

PSIVIDA CORP.

FORM 10-K/A (Amended Annual Report)

Filed 12/27/11 for the Period Ending 06/30/11

Address	400 PLEASANT STREET WATERTOWN, MA 02472
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Fiscal Year	06/30

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K/A
(Amendment No. 1)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2011

or

[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to
Commission File Number 000-51122

PSIVIDA CORP.

(Exact name of registrant as specified in Its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

26-2774444
(I.R.S. Employer
Identification No.)

400 Pleasant Street
Watertown, MA
(Address of principal executive offices)

02472
(Zip Code)

Registrant's telephone number, including area code: (617) 926-5000

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

Table with 2 columns: Title of each class, Name of each exchange on which registered. Row 1: Common Stock, \$.001 par value per share, The NASDAQ Stock Market LLC (NASDAQ Global Market)

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [] No []

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer []

Accelerated filer [X]

Nonaccelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the NASDAQ Global Market on December 31, 2010, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately \$82,346,000.

There were 20,750,642 shares of the registrant's common stock, \$0.001 par value, outstanding as of September 9, 2011.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive proxy statement, to be filed in connection with the Annual Meeting of Stockholders to be held on November 29, 2011, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Explanatory Note

This Amendment No. 1 on Form 10-K/A (this “Amendment No. 1”) amends the Annual Report on Form 10-K of pSivida Corp. (the “Company”) for the fiscal year ended June 30, 2011, filed with the Securities and Exchange Commission (the “Commission”) on September 13, 2011 (the “Original Filing”). This Amendment No. 1 is being filed as an exhibit-only filing solely to furnish the revised redacted version of Exhibit 10.13 to the Original Filing, which has been revised in response to comments that the Company received from the staff of the Commission in connection with the Company’s request for confidential treatment with respect thereto. Item 15 of Part IV of the Original Filing is hereby amended to include the revised redacted version of Exhibit 10.13.

As required by Rule 12b-15 of the Securities Exchange Act of 1934, new certifications by the Company’s principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment No. 1. Except as described above, no attempt has been made in this Amendment No. 1 to modify or update any other items or disclosures presented in the Original Filing. This Amendment No. 1 does not reflect events occurring after the date of the Original Filing or modify or update those disclosures that may be affected by subsequent events.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(3) Exhibits.

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference to SEC Filing</u>		
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit No.</u>
10.13 (a) #	Amended and Restated Collaborative Research and License Agreement, dated as of June 14, 2011, by and among pSivida Corp, pSivida US, Inc., pSiMedica Limited and Pfizer, Inc.			
31.1 (a)	Certification of Principal Executive Officer pursuant to Rule 13a-14 (a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
31.2 (a)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
#	Confidential treatment has been granted for portions of this exhibit			
a	Filed herewith			

CONFIDENTIAL TREATMENT REQUESTED

Final Execution Version

**AMENDED AND RESTATED
COLLABORATIVE RESEARCH AND LICENSE AGREEMENT**

By and Among

pSivida Corp.

pSivida US, Inc.

pSiMedica Limited

and

Pfizer Inc.

Dated June 14, 2011

CONFIDENTIAL TREATMENT REQUESTED

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AMENDED AND RESTATED

COLLABORATIVE RESEARCH AND LICENSE AGREEMENT

This Amended and Restated Collaborative Research and License Agreement (the “Agreement”), dated as of June 14, 2011 (the “Effective Date”), is made by and among pSivida Corp., a Delaware corporation with offices located at 400 Pleasant Street, Watertown, Massachusetts, 02472, pSivida US, Inc., a Delaware corporation with offices located at 400 Pleasant Street, Watertown, Massachusetts 02472, pSiMedica Limited, a United Kingdom limited company with offices located at Malvern Hills Science Park, Geraldine Road, Malvern, Worcestershire, WR14 3SZ (collectively, “PSIVIDA”) and Pfizer Inc., a Delaware corporation with offices located at 235 East 42nd Street, New York, New York, 10017 (“PFIZER”). PSIVIDA and PFIZER are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, PSIVIDA owns or otherwise controls certain patents, patent applications, technology, know-how and scientific and technical information relating to formulations for drug delivery and compatible devices;

WHEREAS PFIZER has extensive experience and expertise in the development and commercialization of pharmaceutical products;

WHEREAS, PFIZER and pSivida Inc. (now pSivida US Inc.) and pSivida Corp. (as successor to pSivida Limited) are currently party to a Collaborative Research and License Agreement dated April 3, 2007 (the “Prior Agreement”);

WHEREAS PFIZER and PSIVIDA wish to enter into this Agreement to amend and restate the Prior Agreement as of the Effective Date;

NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein, PSIVIDA and PFIZER hereby agree as follows:

1. **Definitions**.

1.1 “Accused Device” shall have the meaning assigned to it in Section 8.3.2.

1.2 “Affiliate” means any entity directly or indirectly controlled by, controlling, or under common control with, a Party to this Agreement, 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 (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of at least fifty percent (50%) of the voting securities or other ownership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity.

1.3 “Alimera” means Alimera Sciences, Inc.

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1.4 “Alimera Agreement” means the Amended and Restated Collaboration Agreement between pSivida, Inc. (f/k/a Control Delivery Systems, Inc.) and Alimera dated as of March 14, 2008 as in existence and effect as of the Effective Date.

1.5 “Antecedent Product” means, with respect to a specific Generic Product, (a) in the United States, the Product referenced as the listed drug for a new drug application that is submitted pursuant to Section 505(j) of the FDCA and (b) in any country outside the United States, the Product referenced in an analogous manner under an analogous application process.

1.6 “B&L” means Bausch & Lomb Incorporated.

1.7 “B&L Agreement” means the Amended and Restated License Agreement between Control Delivery Systems, Inc. (presently, PSIVIDA) and B&L dated as of December 9, 2003 as in existence and effect on the Effective Date.

1.8 “Business Day” means a day other than a Saturday, Sunday, or bank or other public holiday in New York, New York or Boston, Massachusetts.

1.9 “Change of Control” means, with respect to a Party or its parent corporation, (a) a merger or consolidation of such Party or such parent corporation with a Third Party which results in the voting securities of such Party or such parent corporation outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party or such parent corporation, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s assets or business or substantially all of such Party’s ophthalmic assets or business.

1.10 “Clinical IP” means (a) all preclinical and clinical protocols, studies, data, results, study-related forms, materials (excluding solely the Compound) and reports (e.g., investigator brochures, informed consent forms, data safety monitoring board related documents, patient recruitment related materials, biocompatibility studies, animal studies, safety studies, and chemistry, manufacturing and control data) resulting from any preclinical or clinical study or trial of the Product or generated in the course of the Development Program, (b) any certificates of any audit of any such preclinical or clinical study or trial, any record or report of any audit of such preclinical or clinical study or trial containing a finding that involves the absence or failure of a critical process, system or related component, a key internal control and/or an issue with considerable risk to a Party and which warrants immediate remediation to address, and any other audit record or report of such preclinical or clinical study to the extent necessary to respond to a request, requirement, or order by a Government Authority, upon the request of the Party that is the subject of the Government Authority’s request, requirement, or order, and (c) all INDs, NDAs, any unfiled applications, components or materials normally associated with an IND or NDA, regulatory filings or applications comparable to INDs or NDAs in any foreign jurisdictions, drug master files, and other regulatory applications and Regulatory Approvals regarding the Product (excluding any of the foregoing relating to the Compound apart from the Product).

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1.11 “ Clinical Trials ” means all Phase I/II Clinical Trials, Phase II Clinical Trials and Phase III Clinical Trials, or such analogous studies and trials of a medical device as are intended to establish scientifically valid evidence to be submitted in an application to a Regulatory Authority for the Product.

1.12 “ Clinical Supply Requirements ” means the quantities of the Compound or Product that are required for the conduct of Clinical Trials or Non-NDA Trials.

1.13 “ Cost of Clinical Supplies ” means the out-of-pocket costs that a Party pays to Third Parties for the manufacture and supply of Clinical Supply Requirements pursuant to this Agreement.

1.14 “ Commence ” or “ Commencement ” when used with respect to a clinical trial, means the first dosing of the first patient for such trial.

1.15 “ Commercially Reasonable Efforts ” means those efforts and resources consistent with the usual practice of a Party in pursuing the development or commercialization of its own products that are of similar market potential as the Product in the Field, taking into account all relevant factors including resource and workload constraints, product labeling or anticipated labeling, present and future market potential, past performance of the Product in the Field and such Party’s own products that are of similar market potential, financial return, medical and clinical considerations, present and future regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due.

1.16 “ Compound ” means latanoprost, which has the chemical name: isopropyl-(Z)-7[(1R,2R,3R,5S)3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate) and is also known as 13, 14-dihydro-17-phenyl-18, 19, 20-trinor PGF₂alpha isopropyl ester, and free acid(s) and salt(s) thereof.

1.17 “ Confidential Information ” means either the PFIZER Confidential Information or the PSIVIDA Confidential Information, or both, as the context may require.

1.18 “ Control ” or “ Controlled ” means, with respect to any intellectual property right, that the Party (i) owns or (ii) has a license to such intellectual property right and has the ability to grant the other Party access, a license, or a sublicense (as applicable) to such intellectual property right as provided herein, without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such access, license or sublicense (such ability, the “ Right to Grant a Sublicense ”).

1.19 “ Courts ” shall have the meaning assigned to it in Section 15.2.

1.20 “ Development Plans ” means the Pre-POC Development Plan and the PFIZER Development Plan.

1.21 “ Development Program ” means the clinical, regulatory, development and associated activities for a Product conducted under this Agreement and the Prior Agreement.

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1.22 “ Development Term ” means the period commencing on the Effective Date and ending on the date of the First Commercial Sale.

1.23 “ Device ” means a bioerodible device for injection or implantation in or adjacent to the eye that has a core, which core contains a drug, and which core is completely or partially surrounded by a polymer layer or tube.

1.24 “ Excluded PSIVIDA Affiliate IP ” shall mean any Patent Rights and Technology Controlled by any Third Party that becomes an Affiliate of PSIVIDA following a Change of Control of PSIVIDA, to the extent, but only to the extent, that such Patent Rights or Technology: (i) are Controlled by such future Affiliate of PSIVIDA at the time such Affiliate becomes an Affiliate of PSIVIDA (other than pursuant to any license or other grant of rights by PSIVIDA or any other Affiliate of PSIVIDA to such future Affiliate) or (ii) are subsequently Controlled by such Affiliate but are developed independently of and without the use of any Patent Rights and Technology Controlled by PSIVIDA as of or prior to the time such Affiliate becomes an Affiliate of PSIVIDA.

