
**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): August 23, 2020

Commission file number 333-184948

PROCESSA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

45-1539785
(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))

Securities registered pursuant to Section 12(b) of the Act: None.

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

Emerging growth company

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

Item 1.01. Entry into a Material Definitive Agreement.

On August 23, 2020, Processa Pharmaceuticals, Inc. (the “Company”) entered into a License Agreement (“Elion License Agreement”) with Elion Oncology, Inc. (“Elion”), pursuant to which it acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally.

The grant of license is conditioned on the closing of an equity offering by the Company with at least \$15 million in gross proceeds and the successful up-listing to Nasdaq by October 30, 2020. Following the satisfaction of the conditions, the Company must pay Elion \$100,000 and issue Elion 500,000 shares of common stock, subject to increase in the event the price per share in the equity offering is less than \$8.34 per share. Such shares will be subject to a lock-up, with 50% of such shares released from such lock up after six months and the remaining 25% tranches to be released following 9 months and 12 months, respectively.

As additional consideration, the Company will pay Elion development and regulatory milestone payments (a portion of which are payable in shares of common stock and a portion of which are payable in cash) upon the achievement of certain milestones, which include 100,000 shares of common stock due on the first two annual anniversaries of the effective date of the agreement, FDA or other regulatory approval and dosing a patient. In addition, the Company must pay Elion one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. The Company is also required to split any milestone payments received with Elion based on any sub-license agreement it may enter into.

The Company is required to use commercially reasonable efforts, at its sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) dosing a first patient in a Phase 1B clinical trial with a product within 12 months; and (ii) dosing a first patient with a product in a Phase 2 or 3 clinical trial within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

The above summary of the Elion License Agreement above is not complete and is subject to the full terms and conditions of such agreement, which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On August 27, 2020, the Company issued a press release announcing the entry into the Elion License Agreement. The press release is attached hereto as Exhibit 99.1 and incorporated by reference in this Item 7.01.

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

Item 9.01. Financial Statements and Exhibits.**Exhibit No. Exhibit Description**

10.1	License Agreement by and between Processa Pharmaceuticals and Elion Oncology dated August 23, 2020
99.1	Press Release dated August 27, 2020

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 August 27, 2020.

PROCESSA PHARMACEUTICALS, INC.
Registrant

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

LICENSE AGREEMENT
BY AND BETWEEN
PROCESSA PHARMACEUTICALS, INC.
AND
ELION ONCOLOGY, INC
DATED AS OF AUGUST 23, 2020

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT is entered into as of this 23 day of August, 2020 (the "Effective Date"), by and between Processa Pharmaceuticals, Inc. a corporation organized under the laws of Delaware, having a business address at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076 ("Processa"), and Elion Oncology, Inc. a corporation organized under the laws of Maryland whose principal place of business is at 4800 Hampden Lane, Bethesda, MD 20814 ("Elion").

WHEREAS, Elion has developed or obtained rights to Elion Know-How, Elion Patent Rights and the Elion Compound (each as defined below); and

WHEREAS, Processa desires to obtain a license of the Elion Patent Rights and the Elion Know-How to Develop and Commercialize Compounds and Products (each as defined below), under the terms and conditions set forth herein, and Elion desires to grant such a license;

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

ARTICLE I DEFINITIONS

The following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Affiliate". Affiliate means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any vested and exercisable option, warrant or other similar arrangement) or other comparable equity interests. For clarity, neither of the Parties shall be deemed to be an "Affiliate" of the other.

1.2 "Bankruptcy Code". Bankruptcy Code means Title 11 of the U.S. Code, as amended from time to time.

1.3 "Business Day". Business Day means a day that is not a Saturday, Sunday or a day on which banking institutions in New York City, New York are authorized by Law to remain closed.

1.4 "Calendar Quarter". Calendar Quarter means each of the periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; provided, however, that the first Calendar Quarter shall begin on the Effective Date and end on the last day of the calendar quarter during which the Effective Date occurs; provided, that, the final Calendar Quarter shall end on the last day of the Term.

1.5 "Calendar Year". Calendar Year means each calendar year during the Term; provided, however, that the first Calendar Year shall begin on the Effective Date and end on December 31 of the calendar year during which the Effective Date occurs; provided, that, the final Calendar Year shall end on the last day of the Term.

1.6 "Combination Product". Combination Product means (a) any pharmaceutical product that is a single formulation consisting of a Compound and one or more other active compounds or active ingredients, which other active compounds or active ingredients are not Compounds ("Other API") or (b) any combination of a Compound sold together with any separately formulated Other API for a single invoiced price.

1.7 "Commercialization" or "Commercialize". Commercialization or Commercialize means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, Manufacturing commercial supplies of, distributing, importing, offering for sale, or selling a product.

1.8 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means, with respect to an objective, the reasonable, diligent, good faith efforts of a Party (including the efforts of its Affiliates and Sublicensees) to accomplish such objective that a biopharmaceutical company of comparable size and resources would normally use to accomplish a similar objective under similar circumstances, and, specifically with respect to obligations hereunder relating to a Compound or Product, the carrying out of such obligations with those efforts and resources that a biopharmaceutical company of comparable size and resources would use were it Developing, Manufacturing or Commercializing its own pharmaceutical products that are at a similar stage of development or product life cycle and of similar market potential as the Compound or Product, taking into account actual and potential issues of safety, efficacy or stability, product profile (including product modality, category and mechanism of action), stage of development or life cycle status, product labeling or anticipated labeling, the present and future market potential, past performance of the Compound or Product, actual and projected Development, Regulatory Approval, pricing and reimbursement approval, Manufacturing and Commercialization costs, existing or projected pricing, sales, reimbursement and financial return, medical and clinical considerations, present and future regulatory environment, any issues regarding the ability to Manufacture the Compound or Product, the likelihood and timing of obtaining Regulatory Approvals and pricing and reimbursement approvals, proprietary position, strength and duration of patent protection and anticipated exclusivity, competitive Third Party products at the time and the likely competitive environment at the time of projected entry into the market and thereafter, and any other relevant scientific, technical, operational and commercial factors, all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts will be determined on a country-by-country and indication-by-indication basis for the Compound or Product, and the level of effort is expected to change over time, reflecting changes in the status and value of the Compound or Product and the market conditions and country(ies) involved.

1.9 “Compound”. Compound means Eniluracil together with all analogs, derivatives, metabolites, stereoisomers, polymorphs, formulations, mixtures or compositions thereof, and any existing or future improved or modified versions of the foregoing developed by or on behalf of Processa, its Affiliates or Sublicensees (or their respective Affiliates or assignees).

1.10 “Clinical Trial” shall mean any study in which human subjects are dosed with a drug, whether approved or investigational, including any Phase 1, 2, 3 or 4 clinical study.

1.11 “Condition Precedent Period”. Condition Precedent Period means the period of time beginning on the Effective Date and ending on October 30, 2020.

1.12 “Control” or “Controlled”. Control or Controlled means, with respect to any tangible property or intellectual property right or other intangible property, the possession (whether by ownership or license (other than by grant of a license to one Party by the other Party pursuant to this Agreement or by grant of a license or sublicense to a Sublicensee by Processa pursuant to a license or sublicense agreement)) by a Person of the ability to grant to another Person access to such tangible property or access to or a license or sublicense to such intellectual property right or other intangible property, as provided herein without violating the terms of any agreement with any other Person. Notwithstanding the foregoing, for the purpose of defining whether intellectual property, Patent Rights, Know-How or Confidential Information is Controlled by a Party, if such intellectual property, Patent Rights, Know-How or Confidential Information is first acquired, licensed or otherwise made available to such Party after the Effective Date and if the use, practice or exploitation thereof by or on behalf of the other Party, its Affiliates or sublicensees would require the first Party to pay any amounts to the Third Party from which the first Party acquired, licensed or otherwise obtained such intellectual property, Patents, Know-How or Confidential Information (“Additional Amounts”), such intellectual property, Patent Rights, Know-How or Confidential Information shall be deemed to be Controlled by the first Party only if the other Party agrees to pay (if necessary) and does in fact pay all Additional Amounts with respect to such other Party’s use of or license to such intellectual property, Patent Rights, Know-How or Confidential Information to the extent specified in this Agreement.

1.13 “Cover”, “Covering” or “Covered”. Cover, Covering or Covered means, with respect to a compound, product, technology, process or method that, in the absence of ownership of or a license granted under a Patent Right, the manufacture, use, offer for sale, sale or importation of such compound or product or the practice of such technology, process or method would infringe such Patent Right (or, in the case of a Patent Right that has not yet issued, would infringe such Patent Right if it were to issue).

1.14 “Development” or “Develop”. Development or Develop means pre-clinical, non-clinical and clinical drug research, discovery and development activities, including IND-enabling toxicology and other IND-enabling pre-clinical development efforts, stability testing, process development, compound property optimization, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, Manufacturing supplies of compounds and products for pre-clinical, non-clinical and clinical use, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.15 “Elion Intellectual Property”. Elion Intellectual Property means the Elion Know-How and the Elion Patent Rights.

1.16 “Elion Know-How”. Elion Know-How means all Know-How that is Controlled by Elion or any of its Affiliates as of the Effective Date or thereafter during the Term (other than any Know-How included in Joint Intellectual Property) that is necessary or useful to Develop, Manufacture or Commercialize any Compound or Product; provided, however, that, if Elion is acquired by a Third Party, “Elion Know-How” shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Elion and the Persons that were Elion’s Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, “Elion Pre-Existing Affiliates”)) (“Elion Excluded Affiliates”) and (b) was not Controlled by Elion or any of the Elion Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Elion Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be an Elion Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Elion Know-How.

1.17 “Elion Patent Rights”. Elion Patent Rights means all Patent Rights in the Territory that are Controlled by Elion or any of its Affiliates as of the Effective Date or thereafter during the Term (other than Joint Patent Rights) that Cover any Compound or Product. The Elion Patent Rights existing as of the Effective Date are set forth on Schedule 1.16; provided, however, that, if Elion is acquired by a Third Party, “Elion Patent Rights” shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Elion and Elion Pre-Existing Affiliates) and (b) were not Controlled by Elion or any of the Elion Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Elion Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be an Elion Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Elion Patent Rights.

1.18 “EMA”. EMA means the European Medicines Agency and any successor agency.

1.19 “FDA”. FDA means the U.S. Food and Drug Administration and any successor agency.

1.20 “Field”. Field means all medical uses.

1.21 “First Commercial Sale”. First Commercial Sale means, with respect to a Product in a country, the first sale of such Product in such country by Processa, any of its Affiliates or any Sublicensee to the first unrelated Third Party (unless any such entity is an end-user of the Product) in such country for use or consumption of such Product in such country after receipt of the first Regulatory Approval for such Product in such country. Sales for purposes of testing the Product and sample purposes shall not be deemed a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Product-by-Product and country-by-country basis, as applicable.

1.22 “Governmental Authority”. Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.23 “IND”. IND means an investigational new drug application filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country or regulatory jurisdiction in the Territory other than the U.S., and all amendments and supplements thereto.

1.24 “Joint Intellectual Property”. Joint Intellectual Property means the Joint Inventions and Joint Patent Rights.

1.25 “Know-How”. Know-How means all unpatented technical information, trade secrets, formulae, standards, knowledge, directions, instructions, test protocols, procedures and results, studies, analyses, raw material sources, data, manufacturing data, and any other confidential or proprietary interest in information.

1.26 “Law” or “Laws”. Law or Laws means all laws, statutes, rules, regulations, orders, judgments, or ordinances of any Governmental Authority.

1.27 “Losses”. Losses means any and all (a) claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, awards, judgments, and settlement amounts (including special, indirect, incidental, and consequential damages, lost profits, and Third Party punitive and multiple damages), and (b) in connection with all of the items referred to in clause (a) above, any and all costs and expenses (including reasonable counsel fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened).

1.28 “Major Market”. Major Market means each of the United States, Canada, France, Germany, Italy, Spain, the United Kingdom, the People’s Republic of China (including Hong Kong, Taiwan and Macau), Republic of Korea, Australia, New Zealand and Japan.

1.29 “Manufacture” or “Manufacturing”. Manufacture or Manufacturing means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.30 “MHLW”. MHLW means the Japanese Ministry of Health, Labour and Welfare, and any successor agency.

1.31 “NDA”. NDA means a New Drug Application, as defined in the Act, filed with the FDA with respect to a Compound or Product, or an equivalent application filed with the Regulatory Authority of a country in the Territory other than the U.S., and all amendments and supplements thereto.

1.32 “Net Sales”. Net Sales means the gross amounts billed or invoiced by Processa, or any of its Affiliates or Sublicensees or assignees, to any Third Party with respect to sales of Products in the Territory, calculated in the same manner as reported in such Person’s audited financial statements, less the following:

- (a) Volume, cash or trade discounts, credits or allowances, including discounts in the form of inventory management fees paid to wholesalers and distributors all to the extent such discounts are included in the invoices and actually granted;
- (b) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;
- (c) Freight, postage, shipping and insurance costs incurred in transporting the applicable Products to the extent that such items are applicable to such sale and are separately itemized and invoiced and actually paid as evidenced by invoices, receipts or other appropriate documents;
- (d) Amounts paid (including rebates and chargeback payments or credits or other equivalents thereof) to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products not to exceed 25% of the originally billed or invoiced amount;
- (e) Bad debts, uncollectible amounts, and collection costs relating to the sale of Products that are actually written off provided that, if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid; and
- (f) To the extent not reimbursed by a third party, taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed, or otherwise imposed on the sales, transportation, delivery, use, exportation, or importation of the applicable Products.

