during the term of this Agreement, Processa shall have the sole right, but not the obligation, to enforce the Licensed Patents with respect to any such Product Infringement or otherwise abate such Product Infringement. In such event, Processa shall have the right to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the Licensed Patents and such Product Infringement, and shall consider, in good faith, the interests of Akashi in so doing. Akashi agrees to cooperate reasonably with Processa in any action to enforce the Licensed Patents with respect to Product Infringements under this Section 10.2.2, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party in any such suit if deemed a necessary party, provided that Processa reimburses Akashi promptly for any costs and expenses incurred by Akashi in providing such assistance and cooperation. Processa shall pay for all other costs and expenses incurred in connection with such enforcement action.

(b) Notwithstanding Section 10.2.2(a), Processa shall not settle any enforcement action under this Section 10.2 or otherwise consent to an adverse judgment in such action that adversely affects the rights or interests of Akashi without the prior written consent of Akashi.

(c) All monies recovered upon the final judgment or settlement of any such suit to enforce the Licensed Patents with respect to a Product Infringement pursuant to this Section 10.2.2 shall be first used to reimburse each Party pro rata for the costs and expenses incurred in connection with such suit, and the remainder, if any, shall be retained by Processa in its entirety, and shall be deemed Net Sales of Licensed Products in the Territory made by Processa and subject to sales milestones payments pursuant to Section 4.3 and royalty payments pursuant to Section 4.4.

10.2.3 Foreground Patents.

(a) Processa, at its sole cost, shall have the sole right, but not the obligation, to enforce the Foreground Patents with respect to any Product Infringement or otherwise abate such Product Infringement. In such event, Processa shall have the right to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the Foreground Patent and such Product

Infringement, and shall consider, in good faith, the interests of Akashi in so doing. Akashi agrees to cooperate reasonably with Processa in any action to enforce the Foreground Patents with respect to Product Infringements under this Section 10.2.3, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party in any such suit if deemed a necessary party, provided that Processa reimburses Akashi promptly for any costs and expenses incurred by Akashi in providing such assistance and cooperation.

(b) All monies recovered upon the final judgment or settlement of any such suit to enforce the Foreground Patents with respect to a Product Infringement pursuant to this Section 10.2.3 shall be first used to reimburse each Party for the costs and expenses incurred in connection with such suit, and the remainder, if any, shall be retained by Processa in its entirety.

11. TERMINATION

11.1 Expiration. Subject to early termination pursuant to the provisions of Sections 11.2, 11.3, and 11.4 below, this Agreement shall expire on the expiration of all of Processa's obligations to pay royalties to Akashi under Section 4.4 above. Upon expiration of the Royalty Term, on a Licensed-Product-by-Licensed Product and country-by-country basis, the licenses granted to Processa by Akashi under this Agreement with respect to the relevant Licensed Product and country shall be fully paid-up and irrevocable.

11.2 Termination by Processa. Processa may terminate this Agreement in its entirety, in its sole discretion, at any time upon ninety (90) days prior written notice to Akashi.

11.3 Termination for Cause. Either Party will have the right to terminate this Agreement in full upon delivery of written notice to the other Party in the event of any material breach by the other Party of any material terms and conditions of this Agreement (a "**Material Breach**"), provided, that such termination will not be effective if such breach has been cured within sixty (60) days (fifteen (15) days with respect to any payment breach) after written notice thereof is given by the non-breaching Party to the breaching Party specifying in reasonable detail the nature of the alleged breach; *provided that* if the allegedly breaching Party notifies the non-breaching Party in writing within thirty (30) days of its receipt of the relevant notice of breach provided pursuant to this Section 11.3 that it disputes in good faith that it has committed a Material Breach, or that it has not timely cured such breach, then such termination shall not be effective unless and until the dispute is resolved in the favor of the non-breaching Party pursuant to Section 13.4, and if Akashi is the allegedly breaching Party, the due date for all payments that become due to Akashi hereunder prior to resolution of the dispute shall be tolled unless and until (i) the dispute is resolved in favor of Akashi, or Processa does not effectuate termination of this Agreement upon resolution of the dispute, in which event they shall be payable in full to Akashi within ten (10) days of such event, or (ii) the dispute is resolved in favor of Processa and Processa terminates the Agreement, in which event fifty percent (50%) of the tolled payment shall be due within ten (10) days of any election by Processa to retain its license after termination as permitted in Section 11.5.1.