1.25 “ Faber ” means Faber Research LLC.

1.26 “ Faber Agreement ” means the License Agreement by and between Faber Research LLC and pSivida Limited dated January 3, 2007 and as in existence and effect as of the Effective Date.

1.27 “ FDA ” means the United States Food and Drug Administration or any successor agency thereto.

1.28 “ FDCA ” means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.

1.29 “ Field ” means the treatment, control or prevention of any ophthalmic disease or condition in humans excluding uveitis.

1.30 “ Firm Order ” has the meaning assigned to it in Section 5.5.2.

1.31 “ Final Report ” has the meaning assigned to it in Section 3.4.

1.32 “ Formulation ” means a solid, solution or suspension suitable for the ocular delivery of the Compound for use with the Device.

1.33 “ First Commercial Sale ” means the first shipment of a Product in commercial quantities for commercial sale by PFIZER, its Affiliates or its sublicensees to a Third Party in an arm’s length transaction in a country in the Territory after receipt by PFIZER of the first Regulatory Approval for such Product in such country.

1.34 “ Funding Option Notice ” has the meaning assigned to it in Section 3.5.

1.35 “ Generic Product ” means a Device that (i) is sold by a Third Party that is not a licensee or sublicensee of a Party or its Affiliates, or any of their licensees or sublicensees, under

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a marketing authorization granted by a Regulatory Authority to such Third Party; (ii) contains the Compound as its sole active pharmaceutical ingredient; and (x) for purposes of the United States, is approved under an abbreviated new drug application that is submitted pursuant to Section 505(j) of the FDCA (or any successor thereto) and that references a Product as its listed drug or (y) for purposes of a country outside the United States, is approved by the applicable Regulatory Authority under an analogous application process.

1.36 “Glaucoma” means any of a group of neuropathies (including without limitation primary open angle glaucoma, angle closure glaucoma and normal tension glaucoma) or conditions where the goal of treatment is to reduce intraocular pressure.

1.37 “Governmental Authority” means any court, agency, department, authority or other instrumentality of any nation, state, county, city or other political subdivision.

1.38 “Government Official” has the meaning assigned to it in Section 10.1.9.

1.39 “HSR Act” shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.40 “HSR Filing” shall mean filings by PFIZER and PSIVIDA with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.41 “HSR Clearance Date” shall mean the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated hereunder have expired or have been terminated.

1.42 “IND” means the Investigational New Drug Application or, if applicable, the Investigational Device Exemption application, filed with FDA, or a similar application filed with an applicable Regulatory Authority outside of the United States.

1.43 “Indemnified Party” shall have the meaning assigned to it in Section 14.4.

1.44 “Indemnifying Party” shall have the meaning assigned to it in Section 14.4.

1.45 “Infringer” has the meaning assigned to it in Section 8.3.2.

1.46 “Joint Steering Committee” and “JSC” have the meaning assigned to them in Section 2.1.

1.47 “Kentucky Study Agreement” means the means the Investigator Initiated Research Agreement dated as of June 1, 2010 among PFIZER, PSIVIDA and the University of Kentucky Research Foundation.

1.48 “Laws” means all laws, statutes, rules, regulations, orders, judgments and/or ordinances of any Governmental Authority.

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1.49 “Litigation Condition” shall have the meaning assigned to it in Section 14.4.1.

1.50 “Losses” shall have the meaning assigned to it in Section 14.2.

1.51 “Major EU Countries” means the United Kingdom, Spain, Italy, France and Germany.

1.52 “Market Penetration” shall mean, with respect to a Product, on a country-by-country and Product-by-Product basis, (a) the quantity of all Generic Products for which such Product is the Antecedent Product sold in the applicable country divided by (b) the total quantity of such Antecedent Product and all such Generic Product sold in the applicable country (quantity of product sold based on data provided by IMS International or, if such data is not available from IMS International, such other reliable data source as reasonably determined by PFIZER and reasonably agreed by PSIVIDA).

1.53 “NDA” means a New Drug Application or a Biological License Application filed with the FDA in accordance with the FDCA with respect to a pharmaceutical or biologic product or a similar application filed with an applicable Regulatory Authority outside of the United States (including any supra national agency such as the European Union) for the purpose of obtaining approval to market and sell a pharmaceutical or biological product in such jurisdiction in the Territory.

1.54 “Net Sales” means with respect to a Product, the gross amount invoiced by PFIZER, its Affiliates and its sublicensees of such Product to Third Parties, less, without duplication, the following to the extent actually invoiced, paid, granted or accrued: sales returns and allowances, trade, quantity and cash discounts and adjustments granted on account of billing errors, rejected goods, damaged or defective goods, recalls, returns, rebates, chargeback rebates, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers or other institutions; adjustments arising from consumer discount programs or other similar programs; customs or excise duties, sales tax, consumption tax, value added tax, and other taxes (except income taxes) or duties relating to sales; any reductions of payment in respect of sales to the United States government, any state government or any foreign government, or to any other Governmental Authority, or with respect to any government-subsidized program or managed care organization (provided that any reductions, discounts or adjustments that apply collectively to multiple products including the Product shall be allocated pro rata to the amounts invoiced for Products); and freight and insurance (to the extent that PFIZER bears the cost of freight and insurance for a Product). Net Sales shall be determined from books and records maintained in accordance with generally acceptable accounting principles in the United States, as consistently applied by PFIZER with respect to sales of all its pharmaceutical or biologic products.

If the Product is sold as part of a bundle of distinct products (i.e., one price is charged for a number of distinct products), the Net Sales for the Product shall be, on a country-by-country basis, the greater of (a) the gross amount invoiced by PFIZER its Affiliates and its sublicensees of such bundle to Third Parties in such country, multiplied by the ratio of the list price for such Product in such country to the sum of the list prices for each product in such bundle in such country (by way of example, if the list price for such Product when sold separately is \$10, and

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the sum of the list prices for each product in such bundle when sold separately is \$40, then the Net Sales attributable to the Product when sold as part of the bundle would be twenty five percent (25%) of the Net Sales of the bundle of products sold) and (b) the number of units of the Product sold by PFIZER, its Affiliates and its sublicensees in such country to Third Parties as part of a bundle, multiplied by the average gross amount invoiced to Third Parties during the relevant PFIZER Quarter for a unit of the Product sold separately in such country (i.e., on a stand-alone basis solely for monetary consideration), or, in the absence of such transactions, the fair market value for the Product, in each case less, without duplication, the deductions described above.

1.55 “Non-NDA Trial” means any clinical trial, or part of a clinical trial, for the Product that is not designed or required to procure data necessary for the acceptance of filing an NDA. Non-NDA Trials may be conducted before or after the filing of an NDA, before Regulatory Approval for the Product or at any time after Regulatory Approval for the Product.

1.56 “Non-Sequential Milestone” shall have the meaning assigned to it in Section 6.3.1.

1.57 “Patent Costs” means the fees and costs associated with filing, prosecution and maintenance of Patent Rights in the Territory.

1.58 “Patent Rights” means all patents and patent applications, whether domestic or foreign, including all continuations, continuations-in-part, divisionals, provisionals and renewals, and letters of patent granted with respect to any of the foregoing, patents of addition, supplementary protection certificates, registration or confirmation patents and all reissues, re-examination and extensions thereof. In all cases, inventorship will be determined in accordance with U.S. law.

1.59 “Patient Outcomes Tool” means a method for identifying clinical trial subjects, which method meets the following criteria: (a) such method is intended to be used in both a clinical trial and clinical use setting; (b) such method does not require the performance of significant additional activities besides completion of a brief questionnaire and clinical status observations; (c) such method is actually used in a Phase II Clinical Trial of the Product except as otherwise provided in this Section 1.59; and (d) if such method is used in a Phase II Clinical Trial, the use of such method in such Phase II Clinical Trial is intended to (i) demonstrate the utility of such method and (ii) provide evidence of the validity of such method and its appropriateness for use in a Phase III Clinical Trial. Notwithstanding anything to the contrary in this Agreement, the foregoing requirements shall not apply if (x) compliance with applicable Law renders compliance with such requirement impracticable or impossible; (y) compliance with such requirement is not authorized by any Governmental Authority or Regulatory Authority or is not consistent with a Regulatory Approval; or (z) compliance with such requirement is prohibited by, or would impede, delay or adversely impact the approval of the Product by, any Governmental Authority or Regulatory Authority.

1.60 “Person” means an individual, corporation, partnership, company, joint venture, unincorporated organization, limited liability company or partnership, sole proprietorship,

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association, bank, trust company or trust, whether or not legal entities, or any Governmental Authority.

1.61 “PFIZER Confidential Information” means all information relating to PFIZER Technology or PFIZER Program Technology, as well as any other information regarding the technology, business and operations of PFIZER of any of its Affiliates, that is or has been disclosed (whether orally or in writing) by PFIZER or its Affiliates to PSIVIDA or its Affiliates to the extent that such information is not (i) as of the date of disclosure known to PSIVIDA or its Affiliates; or (ii) disclosed in published literature, or otherwise generally known to the public through no breach by PSIVIDA of this Agreement; or (iii) obtained by PSIVIDA or its Affiliates from a Third Party free from any obligation of confidentiality to PFIZER; or (iv) independently developed by PSIVIDA or its Affiliates without use of the PFIZER Confidential Information; or (v) required to be disclosed under Law; provided that, in the case of (v), PSIVIDA provides PFIZER prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of PFIZER, with PFIZER’s efforts to preserve the confidentiality of such information.

1.62 “PFIZER Controlled Intellectual Property” means the Patent Rights and Technology Controlled by PFIZER or any of its Affiliates as of the date of a termination described in Section 13.3.2 that are necessary to develop, make, sell, offer for sale, use and import the Product in substantially the form the Product exists on such date of termination, but not including PFIZER Technology, the PFIZER Program Technology, the PFIZER Program Patent Rights, the PFIZER Patent Rights, and Clinical IP Controlled by PFIZER or any of its Affiliates.

1.63 “PFIZER Development Plan” means, with respect to the Product, a strategy and planning document for all research and development activities to be conducted pursuant to this Agreement up to and including filing an NDA, which document shall describe in reasonable detail the Commercially Reasonable Efforts activities to be undertaken by PFIZER (including Clinical Trials, seeking Regulatory Approvals and manufacturing activities) and the expected timing of each activity.

1.64 “PFIZER Option Date” shall have the meaning assigned to it in Section 3.6.1.