Sales of Products between Processa and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, provided that the subsequent resale of such Products to a Third Party are included in the computation of Net Sales. Disposal or use of Products at or below cost for regulatory, development or charitable purposes, such as clinical trials, compassionate use, named patient use, or indigent patient programs, shall not be deemed a sale hereunder.

With respect to any sale of any Product in a given country for any substantive consideration other than monetary consideration on arm’s length terms (which has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary consideration), for purposes of calculating the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for cash at the average Net Sales price charged to Third Parties for cash sales in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, at the fair market value as determined in good faith based on pricing in comparable markets).

For purposes of calculating Net Sales for Combination Products in each applicable country:

(a) If a Product is sold in any country as part of a Combination Product involving a co-formulation or co-packaging of the Compound with an Other API for which Processa has not acquired (whether by acquisition or licensing) all of the exclusive rights to commercialize such Other API in such country, then the Net Sales for such Combination Product in such country used to determine Net Sales Milestone Payments, Net Sales Royalties, and any other use of Net Sales in this Agreement will be equal to the positive difference (if any) between (x) Net Sales of such Combination Product calculated as above (with the deductions set forth in Section 1.32 (a) – (f)) minus (y) all of the direct costs incurred by Processa to obtain, combine and manufacture the Other API into the Combination Product in such country or to obtain, combine and manufacture the other pharmaceutical product which includes the Other API into the Combination Product in such country.

(b) If a Product is sold in any country as part of a Combination Product involving a co-formulation or co-packaging of the Compound with an Other API for which (i) Processa has acquired (whether by acquisition or licensing) all of the exclusive rights to commercialize such Other API in such country and (ii) such Other API has demonstrated through pre-clinical and/or clinical studies an effect on cancer, then the Net Sales for such Combination Product in such country used to determine Net Sales Milestone Payments, Net Sales Royalties, and any other use of Net Sales in this Agreement will be equal to 35% of the positive difference (if any) between (x) Net Sales of such Combination Product calculated as above (with the deductions set forth in Section 1.32 (a) – (f)) minus (y) all of the direct costs incurred by Processa (including for clarity all royalties, milestones and other payments) to obtain, combine and manufacture the Other API in the Combination Product in such country or to obtain, combine and manufacture the other pharmaceutical product which includes the Other API into the Combination Product in such country.

(c) If a Product is sold in any country as part of a Combination Product involving a co-formulation or co-packaging of the Compound with an Other API for which (i) Processa has acquired (whether by acquisition or licensing) all of the exclusive rights to commercialize such Other API in such country and (ii) such Other API has demonstrated through pre-clinical and/or clinical studies no effect on cancer, then the Net Sales for such Combination Product in such country used to determine Net Sales Milestone Payments, Net Sales Royalties, and any other use of Net Sales in this Agreement will be equal to 50% of the positive difference (if any) between (x) Net Sales of such Combination Product calculated as above (with the deductions set forth in Section 1.32 (a) – (f)) minus (y) all of the direct costs incurred by Processa (including for clarity all royalties, milestones and other payments) to obtain, combine, and manufacture the Other API in the Combination Product in such country or to obtain, combine and manufacture the other pharmaceutical product which includes the Other API into the Combination Product in such country.

1.33 “Party”. Party means either Elion or Processa; “Parties” means both Elion and Processa.

1.34 “Patent Rights”. Patent Rights means all patent applications, patents, certificates of invention, applications for certificates of invention and priority patent filings, including any continuations, continuations-in-part, renewals, requests for continued examination and divisions of any such patents and patent applications, any patents or certificates of invention issuing from any of the foregoing, any extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, additions or supplementary patent certificates thereto, and all foreign counterparts thereof.

1.35 “Payments”. Payments means royalties and other amounts payable by Processa to Elion pursuant to this Agreement.

1.36 “Person”. Person means any natural person or any corporation, company, partnership, joint venture, firm, Governmental Authority, or other entity, including a Party. .

1.37 “Phase 1B”. Phase 1B means the clinical study to be conducted pursuant to Protocol ELC101-20 entitled a “Phase 1b Dose-escalation Study of the Safety and Pharmacokinetics of Fixed-dose Eniluracil with Escalating Doses of Capecitabine Administered Orally in Patients with Advanced, Refractory Gastrointestinal (GI) Tract Tumors with Dose Confirmation at the Recommended Phase 2 Dose (RP2D),” as approved by the FDA pursuant to IND for the Product or, after prior notification and discussion with Elion when commercially practicable, any FDA accepted modification of the Protocol that would still classify it as a Phase 1B or Phase 2 study. As used herein, “Dose Confirmation” shall mean any dose confirmation in the Phase 1B or any dose confirmation that facilitates a Phase 2.

1.38 “Phase 2”. Phase 2 means a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular indication or indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.39 “Phase 3”. Phase 3 means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

1.40 “Phase 4”. Phase 4 means a human clinical trial of a product which is (a) conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval or (b) conducted voluntarily after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority for enhancing marketing or scientific knowledge of an approved indication.

1.41 “Pivotal Clinical Trial” shall mean (a) a Phase 3 Clinical Trial that is intended by Company or its Affiliates or Sublicensees to be submitted (together with any other registration trials that are prospectively planned when such Phase 3 Clinical Trial is Initiated) for Regulatory Approval in the U.S. or the EU, or (b) any other Clinical Trial that is intended by Company or its Affiliates or Sublicensees to establish that a Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which Clinical Trial is a registration trial intended by Company or its Affiliates or Sublicensees to be sufficient for filing an application for a Regulatory Approval for such product in the U.S. or another country or some or all of an extra-national territory, solely as evidenced by the acceptance for filing for a Regulatory Approval for such Product after completion of such Clinical Trial.

1.42 “Processa Intellectual Property” means, collectively, Processa Know-How and Processa Patent Rights.

1.43 “Processa Know-How”. Processa Know-How means all Know-How Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than any Know-How included in Joint Intellectual Property) that is used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, “Processa Know-How” shall exclude any Know-How that (a) is Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and the Persons that were Processa’s Affiliates immediately prior to the closing of such acquisition transaction (such Affiliates, “Processa Pre-Existing Affiliates”)) (“Processa Excluded Affiliates”) and (b) was not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Processa Excluded Affiliate and applicable Know-How that is Controlled by such Affiliate shall be included in Processa Know-How.

1.44 “Processa Patent Rights”. Processa Patent Rights means all Patent Rights in the Territory Controlled as of the Effective Date or thereafter during the Term by Processa or any of its Affiliates (other than Joint Patent Rights) that Cover any Compound or Product and are used by Processa or any of its Affiliates in the Development, Manufacture or Commercialization of any Compound or Product; provided, however, that, if Processa is acquired by a Third Party, “Processa Patent Rights” shall exclude any Patent Rights that (a) are Controlled by such Third Party or the Affiliates of such Third Party (other than Processa and Processa Pre-Existing Affiliates) and (b) were not Controlled by Processa or any of the Processa Pre-Existing Affiliates immediately prior to the closing of such acquisition transaction; provided further that, if, after the closing of such acquisition, any such Processa Excluded Affiliate Develops or Commercializes any Compound or Product or otherwise performs any activities or obtains any rights with respect to any Compound or Product, such Affiliate will cease to be a Processa Excluded Affiliate and applicable Patent Rights that are Controlled by such Affiliate shall be included in Processa Patent Rights.

1.45 “Product”. Product means any pharmaceutical preparation containing one or more Compounds as its only active ingredient(s) or a Combination Product with the active ingredient. For the avoidance of doubt, nothing in this Agreement grants to Processa any right or license under any Patent Rights or Know-How Controlled by Elion with respect to any Other API.

1.46 “Regulatory Approval”. Regulatory Approval means an approval by the applicable Regulatory Authority of an NDA and any other approval, license, registration, permit, notification or authorizations (or waiver) of the applicable Regulatory Authority, which is necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given country or regulatory jurisdiction, other than any pricing or reimbursement approval.

1.47 “Regulatory Authority”. Regulatory Authority means any Governmental Authority with responsibility for granting licenses or approvals necessary for the development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a country or regulatory jurisdiction, including but limited to the FDA, EMA or MHLW.

1.48 “Regulatory Exclusivity”. Regulatory Exclusivity means exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or regulatory jurisdiction within the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act.

1.49 “Satisfactory Public Offering”. Satisfactory Public Offering means the firm commitment underwritten public offering of shares of common stock of Processa, par value \$0.0001 per share (the “Common Stock”) pursuant to a Registration Statement on Form S-1 filed and declared effective by the SEC, as more specifically described and satisfying all of the conditions in Sections 2.

1.50 “Satisfactory Public Offering Securities”. Satisfactory Public Offering Securities means shares of Common Stock issued to investors in the Satisfactory Public Offering.

1.51 “Senior Executive”. Senior Executive means, with respect to Elion, the CEO of Elion, or his or her designee, and, with respect to Processa, the CEO of Processa, or his or her designee. “Senior Executives” means the applicable officers of Elion and Processa.

1.52 “Sublicensee”. Sublicensee means a Third Party that has been granted a sublicense under the rights granted to Processa pursuant to Section 2.2 of this Agreement, beyond the mere right to purchase Compound or Product from Processa or its Affiliates.

1.53 “Territory”. Territory means all countries of the world.

1.54 “Third Party”. Third Party means any Person other than Elion or Processa or any of their respective Affiliates.

1.55 “U.S.” U.S. means the United States of America, including its territories and possessions.

1.56 “Valid Claim”. Valid Claim means any claim of (a) an issued and unexpired patent within the Elion Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other Governmental Authority of competent jurisdiction, or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application within the Elion Patent Rights; provided that such a claim within a patent application has not been canceled, withdrawn, or abandoned or been pending for more than seven (7) years from the date of its first priority filing in the applicable country. For clarity, a claim of a patent that, pursuant to clause (b), had ceased to be a Valid Claim before it issued but that subsequently issues and is otherwise described by clause (a), shall again be considered to be a Valid Claim once it issues until it is no longer considered a Valid Claim in accordance with clause (a).

1.57 Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition:	Section:
Abandoned Patents	Section 7.2(a)
Agents	Section 8.1
Commercialization Plan	Section 4.2
Condition Precedent	Section 2.1(a)
Condition Precedent Satisfaction Date	Section 2.1(a)
Confidential Information	Section 8.2
Courts	Section 12.1
Demand Registration	Section 6.2
Effective Date	Preamble
Elion	Preamble
Elion Excluded Affiliates	Section 1.15
Elion Parties	Section 10.1
Elion Pre-Existing Affiliates	Section 1.15
Elion Sole Inventions	Section 7.1(a)
First Tranche Shares	Section 6.1
Indemnified Party	Section 10.3(a)
Indemnifying Party	Section 10.3(a)
Infringement Claim	Section 7.3(a)
Joint Inventions	Section 7.1(b)
Joint Patent Rights	Section 7.2(b)
Late Payment Notice	Section 6.15
Litigation Conditions	Section 10.3(a)
MRS	Section 6.4
Offering Price	Section 2.1(a)
Paragraph IV Claim	Section 7.8(a)
Periodic Report	Section 6.10
Product Liability Claim	Section 10.1(b)
Processa	Preamble
Processa Excluded Affiliates	Section 1.42
Processa Parties	Section 10.2
Processa Pre-Existing Affiliates	Section 1.42
Processa Sole Inventions	Section 7.1(a)
Royalty Term	Section 6.8(b)
Second Tranche Shares	Section 6.1
Sole Inventions	Section 7.1(a)
Sublicensee Intellectual Property	Section 2.2(b)
Sublicense Materials	Section 2.2(b)
Taxes	Section 6.12
Term	Section 11.1
Third Party Claims	Section 10.1
Third Party Patent Licenses	Section 6.8(c)

1.58 Captions; Certain Conventions; Construction. All headings and captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires:

- (a) words of any gender include each other gender;
- (b) words such as “herein”, “hereof” and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear;
- (c) words using the singular shall include the plural, and vice versa;
- (d) the words “include,” “includes” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation”, “inter alia” or words of similar import;
- (e) the word “or” shall be deemed to include the word “and” (*i.e.*, shall mean “and/or”)
- (f) references to “Article,” “Section,” “subsection”, “paragraph”, “clause” or other subdivision, or to a Schedule, without reference to a document, are to the specified provision or Schedule of this Agreement; and
- (g) references to “\$” or “dollars” shall be references to U.S. Dollars.

This Agreement shall be construed as if the Parties drafted it jointly.