11.4 Termination for Patent Challenges. If, during the term of this Agreement, Processa or any of its Affiliates or Sublicensees (a) commences or participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts

any claim, challenging or denying the validity or enforceability of any claim of Akashi's or its Affiliates' patents or patent applications that are licensed to Processa under this Agreement or (b) knowingly assists any other Person in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of Akashi's or its Affiliates' patents or patent applications that are licensed to Processa under this Agreement (each of (a) and (b), a "**Patent Challenge**"), then, to the extent permitted by applicable laws, Akashi shall have the right, in its sole discretion, to give notice to Processa that Akashi intends to terminate the license(s) granted to Processa under such patents and applications pursuant to this Agreement sixty (60) days following such notice, and, unless Processa withdraws or causes to be withdrawn all such Patent Challenge(s) within such sixty (60) day period, Akashi shall have the right to terminate the licenses granted to Processa under such patents and applications pursuant to this Agreement by providing written notice thereof to Processa.

11.5 Effect of Expiration or Termination. Upon termination by Akashi under Sections 11.3 or 11.4 of this Agreement, or by Processa under Section 11.2 or Section 11.3 of this Agreement:

11.5.1 Termination of Licenses. All rights and licenses granted to Processa hereunder shall terminate; *provided*, *however*, that if this Agreement is terminated by Processa in accordance with Section 11.3 due to Material Breach by Akashi, Processa may elect in writing within thirty (30) days of the termination date to retain the rights granted to it pursuant to Article 3, in which event the licenses granted hereunder shall continue in accordance with the terms of this Agreement, and associated payments shall be made to Akashi in accordance with the terms of Article 4, but at a rate of 50% of the amounts otherwise due.

11.5.2 Transfer of Development Activities and Know-How. Upon any termination where Processa does not elect to retain rights as permitted in Section 11.5.1:

(a) If Processa is conducting any development activity with respect to HT-100 or any Licensed Product on the date of notice of termination, and then Akashi shall notify Processa within sixty (60) days after the notice of termination: (i) with regard to any clinical trial, whether Akashi elects to have Processa: (A) complete such clinical trial on behalf of Akashi (unless Processa has material safety concerns regarding continuation of such clinical trial of which it has notified Akashi in writing), (B) wind down such clinical trial as soon as practicable or (C) transfer such clinical trial to Akashi as soon as practicable, in each case, subject to compliance with ethical, legal and contractual requirements; and (ii) with regard to any other development activity, whether Akashi elects to have Processa wind down or transfer such activity to Akashi.

(b) If Akashi notifies Processa of its election to have Processa wind down such clinical trial or other development activity (or fails to provide notice within such sixty (60) day period), then Processa shall wind-down such clinical trial or development activity as soon as practicable, subject to compliance with ethical, legal and contractual requirements.

(c) If Akashi notifies Processa of its election to have Processa transfer such clinical trial or other development activity to Akashi, then Processa shall use

Commercially Reasonable Efforts to transfer, and Akashi shall use Commercially Reasonable Efforts to assume, such clinical trial or other development activity as promptly as practicable (and, in any event, within three (3) months) after the effective date of termination.

(d) To the extent any Know-How Controlled by Processa, its Affiliates or Sublicensees that specifically relates to HT-100 or any Licensed Products is not transferred to Akashi pursuant to subsections (a) through (c) above, Processa will transfer and assign such Know-How to Akashi or its designee within ninety (90) days of the effective date of termination.

(e) The activities set forth in this Section 11.5.2 shall be performed at Processa's expense, unless Processa terminates this Agreement pursuant to Section 11.3 for Akashi's material breach, in which case such activities shall be at Akashi's expense.