1.65 “PFIZER Patent Rights” means the Patent Rights set forth on Schedule 1.65 and any Patent Rights that may issue from or claim priority to or through the Patent Rights set forth on Schedule 1.65.

1.66 “PFIZER Program Patent Rights” means Program Patent Rights (other than PSIVIDA Program Patents Rights) that are determined by United States law to be owned by PFIZER or any of its Affiliates, including without limitation the Program Patent Rights set forth on Schedule 1.66 and any Program Patent Rights that may issue from or claim priority to or through the Program Patent Rights set forth on Schedule 1.66.

1.67 “PFIZER Program Technology” means Program Technology (other than PSIVIDA Program Technology) that is determined by United States law to be owned by PFIZER or any of its Affiliates and includes relevant PFIZER Confidential Information.

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1.68 “PFIZER Quarter” means (A) for the first three (3) quarters in any calendar year, the three (3) successive thirteen (13) week periods (i) with respect to the United States, commencing on January 1 of any calendar year, and (ii) with respect to any country in the Territory other than the United States, commencing on December 1 of any calendar year, and (B) for the fourth (4th) quarter in any calendar year, the period commencing on the day after the end of the third successive thirteen (13) week period in (A) above and (i) with respect to the United States, ending on December 31 of any calendar year, and (ii) with respect to any country in the Territory other than the United States, ending on November 30 of any calendar year.

1.69 “PFIZER Technology” means any Technology and know-how (including Pfizer Confidential Information) owned, licensed or otherwise Controlled by PFIZER or any of its Affiliates as of the Effective Date.

1.70 “PFIZER Year” means the twelve (12) month period (i) with respect to the United States, commencing on January 1 of any calendar year, and (ii) with respect to any country in the Territory other than the United States, commencing on December 1 of any calendar year.

1.71 “Phase I/II Clinical Trial” means a first in human clinical trial that is primarily intended to test the safety of the Product for a specific indication in patients with the disease or condition under study, or an analogous study or trial of a medical device intended to evaluate scientifically valid evidence to be submitted in an application to a Regulatory Authority for the applicable Product.

1.72 “Phase II Clinical Trial” means a Phase II Clinical Trial that is primarily intended to evaluate the effectiveness and dosing regimen for use in a Phase III Clinical Trial of a Product for a specific indication or an analogous study or trial of a medical device intended to establish scientifically valid evidence to be submitted in an application to a Regulatory Authority for the applicable Product.

1.73 “Phase III Clinical Trial” means a clinical trial intended to meet the requirements for approval of an NDA for the Product, or an analogous study or trial of a medical device intended to establish scientifically valid evidence to be submitted in an application to a Regulatory Authority for the Product.

1.74 “Pre-POC Development Plan” means the plan prepared by PSIVIDA setting forth research and development activities to be conducted prior to and including Proof-of-Concept. Such plan will include details regarding the development activities for the Phase II Clinical Trials for the Product and the development of the Patient Outcomes Tool, which activities will include those summarized on Schedule 1.74.

1.75 “Price Approval” means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.76 “Product” means a Device that meets all of the following criteria: (A) it has a core within a polymer tube, which core contains the Compound and no other active ingredient, (B) it

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receives Regulatory Approval or is designed to receive Regulatory Approval to deliver the Compound and no other active ingredient by subconjunctival injection and no other delivery method, (C) it is bioerodible, and (D) [*]. For the avoidance of doubt, Product shall not include the following: (i) the “First Generation Exclusive Licensed Product” and the “Vitraser Licensed Product,” each as defined under the B&L Agreement, and (ii) the “First Product,” “Product,” “Excluded Product,” or “Option Product” (to the extent PSIVIDA has granted a license covering such Option Product pursuant to Section 5.8 of the Alimera Agreement), each as defined under the Alimera Agreement.

1.77 “Program Patent Rights” means all Patent Rights that cover Program Technology and includes PSIVIDA Program Patent Rights and PFIZER Program Patent Rights. For the avoidance of doubt, Program Patent Rights shall not include CDS Improvements (as defined in the Alimera Agreement).

1.78 “Program Technology” means Technology relating to the Product that is or was (a) invented, created or developed by officers, employees or agents of, or consultants to, PSIVIDA or any of its Affiliates, alone or jointly with Third Parties, in the course of conducting activities under the Development Program, (b) jointly invented, created or developed by officers, employees or agents of, or consultants to, both PSIVIDA and PFIZER or any of their respective Affiliates or sublicensees, in each case, alone or jointly with Third Parties, in the course of conducting activities under the Development Program, (c) invented, created or developed by officers, employees or agents of, or consultants to, PFIZER or any of its Affiliates or sublicensees, alone or jointly with Third Parties, in the course of conducting activities under the Development Program, or (d) acquired by purchase, license, assignment or other means from Third Parties by PSIVIDA or any of its Affiliates, by PSIVIDA and PFIZER or any of their respective Affiliates or by PFIZER or any of its Affiliates, in each case, alone or jointly with Third Parties, in order for such Party (or Parties) to perform obligations under the Development Program. For the avoidance of doubt, Program Technology shall not include CDS Improvements (as defined in the Alimera Agreement).

1.79 “Proof-of-Concept” means the time when a Phase II Clinical Trial for the Product that includes the activities set forth in Schedule 1.74 has been completed.

1.80 “PSIVIDA Confidential Information” means all information relating to PSIVIDA Technology or PSIVIDA Program Technology, as well as any other information regarding the technology, business and operations of PSIVIDA or any of its Affiliates, that is or has been disclosed (whether orally or in writing) by PSIVIDA or any of its Affiliates to PFIZER or its Affiliates to the extent that such information is not (i) as of the date of disclosure to PFIZER, known to PFIZER or its Affiliates; or (ii) disclosed in published literature, or otherwise generally known to the public through no breach by PFIZER of this Agreement; or (iii) obtained by PFIZER or its Affiliates from a Third Party free from any obligation of confidentiality to PSIVIDA; or (iv) independently developed by PFIZER or its Affiliates without use of the PSIVIDA Confidential Information; or (v) required to be disclosed under Law; provided that, in the case of (v), PFIZER provides PSIVIDA prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of PSIVIDA, with PSIVIDA’s efforts to preserve the confidentiality of such information.

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1.81 “PSIVIDA Controlled Intellectual Property” means the Patent Rights and Technology Controlled by PSIVIDA or any of its Affiliates as of the PFIZER Option Date that are necessary to develop, make, sell, offer for sale, use and import the Product in substantially the form the Product exists on the PFIZER Option Date, but not including the Excluded PSIVIDA Affiliate IP, PSIVIDA Technology, the PSIVIDA Program Technology, the PSIVIDA Program Patent Rights, the PSIVIDA Patent Rights, Clinical IP Controlled by PSIVIDA or any of its Affiliates and the PSIVIDA Confidential Information.

1.82 “PSIVIDA Patent Rights” means the Patent Rights set forth on Schedule 1.82 and any Patent Rights that may issue from or claim priority to or through the Patent Rights listed on Schedule 1.82.

1.83 “PSIVIDA Program Patent Rights” means (a) all Program Patent Rights to the extent that they claim (i) modifications, improvements and advancements to the Device (but not including Program Patent Rights that solely and specifically claim improvements to the Device with the Compound), (ii) methods of manufacture or monitoring the Device (but not including Program Patent Rights that solely and specifically claim methods of manufacturing or monitoring the Device with the Compound); (iii) the Device with any composition of matter (but not including Program Patent Rights that solely and specifically claim the Device with the Compound); and (iv) method of use claims except for method of use claims that solely and specifically claim (A) the Device with the Compound or (B) Formulations with respect to the Compound, in each case (i)-(iv) regardless of the identity of the inventors; and (b) Program Patent Rights that are determined by United States law to be owned by PSIVIDA or any of its Affiliates, and including without limitation the Program Patent Rights set forth on Schedule 1.83.

1.84 “PSIVIDA Program Technology” means (a) all Program Technology to the extent that it relates to (i) modifications, improvements and advancements to the Device (but not including Program Technology that solely and specifically relates to improvements to the Device with the Compound), (ii) methods of manufacture or monitoring the Device (but not including Program Technology that solely and specifically relates to methods of manufacturing or monitoring the Device with the Compound); (iii) the Device with any composition of matter (but not including Program Technology that solely and specifically relates to the Device with the Compound); and (iv) method of use claims except for method of use claims that solely and specifically claim (A) the Device with the Compound or (B) Formulations with respect to the Compound, in each case (i)-(iv) regardless of the identity of the inventors; and (b) Program Technology that is determined by United States law to be owned by PSIVIDA or any of its Affiliates.

1.85 “PSIVIDA Reserved Interests” shall have the meaning assigned to it in Section 16.3.1.

1.86 “PSIVIDA Technology” means any Technology owned or otherwise Controlled by PSIVIDA or any of its Affiliates as of the Effective Date.

1.87 “PSIVIDA Valid Claim” means any claim from (a) an issued and unexpired patent included within the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other

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Governmental Authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal 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 included within the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights; provided however, that such a claim from a patent application has not been canceled, withdrawn, or abandoned [*]. If a claim of a patent application ceases to be a PSIVIDA Valid Claim under item (b) because of the passage of time and later issues as part of a patent within item (a), then it shall again be considered to be a PSIVIDA Valid Claim effective as of the earlier of the grant, allowance or issuance of such patent.

1.88 “Regulatory Approval” means any and all approvals, with respect to any jurisdiction, or authorizations (other than Price Approvals) of a Regulatory Authority, that are necessary for the commercial manufacture, distribution, use, marketing or sale of a pharmaceutical product in such jurisdiction.

1.89 “Regulatory Authority” means, in respect of a particular country or jurisdiction, the Governmental Authority having responsibility for granting Regulatory Approvals in such country or jurisdiction.

1.90 “Representatives” shall have the meaning assigned to it in Section 14.1.1.

1.91 “Right of Reference” means the right of a Party and its licensees or designees to reference or cross-reference Clinical IP in any regulatory applications or filings.

1.92 “Right to Grant a Sublicense” shall have the meaning assigned to it in Section 1.18.

1.93 “Royalty Term” means, on a country-by-country and Product-by-Product basis, the period commencing upon First Commercial Sale of a Product in a country and ending upon the later to occur of: (i) the date on which such Product is no longer covered by a PSIVIDA Valid Claim in such country; and (ii) ten (10) years from the date of First Commercial Sale of such Product in such country.