ARTICLE II **GRANTS OF RIGHTS**

2.1 Condition Precedent.

(a) The grant of license rights is conditioned upon Procesa’s closing of a Satisfactory Public Offering by October 30, 2020 pursuant to which (i) Procesa has raised in excess of \$15,000,000 in gross proceeds from the sale of shares of its Common Stock pursuant to a firm commitment underwriting registered on a Registration Statement on Form S-1 filed and declared effective by the SEC (such price per share set forth in the applicable Registration Statement on Form S-1 which has been declared effective, the “Offering Price”), and (ii) Procesa has listed its Common Stock for trading on the Nasdaq Capital Markets (collectively, the “Condition Precedent”) during the Condition Precedent Period. The date on which Procesa and Elion satisfy the Condition Precedent, if any, shall be the “Condition Precedent Satisfaction Date.”

(b) Expiration of the Agreement. If, for any reason (including a failure to meet the conditions in Sections 2.1 prior to the end of the Condition Precedent Period) the Condition Precedent is not fully satisfied within the Condition Precedent Period, then this Agreement shall terminate in accordance with Section 11.2.

2.2 Licenses.

(a) License. Subject to the terms of this Agreement, upon Processa's satisfaction of the Condition Precedent pursuant to Section 2.1, Elion shall, and hereby does, grant to Processa an exclusive (even as to Elion and its Affiliates), royalty-bearing right and license, including the right to sublicense in accordance with Section 2.2(b), under the Elion Intellectual Property and Elion's interest in the Joint Intellectual Property, to Develop, Manufacture, use and Commercialize, including filing for, obtaining and maintaining Regulatory Approval for, Products in the Field in the Territory.

(b) Sublicenses. From and after the Condition Precedent Satisfaction Date, Processa shall have the right to grant sublicenses under the licenses to Elion Intellectual Property and Elion's interest in the Joint Intellectual Property granted to Processa under Section 2.2(a) to its Affiliates and to Third Parties subject to Elion's prior written approval; provided, however, that any such sublicense shall be subject to all applicable terms and conditions of this Agreement. Each agreement with each Sublicensee must include grants of rights to Processa sufficient to enable Processa to grant substantially the rights set forth in Sections 11.8(b) through 11.8(f) with respect to (i) all Know-How and Patent Rights (including all applicable pre-clinical and clinical data, including pharmacology and biology data; Manufacturing documents and materials; and Manufacturing technologies) Controlled by such Sublicensee during the Term and used by such Sublicensee in the Development, Manufacture or Commercialization of any Compound or Product (collectively, "Sublicensee Intellectual Property"); (ii) all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held by such Sublicensee, including related correspondence with Regulatory Authorities; (iii) all Manufacturing agreements to which such Sublicensee is a party that are related to Compounds or Products; (iv) all of such Sublicensee's inventory of Compounds and Products existing as of the applicable date; and (v) all trademarks owned by such Sublicensee and used solely in connection with the Products, along with all associated goodwill ((i) – (v), collectively, "Sublicense Materials").

2.3 Rights Retained by the Parties. Any rights of Elion or Processa, as the case may be, not expressly granted to the other Party under the provisions of this Agreement shall be retained by such Party.

2.4 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, including the licenses granted under Section 2.1, 2.2 or 11.8(e) to Patent Rights and Know-How (including any data included in the Know-How), are and will otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined in Section 101(35A) of the Bankruptcy Code. Each Party will retain and may fully exercise all of its respective rights and elections under the Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of applicable Law outside the United States that provide similar protection for “intellectual property.”

2.5 Transfer of Elion Material and Know-How. During the period beginning on the Condition Precedent Satisfaction Date and ending on the date that is thirty (30) days after the Condition Precedent Satisfaction Date, Elion shall transition Elion Know-How to Processa and provide Processa with reasonable amounts of consultation regarding the transferred Elion Know-How. In addition, Elion, will transfer all material to Processa related to Eniluracil including but not limited to i) documents including communications, reports, white papers and supporting material, lab or study notes, manufacturing documents, and similar material, ii) drug substance, iii) drug product, iv) know-how related to the development of Eniluracil, and v) regulatory approvals or clearances or submissions, such as transferring the Eniluracil IND to Processa.

ARTICLE III **DEVELOPMENT**

3.1 General. From and after the Condition Precedent Satisfaction Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Processa (together with its Affiliates or Sublicensees) shall control and be solely responsible for the Development of and regulatory activities with respect to Compounds and Products in the Field in the Territory, including all costs and expenses relating thereto; provided, however, that, prior to the Condition Precedent Satisfaction Date, Elion will reasonably cooperate with Processa, as Processa may reasonably request and at Processa’s expense, to enable Processa to interact with FDA in order to discuss the Development of and regulatory activities with respect to Compounds and Products for the indications Processa desires to pursue with respect to such Compounds and Products. If Processa requests Elion’s cooperation as described above, the Parties shall mutually agree in advance on a budget therefor, and Processa shall reimburse Elion for any expenses incurred by Elion under this Section 3.1 within thirty (30) days after receiving an invoice therefor.

3.2 Exchange of Information Regarding Development. At least once each Calendar Year, beginning on the Effective Date and ending on the date on which Processa obtains the first Regulatory Approval for a Product in a Major Market, Processa shall provide Elion with a reasonably detailed report describing Processa’s Development activities and the summary results thereof with respect to all Compounds and Products.

ARTICLE IV
COMMERCIALIZATION

4.1 **General.** From and after the Condition Precedent Satisfaction Date, and subject to the terms of this Agreement, including the requirements of ARTICLE V, Processa (together with its Affiliates or Sublicensees) shall control and be solely responsible for the Commercialization of Products in the Field in the Territory, including all costs and expenses relating thereto.

4.2 **Commercialization Plans.** During the Royalty Term with respect to each Product, at least thirty (30) days prior to the commencement of each Calendar Year, Processa shall provide Elion, for information purposes only, a summary of the planned Commercialization activities to be conducted by or on behalf of Processa and its Affiliates and Sublicensees with respect to such Product in each country in the Territory during such Calendar Year (each such plan, a "Commercialization Plan").

ARTICLE V
DILIGENCE

5.1 **Commercially Reasonable Efforts.** From and after the Condition Precedent Satisfaction Date during the Term, Processa shall, directly or through its Affiliates or Sublicensees, use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval for one (1) Product in the Field in the U.S. Without limiting or derogating from the foregoing, Processa, by itself or through its Affiliates or Sublicensees, shall meet each of the following milestones within the respective time periods set forth herein:

- (a) Dosing of a first patient in a Phase 1B trial for the Product within 12 months from the Condition Precedent Satisfaction Date; and
- (b) Dosing of a first patient in a Phase 2 or Phase 3 trial for the Product within 48 months from the Condition Precedent Satisfaction Date.

5.2 **Termination for Failure to Meet Diligence Obligations.** If, at any time during the Term, Processa fails to timely achieve any of the foregoing milestones, or if Elion reasonably believes that Processa (itself and through its Affiliates and Sublicensees or assignees) has not complied with its obligations under Section 5.1, Elion shall provide written notice to Processa specifying the nature of such reasonable belief, and Elion may terminate this Agreement pursuant to Section 11.5.

ARTICLE VI
FINANCIAL PROVISIONS

6.1 Equity and Cash Upon Satisfying Condition Precedent. In partial consideration for the rights granted to Processa hereunder, if the Condition Precedent pursuant to Section 2.1 is satisfied, Processa: (a) shall pay to Elion, as Elion shall direct, \$100,000 in immediately available funds within five (5) Business Days following the Condition Precedent Satisfaction Date; (b) shall issue to Elion (which may include its designees who are Affiliates of Elion), for no additional consideration, 100,000 shares of Common Stock within twenty (20) Business Days following the Condition Precedent Satisfaction Date (the "First Tranche Shares") and (c) subject to the proviso to this sentence, shall for no additional consideration issue 400,000 shares of Common Stock (the "Second Tranche Shares") directly to a grantor trust at Elion's sole cost (the "Trust"), which shares shall be held by the trustee of such trust in a brokerage account held by Merrill Lynch or a similar brokerage firm if possible, pursuant to a grantor trust arrangement that is consistent with the principles of IRS Rev. Proc. 92-64 and IRS Notice 2000-56; provided that (x) the trustee of the grantor trust shall be required to release the Second Tranche Shares from the grantor trust to Elion (or its designees who are Affiliates of Elion) on January 15, 2021, and (y) in the case that the Offering Price is less than \$8.34, then the number of Second Tranche Shares shall be increased (and therefore Processa shall cause additional Second Tranche Shares to be issued to and held by such grantor trust) to equal the sum of 100,000 shares plus the quotient obtained by dividing \$2,500,000 by the Offering Price. *By way of example, if the Offering Price equals \$5 per share, then the number of Second Tranche Shares issued by Processa and held by the grantor trust would equal 600,000 (which is the sum of 100,000 plus 500,000).* The First Tranche Shares and Second Tranche Shares will contain a restrictive legend that restricts the sale, transfer, or disposition of these shares ("Lock-up") as follows: 50% of the shares of Common Stock shall subject to the Lock-up for six months following the Effective Date; 25% of the shares of Common Stock shall be subject to the Lock-up for nine months following the Effective Date and the remaining 25% of the shares of Common Stock shall be subject to the Lock-up for one year following the Effective Date. In addition, the shares of Common Stock received by Elion shall contain a customary restrictive legend that specifies that such shares of Common Stock have not been registered with the Securities and Exchange Commission ("SEC") until such time as Processa shall receive a satisfactory opinion of legal counsel (which may be Processa's legal counsel) that specifies that such restrictive legend is no longer required by law; it being understood and agreed that Processa shall reimburse Elion for the reasonable costs associated with such opinion if not delivered by Processa's legal counsel.

6.2 Demand Registration. Notwithstanding the foregoing, unless a resale exemption from registration is available to Elion for the shares proposed to be transferred (such as Rule 144 of the Securities Act of 1933, as amended) pursuant to Section 6.1, at any time following the date that is one hundred and eighty (180) days following the Effective Date, Elion may request that the shares of Common Stock issued to it pursuant to this Article VI be registered for resale with the SEC from time to time by Processa (without an underwriter or placement agent) (the "Demand Registration"). Upon receipt of a Demand Registration, Processa shall use commercially reasonable efforts to register such shares for resale by Elion and shall use its commercially reasonable efforts to and keep such registration statement effective for at least 12 months (or such shorter period as will terminate when all the shares covered by the registration statement have been sold or withdrawn).

6.3 Cessation of Demand Registration. The Demand Registration right shall cease and no longer be applicable once the shares issued to Elion issued under Section 6.1 are sold or may be sold without volume limitation restrictions under Rule 144 of the Securities Act of 1933, as amended, provided, however, that if a director, officer, employee or agent of Elion should become a member of Processa's Board of Directors or employed as an Officer in Processa after the Effective Date, the Demand Registration right shall cease and no longer be applicable once the shares issued to Elion under Section 6.1 are sold or may be sold under Rule 144 of the Securities Act of 1933, as amended, in compliance with the requirements for sales by Affiliates (as defined under Rule 144). Processa agrees that the rights granted to Elion under this Article VI shall be assignable to the assignees of the shares of Common Stock of Processa who are designated by Elion and who are Affiliates of Elion provided that the Rule 144 holding period with respect to such shares is not extended as a result of such transfer (in which case, the Demand Registration right shall immediately cease with respect to such shares).

6.4 Development and Regulatory Milestone Payments. The development and regulatory milestone payments shall be provided to Elion in 2 forms: Milestone Restricted Shares which shall be identical to the shares of Common Stock which constitute the Satisfactory Public Offering Securities (“MRSs”) or cash. The MRSs shall be issued within five (5) Business Days following satisfaction of the applicable Milestone Event and shall be subject to a six month Lock-up following the date of satisfaction of such applicable Milestone Event. All MRSs shall contain a customary restrictive legend that specifies that such shares of Common Stock have not been registered with the SEC until such time as Processa shall receive a satisfactory opinion of legal counsel (which may be Processa’s legal counsel) that specifies that such restrictive legend is no longer required by law; it being understood and agreed that Processa shall reimburse Elion for the reasonable costs associated with such opinion if not delivered by Processa’s legal counsel. Each milestone cash payment owed by Processa to Elion pursuant to this Section 6.4 shall be payable by Processa within thirty (30) days following the first achievement of the corresponding milestone event. For the avoidance of doubt each milestone payment, whether it be MRSs or cash, is only payable once, regardless of the number of times such milestone may be achieved by Processa, its Affiliates, and Sublicensees. For purposes of this Section 6.4, if the Initiation of a clinical trial of a Licensed Product satisfies more than one of the clinical milestone events below (*e.g.*, if the first clinical trial of a Licensed Product is a Pivotal Trial), then the milestone payments corresponding to both of such clinical milestone events shall be made simultaneously upon the dosing of the first patient of such clinical trial. In addition, if a given milestone event is achieved by a Licensed Product without one or more preceding milestone events having been achieved by such Licensed Product, then the milestone payments corresponding to such skipped milestone events shall be made simultaneously upon achievement of such milestone event by such Licensed Product.