11.5.3 Confidential Information. Processa shall, within sixty (60) days after the effective date of termination and at Processa's expense, return or destroy, at Akashi's election, all Licensed Know-How and other Confidential Information of Akashi (provided that Processa may keep one copy of such Confidential Information for archival purposes only and such additional copies of or any computer records or files containing such Confidential Information that have been created solely by Processa's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with Processa's standard archiving and back-up procedures, but not for any other use or purpose, subject to an ongoing obligation of confidentiality in accordance with Section 9). All Know-How assigned or transferred to Akashi pursuant to this Section 11.5 shall thereafter be deemed to be Confidential Information of Akashi for the purposes of Section 9. Accordingly, Akashi shall be deemed the Discloser and Processa shall be deemed the Recipient with respect to such information, and Section 1.4(d) shall not apply to such information.

11.5.4 Product Records/Filings. Processa shall, and hereby does, and shall cause its Affiliates and Sublicensees to, assign to Akashi, as of the effective date of termination, all its right, title and interest in, to and under all of Processa's and its Affiliates' and Sublicensees' ownership interest in any and all Product Records/Filings, including any Regulatory Approvals for the Products, and Processa shall transfer or cause to be transferred all such Product Records/Filings to Akashi promptly after the effective date of termination.

11.5.5 License. Processa shall, and hereby does, and shall cause its Affiliates and Sublicensees to, grant to Akashi, as of the effective date of termination, an exclusive, perpetual, irrevocable, royalty-free, sublicensable (through multiple tiers) license, under all Patents, Know-How and other intellectual property Controlled by Processa, its Affiliates or Sublicensees as of the effective date of termination (and not subject to assignment to Akashi hereunder) solely to the extent necessary or specifically useful to Exploit HT-100 and Licensed Products in the Territory.

11.5.6 Inventory. At Akashi's request, Processa shall assign and transfer to Akashi any inventory of HT-100 and Licensed Products then in Processa's or any of its Affiliates' possession or control subject to Akashi's reimbursement of Processa's reasonable,

documented, out-of-pocket costs incurred in acquiring such inventory and with respect to shipping thereof.

11.5.7 Sublicenses. All sublicenses that are granted by Processa pursuant to this Agreement and in accordance with Section 3.2 where the Sublicensee is in compliance with its sublicense agreement and this Agreement as of the date of such termination will remain in effect and will be assigned to Akashi, provided that such Sublicensee agrees in writing to assume and perform all obligations of Processa hereunder, and provided further that Akashi will not be bound to perform any duties or obligations, or to grant any rights, set forth in any sublicense agreements that extend beyond the duties and obligations of Akashi, or grant of rights by Akashi, set forth in this Agreement.

11.5.8 Further Actions. Processa shall, and shall cause its Affiliates and Sublicensees to, take such other actions, and execute any instruments, assignments, and documents, as reasonably requested by Akashi as may be necessary to effect the foregoing provisions of this Section 11.5.

11.5.9 Termination Not Sole Remedy. For clarity, termination is not the sole remedy under this Agreement for any Material Breach and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as otherwise expressly set forth herein.

11.6 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 5.2, 6, 7, 9, 10, 11.5, 12 and 13 shall survive the expiration or termination of this Agreement.

12. INDEMNIFICATION

12.1 Indemnification by Processa. Processa shall defend, indemnify and hold Akashi and its Affiliates and their respective directors, officers, employees and agents harmless from all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) (collectively, "**Losses**") resulting from any claims, demands, actions and other proceedings by any Third Party to the extent resulting from (a) Processa's or its Affiliates' or Sublicensees' use of the Licensed IP or Foreground IP or research, development, registration, use, manufacturing, commercialization, promotion, sale, storage, transportation or other disposition or Exploitation of HT-100 or any Licensed Product under this Agreement or (b) Processa's breach of this Agreement except to the extent such Losses are subject to Akashi's indemnification obligations under Section 12.2 below.

12.2 Indemnification by Akashi. Akashi shall defend, indemnify and hold Processa and its Affiliates and their respective directors, officers, employees and agents harmless from all Losses resulting from any claims, demands, actions and other proceedings by any Third Party to the extent resulting from the material breach of the representations and warranties made by Akashi or its Affiliates in this Agreement.