1.94 “Technology” means all inventions, materials, technology, data, technical and scientific information, know-how, expertise and trade secrets, and intellectual property rights embodying any of the foregoing, but excluding any Patent Rights.

1.95 “Term” means the period of time commencing on the Effective Date and ending on the earlier of (a) the last to expire Royalty Term or (b) the effective date of termination of this Agreement pursuant to the terms hereof.

1.96 “Territory” means the entire world.

1.97 “Third Party” means any person or entity other than PFIZER, PSIVIDA, or any of their respective Affiliates.

1.98 “Third Party Claim” shall have the meaning assigned to it in Section 14.4.

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1.99 **Construction** . Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (i) “include”, “includes” and “including” are not limiting and mean include, includes and including, without limitation; (ii) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (iii) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (iv) references to a person are also to its permitted successors and assigns; (v) references to an “Article”, “Section”, “Exhibit” or “Schedule” refer to an Article or Section of, or any Exhibit or Schedule to, this Agreement unless otherwise indicated; (vi) the word “will” shall be construed to have the same meaning and effect as the word “shall”; (vii) the word “any” shall mean “any and all” unless otherwise indicated by context and (viii) references to “dollars” or “\$” shall refer to United States Dollars.

2. Management of the Development Program .

- 2.1. **Joint Steering Committee** . The research and development activities conducted under this Agreement shall be overseen by a joint research committee composed of two (2) (or such larger number mutually agreed to by the Parties) representatives from each Party (the “Joint Steering Committee” or “JSC”). An alternate member designated by a Party may serve temporarily in the absence of a permanent member of the JSC for such Party. Each Party shall designate one of its representatives as a co-chair of the JSC. The co-chairs of the JSC shall be jointly responsible for setting the agenda for each meeting, and each co-chair will be responsible for chairing alternating JSC meeting. From time to time, the JSC may establish subcommittees or subordinate committees (that may or may not include members of the JSC itself) to oversee particular projects or activities, and such subcommittees or subordinate committee shall be constituted and shall operate as the JSC agrees. After the First Commercial Sale of the Product the JSC shall be disbanded. The initial members of the JSC shall be designated by each Party promptly after the Effective Date. For the avoidance of doubt, following the PFIZER Option Date, the Parties agree that PSIVIDA’s participation in the JSC is not an obligation, and PSIVIDA may, in its discretion, participate or not participate from time to time.
- 2.2. **Decision-Making** . Except as otherwise set forth in this Agreement, all decisions of the JSC made pursuant to this Agreement shall be made by consensus; provided, however, that:
- 2.2.1. PSIVIDA shall have final decision-making authority (if unresolved after escalation to members of senior management as set forth in Section 2.3) with respect to research and development activities for the Product at any time prior to the PFIZER Option Date.

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- 2.2.2. Following the PFIZER Option Date, PFIZER shall have final decision-making authority (if unresolved after escalation to members of senior management as set forth in Section 2.3) with respect to research and development activities for the Product.
- 2.3. Dispute Resolution. The representatives of each Party on the JSC shall each have one vote and no vote shall be taken at a meeting of the JSC unless all members of the JSC are present and participating in the vote. In the event a matter is not resolved by unanimous consent of the JSC, or in the event the Parties are unable to agree upon matters relating to a Development Plan, the matter shall be referred to senior management of the Parties for resolution. In the event such members of senior management are unable to resolve the dispute within fifteen (15) days of such referral, the Party having final decision-making authority pursuant to Section 2.2 shall make the final decision on such matter.
- 2.4. Meetings. The JSC shall hold meetings at such times and places as shall be determined by the co-chairs of the JSC (it being expected that any in-person meetings will alternate between the appropriate offices of each Party), but in no event shall such meetings be held less frequently than once every calendar quarter during the Development Term. The JSC may:
- 2.4.1. conduct meetings in person, by videoconference or by telephone conference; and
- 2.4.2. invite other personnel of the Parties to attend meetings of the JSC as appropriate to the agenda for such meeting, after giving advance notice to the other Party.
- 2.5. Minutes. At each meeting, the JSC shall elect a secretary who will prepare minutes after each meeting, reporting in reasonable detail the actions taken by the JSC during such meeting, issues requiring resolution, and resolutions of previously reported issues. Such minutes are to be reviewed and, if reasonably complete and accurate, signed by one JSC member from each Party. The secretary shall revise such minutes as necessary to obtain such signatures.

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- 2.6. **JSC Functions and Powers**. The research and development activities of the Parties performed in accordance with this Agreement shall be managed only to the extent set forth herein, unless otherwise agreed to by the Parties in writing. The JSC shall foster the collaborative relationship between the Parties in order to assist each Party in fulfilling its obligations under the Development Plans, and shall in particular have the functions and powers set forth below.
- 2.6.1. With respect to the Product, the JSC shall:
- (a) encourage and facilitate ongoing cooperation and information exchange between the Parties;
 - (b) monitor the progress of the Development Plans and the Parties' diligence in carrying out their responsibilities thereunder; provided, however, that the JSC shall not have the authority to make any determination that either Party is in breach of its obligations under a Development Plan or this Agreement;
 - (c) review and comment on the Development Plans; and
 - (d) perform such other functions as appropriate to further the purposes of this Agreement as mutually determined by the Parties.
- 2.6.2. For the avoidance of doubt, the JSC shall have no power to amend this Agreement or a Development Plan and shall have only such powers as are specifically delegated to it in this Agreement.
- 2.7. **Independence**. Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between PSIVIDA and PFIZER is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as is expressly set forth in this Agreement. PSIVIDA and PFIZER are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties.

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3. **Development** .

- 3.1. Pre-POC Development Plan . Commencing on the first anniversary of the Effective Date and on or prior to each anniversary thereafter until the PFIZER Option Date, and at such additional times as PSIVIDA in its sole discretion may choose, PSIVIDA shall update the Pre-POC Development Plan.
- 3.2. Development Costs Prior to Proof-of-Concept . PSIVIDA shall use Commercially Reasonable Efforts to conduct, directly or through its agents and contractors, the activities set forth in the Pre-POC Development Plan at PSIVIDA's sole expense, unless PSIVIDA elects to cease development under Section 3.3.
- 3.3. Ceasing Development Prior to Proof of Concept . PSIVIDA may elect to cease development at any time after the first anniversary of the Effective Date but prior to Proof-of-Concept. PSIVIDA shall notify PFIZER of such election. After providing such notice, PSIVIDA shall have no further obligations with respect to the Product under this Agreement. PFIZER shall have the right to elect to solely fund further development and commercialization of the Product, provided that PFIZER makes such election and notifies PSIVIDA no later than sixty (60) days after receiving notice from PSIVIDA pursuant to this Section 3.3, such notice by PFIZER to be deemed a Funding Option Notice. In the event PFIZER submits a Funding Option Notice as set forth in the preceding sentence, the terms of Section 3.6 shall apply, including the obligation to make the payments pursuant to Section 3.6.1, as well as all other terms of this Agreement that apply to the Product; provided, however, that if PSIVIDA elects to cease development prior to achieving Proof-of-Concept for the Product and PFIZER submits such Funding Option Notice, all amounts otherwise payable by PFIZER under Section 3.6.1 or Section 6 shall be reduced by [*]. In the event PFIZER does not submit a Funding Option Notice with respect to the Product, neither Party shall have any further rights or obligations under this Agreement and the Agreement shall automatically terminate at the end of the sixty-day election period, after which termination nothing in this Agreement shall be construed as limiting PSIVIDA's right, alone or with or through other Persons, to develop, manufacture and commercialize the Product, which development, manufacturing and commercialization activities shall not be subject to this Agreement; provided, however, that if PSIVIDA provides the notice referred to

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in this Section 3.3 but does not actually cease all development activities with respect to the Product for at least one year, this Agreement shall not terminate as set forth above and all rights of PFIZER under this Agreement shall remain in effect notwithstanding the foregoing.

- 3.4. Achievement of Proof-of-Concept. Promptly after PSIVIDA determines that the Product has reached Proof-of-Concept, PSIVIDA shall provide to PFIZER a written report (a “ Final Report ”) setting forth the following information for such Product:
- (a) A statement that the Product has achieved Proof-of-Concept;
 - (b) A summary of relevant Clinical IP for the Product in PSIVIDA’s possession and Control (including Clinical IP generated by Third Parties under any services arrangement with PSIVIDA);
 - (c) Copies of any correspondence and official meeting minutes with Regulatory Authorities with respect to the Product;
 - (d) All pre-specified safety and efficacy analyses as outlined in the Clinical Trial protocols and statistical analysis plans; and
 - (e) A summary of any research or development programs in Glaucoma then being conducted by PSIVIDA itself or through a contract service provider or consultant, but excluding programs being conducted by PSIVIDA with a Third Party to which PSIVIDA has granted development and commercialization rights or licenses.

Notwithstanding any other provisions of this Agreement, in the event the Parties disagree whether the Product has achieved Proof-of-Concept, PSIVIDA may elect to continue developing the Product, and, if PSIVIDA so elects and Commences a Phase III Clinical Trial, then the Product will be deemed to have achieved Proof-of-Concept for purposes of this Section 3.4 and PSIVIDA will deliver another or an updated Final Report to PFIZER, in which case Section 3.5 shall apply, and if PFIZER subsequently submits a Funding Option Notice, PFIZER shall pay to PSIVIDA both the Event Milestone payment of [*] for Commencement of the first Phase III Clinical Trial for the Product described in Section 6.2.1 and the payment of \$20 million described in Section 3.6.1, both at such time as the payment under Section 3.6.1 is due.

- 3.5. Funding Option Notice. Within ninety (90) days following

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PFIZER's receipt of a Final Report, PFIZER shall notify PSIVIDA in writing of (a) PFIZER's election to solely fund further development and commercialization of the Product as further set forth in this Agreement (the "Funding Option Notice"); or (b) PFIZER's determination that it will not solely fund such further development and commercialization of the Product. From the Effective Date until the earlier of the end of such ninety (90) day time period (the "Option Notice Period") or PFIZER providing notification pursuant to Section 3.5(a) or 3.5(b), PSIVIDA shall not (x) disclose the Final Report or any of its contents to any Third Party except as may be required by applicable Law or (y) enter into any agreement with a Third Party pursuant to which PSIVIDA grants or conveys to such Third Party licenses, rights, options or other legal interests to develop and or commercialize the Product in the Field or uveitis or engage in any discussions with any Third Party with respect to any such agreement. In the event PFIZER fails to submit a Funding Option Notice during the Option Notice Period, this Agreement shall automatically terminate at the end of the Option Notice Period, after which time nothing in this Agreement shall be construed as limiting PSIVIDA's right, alone or with or through other Persons, to develop, manufacture and commercialize the Product, which development, manufacturing and commercialization activities shall not be subject to this Agreement.