Milestone Event	Milestone Payment (\$)
1. 1st Year Anniversary of Effective Date	100,000 MRSs
2. 2nd Year Anniversary of Effective Date	100,000 MRSs
3. 1st Patient in Dose Confirmation Study	100,000 MRSs
3. NDA Submission	300,000 MRSs
4. 1st FDA Approval in US	\$5,000,000
5. 2nd FDA Approval in US	\$3,000,000
6. 1st Regulatory Approval Outside US	\$2,000,000
7. 2nd Regulatory Approval Outside US	\$2,000,000

6.5 Anti-Dilution from Reverse Split and Other Adjustments. Processa hereby agrees that if the Common Stock (including the First Tranche Shares and Second Tranche Shares) and MRSs issuable pursuant to this Article VI (or any securities to which such shares are converted or otherwise exchanged into as a result of any merger, consolidation or other comparable business reorganization) are the subject of any reverse stock split, stock dividend or other comparable adjustment, then Processa covenants and agrees to cause and otherwise ensure that the Common Stock (including the First Tranche Shares and Second Tranche Shares) and MRSs (and any conversion securities or other consideration) will be proportionately adjusted accordingly to achieve a result as if no such reverse stock split, stock dividend or other comparable adjustment occurred.

6.6 Development and Commercialization Costs. For clarity, following the Effective Date, Processa shall be solely responsible for all costs it incurs in Developing and Commercializing Compounds and Products, including all Manufacturing costs.

6.7 Sales Milestone Payments. Processa shall pay Elion the one-time, non-refundable, non-creditable sales milestone payments set forth in the table below within thirty (30) days after the end of the first Calendar Quarter during which the Worldwide Annual Net Sales first reach the values indicated below. For clarity, the milestone payment reached will apply once and only once when the milestone is first achieved (and more than one payment may occur in each Calendar Year). Thereafter, the milestone will no longer apply.

Worldwide Annual Net Sales	Amount
\$50M	\$2,000,000
\$100M	\$4,000,000
\$250M	\$10,000,000
\$500M	\$20,000,000
\$1 Billion	\$40,000,000

6.8 Product Royalties.

(a) Royalty Rate. Processa shall pay to Elion royalties, on a Product-by-Product and country-by-country basis, equal to 9% of Net Sales of Products in the Territory during each Calendar Quarter during the applicable Royalty Term for the aggregate Worldwide Annual Net Sales in the Territory, subject to adjustment as provided in this Section 6.8. Upon the expiration of the Royalty Term with respect to each Product in each country, Processa shall have a fully-paid up irrevocable license with respect to such Product in such country. Notwithstanding anything to the contrary contained herein, in no event shall the royalty reductions described in this Section 6.8, alone or together, reduce the royalties payable to Elion below 4.5% of Net Sales for a Product in a country in any given Calendar Quarter; it being understood and agreed that Processa may carry over and apply any such royalty reductions, which are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth above in this 6.8(a), to any subsequent Calendar Quarter(s) and shall continue applying such reduction on a Calendar Quarter basis thereafter until fully deducted, in all cases subject to the limitation set forth in this sentence.

(b) Royalty Term and Adjustments. Processa's royalty obligations to Elion under this Section 6.8 shall commence on a country-by-country and Product-by-Product basis on the Effective Date and shall expire on a country-by-country basis and Product-by-Product basis on the latest of (i) expiration or invalidation of the last Valid Claim Covering such Product in such country and (ii) the tenth (10th) anniversary of the date of the First Commercial Sale by Processa or any of its Affiliates or Sublicensees to a non-Sublicensee Third Party of such Product in such country and (iii) the expiration of the last Regulatory Exclusivity relating to such Product in such country (the "Royalty Term"); provided that, during any period within the Royalty Term remaining after the expiration of all Valid Claims Covering such Product in such country and all Regulatory Exclusivity as to such Product in such country, the royalties payable as to such Product in such country under this Section 6.8 shall be reduced to 4.5% of Net Sales for such Product in such country pursuant to Section 6.8.

(c) Third Party Payments. If, in the opinion of patent counsel mutually acceptable to both Processa and Elion, in order to Develop, Manufacture, use or Commercialize a Product in the Field in a country of the Territory without infringing any third party intellectual property rights relating to the Elion Intellectual Property, Processa or its Affiliate or Sublicensee is obligated to obtain a license or comparable grant of rights (*e.g.*, a covenant not to sue) under any Patent Rights from a Third Party ("Third Party Patent Licenses") and pay a royalty under such Third Party Patent License with respect to such Product in such country, then, subject to Section 6.8, forty percent (40%) of such royalties actually paid by Processa, its Affiliates or Sublicensees shall be creditable against royalties payable to Elion hereunder with respect to such Product in such country; provided that, if Processa is obligated to enter into any Third Party Patent License, Processa shall use Commercially Reasonable Efforts to minimize the royalties owed by Processa under such Third Party Patent License.

6.9 Sublicense. Subject to the examples provided below, if (a) Processa sub-licenses all rights to the Product in any country in the Territory to a Third Party, Elion shall receive thirty-three percent (33%) of any Sublicense Consideration including Development and Regulatory Milestones (Section 6.4 and 6.5), Sales Milestones (Section 6.7) and Product Royalties (Section 6.8); and (b) notwithstanding the foregoing, in the event that Processa receives Sublicense Consideration on account of a specific Product, then in such case Processa shall be required to pay Elion thirty-three percent (33%) of all Sublicense Consideration within thirty (30) days of receipt, but shall not be required to pay Development and Regulatory Milestone Payment (Section 6.4 and 6.5) or Sales Milestone Payment (Section 6.7) or Product Royalties (Section 6.8) on account of such specific Product in addition to the Sublicense Payments. To clarify, three example scenarios are presented:

Example 1: If Processa Develops the Product and receives Regulatory Approval in multiple countries in the Territory and licenses out the commercial sales to Sublicensee in these multiple countries in the Territory such that Processa no longer retains any rights to commercialize the Product in these multiple countries in the Territory, then the financial terms of this ARTICLE VI would then be the following: Sections 6.4 - 6.5 would apply, Sections 6.7 - 6.8 would no longer apply, and this Section 6.9 would apply such that Processa shall pay Elion thirty-three percent (33%) of all Sublicense Consideration.

Example 2: If Processa Develops and Commercializes the Product in US while Sublicensing the Product for Development and Commercialization in other territories, then the financial terms of ARTICLE VI would then be the following: Sections 6.4 - 6.5 would apply, Sections 6.7 - 6.8 would only apply to the countries in the Territory in which Processa Commercializes the Product, and this Section 6.9 would apply such that Processa shall pay Elion thirty-three percent (33%) of all Sublicense Consideration.

Example 3: If Processa sublicenses the Product prior to Phase 3 trial prior to any Regulatory Approval of the Product and Sublicensee completes Development, obtains Regulatory Approval, and Commercializes the Product, then the financial terms of ARTICLE VI would then be the following: for Sections 6.4 – 6.5 Processa would pay for milestones that it has completed, the remaining milestones of Section 6.4 – 6.5 not completed by Processa would no longer apply, Sections 6.7 – 6.8 would not apply, and this Section 6.9 would apply such that Processa shall pay Elion thirty-three percent (33%) of all Sublicense Consideration.

“Sublicense Considerations” shall mean any payments or other consideration that Processa or its Affiliates receive as a direct result of the grant of a sublicense or an option to obtain such sublicense, including without limitation license fees, license option fees, milestone payments, license maintenance fees and equity and other securities (including earnouts and contingent value rights and other comparable deferred payment mechanisms), provided that in the event that Processa or its Affiliates receive non-monetary consideration in connection with a sublicense, Sublicense Considerations shall be calculated based on the fair market value of such consideration or transaction, assuming an arm’s length transaction made in the ordinary course of business. Notwithstanding the foregoing, “Sublicense Considerations” shall not include: (a) Net Sales or (b) amounts expressly dedicated to, and actually expended upon to reimburse Processa and its Affiliates, following any such sublicense, for, the Development of Products, up to the actual costs incurred by Processa and its Affiliates for such activities. Processa shall pay Elion the sublicense fee within thirty (30) days after the receipt of the Sublicense Consideration.

6.10 Reports; Payments. Within thirty (30) days after the end of each Calendar Quarter commencing from the earlier of (a) the First Commercial Sale of a Product; or (b) the grant of a sublicense or receipt of Sublicense Consideration, Processa shall furnish Elion with a quarterly report (“Periodic Report”) detailing, at a minimum, the following information for the applicable Calendar Quarter, each listed by Product and by country of sale: (i) the total number of units of Product sold by Company, its Affiliates and Sublicensees for which royalties are owed to Elion hereunder, including a breakdown of the number and type of Products sold, (ii) gross amounts received for all such sales, (iii) deductions by type taken from Net Sales as specified herein, (iv) Net Sales, (v) Royalties and milestone payments owed to Elion, listed by category, (vi) Sublicense Consideration received during the preceding Calendar Quarter and sublicense fees due to Elion, (vii) the currency in which the sales were made, including the computations for any applicable currency conversions, (viii) invoice dates and all other data enabling the royalties and sublicense fees payable to be calculated accurately and (ix) a detailed summary of progress against each development and commercial milestone, and an estimate of the timing of the achievement of the next development and commercial milestone. Once the events set forth in sub-section (a) or (b), above, have occurred, Periodic Reports shall be provided to Elion whether or not royalties, milestone payments or sublicense fees are payable for a particular Calendar Quarter. In addition to the foregoing, upon Elion’s reasonable request, Processa will provide to Elion such other information as may be reasonably requested by Elion, and will otherwise cooperate with Elion as reasonably necessary, to enable Elion to verify Processa’s compliance with the payment and related obligations under this Agreement, including verification of the calculation of amounts due to Elion under this Agreement and of all financial information provided or required to be provided in the Periodic Reports. Concurrently with each such report, Processa shall pay to Elion all amounts payable by it under Sections 6.4, 6.7, 6.8 and 6.9.

6.11 Books and Records; Audit Rights. Processa shall keep complete and accurate records of the underlying revenue and expense data relating to the calculations of Net Sales and payments required by 6.4, 6.7, 6.8 and 6.9. Elion shall have the right, once annually at its own expense, to have an independent, certified public accounting firm, selected by Elion and reasonably acceptable to Processa, review any such records of Processa in the location(s) where such records are maintained by Processa upon reasonable notice (which shall be no less than fourteen (14) days prior notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under 6.4, 6.7, 6.8 and 6.9 within the thirty-six (36) month period preceding the date of the request for review. The report of such accounting firm shall be limited to a certificate stating whether any report made or payment submitted by Processa during such period is accurate or inaccurate and the actual amounts of Net Sales, milestone payments, Sublicense Consideration and royalties due, for such period. Processa shall receive a copy of each such report concurrently with receipt by Elion. Should such inspection lead to the discovery of a discrepancy to Elion's detriment, Processa shall pay within five (5) Business Days after its receipt from the accounting firm of the certificate the amount of the discrepancy plus interest calculated in accordance with Section 6.15. Elion shall pay the full cost of the review unless the underpayment of royalties is greater than five percent (5%) of the amount due for any applicable Calendar Year, in which case Processa shall pay the reasonable cost charged by such accounting firm for such review. Any overpayment by Processa revealed by an examination shall be fully creditable against future Payments.

6.12 Tax Matters. All payments to be made to Elion by Processa hereunder shall be reduced by or on account of any taxes, levies, imposts, duties, charges, value added taxes ("VAT"), assessments or fees (collectively, "Taxes") that are required by any applicable Law (with due regard to any relief to which Elion may be entitled) that Taxes be deducted and withheld from any payment made to Elion by Processa under this Agreement. If any such applicable Law requires (with due regard to any relief to which Elion may be entitled) that Taxes be deducted and withheld from any payment made to Elion by Processa under this Agreement, Processa shall (a) deduct those Taxes, together with any interest and penalties properly assessed thereon, from such payment or from any other payment owed by Processa hereunder; (b) transmit the amounts so deducted to the proper Governmental Authority; (c) send evidence of the requirement together with proof of due transmission of the amounts described in clause (b) to Elion promptly following such payment; and (d) remit to Elion the net amount of such payment remaining after the payment of such Taxes. In determining whether to deduct any amount hereunder and prior to making such deduction, Processa shall contact Elion and reasonably consider the documentation supplied by Elion, and of other facts known to Processa, supporting a reduction in any Tax otherwise required to be deducted, or a credit therefor or refund thereof. Processa will reasonably cooperate with Elion in respect of Tax matters relating to payments made by Processa to Elion under this Agreement and any disputes with a Governmental Authority regarding such matters (at Elion's sole cost and expense), including without limitation: (y) complying with reasonable requests from Elion to change the form, place or other circumstances of payments to be made to Elion by Processa under this Agreement so as to reduce the incidence of Taxes on such payments or recover any Taxes imposed on such payments (any such recovery to be for the benefit of Elion); and (z) in connection with any official or unofficial audit or contest relating to such payments. Notwithstanding anything in this Agreement to the contrary, if any failure to comply with applicable Laws or filing or record retention requirements by a Party leads to the imposition of withholding Tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then (i) the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no such action occurred, and (ii) otherwise, the sum payable by that Party (in respect of which such deduction or withholding is required to be made) shall be made to the other Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable Law.