12.3 Procedure. The Party seeking indemnification (the "**Indemnified Party**") promptly shall notify the other Party (the "**Indemnifying Party**") of any claim, demand, action,

or other proceeding for which the Indemnified Party intends to claim indemnification. The Indemnifying Party shall have the right to participate in, and to the extent the Indemnifying Party so desires jointly with any other indemnitor similarly noticed, to assume the defense thereof with counsel selected by the Indemnifying Party; provided, however, that the Indemnified Party shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnified Party, if representation of the Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceedings. The indemnity obligations under this Section 12 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the prior express written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned, or delayed. The failure to deliver notice to the Indemnifying Party within a reasonable time after notice of any such claim or demand, or the commencement of any such action or other proceeding, if prejudicial to its ability to defend such claim, demand, action or other proceeding, shall relieve such Indemnifying Party of any liability to the Indemnified Party under this Section 12 with respect thereto, but the omission so to deliver notice to the Indemnifying Party shall not relieve it of any liability that it may have to the Indemnified Party other than under this Section 12. The Indemnifying Party may not settle or otherwise consent to an adverse judgment in any such claim, demand, action, or other proceeding, that diminishes the rights or interests of, or places any obligations upon, the Indemnified Party without the prior express written consent of the Indemnified Party, which consent shall not be unreasonably withheld, conditioned, or delayed. The Indemnified Party, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action, or other proceeding covered by this Section 12.

12.4 LIMITATION OF DAMAGES. IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS OR LOST SAVINGS, EXCEPT TO THE EXTENT CONSTITUTING DIRECT DAMAGES) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 12.4 SHALL NOT APPLY WITH RESPECT TO (I) ANY BREACH OF SECTION 9 OR (II) THE INTENTIONAL MISCONDUCT OR GROSS NEGLIGENCE OF A PARTY. NOTHING IN THIS SECTION 12.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER THIS SECTION 12 WITH RESPECT TO ANY DAMAGES OWED OR PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM.

12.5 Insurance.

12.5.1 Processa shall maintain at its own cost and at all times during the term of this Agreement policies of insurance consistent with normal business practices of prudent pharmaceutical companies similarly situated. Such insurance policies shall include, without limitation, commercial general liability insurance, including, without limitation, product liability, covering claims for damages because of bodily injury (including, without limitation, death), personal injury, and property damage arising out of Processa's acts or omissions and including coverage for contractual liabilities. Without limiting the foregoing, no later than Processa's

commencement of clinical trials in respect of any Licensed Product, Processa shall obtain, and maintain in full force and effect, adequate clinical trials insurance, for claims arising out of or in connection with such clinical trials. In addition, no later than the commencement of commercial distribution of any Licensed Product by or on behalf of Processa, Processa shall obtain, and maintain in full force and effect, adequate general and product liability insurance for bodily injury and property damage claims.

12.5.2 The policies described in Section 12.5.1 above will be in such amounts and cover such risks as are reasonable and prudent for those types of policies, but shall in no event be less than, in the aggregate: (a) one million U.S. dollars (US$1,000,000) as of the Effective Date, (b) ten million U.S. dollars (US$10,000,000) as of the commencement of any clinical trial of Licensed Product and for so long as such clinical trials are continuing, and (c) twenty million U.S. dollars (US$20,000,000) as of the commercial launch of any Licensed Product and for so long as sales of Licensed Products are continuing. Such policies will be written by insurance companies with an A.M. Best's rating of A:VIII or higher (or if such policies are not subject to the Best rating, then by carriers who are reasonably acceptable to Akashi). The foregoing policies will: (i) cover claims arising out of the performance of this Agreement that are made within a period of not less than six (6) years after the expiration or earlier termination of this Agreement; and (ii) be primary and non-contributory to any liability insurance carried by Akashi, which insurance will be excess for claims and losses arising out of the performance of this Agreement. The policies described above will be specifically endorsed to list Akashi as an additional insured, and Processa will notify Akashi at least sixty (60) days in advance of any cancellation or non-renewal of or material changes in of such insurance coverage. Processa shall provide Akashi with a valid, current certificate of insurance as evidence of the insurance required herein upon request. Maintenance of such insurance coverage will not relieve Processa of any responsibility under this Agreement for damages in excess of insurance limits or otherwise.