- 3.6. PFIZER Funding Option . The terms of this Section 3.6 shall apply if PFIZER submits to PSIVIDA a Funding Option Notice.
- 3.6.1. Within forty-five (45) days of PFIZER submitting to PSIVIDA a Funding Option Notice, PFIZER shall pay to PSIVIDA Twenty Million Dollars (\$20,000,000), provided, however, that if PFIZER determines that an HSR Filing with respect to this Agreement is required to be made under the HSR Act, it shall so notify PSIVIDA and in such case PFIZER shall make such payment within forty-five (45) days after the HSR Clearance Date. The date on which PFIZER makes such payment in full shall be the "PFIZER Option Date."
- 3.6.2. Following the submission of the Funding Option Notice, PFIZER shall have sole authority and discretion with respect to developing and commercializing the Product at PFIZER's sole expense, subject to Section 5.1.
- 3.6.3. Within fifteen (15) days after the PFIZER Option Date, PSIVIDA shall (i) use Commercially Reasonable Efforts to transfer ownership of all regulatory filings and Regulatory Approvals that relate solely to the Product to PFIZER; (ii) deliver to PFIZER a copy of all Clinical IP in PSIVIDA's (or any of its Affiliates') possession and Control (including Clinical IP generated by Third Parties under any services arrangement) related to the Product, if any, in the same form in which PSIVIDA (or such Affiliate) maintains such data; (iii) provide PFIZER

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with copies of any then-existing documentation and technical information, in the form and format in which such materials are maintained by PSIVIDA or any of its Affiliates in the ordinary course of its business, that are necessary for the manufacture of the Product, which documentation and technical information shall include (A) copies of flow charts of the manufacturing procedures and work instructions related to manufacturing the Product, (B) a list of all equipment, including the source of the equipment, utilized in the production of the Product, (C) copies of all current specifications for the Product, (D) copies of all standard operating procedures for the manufacturing procedures to be transferred, (E) all environmental conditions necessary to manufacture the Product and copies of any existing external environmental impact studies based on the materials or methods employed in the manufacturing method to be transferred, and (F) such other documentation as the Parties may mutually agree, in each case of the foregoing subsections (iii) and (A) through (F), that are in PSIVIDA's or any of its Affiliates' possession and Control (including any of the foregoing that are generated by Third Parties under any services arrangement) and are necessary to manufacture Products; and (iv) deliver to PFIZER, in the same form in which PSIVIDA or any of its Affiliates maintains such items, copies of all regulatory reports, records, correspondence and other regulatory materials in PSIVIDA's or any of its Affiliates' possession and Control related solely to such Product and any Regulatory Approval therefor (including any of the foregoing that are generated by Third Parties under any services arrangement), including, if applicable, any information contained in the global safety database established and maintained by PSIVIDA or any of its Affiliates.

- 3.6.4. Within sixty (60) days after the PFIZER Option Date, PFIZER shall prepare and deliver to PSIVIDA the PFIZER Development Plan. PFIZER shall update the PFIZER Development Plan and deliver such updated PFIZER Development Plan to PSIVIDA on each anniversary date of the PFIZER Option Date up to the date of the First Commercial Sale of the Product if PFIZER has made any material changes to such plan during the prior year. PFIZER shall also deliver a copy of the then-current PFIZER Development Plan to PSIVIDA promptly after PSIVIDA's request. In the event of an inconsistency or discrepancy between the PFIZER Development Plan and this Agreement, the terms of this Agreement shall prevail.
- 3.6.5. If PFIZER notifies PSIVIDA pursuant to Section 3.6.1 that an HSR Filing is required, each of PFIZER and PSIVIDA shall, within fifteen (15) Business Days after such notice from PFIZER (or such later time as may be agreed to in writing by the Parties), file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any HSR Filing required of it

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with respect to the transactions contemplated hereby. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own costs and expenses (other than filing fees, which shall be paid by PFIZER) associated with any HSR Filing.

- 3.7. Cooperation. Each Party shall use Commercially Reasonable Efforts to cooperate with the other Party in connection with all activities to be performed pursuant to this Section 3. PFIZER will provide reasonable support to PSIVIDA with respect to the development of the Patient Outcomes Tool, including by making available (through telephonic or electronic means) to PSIVIDA a PFIZER employee who is expert in the development of patient outcomes tools for consultation and review of documents for up to one hundred hours prior to the delivery of a Funding Option Notice by PSIVIDA.
- 3.8. Conduct of Development. The Parties shall perform all activities under this Agreement and the Development Plans in compliance in all material respects with the requirements of applicable Laws and each Party will use Commercially Reasonably Efforts to achieve the objectives of the Development Plans efficiently and expeditiously. For the avoidance of doubt, a Party, unless it agrees otherwise, shall have no obligation to undertake any development activity allocated to it in any Development Plan prepared by the other Party.
- 3.9. Development Plan Records. Each Party shall maintain complete and accurate records of all work conducted under the Development Plans and all results, data and developments made pursuant to its efforts under the Development Plans. Such records shall reflect work done and results achieved in the performance of the Development Plans in sufficient detail and in a manner appropriate for patent and regulatory purposes. Subject to bona fide confidentiality obligations to a Third Party, the other Party shall have the right to request copies of such records at reasonable times and upon reasonable notice to the extent necessary or useful for such Party to perform its other obligations under this Agreement, or to secure or enforce patents licensed under this Agreement as permitted under this Agreement.
- 3.10. Reports. Each Party shall report to the JSC no less than once per calendar quarter, and such reports shall consist of a written progress report summarizing the work performed under the Development Plans, data obtained in connection with the Product and other material information regarding the Product since the previous report. The JSC shall define the format and the nature of the content of such quarterly reports, which format and nature shall be reasonably acceptable to both Parties. Beginning six months after the date

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of the First Commercial Sale of the Product and once per year thereafter, PFIZER shall provide PSIVIDA with a written report describing development and regulatory activities for the Product undertaken during the previous year, if any, and such activities planned for the next year, if any, including any planned and actual submissions for Regulatory Approval.

3.11. Termination of Development Plans. The Development Plans shall automatically terminate on the effective date of any termination of this Agreement. Additionally, the Pre-POC Development Plan may terminate as specifically set forth in this Section 3.

4. Licenses.

4.1. License to PFIZER. Subject to the terms of this Agreement and except to the extent rights granted hereunder were granted under Sections 2.1.1 or 2.1.2 of the B&L Agreement, or under Sections 4.1, 5.1, 5.4 and 5.8 of the Alimera Agreement, or include rights that PSIVIDA is otherwise obligated not to convey to a Third Party under Sections 2.3, 2.4 and 2.5 of the B&L Agreement, or under Sections 4.1, 5.1, 5.4 and 5.8 of the Alimera Agreement, PSIVIDA hereby grants, and shall cause its Affiliates to grant, to PFIZER, and PFIZER hereby accepts:

- 4.1.1. subject to PSIVIDA's retained rights pursuant to Section 4.3, an exclusive (even as to PSIVIDA and its Affiliates), royalty-bearing license, with the right to sublicense, under the PSIVIDA Technology, the PSIVIDA Program Technology, the PSIVIDA Program Patent Rights, the PSIVIDA Patent Rights, the Clinical IP Controlled by PSIVIDA or any of its Affiliates and the PSIVIDA Confidential Information, to research, develop, make, have made, use, sell, import or otherwise exploit the Product only in the Field in the Territory following the PFIZER Option Date; and
- 4.1.2. a non-exclusive, royalty-free, worldwide license, with the right to sublicense, under the PSIVIDA Technology, the PSIVIDA Program Technology, the PSIVIDA Program Patent Rights, the PSIVIDA Patent Rights, the Clinical IP Controlled by PSIVIDA or any of its Affiliates and the PSIVIDA Confidential Information, solely for PFIZER to perform its obligations hereunder that are required to be performed prior to the PFIZER Option Date.
- 4.1.3. following the PFIZER Option Date, a non-exclusive, royalty-free (except as set forth below), world-wide license, with the right to sublicense, under and to all PSIVIDA Controlled Intellectual Property, solely to develop, make, have made, sell, offer for sale, use and import the Product; provided that such license shall continue only so long as

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(a) PFIZER elects to accept such license, and (b) if any such PSIVIDA Controlled Intellectual Property is licensed to PSIVIDA from a Third Party (“Third Party Licensor”), PFIZER agrees in writing to comply with, and thereafter fulfills, all non-financial obligations of PSIVIDA to such Third Party Licensors applicable to sublicensees under the applicable license agreements and all royalties and other payments payable to such Third Party Licensors under the applicable Third Party license arising solely from the sublicense grant under this Section or from activities conducted by PFIZER or its Affiliates or its sublicensees pursuant to such sublicenses. Without limiting the foregoing, PSIVIDA shall disclose such obligations, royalties and other payments to PFIZER in advance of PFIZER taking such sublicense and, if PFIZER elects to take such sublicense, PFIZER shall pay such disclosed royalties and other payments that become payable on and after the PFIZER Option Date either, at PSIVIDA’s option and direction, to PSIVIDA reasonably before the amounts are due so that PSIVIDA can make timely payment to the Third Party Licensor, or to the Third Party Licensor in a timely fashion, provided if PFIZER fails at any time to make timely payment of such disclosed royalties and other payments to PSIVIDA or the Third Party Licensor, PFIZER’s license rights hereunder shall terminate upon thirty (30) days notice from PSIVIDA unless PFIZER cures such non-payment during such period. PFIZER’s payment of such disclosed royalties and other payments under this Section 4.1.3 shall be limited to only those attributable to the development, making, having made, selling, offering for sale, using and importing the Product. In addition, PFIZER shall be responsible for the payment of such disclosed royalties and other payments under this Section 4.1.3 on a pro-rata basis as may be appropriate in the case where PSIVIDA has granted sublicenses to additional Third Party sublicensees. To the extent certain rights would be PSIVIDA Controlled Intellectual Property but for the fact that PSIVIDA does not have a Right to Grant a Sublicense with respect to such rights, PSIVIDA shall not bring (and shall not authorize or directly assist an Affiliate of PSIVIDA or a Third Party to bring, except as may be required under any contractual obligation of PSIVIDA) any action against PFIZER or any of its Affiliates, or a sublicensee of PFIZER’s rights related to the Product, alleging misappropriation, misuse, or infringement of such rights arising from PFIZER or such Affiliate or sublicensee researching, developing, making, having made, using, selling, importing or otherwise exploiting the Product. For the purpose of clarity, PSIVIDA has no obligation to maintain Control of any rights for the purposes of this Section.