6.13 Payment Method and Currency Conversion. All Payments shall be made in U.S. dollars in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Processa's election, to Elion's bank account, or to such other bank account as Elion shall designate in a notice at least ten (10) days before the payment is due. For the purposes of determining the amount of any royalties or other payments due for the relevant Calendar Quarter under this Agreement, the amount of Net Sales in any foreign currency shall be converted into U.S. dollars in accordance with the prevailing rates of exchange for the relevant month for converting such first currency into such other currency used by Processa's (or its Sublicensee's) internal accounting systems, which are independently audited on an annual basis. Upon request by Elion, Processa shall disclose the bases for the rates of exchange used for purposes of assuring that such rates reflect prevailing rates of exchange.

6.14 Blocked Payments. If by reason of applicable Laws in any country in the Territory, it becomes impossible or illegal for Processa or its Affiliates or Sublicensees to transfer, or have transferred on its behalf royalties or other payments to Elion or to Processa or its Affiliates or Sublicensees, Processa shall promptly notify Elion of the conditions preventing such transfer. To the extent any payments to Elion cannot be transferred pursuant to the preceding sentence, such amounts shall be deposited in local currency in the relevant country to the credit of Elion in a recognized banking institution designated by Elion or, if none is designated by Elion within a period of thirty (30) days, in a recognized banking institution selected by Processa or its Affiliate or Sublicensee, as the case may be, and identified in a notice given to Elion. If so deposited in a foreign country, Processa shall provide, or cause its Affiliate or Sublicensee to provide, reasonable cooperation to Elion so as to allow Elion to assume control over such deposit as promptly as practicable.

6.15 Late Payments. If a Party shall fail to make a timely payment pursuant to the terms of this Agreement, the other Party shall provide written notice of such failure to the non-paying Party (a "Late Payment Notice"), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at an annual rate equal to the "prime rate", as reported by The Wall Street Journal, plus five percent (5%).

ARTICLE VII
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION
AND RELATED MATTERS

7.1 Ownership of Inventions.

(a) Sole Inventions. Each Party shall exclusively own all inventions relating to any Compound or Product or its manufacture or use made solely by such Party, its employees, agents, and consultants ("Sole Inventions"). Sole Inventions made solely by Processa, its employees, agents and consultants are referred to herein as "Processa Sole Inventions". Sole Inventions made solely by Elion, its employees, agents and consultants are referred to herein as "Elion Sole Inventions". For clarity, products Covered by Processa Sole Inventions shall be deemed Products for the purpose of this Agreement.

(b) Joint Inventions. The Parties shall jointly own all inventions relating to any Compound or Product or its manufacture or use made jointly by employees, agents and consultants of Processa, on the one hand, and employees, agents and consultants of Elion, on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions"). Joint Inventions may only be used in accordance with and subject to the terms and conditions of this Agreement.

(c) Inventorship. For purposes of determining whether an invention is a Processa Sole Invention, an Elion Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent Laws.

7.2 Prosecution and Maintenance of Patent Rights

(a) Prosecution of Elion Patent Rights. With respect to Elion Patent Rights, Elion and Processa shall cooperate in good faith in connection with the continued prosecution and maintenance by Elion of such Elion Patent Rights. If Processa satisfies the Condition Precedent pursuant to Section 2.1, the out-of-pocket costs and expenses incurred by Elion after the Condition Precedent Satisfaction Date to obtain, prosecute and maintain Elion Patent Rights shall be borne one hundred percent (100%) by Processa. Elion shall notify Processa at least ninety (90) days prior to the deadline for entering into national phase with respect to any PCT application included in Elion Patent Rights. No later than sixty (60) days prior to entry into national phase, Processa shall provide Elion with a list of any countries in which Processa would like Elion to file. Elion shall file international patent applications, or designate for national filing and file, in all countries requested by Processa. Elion shall promptly deliver to Processa copies of all official correspondence with the applicable patent and trademark offices in the Territory relating to the Elion Patent Rights and, after the Condition Precedent Satisfaction Date shall promptly provide Processa drafts of all proposed material filings and correspondence to any patent authority with respect to the Elion Patent Rights for Processa's review and comment prior to the submission of such proposed filings and correspondences. Elion shall keep Processa informed of the status of all pending patent applications that pertain to any Compound or Product. Elion, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Processa regarding any aspect of such patent prosecutions. Elion shall not abandon any Elion Patent Rights (the "Abandoned Patents") without at least ninety (90) days' prior notice to Processa. If Elion decides to abandon any Elion Patent Rights, Processa shall have the option to continue to prosecute and maintain the Abandoned Patents in Elion's name.

(b) Prosecution of Joint Patent Rights Processa shall be responsible for obtaining, prosecuting, and/or maintaining patents and patent applications, in any countries in the Territory, Covering Joint Inventions (“Joint Patent Rights”). The out-of-pocket costs and expenses incurred to obtain, prosecute and maintain Joint Patent Rights shall be borne one-hundred percent (100%) by Processa. Processa shall keep Elion informed of the status of all pending Joint Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Elion regarding any aspect of such patent prosecutions. Processa shall not abandon any Joint Patent Right without at least ninety (90) days’ prior notice to Elion. If Processa decides to abandon any Joint Patent Right, Elion shall have the option to continue to prosecute and maintain such Joint Patent Right jointly in both Parties’ names, at Elion’s sole expense.

(c) Prosecution of Processa Patent Rights Processa has the sole right, but not the responsibility, to obtain, prosecute, and/or maintain the Processa Patent Rights. Processa shall keep Elion informed of the status of all pending Processa Patent Rights. Processa, its agents and attorneys shall not unreasonably decline to implement or incorporate any comments of Elion regarding any aspect of such patent prosecutions. Processa shall not abandon any Processa Patent Right without at least ninety (90) days’ prior notice to Elion. If Processa decides to abandon any Processa Patent Right, Elion shall have the option to continue to prosecute and maintain such Processa Patent Right jointly in both Parties’ names, at Elion’s sole expense.

(d) Cooperation. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of Elion Patent Rights, Joint Patent Rights, and Processa Patent Rights, pursuant to this Section 7.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates, pediatric extensions, and their equivalent with respect thereto. Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by this Section 7.2; and (ii) promptly informing the other Party of any matters coming to such Party’s attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications.

7.3 Third Party Infringement.

(a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Elion Patent Rights, Processa Patent Rights or Joint Patent Rights, or (ii) unauthorized use or misappropriation of any of the Elion Know-How, Processa Sole Invention or Joint Inventions, in the case of either clause (i) or clause (ii), that would reasonably be expected to adversely impact the (A) Development, Manufacture, use or Commercialization of a Compound or Product in the Field in the Territory, or (B) the valid scope of the rights licensed to Processa under ARTICLE II (an “Infringement Claim”), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.

(b) Initial Right to Enforce. Subject to Section 7.3(c), Processa (itself or through its Affiliate or Sublicensee) shall have the first right, but not the obligation, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (*i.e.*, prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce the Processa Intellectual Property, Elion Intellectual Property and Joint Intellectual Property with respect to an Infringement Claim; provided, however, that Processa shall (i) consult with Elion in good faith with respect to any claim that any Elion Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any reasonable comment from Elion regarding any aspect of defending against any such claim described in clause (i). Any such suit by Processa shall be brought either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Elion shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Processa in connection with such suit, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Elion in connection with such cooperation. For clarity, as between Elion and Processa, (A) Elion shall have the sole right, but not the obligation, to protect Elion Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim and (B) the Parties shall jointly determine by mutual agreement whether and how to protect Joint Intellectual Property against any suspected misappropriation or infringement that does not constitute an Infringement Claim, and the provisions of this ARTICLE VII shall not apply with respect thereto.

(c) Step-In Right. If Processa does not initiate a suit or take other appropriate action that it has the initial right to initiate or take with respect to an Infringement Claim pursuant to Section 7.3(b), then Elion may, in its discretion, provide Processa with notice of Elion's intent to initiate a suit or take other appropriate action. If Elion provides such notice and Processa does not initiate a suit or take such other appropriate action within thirty (30) days after receipt of such notice from Elion, then Elion shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Processa Intellectual Property, Elion Intellectual Property and Joint Intellectual Property. Any suit by Elion shall be either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses as reasonably requested by Elion in connection with such suit, as may be reasonably requested by Elion; provided that Elion shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation.

(d) Conduct of Certain Actions; Costs. The Party initiating suit or taking other action with respect to an Infringement Claim shall have the sole and exclusive right to select counsel for, and otherwise control, any suit or action initiated by it pursuant to Section 7.3(b) or 7.3(c). The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to Sections 7.3(b) and 7.3(c), including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate, but not control, and be represented in, any such suit by its own counsel at its own expense.

(c) Recoveries. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Party that assumes control over enforcing any Infringement Claim shall be allocated between the Parties as follows:

(i) first, to reimburse the Parties' actual out-of-pocket expenses (including reasonable counsel fees and expenses) incurred in pursuing such Infringement Claim; and

(ii) second, if Processa controlled the defense of the Infringement Claim any remaining amount shall be shared by the Parties, with Processa retaining 75% of such remaining amount and Elion retaining 25% of such remaining amount. If Elion controlled the defense of the Infringement Claim any remaining amount following reimbursement of expenses under clause (i) shall be retained by Elion.

7.4 Patent Invalidation Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against an Elion Patent Right, Processa Patent Right or Joint Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Elion shall have the first right, but not the obligation, to defend against any such action involving an Elion Patent Right, and the costs of any such defense shall be at Elion's expense; provided, however, that, in the case of any *inter partes* review or similar post-grant matter before the Patent Trial and Appeal Board or similar administrative body that is based on the same subject matter as any claim or counterclaim in any Infringement Claim or Paragraph IV Claim, Processa shall have the first right, but not the obligation, to defend against any such action involving an Elion Patent Right, and the costs of any such defense shall be at Processa's expense. Processa shall have the first right, but not the obligation, to defend against any such action involving a Processa Patent Right or Joint Patent Right, and the costs of any such defense shall be at Processa's expense. If the Party that has the first right to defend against any such action involving such Elion Patent Right, Processa Patent Right or Joint Patent Right does not do so, then the other Party shall have the right, but not the obligation, to defend such action and any such defense shall be at such other Party's expense. Upon request of the Party that defends against any such action involving an Elion Patent Rights, Processa Patent Right or Joint Patent Right, the other Party agrees to join in any such action and to cooperate reasonably with the defending Party, including providing full access to documents, information and witnesses as reasonably requested by the defending Party in connection with such action, provided that the defending Party shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by the other Party in connection with such cooperation.

7.5 Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the practice by either Party of the Elion Patent Rights infringes, or is suspected or alleged to infringe, the intellectual property rights of any Third Party in the Territory, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected, alleged or actual infringement.

7.6 Patent Term Extensions. Processa shall have the exclusive right and obligation to seek patent term extensions or supplemental patent protection, including supplementary protection certificates, in each country in the Territory in relation to the Products at Processa's expense. Elion and Processa shall cooperate in connection with all such activities, and Processa, its agents and attorneys will give due consideration to all timely suggestions and comments of Elion regarding any such activities; provided that all final decisions shall be made by Processa.

7.7 Patent Marking. Processa shall comply with the patent marking statutes in each country in the Territory in which any Product is sold by Processa, its Affiliates, or its Sublicensees.

7.8 Certification under Drug Price Competition and Patent Restoration Act.

(a) Notice. If a Party becomes aware of any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions, or any similar provision in any country in the Territory other than the U.S., claiming that any Elion Patent Rights, Processa Patent Rights or Joint Patent Rights are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party (a "Paragraph IV Claim"), such Party shall promptly notify the other Party in writing within five (5) Business Days after its receipt thereof.

(b) Control of Response; Recoveries. Processa shall have the first right, but not the obligation, to initiate and control patent infringement litigation for any Paragraph IV Claim; provided, however, that Processa shall (i) consult with Elion in good faith with respect to any claim that any Elion Patent Right, Processa Patent Right or Joint Patent Right is invalid or unenforceable and (ii) implement any comment from Elion regarding any aspect of defending against any such claim. Any suit by Processa shall be brought either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Elion shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Processa; provided that Processa shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Elion in connection with such cooperation. If Processa elects not to assume control over litigating any Paragraph IV Claim, Processa shall notify Elion as soon as practicable but in any event not later than ten (10) days before the first action required to litigate such Paragraph IV Claim so that Elion may, but shall not be required to, assume sole control over litigating such Paragraph IV Claim using counsel of its own choice. Any suit by Elion shall be either in the name of Elion or its Affiliate, the name of Processa or its Affiliate, or the names of Processa, Elion, and their respective Affiliates, as may be required by the Law of the forum. For this purpose, Processa shall execute such legal papers and cooperate in the prosecution of such suit, including providing full access to documents, information and witnesses, as may be reasonably requested by Elion; provided that Elion shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Processa in connection with such cooperation. Any compensation recovered as a result of such litigation shall be allocated as set forth in Section 7.3(e) above.