13. MISCELLANEOUS

13.1 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor for purposes of this Section 13.1, and shall be effective upon receipt by the addressee.

If to Akashi:

Akashi Therapeutics, Inc.
635 Main Street, Suite 3
Great Barrington, MA 01230

Attention: Tom Wicka

If to Processa:

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy

13.2 Assignment. Except as otherwise expressly provided under this Agreement, neither this Agreement nor any of Processa's rights or obligations hereunder may be assigned or otherwise transferred (whether voluntarily, by operation of law or otherwise) by Processa without the prior express written consent of Akashi, which will not be unreasonably withheld, conditioned, or delayed; provided, however, that such consent shall not be required in connection with the sale of substantially all of the assets of Processa to which this Agreement relates, or in the case of a merger, consolidation or other reorganization of Processa, subject in each case to the assignee agreeing in writing to be bound by the terms of this Agreement and with notice thereof to be provided to Akashi. Akashi may assign this Agreement or any of its rights or obligations under this Agreement to any Third Party without Processa's consent. In the case of any permitted assignment or transfer of or under this Agreement, this Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assignees of the Parties hereto. Any permitted assignee shall assume in writing all obligations of its assignor under this Agreement. Any purported assignment or transfer in violation of this Section 13.2 shall be void.

13.3 Governing Law; Costs. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law principles thereof.

13.4 Dispute Resolution.

13.4.1 Resolution by Senior Executives. The Parties shall seek to settle amicably any and all disputes or differences arising out of or in connection with this Agreement ("**Dispute**"). Any Dispute between the Parties shall be promptly presented to the Chief Executive Officer of Processa and the Chief Executive Office of Akashi, or their respective designees, for resolution. Such officers, or their designees, shall attempt in good faith to promptly resolve such Dispute.

13.4.2 Arbitration. If a dispute between the Parties arising out of or relating to the validity or interpretation of, compliance with, breach or alleged breach of or termination of this Agreement cannot be resolved within thirty (30) days of presentation to the Chief Executive Officers, or their respective designees, for resolution, either Party may refer such dispute to binding arbitration to be conducted as set forth below in this Section 13.4.2.

(a) A Party may submit such dispute to arbitration by notifying the other Party, in writing, of such dispute. The number of arbitrators shall be one. Within thirty (30) days after receipt of such notice, the Parties shall designate in writing a single arbitrator to resolve the dispute; provided, however, that if the Parties cannot agree on an arbitrator within such thirty (30) day period, the arbitrator shall be selected by the New York, NY, office of the American Arbitration Association (the "AAA") or, if such office does not exist or is unable to make a selection, by the office of the AAA nearest to New York, NY. The arbitrator shall have scientific and legal experience relevant to the subject matter of the dispute. In any case the arbitrator shall not be an Affiliate, employee, consultant, officer, director or stockholder of either Party, or otherwise have any current or previous relationship with either Party or their respective Affiliates. The governing law in Section 13.3 shall govern any such proceedings. The language of the arbitration shall be English.

(b) Within sixty (60) days after the designation of the arbitrator, the arbitrator and the Parties shall meet, and each Party shall provide to the arbitrator a written summary of all disputed issues, such Party's position on such disputed issues and such Party's proposed ruling on the merits of each such issue.

(c) The arbitrator shall set a date for a hearing, which shall be no later than thirty (30) days after the submission of written proposals pursuant to Section 13.4.2(b), for the presentation of evidence and legal argument concerning each of the issues identified by the Parties. The Parties shall have the right to be represented by counsel. Except as provided herein, the arbitration shall be governed by the Commercial Arbitration Rules of the AAA applicable at the time of the notice of arbitration pursuant to Section 13.4.2(a); provided, however, that the Federal Rules of Evidence shall apply with regard to the admissibility of evidence in such hearing. In any such arbitration proceeding, the Parties shall be entitled to all remedies to which they would be entitled in a United States District Court and to full discovery to the same degree permitted under the Federal Rules of Civil Procedure.