Notwithstanding anything to the contrary in this Agreement, (i) the Parties agree and acknowledge that, under the B&L Agreement and the Alimera Agreement, PSIVIDA has granted certain rights to B&L and Alimera, respectively, both exclusively and nonexclusively, and has agreed not to grant

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certain licenses or other rights to Third Parties; and (ii) to the extent any rights granted hereunder have been granted under the B&L Agreement or the Alimera Agreement or are restricted pursuant to a covenant not to convey under the B&L Agreement or Alimera Agreement, such rights shall not be and are not granted to PFIZER under this Agreement.

- 4.2. License to PSIVIDA. Subject to the terms of this Agreement, PFIZER hereby grants, and shall cause its Affiliates to grant, to PSIVIDA, and PSIVIDA hereby accepts a non-exclusive, royalty-free (except as set forth below), worldwide license, with the right to sublicense, under and to (a) the Clinical IP Controlled by PFIZER or any of its Affiliates, PFIZER Technology, the PFIZER Program Technology, the PFIZER Program Patent Rights, the PFIZER Patent Rights and the PFIZER Confidential Information, solely for PSIVIDA to perform or have others perform activities and exercise its rights under the Development Plans, and (b) the Clinical IP Controlled by PFIZER or any of its Affiliates (i) to research, develop, make, have made, use, sell, import or otherwise exploit any product in any country in the world (other than a product prohibited under Section 11.3), and (ii) to incorporate, disclose, use or exercise a Right of Reference to such Clinical IP for any research, development or commercial purpose (other than for a product prohibited under Section 11.3); provided that in the case of (i) and (ii) such license shall not grant any rights under or to the Product in the Territory in the Field or for uveitis for so long as PFIZER has an exclusive license to the Product in the Field in the Territory under this Agreement; provided further that, if PSIVIDA exercises its right under this Section to sublicense such Clinical IP to a Third Party, the rights granted under such sublicense may include only such Clinical IP as existed on the first effective date of such sublicense between PSIVIDA and such Third Party and PSIVIDA shall not provide or disclose to such Third Party or use for the benefit or on behalf of such Third Party, directly or indirectly, any Clinical IP arising or created after such date. With respect to the license granted under clause (b) above, if any of the foregoing Clinical IP is licensed to Pfizer from a Third Party ("Third Party Licensor"), PSIVIDA must agree in writing to comply with, and thereafter must fulfill, all non-financial obligations of PFIZER to such Third Party Licensors applicable to sublicensees under the applicable license agreements and all royalties and other payments payable to such Third Party Licensors under the applicable Third Party license arising solely from the sublicense grant under this Section or from activities conducted by PSIVIDA or its Affiliates or its sublicensees pursuant to such sublicenses. Without limiting the foregoing, PFIZER shall disclose such obligations, royalties and other payments to PSIVIDA in advance of PSIVIDA taking such sublicense and, if PSIVIDA elects to take such sublicense, PSIVIDA shall pay such disclosed royalties and other payments that become payable on and after the PFIZER Option Date either, at PFIZER's option and direction, to PFIZER reasonably before the amounts are due so that PFIZER can make timely payment to the Third Party Licensor, or to the Third Party Licensor in a timely fashion, provided if PSIVIDA fails at any time to make

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timely payment of such disclosed royalties and other payments to PFIZER or the Third Party Licensor, PSIVIDA's license rights hereunder shall terminate upon thirty (30) days notice from PFIZER unless PSIVIDA cures such non-payment during such period. PSIVIDA's payment of such disclosed royalties and other payments under this Section 4.2 shall be limited to only those attributable to the development, making, having made, selling, offering for sale, using and importing the Product. In addition, PSIVIDA shall be responsible for the payment of such disclosed royalties and other payments under this Section 4.2 on a pro-rata basis as may be appropriate in the case where PFIZER has granted sublicenses to additional Third Party sublicensees. From time to time upon PSIVIDA's request, PFIZER shall deliver to PSIVIDA a copy of all Clinical IP in PFIZER's or any of its Affiliates' possession and Control (including Clinical IP generated by Third Parties under any services arrangement) covered by the foregoing grant but not previously provided to PSIVIDA, if any, in the same form in which PFIZER or such Affiliate maintains such data.

4.3. Retained Rights. Notwithstanding anything to the contrary in this Section 4, each Party shall retain such rights as are necessary for such Party to perform its obligations under this Agreement, including the Development Plans.

5. **Diligence, Regulatory Approvals and Manufacturing/Supply**.

5.1. Diligence.

5.1.1. After the PFIZER Option Date, PFIZER shall use Commercially Reasonable Efforts to develop the Product in accordance with the PFIZER Development Plan for the Product, and to seek Regulatory Approval for and commercialize the Product in the United States and the Major EU Countries.

5.2. Regulatory Affairs.

5.2.1. Until the PFIZER Option Date, PSIVIDA shall determine all regulatory plans and strategies for the Product and will own and be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for the Product, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Without limiting the generality of the foregoing, PSIVIDA shall have the right, consistent with applicable law, to amend the protocol for any Phase I/II Clinical Trial or Phase II

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Clinical Trial conducted in connection with the Pre-POC Development Plan. Notwithstanding the foregoing, in addition to or in lieu of Clinical Trials sponsored by PSIVIDA, PSIVIDA may, in its sole discretion, authorize a Third Party to sponsor Clinical Trials and to prepare and submit an IND to the FDA for the Product.

- 5.2.2. Following the PFIZER Option Date, PFIZER shall determine all regulatory plans and strategies for the Product in the Territory and will own and be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for the Product, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval.
- 5.2.3. During the Term of this Agreement, the Party responsible for submitting regulatory filings (the “Regulatory Submission Party”) shall provide the other Party (the “Regulatory Non-Submission Party”) with drafts of substantive submissions it plans to make to FDA or other Regulatory Authority with respect to the Product. The Regulatory Non-Submission Party may provide comments regarding such submission prior to its submission, and the Regulatory Submission Party shall consider in good faith incorporating such comments into the submission. The Regulatory Submission Party shall provide the Regulatory Non-Submission Party with copies of all substantive submissions it makes to, and all correspondence it receives from, FDA or other Regulatory Authority with respect to the Product. The Regulatory Submission Party shall provide the Regulatory Non-Submission Party with reasonable advance notice of all meetings, conferences, and discussions, whether in person or by teleconference (including, but not limited to, advisory committee meetings and any other meeting of experts convened by FDA or other regulatory authorities concerning any topic relevant to such Product), scheduled with FDA or such other regulatory authorities concerning any regulatory matters relating to such Product, and the Regulatory Non-Submission Party shall have the right to participate in such meetings, conferences or discussions and to confer with the Regulatory Submission Party in advance on the scheduling of, the objectives to be accomplished at, and the agenda and strategy for, such meetings, conferences, and discussions with FDA or other regulatory authorities; provided, however, that, in the event that the Parties have disagreement relating to such meetings, conferences and discussions, the Regulatory Submission Party shall have the final decision-making authority.
- 5.2.4. The Regulatory Submission Party shall provide the Regulatory Non-Submission Party with a summary of any such meeting, conference or discussion the Regulatory Non-Submission Party does not attend, or of any other material verbal communication with a Regulatory Authority

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with respect to the Product, promptly (and in any case within three (3) Business Days) after it occurs, and generally shall keep the Regulatory Non-Submission Party reasonably informed about the progress of the regulatory approval process for the Product.

- 5.3. Recalls or Other Corrective Action . After the PFIZER Option Date, PFIZER shall promptly notify PSIVIDA of any material actions to be taken by PFIZER in the Territory with respect to any recall or market withdrawal or other corrective action related to the Product prior to such action, and, if reasonably practicable under the circumstances, to permit PSIVIDA a reasonable opportunity to consult with PFIZER with respect thereto. After the PFIZER Option Date all costs and expenses with respect to a recall, market withdrawal or other corrective action shall be borne by PFIZER.
- 5.4. Manufacturing and Supply—General . The terms of this Section 5.4 shall apply to the Party manufacturing or supplying Clinical Supply Requirements pursuant to Section 5.5 (the “ Manufacturing Party ”).
- 5.4.1. Capacity . The Manufacturing Party’s obligations to supply Products or Compounds pursuant to Section 5.5 shall be limited to the supply of Clinical Supply Requirements as specified in Section 5.5.1 or 5.5.2 and in each case shall be subject to such Party’s actual capacity for the manufacture and supply of such Products or Compounds. The Manufacturing Party shall use Commercially Reasonable Efforts to notify the other Party in the event the forecasted or ordered amount of Product or Compound is likely to exceed the Manufacturing Party’s then-existing capacity for manufacturing such Product or Compound.
- 5.4.2. Conforming Product . Upon delivery to the other Party, all Products and Compounds supplied by the Manufacturing Party shall meet the reasonable specifications provided in advance (in writing) by the other Party. For purposes of this Section 5.4.2, “reasonable specifications” shall mean specifications that may be met with the Manufacturing Party’s then-existing manufacturing capabilities. In the event the Manufacturing Party is unable to provide Products or Compounds meeting the reasonable specifications provided in advance in writing by the other Party, the Manufacturing Party shall have the right to obtain Compounds or Products, as applicable, from a Third Party supplier. The non-Manufacturing Party shall provide reasonable cooperation, information and assistance necessary in order for the Manufacturing Party to do so.
- 5.4.3. Title and Delivery . All Products and Compounds to be supplied pursuant to Section 5.5 shall be delivered FCA (Manufacturing Party’s loading dock). The receiving Party shall have the right to designate

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the common carrier for shipments of Products and Compounds. Title, possession and risk of loss for Products and Compounds shall pass to the receiving Party upon delivery of Products and Compounds to the receiving Party's designated carrier.