7.9 Privileged Communications. In furtherance of this Agreement, it is expected that Processa and Elion will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters, and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Elion and Processa, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Elion Patent Rights, Processa Patent Rights and Joint Patent Rights.

7.10 Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any suit, action or proceeding under this ARTICLE VII that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

ARTICLE VIII CONFIDENTIAL INFORMATION

8.1 Treatment of Confidential Information. During the Term and for five (5) years thereafter, each Party shall maintain Confidential Information (as defined in Section 8.2) of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except for agents, directors, officers, employees, consultants, subcontractors, licensees, sublicensees, partners, Affiliates and advisors who have a need to know such information to perform obligations or exercise rights on behalf of such Party (collectively, "Agents") under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII) or use it for any purpose other than in connection with the Development, Manufacture, use or Commercialization of Compounds or Products pursuant to this Agreement or otherwise to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations hereunder, and each Party shall exercise Commercially Reasonable Efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Agents, which efforts shall be at least as diligent as those generally used by such Party in protecting its own confidential and proprietary information, and in any event no less than reasonable efforts. Each Party will be responsible for any breach of this ARTICLE VIII by its Agents. Either receiving Party may disclose Confidential Information of the disclosing Party (a) to Governmental Authorities in order to comply with applicable Laws, respond to inquiries, requests or investigations by Governmental Authorities, including filing, prosecuting or maintaining Patent Rights as permitted by this Agreement; (b) to comply with the regulations or requirements of any stock exchange; (c) to the extent useful to Develop, Manufacture, use or Commercialize any Compound or Product, including making regulatory filings for any Compound or Product, in accordance with this Agreement; (d) to the extent necessary or useful in order to defend or prosecute litigation; and (e) to potential and actual *bona fide* investors, acquirors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that (x) with respect to any disclosure in accordance with Section 8.1(a), (b) or (d), the receiving Party shall promptly provide prior notice of such disclosure to the disclosing Party and use Commercially Reasonable Efforts to avoid or minimize the degree of such disclosure, (y) with respect to any disclosure in accordance with Section 8.1(a) or (d), the receiving Party will use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (z) with respect to any disclosure in accordance with Section 8.1(e), the receiving Party shall obtain the same confidentiality obligations from any Third Parties to which it discloses the Confidential Information of the disclosing Party as it obtains with respect to its own similar types of confidential information, and in any event such obligations shall be no less stringent than those set forth in this ARTICLE VIII.

8.2 Confidential Information. “Confidential Information” means all trade secrets or other proprietary information, including any proprietary data and materials (whether or not patentable or protectable as a trade secret), that is disclosed by a Party to the other Party. Notwithstanding the foregoing, there shall be excluded from the foregoing definition of Confidential Information any of the foregoing that:

(a) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by a Third Party without any violation of any obligation to the other Party; or

(b) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Agents; or

(c) is independently developed by or for the receiving Party without reference to or reliance upon the disclosing Party’s Confidential Information as demonstrated by contemporaneous written records of the receiving Party.

8.3 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of clinical trials of pharmaceutical products. Accordingly, subject to coordination through designated representatives of each Party, Processa shall be free to publicly disclose the results of clinical trials involving Compounds or Products, subject to prior review by Elion for issues of patentability and protection of its Confidential Information, in a manner consistent with all Laws applicable to Processa and best industry practices. In addition, if Processa intends to publish articles in scientific or medical journals or to make presentations of the results of clinical trials involving Compounds or Products, Processa shall provide Elion through the designated representatives of each Party at its earliest opportunity with any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development of any Compound or Product. Elion shall respond promptly through its designated representative, and in any event no later than thirty (30) days after receipt of such proposed publication or presentation, or such shorter period as may be required by the publication. If timely requested by Elion, Processa agrees to allow a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Elion. In addition, Processa will consider in good faith any comments furnished by Elion to Processa during such period. Processa shall be responsible to assure that its Affiliates and licensees agree to, and comply with, equivalent undertakings in favor of Elion. Elion and its Affiliates may make any publication or public disclosure of any data concerning the Compounds or Products that existed as of the Effective Date, provided that Elion provides Processa at least thirty (30) days (or such shorter period as may be required by the publication) to review such publication or public disclosure, allows a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of Processa, and reasonably considers any timely comments provided by Processa with respect to such publication or public disclosure. Elion shall not, and shall cause each of its Affiliates, licensees, and sublicensees not to, make any other publications or public disclosures regarding the Compounds or Products without Processa’s prior written consent. If Processa consents to Elion making such publications, Elion shall provide Processa a reasonable opportunity to comment on any such publications and such comments shall not be unreasonably rejected. All publications involving Compounds or Products shall include appropriate acknowledgement consistent with standard scientific practice of any contributions of each Party to the results being publicly disclosed.

8.4 Press Releases and Other Disclosures. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or disclosures regarding the subject matter of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure shall provide the other Party with a copy of the proposed press release, statement or disclosure for review and approval in advance (except that neither Party shall have any obligation to disclose or approve the disclosure of Confidential Information except to the extent required or permitted pursuant to this ARTICLE VIII). No other public statement or disclosure concerning the existence or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 8.4, then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Section 8.4 this ARTICLE VIII, a Party may (a) disclose the existence and terms of this Agreement where required, as reasonably determined by the disclosing Party, by applicable Law, by applicable stock exchange regulation or by order or other ruling of a competent court and (b) disclose the existence and terms of this Agreement under obligations of confidentiality no less stringent than those set forth in this ARTICLE VIII to agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners, and to potential agents, advisors, contractors, licensees, sublicensees, and *bona fide* investors, acquirors and other financial or commercial partners. To the extent a Party determines in good faith that it is required by applicable Law to publicly file, register or notify this Agreement with a Governmental Authority, including public filings pursuant to securities Laws, it shall provide a proposed redacted form of the Agreement to the other Party a reasonable amount of time prior to filing for the other Party to review such draft and propose changes to such proposed redactions. The Party making such filing, registration or notification shall incorporate any proposed changes timely requested by the other Party, absent a reasonable basis for not making such changes, and shall use Commercially Reasonable Efforts to seek confidential treatment for any terms that the other Party timely requests be kept confidential, to the extent such confidential treatment is reasonably available consistent with applicable Law. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration, or notification.

8.5 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this ARTICLE VIII. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE VIII.

ARTICLE IX
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Elion's Representations. Elion hereby represents and warrants as of the Effective Date as follows:

(a) Elion has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Elion. Elion has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or by which it or its assets are bound, to authorize such execution, delivery, and performance. Assuming due authorization, execution, and delivery on the part of Processa, this Agreement constitutes a legal, valid, and binding obligation of Elion, enforceable against Elion in accordance with its terms.

(b) The execution and delivery of this Agreement by Elion do not require Elion to obtain any permit, authorization or consent from any Governmental Authority or from any other Person which has not been obtained prior to the Effective Date, and such execution and delivery by Elion will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Elion may be a party that relates to the Elion Patent Rights or the Elion Know-How.

(c) Schedule 1.16 is a complete and correct list of all Patent Rights owned by Elion as of the Effective Date that Cover any Compound or Product. No Patent Right that covers any Compound or Product has been licensed to Elion.

(d) Elion is the legal and beneficial owner of all the Patent Rights identified on Schedule 1.16, free and clear of any liens, mortgages, security interests or other similar encumbrances. All assignments to Elion of ownership rights relating to such Patent Rights are valid and enforceable. All of the Patent Rights listed identified on Schedule 1.16 that are issued patents are in full force and effect, and all applicable filing, maintenance and other fees required to be paid to a patent office with respect to the Patent Rights listed identified on Schedule 1.16 have been timely paid. Elion has the right to grant the licenses granted by it in this Agreement and has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Elion Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

(e) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to Elion's knowledge, threatened against Elion in connection with the Compounds or Products or any Elion Patent Rights, Elion Know-How or against or relating to the transactions contemplated by this Agreement. Elion has not received any written notice from a Third Party that the Development of any Compound or Product conducted by Elion has infringed, or that any Development or Commercialization of any Compound or Product will infringe, any Patent Rights of any Third Party.

(f) No claim or action has been brought or, to Elion's knowledge, threatened by any Third Party alleging that the Elion Patent Rights are invalid or unenforceable, and no Elion Patent Rights are the subject of any litigation, interference, post-grant review, opposition, cancellation or other proceeding challenging the validity or enforceability of the Elion Patent Rights.

(g) Neither Elion nor, to the knowledge of Elion, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

(h) The shares of Common Stock of Processa that may be issued under this Agreement shall be acquired for investment for Elion's own account (or that of its permitted designee), not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and as of the date hereof, Elion (or, if applicable, its permitted designee) has no present intention of selling, granting any participation or otherwise distributing the shares. Elion, either alone or together with its Affiliates and representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the shares, and has so evaluated the merits and risks of such investment. Elion (or, if applicable, its permitted designee) is able to bear the economic risk of an investment in the shares and, at the present time, is able to afford a complete loss of such investment. Elion (or, if applicable, its permitted designee) is not acquiring the shares as a result of (a) any advertisement, article, notice or other communication published in any newspaper, magazine or similar media or broadcast over television, radio or the Internet, in each case, relating to Processa, or (b) any seminar or meeting whose attendees, including Elion, have been invited by any general solicitation or general advertising related to Processa.

(i) Elion (or, if applicable, its permitted designee) is as of the date hereof, and as of the date any shares are issued under this Agreement will be, an "accredited investor" as defined in Rule 501 under the Securities Act of 1933, as amended.

(j) Elion (or, if applicable, its permitted designee) acknowledges that it has had the opportunity to review the reports filed by Processa with the SEC and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of Processa concerning the terms and conditions of the offering of the shares of Common Stock hereby and the merits and risks of investing in the shares; (ii) access to information about Processa and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that Processa possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

9.2 Processa's Representations. Processa hereby represents and warrants as of the Effective Date as follows:

(a) Processa has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery, and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of Processa. Processa has taken all other action required by Law, its certificate of incorporation or by-laws or any agreement to which it is a party or by which it or its assets are bound to authorize such execution, delivery and (subject to obtaining all necessary governmental approvals with respect to the Development, Manufacture, use and Commercialization of Compounds and Products) performance. Assuming due authorization, execution, and delivery on the part of Elion, this Agreement constitutes a legal, valid, and binding obligation of Processa, enforceable against Processa in accordance with its terms.

(b) The execution and delivery of this Agreement by Processa will not violate any U.S. Law or, to Processa's knowledge, any Law of any Governmental Authority outside the U.S.

(c) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Processa, threatened against Processa in connection with or relating to the transactions contemplated by this Agreement.

(d) The execution and delivery of this Agreement do not require Processa to obtain any permit, authorization or consent from any Governmental Authority or from any other Person, and such execution and delivery by Processa will not result in the breach of or give rise to any termination of, rescission, renegotiation or acceleration under or trigger any other rights under any agreement or contract to which Processa may be a party that relates to the Products, Processa Patent Rights or Processa Know-How.

(e) Neither Processa nor, to the knowledge of Processa, any of its directors, officers, employees, agents or subcontractors has been convicted of any crime or engaged in any conduct that has resulted in, or would reasonably be expected to result, in debarment by the FDA under 21 U.S.C. § 335a or any similar state or foreign Law.

9.3 Elion Covenants. Elion covenants and agrees during the Term that, subject to Processa's, its Affiliates' and Sublicensees' performance of their obligations under this Agreement:

(a) Elion shall not grant to any Third Party any rights that would be inconsistent or conflict with Processa's rights hereunder.

(b) Subject to Section 12.7, Elion shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Elion Intellectual Property in a manner that conflicts with any rights granted to Processa hereunder.

9.4 Processa Covenant.

(a) Processa shall conduct, and shall use Commercially Reasonable Efforts to cause its contractors and consultants to conduct, all of their activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted, including applicable requirements of “good laboratory practices”, “good clinical practices” and “good manufacturing practices”, as applicable, as defined by the FDA.

(b) Subject to Section 12.7, Processa shall not assign, transfer, convey, or otherwise encumber its right, title, and interest in the Processa Intellectual Property in a manner that conflicts with any rights granted hereunder to Elion upon termination.

9.5 No Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED. IN PARTICULAR, BUT WITHOUT LIMITATION, EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY CONCERNING WHETHER ANY OF THE COMPOUNDS OR PRODUCTS ARE FIT FOR ANY PARTICULAR PURPOSE OR SAFE FOR HUMAN CONSUMPTION.

ARTICLE X **INDEMNIFICATION**

10.1 Indemnification in Favor of Elion Processa shall indemnify, defend and hold harmless the Elion Parties from and against any and all Losses incurred, suffered or sustained by any of the Elion Parties or to which any of the Elion Parties becomes subject as a result of any Third Party claim, action, suit, proceeding, liability or obligation (which in no event includes any claim by any Processa Party or any Elion Party) (collectively, “Third Party Claims”) arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Processa in this Agreement; or

(b) the Development Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees, including all Third Party Claims involving death or bodily injury caused or allegedly caused by the use of such a Compound or Product, and even if such a Compound or Product is altered for use for a purpose not intended (any and all such Third Party Claims “Product Liability Claims”); or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Processa, its Affiliates or Sublicensees; or

(d) the gross negligence or willful misconduct of any of the Processa Parties (as hereinafter defined) in connection with Processa’s performance of this Agreement.