(d) The arbitrator shall use his or her best efforts to rule on each disputed issue within thirty (30) days after completion of the hearing described in Section 13.4.2(c). The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon all Parties. All rulings of the arbitrator shall be in writing and shall be delivered to the Parties except to the extent that the Commercial Arbitration Rules of the AAA provide otherwise. Nothing contained herein shall be construed to permit the arbitrator to award punitive, exemplary or any similar damages. The arbitrator shall render a "reasoned decision" within the meaning of the Commercial Arbitration Rules, which shall include findings of fact and conclusions of law.

(e) The (i) attorneys' fees of the Parties in any arbitration, (ii) fees of the arbitrator and (iii) costs and expenses of the arbitration shall be borne by the Parties in a proportion determined by the arbitrator.

(f) Any arbitration pursuant to this Section 13.4.2 shall be conducted in a place to be mutually agreed, provided that if the Parties cannot agree on such place, the arbitration shall be conducted in New York, NY. Any arbitration award may be entered in and enforced by a court in accordance with Section 13.3.

(g) Notwithstanding anything in this Section 13.4, each Party shall have the right to seek injunctive or other equitable relief from a court of competent jurisdiction that may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration.

13.5 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. There are no agreements, representations, warranties, covenants, or undertakings with respect to the subject matter hereof other than those expressly set forth herein. All express or implied representations, agreements and understandings relating to such subject matter, either oral or written, heretofore made are expressly superseded by this Agreement, including, without limitation the Confidentiality Agreement.

13.6 Modifications. The terms and conditions of this Agreement may not be amended or modified, except in a writing signed by both Parties.

13.7 Independent Contractors. Each Party hereby acknowledges that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency. Neither Party shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of the other Party to do so.

13.8 Remedies. All remedies, either under this Agreement, by law, or otherwise afforded to any Party, shall be cumulative and not alternative.

13.9 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement solely to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party. If any such event continues for more than ninety (90) days, then such other Party shall have the right to terminate this Agreement upon sixty (60) days prior written notice to the affected Party.

13.10 Fees and Expenses. Each Party shall pay its own costs and expenses in connection with this Agreement and the transactions contemplated hereby (including the fees and expenses of its advisers, accountants, and legal counsel).

13.11 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property (solely to the extent that such license in effect at such time), and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

13.12 Further Assurances. At any time or from time to time after the date hereof, the Parties agree to cooperate with each other, and at the request of the other Party, to execute and deliver any further instruments or documents and to take all such further action as the other Party may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the Parties hereunder.

13.13 Interpretation. The captions to the Sections of this Agreement are not a part of this Agreement, however, are included for convenience of reference and shall not affect its

meaning or interpretation. In this Agreement: (i) the word "including," "includes," "included," and "include" shall be deemed to be followed by the phrase "without limitation" or like expression; (ii) the singular shall include the plural and *vice versa*; (iii) masculine, feminine, and neuter pronouns and expressions shall be interchangeable; (iv) the words "hereof," "herein," "hereto," "hereby," "hereunder," and derivative or similar words refer to this Agreement as an entirety and not solely to any particular provision of this Agreement; (v) each reference in this Agreement to a particular Section, appendix, schedule, or exhibit means a Section, appendix, schedule, or exhibit of or to this Agreement, as amended in accordance with Section 13.5, unless another agreement is specified; (vi) "the word "will" shall be construed to have the same meaning and effect as the word "shall"; (vii) "or" is not disjunctive (i.e., it means "and/or") unless the context clearly requires otherwise; (viii) references to any Party or Person shall include its permitted successors or assigns; and (ix) whenever this Agreement refers to a number of days, such number shall refer to calendar days unless business days are specified; and business days means any day, except Saturday and Sunday, on which commercial banking institutions in New York, New York are open for business. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

13.14 Waivers. It is agreed that no delay or omission to exercise any right, power or remedy accruing to any Party, upon any breach, default or noncompliance by the other Party under this Agreement, shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of or in any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent or approval of any kind or character on the part of any Party hereto of any breach, default or noncompliance under this Agreement or any waiver on such Party's part of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. The waiver by a Party of any right hereunder, or of any failure to perform or breach by the other Party hereunder, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by the other Party hereunder whether of a similar nature or otherwise.