5.5. Manufacture and Supply—Clinical Supplies.

- 5.5.1. Supply for Pre-POC Activities. PFIZER shall supply to PSIVIDA, at PFIZER's sole expense, [*] of Compound with a remaining shelf life expiring no earlier than [*], for conducting activities under the Pre-POC Development Plan. Such supply of Compound shall be shipped to PSIVIDA at a time and to a destination that are mutually acceptable to the Parties.
- 5.5.2. Supply of Product. After the PFIZER Option Date, PSIVIDA shall supply to PFIZER, at PSIVIDA's Cost of Clinical Supplies, all or a portion of PFIZER's Clinical Supply Requirements for the Product, in accordance with the PFIZER Development Plan. For the avoidance of doubt, and subject to PFIZER's obligation to purchase such Clinical Supply Requirements as are set forth in the binding portion of the rolling forecast for such Clinical Supply Requirements, PFIZER shall have the right to procure all or any portion of its Clinical Supply Requirements at its sole expense for the Product from a Third Party. On the first Business Day of the second calendar month after the PFIZER Option Date and thereafter on a monthly basis on the first Business Day of each calendar month until PFIZER completes clinical trials for the Product (or such earlier date that PFIZER notifies PSIVIDA that it no longer requires PSIVIDA to supply PFIZER with Clinical Supply Requirements), PFIZER shall provide to PSIVIDA a twelve (12) month rolling forecast for such Clinical Supply Requirements, the first three (3) months of each forecast shall be binding. Along with each forecast PFIZER shall deliver to PSIVIDA a purchase order in a form to be agreed by the parties for the third (3rd) month of the forecast (each a "Firm Order") (for clarity, the first and second months of each forecast will be covered by earlier submitted Firm Orders) this Section 5.5.2. provided however the quantity in each Firm Order shall not be less than eighty percent (80%) nor more than one hundred twenty percent (120%) of the quantity for any calendar month as most recently updated in the Firm Order period of the most recent forecast, and, that PSIVIDA's obligations under this Section 5.5.2 are conditioned on PFIZER's timely supply of Compound to

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PSIVIDA at PFIZER's sole expense. PFIZER may terminate the supply arrangement described in this Section 5.5.2 upon ninety (90) days prior written notice

- 5.6. Commercialization/Pricing. After the PFIZER Option Date, PFIZER shall be solely responsible for commercial manufacturing, marketing, promoting, selling, distributing and determining pricing and other terms of sale for the Product.
- 5.7. Disclosure of Technology by PSIVIDA. During the Term at PFIZER's reasonable request, but in no event later than ten business (10) days following such request, PSIVIDA will disclose to PFIZER or its designated Affiliates, all documentation, manuals, tangible materials, protocols or standard operating procedures or Clinical IP embodying PSIVIDA Technology relating to the Product and PSIVIDA Program Technology relating to the Product that is reasonably necessary for PFIZER to practice the licenses under this Agreement, including such information from Third Parties to the extent permitted under any applicable agreements.
- 5.8. Disclosure of Technology by PFIZER. During the Term at PSIVIDA's reasonable request, but in no event later than ten business (10) days following such request, PFIZER will disclose to PSIVIDA or its designated Affiliates, all documentation, manuals, tangible materials, protocols, standard operating procedures or Clinical IP embodying PFIZER Technology relating to the Product and PFIZER Program Technology relating to the Product that is reasonably necessary for PSIVIDA to practice the licenses under this Agreement, including such information from Third Parties to the extent permitted under any applicable agreements.

6. **Fees, Milestones and Royalties**.

- 6.1. Upfront Payment. Within fifteen (15) days after the Effective Date, PFIZER shall pay to PSIVIDA \$2,300,000, which constitutes a payment for rights granted with respect to the Product pursuant to this Agreement.
- 6.2. Product Milestone Payments.
 - 6.2.1. Event Milestone Payments. In consideration of the rights granted hereunder with respect to the Product, and subject to the terms and conditions of this Agreement, PFIZER shall pay to PSIVIDA

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the amount set forth in the table below opposite the corresponding event milestone (each an “Event Milestone”) within forty-five (45) days after the occurrence of such Event Milestone under this Agreement (each amount payable one time only):

<u>Event Milestone</u>	<u>Event Milestone Payment</u>
Commencement of the first Phase III Clinical Trial for the Product	\$[*] million
First date of acceptance by FDA of the first NDA for the Product (the “FDA Filing Milestone”)	\$[*] million
Receipt of the first Regulatory Approval from the FDA for the Product (the “FDA First Indication Approval Milestone”)	\$[*] million
Receipt of the first Regulatory Approval from the FDA for the Product for the first indication that (a) is different from any indication included in the Regulatory Approval from the FDA with respect to which the FDA First Indication Approval Milestone became payable and (b) is not Glaucoma	\$[*] million
Receipt of the first Regulatory Approval and Price Approval, where applicable, for the Product in the first Major EU Country (the “EU First Indication Approval”)	\$[*] million
Receipt of the first Regulatory Approval and Price Approval, where applicable, for the Product in the first Major EU Country for the first indication that (a) is different from any indication included in the Regulatory Approval in the Major EU Country with respect to which the EU First Indication Approval Milestone became payable and (b) is not Glaucoma	\$[*] million

6.2.2. Sales Milestones. In addition to the Event Milestone Payments for the Product, in consideration of the rights granted hereunder, and subject to the terms and conditions of this Agreement, PFIZER shall pay to PSIVIDA the following one-time payments within forty-five (45) days

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after the end of the calendar year that most nearly coincides with the applicable PFIZER Year in which aggregate Net Sales of the Product for all indications in the Territory first reach the respective thresholds (each, a “Sales Milestone”) indicated below:

<u>Product Annual Net Sales in the Territory</u>	<u>Sales Milestone Payment</u>
Net Sales in a PFIZER Year exceed \$[*] million	\$ [*] million
Net Sales in a PFIZER Year exceed \$[*] billion	\$ [*] million
Net Sales in a PFIZER Year exceed \$[*] billion	\$ [*] million
Net Sales in a PFIZER Year exceed \$[*] billion	\$ [*] million

6.3. Milestone Payments Generally .

- 6.3.1. The milestone payments set forth in this Section 6 shall be cumulative rather than mutually exclusive. For the avoidance of doubt, if at any time the FDA Filing Milestone or the FDA First Indication Approval Milestone (each a “Non-Sequential Milestone”) for the Product occurs prior to the occurrence of all Event Milestones set forth in the rows preceding such Non-Sequential Milestone for the Product in the tables set forth above, PFIZER shall pay to PSIVIDA the sum of (a) all Event Milestone Payments associated with Event Milestones in rows preceding the Non-Sequential Event Milestone which have not otherwise been paid by PFIZER, and (b) the FDA Filing Milestone or the FDA First Indication Approval Milestone associated with the Non-Sequential Milestone.
- 6.3.2. PFIZER’s payment of any Sales Milestone payment shall be accompanied by a report identifying the Net Sales of the Product and the amount payable to PSIVIDA. All such reports shall be kept confidential by PSIVIDA and not disclosed to any other party, other than PSIVIDA’s accountants which shall be obligated to keep such information confidential, and such information and reports shall only be used for purposes of this Agreement.

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- 6.4. **PFIZER Royalty Payments** . In addition to the payments under Sections 6.1-6.3, in consideration of the rights granted hereunder, and subject to the terms and conditions of this Agreement, on a country-by-country basis during the Royalty Term for each country in the Territory, PFIZER shall pay to PSIVIDA an amount equal to [*] of Net Sales of the Product in a PFIZER Quarter in such country. The Parties agree and acknowledge that the payment of royalties by PFIZER to PSIVIDA for sales when there is no PSIVIDA Valid Claim covering the Product shall represent consideration for the license granted to PFIZER for PSIVIDA Technology pursuant to this Agreement.
- 6.5. **Generic Products** . Any payments owed with respect to sales of a Product pursuant to Section 6.4 shall be reduced by [*] for so long as one or more Generic Products for which the Product is the Antecedent Product together maintain [*] or greater Market Penetration in the Territory; with any such reduction to be prorated appropriately for the then-current PFIZER Quarter.
- 6.6. **Duration of Royalty Payments** . Payments under Section 6.4 shall continue until the expiration of the Royalty Term. Thereafter PFIZER shall have a non-exclusive, royalty-free, perpetual, irrevocable, worldwide license, with the right to sublicense, under the PSIVIDA Technology and PSIVIDA Program Technology to research, develop, make, have made, use, sell, import or otherwise exploit the Product only in the Field in the Territory.
- 6.7. **Notices of Termination** . In the event that this Agreement has been terminated as permitted under Section 3 or Section 13, no further payments that have not yet accrued under Section 6 shall become due following the effective date of such termination.

7. **Accounting and Procedures for Payment** .

- 7.1. **Inter-Company Sales** . Sales between or among PFIZER, its Affiliates or sublicensees shall not be subject to royalties under Section 6.4. PFIZER shall be responsible for the payment of royalties on Net Sales by or on behalf of its Affiliates or sublicensees to Third Parties.

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- 7.2. Currency . All royalty payments shall be computed and paid in United States dollars. For the purposes of determining the amount of any Sales Milestone Payments or royalties due for the relevant PFIZER Quarter, the amount of Net Sales in any foreign currency shall be converted into United States dollars in a manner consistent with the paying Party's customary practices used to prepare its audited financial reports; provided that such practices use a widely accepted source of published exchange rates.
- 7.3. Royalty Payments . PFIZER shall make royalty payments to PSIVIDA with respect to each PFIZER Quarter within forty-five (45) days after the end of the calendar quarter that most nearly coincides with such PFIZER Quarter, and each payment shall be accompanied by a report identifying Net Sales and the amount payable, as well as the computation thereof and the basis of any reductions allowable under Section 6. Said reports shall be kept confidential by the Parties and not disclosed to Third Parties, other than the Parties' certified public accountants which shall be obligated to keep such information confidential, and such information and reports shall only be used for purposes of this Agreement.
- 7.4. Method of Payments . Each payment hereunder shall be made by electronic transfer 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 the paying Party's election, to such bank account as the receiving Party shall designate in a notice at least five (5) Business Days before the payment is due. All payments under this Agreement shall bear interest from the fifteenth (15th) day after the date due until paid at a rate equal to the thirty (30)-day United States dollar LIBOR rate in effect on the date that payment was due, as published by The Financial Times.
- 7.5. Inspection of Records . PFIZER shall, and shall cause its Affiliates and sublicensees to, keep accurate books and records setting forth gross sales of the Product, Net Sales of the Product, and amounts payable hereunder to PSIVIDA for the Product. Each Party shall, and shall cause its Affiliates and sublicensees to, keep accurate books and records setting forth all other payments and reimbursements due hereunder by one Party to the other. Each Party shall permit, and shall cause its Affiliates and sublicensees to permit, the other Party and independent certified public accountants employed by the other Party (reasonably acceptable to the Party providing access to records) to examine such books and records at any reasonable time, upon reasonable notice, but not later than [*] years following the rendering date the

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applicable payment under this Agreement is due. The foregoing right of examination may be exercised only once during each twelve (12)-month period of the Term. The Party being examined may require such accountants to enter into a reasonably acceptable confidentiality agreement and such accountants shall disclose to the examining Party only information that relates to the accuracy of the payments due under this Agreement. The opinion of said independent accountants regarding such reports and related payments shall be binding on the Parties, other than in the case of manifest error. The examining Party shall bear the cost of any such examination and review; provided that if the examination shows an underpayment of royalties or other payments due under this Agreement or an overstatement of amounts invoiced of more than ten percent (10%) of the amount due for the applicable period, then the Party being examined shall promptly reimburse the examining Party for all costs incurred in connection with such examination. If any such examination reveals an underpayment, the underpaying Party shall promptly pay the other Party the amount of such underpayment. Any overpayment of royalties or other payments due under this Agreement revealed by an examination shall be fully-creditable against future payments due under this Agreement or if no future payments will become due, the Party that received such overpayment shall promptly refund such overpayment to the paying Party.