For purposes of this ARTICLE X, “Elion Parties” means Elion, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.1 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Elion in this Agreement or (ii) the gross negligence or willful misconduct of any applicable Elion Party.

10.2 Indemnification in Favor of Processa Elion shall indemnify, defend and hold harmless the Processa Parties from and against any and all Losses incurred, suffered or sustained by any of the Processa Parties or to which any of the Processa Parties becomes subject as a result of any Third Party Claim arising out of, relating to or resulting from:

(a) any misrepresentation or breach of any representation, warranty, covenant or agreement made by Elion in this Agreement; or

(b) the Development, Manufacture or Commercialization of Compounds or Products by Elion, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement, including all Product Liability Claims arising out of any such pre-Agreement, post-termination Development, Manufacture or Commercialization by Elion, its Affiliates, licensees (excluding Processa) or sublicensees; or

(c) any actual or alleged infringement of any trademark, Patent Right or other intellectual property right, or misappropriation of any trade secret, of any Third Party as a result of the Development, Manufacture or Commercialization of Compounds or Products by Elion, its Affiliates, licensees (excluding Processa) or sublicensees prior to the execution of this Agreement and after any termination of this Agreement; or

(d) the gross negligence or willful misconduct of any of the Elion Parties in connection with Elion's performance of this Agreement; or

(e) the formation of the Trust, issuance of the shares of Common Stock to the Trust for the benefit of Elion as provided in Section 6.1 or as a result of the shares of Common Stock being held in such Trust.

For purposes of this ARTICLE X, "Processa Parties" means Processa, its Affiliates and their respective agents, directors, officers, licensees, sublicensees and employees.

The indemnification obligations set forth in this Section 10.2 shall not apply to the extent that any Loss is the result of (i) a breach of any representation, warranty, covenant, or agreement made by Processa in this Agreement, or (ii) the gross negligence or willful misconduct of any applicable Processa Party.

10.3 General Indemnification Procedures.

(a) An Elion Party or Processa Party seeking indemnification pursuant to this ARTICLE X (an "Indemnified Party") shall give prompt notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect to any indemnified matter as the Indemnifying Party may reasonably request, and shall not make any admission concerning any Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby (and no admission required by applicable Law or legal process shall be deemed to result in prejudice). The Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within ten Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party will be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the "Litigation Conditions"). Within ten Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party will give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party will continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party will be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within ten Business Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

(b) Any Indemnified Party or Indemnifying Party not managing the defense of a Third Party Claim shall have the right to participate in (but not control), at its own expense (subject to the immediately succeeding sentence), the defense. The Indemnifying Party managing the defense shall not be liable for any litigation cost or expense incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of such Indemnifying Party; provided, however, that, if the Indemnifying Party managing the defense fails to take reasonable steps necessary to defend such Third Party Claim, the Indemnified Party may assume its own defense, and the Indemnifying Party managing the defense will be liable for all reasonable costs or expenses paid or incurred in connection therewith.

(c) The Indemnifying Party shall not, except with the consent of the Indemnified Party, consent to a settlement of, or the entry of any judgment against, an Indemnified Party arising from any Third Party Claim to the extent such settlement or judgment involves equitable or other non-monetary relief from the Indemnified Party. No Party shall, without the prior written consent of the other Party or the Indemnified Party, enter into any compromise or settlement that commits the other Party or the Indemnified Party to take, or to forbear to take, any action.

(d) The Parties shall cooperate in the defense or prosecution of any Third Party Claim and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith; provided, however, that the Indemnifying Party shall reimburse the Indemnified Party for any out-of-pocket expenses actually and reasonably incurred in connection with any such cooperation.

(e) Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this ARTICLE X, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the Indemnifying Party.

(f) The Parties agree and acknowledge that the provisions of this ARTICLE X represent the Indemnified Party's exclusive recourse with respect to any Losses for Third Party Claims for which indemnification is provided to the Indemnified Party under this ARTICLE X.

10.4 Insurance. During the Term, if the Condition Precedent is satisfied, and thereafter for so long as a Third Party Claim may be brought for which Processa must indemnify Elion pursuant to Section 10.1, Processa shall obtain and maintain, at its sole cost and expense, product liability insurance in amounts that are reasonable and customary in the pharmaceutical industry, but in no event less than \$5 million per occurrence or claim, and \$10 million in the aggregate, or a comparable program of self-insurance. Such product liability insurance shall insure against all liability, including product liability and property damage arising out of the Development, use or Commercialization of Compounds and Products by Processa, its Affiliates, or Sublicensees in the Territory. Without limiting the generality of the foregoing, Processa shall maintain comprehensive general liability insurance, including product liability insurance, to cover its activities and, unless its Affiliates and Sublicensees maintain comparable coverage, the activities of its Affiliates and Sublicensees, with respect to Compounds and Products. Processa shall provide satisfactory evidence of adequate insurance coverage to Elion upon the request of Elion prior to the Condition Precedent Satisfaction Date and, upon the written request of Elion, concurrent with any renewal or replacement of such coverage.

ARTICLE XI
TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE XI, shall continue in full force and effect until the expiration of the last Royalty Term. On a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term in such country with respect to such Product, Processa shall have a fully paid-up, perpetual, irrevocable license under the Elion Intellectual Property and Elion's interest in the Joint Intellectual Property with respect to such Product in such country.

11.2 Termination for Failure to Satisfy Condition Precedent. If, for any reason (including a failure to meet the conditions in Section 2.1 prior to end of the Condition Precedent Period), the Condition Precedent is not fully satisfied within the Condition Precedent Period, then this Agreement shall automatically terminate in its entirety on the day after the last day of the Condition Precedent Period.

11.3 Termination for Convenience. Processa shall have the right upon sixty (60) days prior written notice to Elion to terminate this Agreement in its entirety for any reason.

11.4 Termination for Cause. In the event of a material breach of this Agreement by a Party, the other Party may give the Party in default notice requiring it to cure such default, which notice shall specify the nature of the breach. If such material breach is not cured within ninety (90) days after receipt of such notice (or within fifteen (15) days in the case of a payment breach), the notifying Party shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement by giving written notice to the defaulting Party. The right of either Party to terminate this Agreement as set forth in this Section 11.4 shall not be affected in any way by its waiver of, or failure to take action with respect to, any previous default.

11.5 Additional Termination by Elion. In the event that Elion has provided written notice to Processa pursuant to Section 5.2, if (a) Processa does not respond to Elion in writing within sixty (60) days of receipt of such notice from Elion and reasonably demonstrate in such response compliance with Processa's obligations under Section 5.1, or (b) Processa has failed to comply with Section 5.1 (a) or Section 5.1(b), Elion shall be entitled (without prejudice to any other rights conferred on it by this Agreement or under applicable Law) to terminate this Agreement with immediate effect by giving written notice to Processa.

11.6 Termination for Insolvency. This Agreement may be terminated by a Party upon written notice to the other Party if (a) the other Party shall make a general assignment for the benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; or (b) if there shall have been filed against the other Party any such *bona fide* petition or application, or any such proceeding shall have been commenced against it, in which an order for relief is entered or that remains undismissed or unstayed for a period of ninety (90) days or more; or (c) if the other Party by any act or omission shall consent to, approve of or acquiesce in any such petition, application or proceeding or order for relief or the appointment of a custodian, receiver or trustee for it or any substantial part of its assets, or shall suffer any such custodianship, receivership or trusteeship to continue undischarged or unstayed for a period of ninety (90) days or more. Termination shall be effective upon the date specified in such notice.

11.7 Termination for Challenge of Elion Patent Rights. If Processa or any of Processa's Affiliates or Sublicensees commences an action in any court or tribunal of competent jurisdiction that challenges, opposes or disputes the validity, enforceability or patentability of any Elion Patent Rights, or any of the claims thereof, or supports or assists any Third Party that commences such an action in any such court or tribunal, Elion shall have the right to terminate this Agreement upon notice to Processa; provided, however, that Elion shall not have a right to terminate if the challenge is brought by a Sublicensee, either directly or indirectly through any Third Party, and Processa or the Affiliate, as the case may be, terminates such Sublicensee's sublicense rights hereunder within thirty (30) days after becoming aware of such challenge.

11.8 Consequences of Termination. If this Agreement (w) terminates automatically pursuant to Section 11.2, (x) is terminated by Elion under Section 11.4, 11.5, 11.6 or 11.7, (y) is terminated by Processa under Section 11.3, or (z) is terminated by Processa under Section 11.4 or 11.6, then the licenses granted to Processa in Section 2.2 and, except as provided in this Section 11.8 and Sections 11.9 and 11.10 (and any Articles and Sections referenced therein), all other rights and obligations of the Parties under this Agreement shall terminate. Upon a termination described in clause (x) (but not clause (w), (y) or (z)) of this Section 11.8, clause (a) shall apply, and, upon a termination described in clause (w), (x) or (y) (but not clause (z)), Processa shall grant, and shall cause any applicable Affiliate to grant, Elion any combination of the following clauses (b) through (f) elected by Elion, provided that (i) upon a termination described in clause (w), only clause (c) and, to the extent that any Processa Intellectual Property, Sublicensee Intellectual Property or Joint Intellectual Property exists as of such termination, clause (e) shall apply, and (ii) Processa shall only be required to grant Elion rights to Sublicensee Materials under the applicable sublicense agreement(s) with Sublicensee(s) to whom Elion has not granted a direct license pursuant to Section 11.8(a):

(a) Sublicenses. Elion hereby grants, effective automatically upon any termination of this Agreement by Elion pursuant to Section 11.4, 11.5, 11.6 or 11.7, a direct license to each then-existing Sublicensee, provided that (i) such Sublicensee is not in breach under the applicable sublicense, (ii) such Sublicensee's failure to comply with the terms of its sublicense or other actions or omissions were not a basis for such termination, and (iii) such Sublicensee continues to satisfy all obligations under this Agreement applicable to such sublicense, including the diligence obligations set forth in ARTICLE V and all payments to Elion required under Section 6, from and after the date that such direct license becomes effective.

(b) Regulatory Matters. Ownership of all filings with Regulatory Authorities in the Territory relating to Compounds and Products and Regulatory Approvals relating to Compounds and Products held Processa or its Affiliates or applicable Sublicensees, including related correspondence with Regulatory Authorities, and Processa shall provide copies thereof to Elion;

(c) Pre-clinical and Clinical Matters. Possession of all pre-clinical and clinical data, including pharmacology and biology data, within the Processa Know-How and applicable Sublicensee Intellectual Property;

(d) Manufacturing Matters. At Elion's option, to be exercised no later than the later of (x) thirty (30) days after the effective date of termination or (y) thirty (30) days after Elion's receipt of the applicable Manufacturing agreements,

(i) use of Commercially Reasonable Efforts by Processa and its Affiliates and applicable Sublicensees to effect the assignment of each Manufacturing agreement specific and exclusive to Compounds or Products to Elion, if such agreement is then in effect and such assignment is permitted under such agreement or by the applicable Third Party; provided that Processa and its applicable Affiliates and applicable Sublicensees shall be released to the extent the applicable Third Party will permit from any obligation arising out of such agreement following such assignment and Elion shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; provided further that if any such agreement is specific but not exclusive to Compounds or Products, or is not assigned to Elion for any reason, Processa will discuss in good faith with Elion terms upon which Processa and its Affiliates and applicable Sublicensees shall use Commercially Reasonable Efforts to provide Elion with the benefits of such agreement to the extent it relates to Compounds or Products for a limited period of time (not to exceed six (6) months) and upon payment of a reasonably acceptable fee to Processa;

(ii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with Elion in reasonable respects to transfer Manufacturing documents and materials within the Processa Know-How and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products to the extent such Manufacturing documents and materials are not obtained by Elion pursuant to the assignment of agreements pursuant to paragraph (i) above, and (B) cooperation with Elion to provide Elion with reasonable access to and right to use such Manufacturing documents and materials in Processa's or its Affiliates' or applicable Sublicensees' possession or Control to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products, subject to appropriate confidentiality and limitation on use protections applicable to for Manufacturing documents and materials;

(iii) for a period of up to six (6) months following the effective date of termination, (A) cooperation with Elion in reasonable respects to transfer Manufacturing technologies within the Processa Intellectual Property and applicable Sublicensee Intellectual Property that are used (at the time of the termination) by Processa or its Affiliates or applicable Sublicensees exclusively in the Manufacture of Compounds and Products, and (B) cooperation with Elion to provide Elion with reasonable access to and right to use such Manufacturing technologies Controlled by Processa or its Affiliates (other than Processa Excluded Affiliates) or applicable Sublicensees to the extent they relate to, but are not used exclusively in, the Manufacture of Compounds and Products and that Processa or such Affiliates or Sublicensees are permitted to provide such access to Elion; provided that Elion shall reimburse Processa for Processa's reasonable out-of-pocket expenses to provide such requested assistance, to the extent such Manufacturing technologies are not obtained by Elion pursuant to the assignment of agreements pursuant to paragraph (i) above; and