13.15 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, all other provisions shall continue in full force and effect, and the Parties shall substitute for the invalid, illegal or unenforceable provision a valid, legal and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

13.16 Enforcement. Each Party hereto acknowledges that money damages would not be an adequate remedy in the event that any of the covenants or agreements in this Agreement are not performed by the Parties in accordance with its terms, and it is therefore agreed that in addition to and without limiting any other remedy or right each Party may have, each Party will have the right to seek an injunction, temporary restraining order or other equitable relief in any court of competent jurisdiction enjoining any such breach and enforcing specifically the terms and provisions hereof.

13.17 Extension to Affiliates. Processa shall have the right to extend the rights and obligations granted in this Agreement to one or more of its Affiliates, subject to any relevant requirements of Section 3.2.1. All applicable terms and provisions of this Agreement shall apply

to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Processa. Processa shall remain directly liable for any acts or omissions of its Affiliates, and Processa hereby expressly waives any requirement that Akashi exhaust any right, power or remedy, or proceed directly against such Affiliate, for any obligation or performance hereunder prior to proceeding directly against Processa.

13.18 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Signature Page Follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

AKASHI THERAPEUTICS, INC.

By DocuSigned by: Thomas Wicka 05DEEEC1037F480...

Name Thomas Wicka

Title CEO

PROCESSA PHARMACEUTICALS, INC.

By DocuSigned by: Wendy Guy 3E95D4CBD5424AF...

Name Wendy Guy

Title Chief Administrative Officer

[Signature Page to License Agreement]

PROCESSA PHARMACEUTICALS ANNOUNCES THE LICENSING OF AN ANTI-FIBROTIC, ANTI-INFLAMMATORY DRUG FOR THE TREATMENT OF MULTIPLE UNMET MEDICAL NEED CONDITIONS

HANOVER, MD – September 3, 2019 – Processa Pharmaceuticals, Inc. (OTCQB: PCSA), a clinical stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have a high unmet medical need condition, announced today that they have signed an exclusive worldwide license agreement with Akashi Therapeutics to develop and commercialization Akashi's lead drug, HT-100.

HT-100 is an orally available anti-fibrotic, anti-inflammatory drug that also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), HT-100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off of clinical hold and defined how HT can resume clinical trials in DMD.

Processa plans to begin developing HT-100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis (FSGS), idiopathic pulmonary fibrosis (IPF) or Scleroderma, where there are still few therapeutic options. The company will revisit potential pediatric indications, such as DMD, at a later time.

"Processa needs to learn more about the safety and dose response of HT-100 while we determine the best way to clinically manage patients on this anti-fibrotic drug," said Dr. Sian Bigora, Chief Development Officer at Processa Pharmaceuticals. "In early 2020 we hope to begin to define, in collaboration with the FDA, an efficient way to develop HT-100 for all those patients who would benefit from this drug."

Dr. David Young, Chief Executive Officer at Processa, added, "The Processa strategy is to add drugs to our portfolio which already have some clinical evidence of efficacy. This enables our team to efficiently develop these drugs for patients with a high unmet medical need condition while the risk of failure associated with the clinical trials is decreased. This strategy was implemented when PCS-499 was acquired and will now be implemented for HT-100. Since the quality of life for these patients is so often impaired given the lack of treatment options, the more efficiently we can develop these products, the sooner patients will experience the positive impact of these drugs on their lives."

Additional information and updates are available on our website: http://www.processapharma.com

About Processa Pharmaceuticals, Inc.

Processa Pharmaceuticals, Inc. was founded in 2017 in Hanover, Maryland, with a mission to develop products that can improve the survival and/or quality of life for patients who have a high unmet medical need. The Company has assembled a proven regulatory science development team, management team, and Board of Directors. The Processa drug development team members have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and 100 FDA meetings. For more information, please visit http://www.processapharma.com.

Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors that could cause actual results to differ from those contained in the forward-looking statements.

For More Information:
Investor Relations: Patrick Lin
plin@processapharma.com
925-683-3218

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