(iv) sale of Processa's or its Affiliates' or applicable Sublicensees' then-existing inventory of Compounds and Products to Elion, at Processa's or its applicable Affiliates' or applicable Sublicensees' cost of Manufacture, but only if the following conditions have been met: (A) such Compounds and Products meet the applicable release specifications; and (B) Processa does not reasonably believe the continued use of such Compounds and Products causes safety concerns;

(e) License Grant. At Elion's option, to be exercised by written notice to Processa no later than thirty (30) days after the effective date of termination, a worldwide license, with the right to sublicense, under the Processa Patent Rights, Processa Know-How, Processa's interest in the Joint Intellectual Property, and applicable Sublicensee Intellectual Property, solely to make, have made, use, sell, offer for sale and import Compounds and Products in the Field that were Developed or Commercialized prior to the effective date of termination, which license would be, at Elion's election, either (i) non-exclusive, fully paid-up, non-royalty-bearing, irrevocable and perpetual or (ii) exclusive and royalty-bearing subject to mutual agreement by Elion and Processa on commercially reasonable terms; provided that, notwithstanding the foregoing, with respect to any Processa Patent Rights or Processa Know-How that Processa acquired from a Third Party (by license or otherwise), or any applicable Sublicensee Intellectual Property that the applicable Sublicensee(s) acquired from a Third Party (by license or otherwise), Processa or the applicable Sublicensee(s) shall only be required to grant to Elion a license to such Processa Patent Rights, Processa Know-How or Sublicensee Intellectual Property to the extent permitted under the applicable agreement with such Third Party, and Elion shall pay Processa or such Sublicensee or such Third Party, as determined by Processa, any payment due to such Third Party relating to the Compounds and Products; provided further that Elion shall execute such documentation reasonably satisfactory to Processa to effectuate such agreement; and if the license granted to Elion is exclusive, Elion shall have the same enforcement rights with respect to any Processa Patent Rights and Patent Rights within the Sublicensee Intellectual Property that exclusively Cover Products that are licensed to Elion pursuant to this Section 11.8(e) as Processa has with respect to Infringement Claims pursuant to Section 7.3 (to the extent that Processa or the applicable Sublicensee(s) have such rights with respect to such Processa Patent Rights or Patent Rights within the Sublicensee Intellectual Property, as applicable), provided that any enforcement of Processa Patent Rights, Joint Patent Rights or Patent Rights within the Sublicensee Intellectual Property that Cover subject matter other than such Products shall be performed by Elion only with the consultation and prior agreement of Processa or the applicable Sublicensee, which such agreement shall not unreasonably withheld, delayed or conditioned.

(f) Assignment of Trademarks. Assign to Elion all of Processa's or its applicable Sublicensees' right, title and interest in any trademark owned by Processa or its Affiliates or applicable Sublicensees and used solely in connection with the Products, along with all associated goodwill.

11.9 Effect of Termination or Expiration; Accrued Rights and Obligations. Termination or expiration of this Agreement for any reason shall not release either Party from any liability that, at the time of such termination or expiration, has already accrued or that is attributable to a period prior to such termination (including payment obligations accrued prior to the effective date of termination or expiration pursuant to ARTICLE VI) nor preclude either Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement.

11.10 Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination or expiration of this Agreement only to the extent expressly provided for in this Agreement or to the extent required to give effect to a termination or expiration of this Agreement or the consequences of a termination or expiration of this Agreement as expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of ARTICLE I, Sections 2.3, 2.4, 6.11 (only for thirty-six (36) months after expiration or termination), 6.121, 6.132, 6.143, 6.15, 7.1, 7.9, 8.1, 8.2, 8.5, 9.5, ARTICLE X, and Sections 11.1 (last sentence as to any such license that became perpetual and irrevocable prior to expiration or termination), 11.8, 11.9, 11.10 and ARTICLE XII shall survive expiration or termination of this Agreement for any reason.

ARTICLE XII MISCELLANEOUS

12.1 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without regard to its conflicts of laws rules. Each Party (a) irrevocably submits to the exclusive jurisdiction in the state court sitting in New York City, New York (collectively, the “Courts”), for purposes of any action, suit or other proceeding arising out of this Agreement, and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Either Party may serve any process required by such Courts by way of notice under this Agreement. Notwithstanding anything to the contrary in this Section 12.1, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through, or under such other Party, in any court of competent jurisdiction, in order to enforce the instituting Party’s rights hereunder through reformation of contract, specific performance, injunction, or similar equitable relief.

12.2 Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement, either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Executives of each Party, for attempted resolution by good faith negotiations within twenty (20) days after such notice is received. In the event the Senior Executives do not resolve such dispute within the allotted twenty (20) days, either Party may, after the expiration of the twenty (20) day period, seek to resolve the dispute in accordance with Section 12.1.

12.3 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a Party to exercise or avail itself of any right, power, or privilege that it has or may have hereunder shall operate as a waiver of any right, power, or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

12.4 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address specified in this Section 12.4 and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile or other electronic transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with confirmation of receipt, if transmitted by facsimile or other electronic transmission (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to Processa shall be addressed to

Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076
Attn: Wendy Guy, Chief Administrative Officer
Email: wguy@processapharmaceuticals.com

Notices to Elion shall be addressed to

Elion Oncology, Inc.
4800 Hampden Lane
Bethesda, MD 20814
Attn: Chief Executive Offer

With a copy to:

Dechert LLP
1900 K Street, NW
Washington, DC 20006
Attn: David E. Schulman

Either Party may change its address by giving notice to the other Party in the manner provided above.

12.5 Entire Agreement. This Agreement (including Schedules) contains the complete understanding of the Parties with respect to the subject matter of this Agreement and supersedes all prior understandings and writings between the Parties relating to such subject matter.

12.6 Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any Law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected. In such event, the Parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

12.7 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by any Party without the consent of the other Party; provided, however, that any Party may, without such consent, assign this Agreement, in whole or in part: (a) to any of its respective Affiliates, provided that such Affiliate has acknowledged and confirmed in writing that effective as of such assignment, such Affiliate shall be bound by this Agreement to the identical extent applicable to the assigning Party and the assignor confirms to the non-assigning party that it shall remain liable as if no such liability had occurred; or (b) to any successor in interest by way of merger, acquisition or sale of all or substantially all of its business or assets relating to the subject matter of this Agreement, provided that such successor (if the applicable Party is not the surviving entity in such transaction) agrees in writing to be bound by the terms of this Agreement to the identical extent applicable to the assigning Party. Any purported assignment in violation of this Section 12.7 shall be void. Subject to this Section 12.7, any permitted assignee shall assume all obligations of its assignor under this Agreement.

12.8 Counterparts; Exchange by Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and that together shall constitute one and the same instrument. Such counterparts may be exchanged by facsimile or PDF (provided that each executed counterpart is transmitted in one complete transmission or electronic mail message). Where there is an exchange of executed counterparts by facsimile or PDF, each Party shall be bound by the Agreement notwithstanding that original copies of the Agreement may not be exchanged immediately. The Parties shall cooperate after execution of the Agreement and exchange by facsimile or PDF to ensure that each Party obtains an original executed copy of this Agreement with reasonable promptness.

12.9 Force Majeure. No Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and no Party shall be deemed in breach of its obligations, if such failure or delay is due to a natural disaster, explosion, fire, flood, tornadoes, pandemic, quarantine, thunderstorms, earthquake, war, terrorism, riots, embargo, losses or shortages of power, labor stoppage, substance or material shortages, damage to or loss of product in transit not due to a failure by such Party or its Affiliates to exercise reasonable care, events caused by reason of Laws of any Governmental Authority, events caused by acts or omissions of a Third Party not induced or solicited by such Party or its Affiliates, or any other cause reasonably beyond the control of such Party or its Affiliates; provided that such Party uses Commercially Reasonable Efforts to overcome the difficulties created by such force majeure event and to resume performance of its obligations as soon as practicable.

12.10 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party other than an Elion Party or a Processa Party, as applicable, that is an Indemnified Party under ARTICLE X, and no Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

12.11 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other, except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said other Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, the legal relationship under this Agreement of each Party to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

12.12 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

12.13 No Consequential or Punitive Damages. NEITHER PARTY WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 12.13 IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT WITH RESPECT TO THIRD PARTY CLAIMS, OR (B) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR BREACH OF CONFIDENTIALITY AND LIMITATION ON USE OBLIGATIONS SET FORTH IN THIS AGREEMENT, OR (C) DAMAGES TO WHICH A PARTY MAY BE ENTITLED FOR THE WILLFUL MISCONDUCT, INTENTIONAL BREACH OR FRAUD OF THE OTHER PARTY.

[Signature page follows]

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

PROCESSA PHARMACEUTICALS, INC.



By: _____
Name: David Young
Title: CEO

ELION ONCOLOGY, INC.



By: _____
Name: R. Michael Floyd
Title: Chief Executive Officer

Issued:

- U.S. Patent - 8,658,618; Granted 2014: Methods for preventing or reducing neurotoxicity associated with administering DPD inhibitors in combination with 5-FU and 5-FU prodrugs.
- US Patent - 8,318,756; Granted 2012: Methods for administering DPD inhibitors in combination with 5-FU and 5-FU prodrugs.
- Orphan Drug Designation for Eniluracil in Hepatocellular Carcinomas; Granted in 2005: ADH300004 (ENILURACIL) IN COMBINATION WITH FLUOROPYRIMIDINES FOR THE TREATMENT OF PATIENTS WITH HEPATOCELLULAR CARCINOMA

Filed:

- Formulation patents on formulation of Extended Release Colon Targeted delivery of drugs (May 2018) and ERCT5-FU and Use with Eniluracil (July 2018)

To Be Filed Patents:

- Draftsm pending patents of all other Eniluracil and DPD related patents.

FOR IMMEDIATE RELEASE

**PROCESSA PHARMACEUTICALS ENTERED INTO A CONTINGENT PRECEDENT
IN-LICENSING AGREEMENT WITH ELION ONCOLOGY FOR THE DEVELOPMENT OF ENILURACIL (PCS6422) FOR THE TREATMENT OF
ADVANCED GASTROINTESTINAL TUMORS**

HANOVER, MD – August 27, 2020 – Processa Pharmaceuticals, Inc. (OTCQB: PCSA) announced today that it has entered into a contingent precedent exclusive licensing agreement with Elion Oncology, Inc. to develop, manufacture and commercialize eniluracil (PCS6422) globally. PCS6422 is an oral drug to be administered with fluoropyrimidine cancer drugs (e.g., capecitabine, 5-FU) to decrease the breakdown of the cancer drug to inactive metabolites or metabolites that are known to cause unwanted side effects and to interfere with the anticancer activity.

Fluoropyrimidines are still the cornerstone of treatment for many different types of cancers, either as monotherapy or in combination with other chemotherapy agents. Capecitabine, an oral prodrug of 5-FU, is approved as first-line therapy for metastatic colorectal and breast cancer. However, its use is limited by adverse effects that usually requires dose interruptions/adjustments and even therapy discontinuation resulting in suboptimal tumor effects.

PCS6422 is an oral, potent, selective, and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes 5-FU to inactive metabolites, such as α -fluoro- β -alanine (F-Bal). F-Bal is thought to cause the neurotoxicity and Hand-Foot Syndrome associated with 5-FU while greater formation of F-Bal has been associated with a decrease in the antitumor activity of 5-FU. Inhibition of DPD by PCS6422 is expected to significantly increase the cancer exposure to the 5-FU cytotoxic metabolites, potentially improving tumor response while reducing side effects.

An IND for a Phase 1B study was cleared by the FDA in May 2020 and Processa plans to initiate the study in the first half of 2021. The study will evaluate the safety and tolerability of several dose combinations of PCS6422 and capecitabine in advanced gastrointestinal (GI) tumor patients.

“Having worked on 5-FU and other cancer agents in the past, adding PCS6422 to our pipeline and expanding our involvement in oncology was an easy decision given the significant impact that PCS6422 may have on improving the efficacy and safety of capecitabine or other fluoropyrimidines,” said Dr. David Young, CEO of Processa.

The grant of license is conditioned on the closing of an equity offering by Processa with at least \$15 million in gross proceeds and the successful up-listing to Nasdaq by October 30, 2020. Following the satisfaction of the conditions, Processa must pay Elion \$100,000 and issue Elion shares of common stock. As additional consideration, Processa will pay Elion development, regulatory, and commercial milestone payments up to a maximum of \$88 million in cash and additional shares of common stock. Royalties on net sales will also be paid to Elion.

Additional information and updates are available on the company's website: <http://www.processapharma.com>

About Processa Pharmaceuticals, Inc.

The mission of Processa has been to develop products where existing clinical evidence of efficacy already exists in unmet medical need conditions, medical conditions where patients need treatment options that will improve survival and/or quality of life. The Company has assembled a proven regulatory science development team, management team, and Board of Directors. The Processa development team has 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 which could cause actual results to differ from those contained in the forward-looking statements.

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