7.6. Tax Matters .

- 7.6.1. VAT . It is understood and agreed between the Parties that any payments made under this Agreement are inclusive of any value added or similar tax imposed upon such payments.
- 7.6.2. Tax Cooperation . The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made under this Agreement. Each Party further agrees to provide reasonable cooperation to the other Party, at the other Party's expense, in connection with any official or unofficial tax audit or contest relating to payments made under this Agreement.
- 7.6.3. Withholding Tax Matters . In addition, in the event any of the payments made by PFIZER pursuant to Section 6 become subject to withholding taxes under the Laws of any jurisdiction, PFIZER shall deduct and withhold the amount of such taxes for the account of PSIVIDA to the extent required by Law, such payment shall be reduced by the amount of taxes deducted and withheld, and PFIZER shall pay the amount of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to PSIVIDA an official tax certificate or other evidence of such tax obligations, together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable

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PSIVIDA to claim such payment of taxes. PFIZER shall act in good faith to withhold taxes at the lowest rate allowed by the tax treaties applicable to the payments made by PFIZER. PSIVIDA shall act in good faith to provide PFIZER with any required documentation to enable PFIZER to withhold taxes at such rate. Any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, PSIVIDA. Each Party will provide the other Party with reasonable assistance, at such Party's expense, to enable a Party to recover such taxes as permitted by Law.

8. **Patents and Infringement.**

- 8.1. Disclosure and Ownership of Program Technology and Program Patent Rights. Each Party shall (and shall cause its Affiliates to) disclose to the other Party all Program Technology or Program Patent Rights in writing promptly after they are invented, created or developed or their significance is first appreciated, and in any event no later than sixty (60) days prior to any public disclosure or filing of a United States or international provisional or non-provisional patent application disclosing or claiming such Program Technology or Program Patent Rights. PSIVIDA shall have sole ownership of, and PFIZER shall and hereby does assign to PSIVIDA, all rights, title and interest in any PSIVIDA Program Technology and PSIVIDA Program Patent Rights, regardless of the identity of the inventors. Inventorship and ownership of Program Technology and Program Patent Rights other than PSIVIDA Program Technology and PSIVIDA Program Patent Rights shall be determined by United States law. The Parties shall provide each other with reasonable assistance to evidence, perfect or defend ownership of Program Technology or Program Patent Rights as set forth in this Agreement, including (i) executing any assignments and other documents requested by the other Party, (ii) providing good faith testimony by affidavit, declaration or in person, and (iii) assisting with filing or maintaining patents.
- 8.2. Prosecution and Maintenance of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory.
- 8.2.1. Filing, Prosecution, and Maintenance of PSIVIDA Patent Rights. PSIVIDA shall have primary responsibility for and control over the preparation, filing, prosecution, and maintenance of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory. PSIVIDA shall have the authority to select patent counsel, and to determine the form and content of such prosecution documents and to make all decisions regarding whether to file, prosecute and maintain

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patents and patent applications, and in which countries to do so. PSIVIDA shall be [*] of the Patent Costs associated with the PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. PSIVIDA shall keep PFIZER reasonably informed regarding the status of each patent or patent application included within PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory and shall provide PFIZER with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of these Patent Rights. PFIZER shall have the right to review pending patent applications and other proceedings for, and to make recommendations to PSIVIDA regarding, the prosecution of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory relating to the Product; provided that all final decisions regarding the prosecution and maintenance of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights shall be made by PSIVIDA. Notwithstanding the foregoing, with respect to the PSIVIDA Program Patent Rights, on and after the date that PFIZER submits a Funding Option Notice, PSIVIDA agrees to act in good faith to cooperate and coordinate with PFIZER, as reasonably requested, on the prosecution and maintenance of such PSIVIDA Program Patent Rights.

- 8.2.2. Abandonment of PSIVIDA Patent Rights or PSIVIDA Program Patent Rights . PSIVIDA may, at its sole discretion, abandon any patent or pending patent application, on a patent-by-patent or application-by-application basis, within the PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. PSIVIDA shall not abandon prosecution or maintenance of any PSIVIDA Patent Rights or PSIVIDA Program Patent Rights relating to the Product in the Territory without notifying PFIZER in a timely manner of PSIVIDA's intention and reason therefor and providing PFIZER with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance in the Territory of such PSIVIDA Patent Rights and/or PSIVIDA Program Patent Rights at PFIZER's sole expense, provided, however, that such abandoned PSIVIDA Patent Rights or PSIVIDA Program Patent Rights shall be excluded from the definition of PSIVIDA Valid Claim for the purposes of the Royalty Term. The cancellation or amendment of a claim or claims during the prosecution of a patent application, or during a reissue or reexamination proceeding with respect to an issued patent, within the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights shall not in and of itself constitute a discontinuance or abandonment under this Section. Notwithstanding the foregoing, PFIZER's rights under this

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Section 8.2.2 with respect to PSIVIDA Patent Rights and PSIVIDA Program Patent Rights shall be subject to rights granted to Faber under the Faber Agreement, including Section 4.1 thereof, to Alimera under the Alimera Agreement, including the rights set forth in Section 7.1 and 7.2 thereof, and to B&L under the B&L Agreement, including the rights set forth in Article 9 thereof.

8.2.3. Information Disclosure; Cooperation . Subject to any limitations imposed by the confidentiality obligations set forth in the Faber Agreement, Alimera Agreement and the B&L Agreement, upon PFIZER’s request PSIVIDA shall disclose and make available to PFIZER all material information controlled by PSIVIDA or any of its Affiliates that is reasonably necessary for PFIZER to perform its obligations and to exercise its rights under this Section 8. PSIVIDA agrees to cooperate with PFIZER with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Section 8.

8.3. Enforcement of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights .

8.3.1. Notification . During the Term, each of the Parties shall promptly notify the other in the event they learn of any known infringement or suspected infringement of any of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights that cover the Product and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

8.3.2. Enforcement . [*], but not the obligation, to initiate or prosecute an infringement or other appropriate suit or action against any Third Party who at any time has infringed or is suspected of infringing (an “Infringer”) any of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights. [*] shall give [*] advance notice of its intent to file a suit against an Infringer of PSIVIDA Patent Rights or PSIVIDA Program Patent Rights relating to the Product in the Territory and the reasons therefor, and shall provide [*] with an opportunity to make suggestions and comments regarding such filing; provided, however , that [*] shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by [*], and further provided that it shall be within [*] sole discretion whether to incorporate such suggestions or comments. [*] shall keep [*] reasonably informed of the status and progress of such litigation. [*] shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of

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the suit, including, but not limited to, attorneys' fees and court costs. With respect to PSIVIDA Patent Rights and PSIVIDA Program Patent Rights relating to the Product in the Territory, if [*] has not taken legal action or been successful in obtaining cessation of the infringement within (a) ninety (90) days from the date of notice by either Party under Section 8.3.1; or (b) thirty (30) days after [*] notifies [*] that [*] would like to move for injunctive relief; or (c) ten (10) days before the expiration of a period of time set by applicable Law in which action must be taken with respect to the alleged infringement (e.g., as may be required under the Hatch-Waxman Act and 35 USC §271), then, subject to the rights with respect to the PSIVIDA Patent Rights granted to Faber under the Faber Agreement, including 4.2 thereof, to Alimera under the Alimera Agreement, including Section 7.6 thereof, and to B&L under the B&L Agreement, including Article 10 thereof, [*] shall have the right to bring suit against an Infringer at [*] own expense. [*]
[*]

8.3.3. Upon request of the other Party, either Party shall join as a party to or shall commence the suit on behalf of the other Party if required for standing, at the other Party's expense, and shall offer reasonable assistance to the other Party in connection therewith at its own expense. Any damages, royalties, settlement fees or other consideration for infringement resulting from the suit shall be distributed as follows: (i) first, each Party shall be reimbursed for its reasonable out-of-pocket costs paid in connection with the proceeding; and (ii) thereafter, PFIZER will receive [*] and PSIVIDA will receive [*] of any damages, royalties, settlement fees or other consideration. Neither Party shall settle any such suit or otherwise consent to an adverse judgment in any such suit that adversely affects the rights or interests of the other Party under this Agreement, including, issues of validity of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights, without the prior written consent of the other Party.

8.4. Prosecution and Maintenance of PFIZER Program Patent Rights in the Territory.

8.4.1. Filing, Prosecution, and Maintenance of PFIZER Program Patent Rights. PFIZER shall have primary responsibility for and control over the preparation, filing, prosecution, and maintenance of PFIZER Program Patent Rights. PFIZER shall have the authority to select patent counsel, and to determine the form and content of such prosecution documents

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and to make all decisions regarding whether to file, prosecute and maintain patents and patent applications, and in which countries to do so. PFIZER shall be [*] of the Patent Costs associated with the PFIZER Program Patent Rights. PFIZER shall keep PSIVIDA reasonably informed regarding the status of each patent or patent application included within the PFIZER Program Patent Rights and shall provide PSIVIDA with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of these Patent Rights. PSIVIDA shall have the right to review pending patent applications and other proceedings for, and to make recommendations to PFIZER regarding the prosecution of PFIZER Program Patent Rights; provided that all final decisions regarding the prosecution and maintenance of PFIZER Program Patent Rights shall be made by PFIZER.

8.4.2. Abandonment of PFIZER Program Patent Rights. PFIZER may, at its sole discretion, abandon any patent or pending patent application, on a patent-by-patent or application-by-application basis, within the PFIZER Program Patent Rights. PFIZER shall not abandon prosecution or maintenance of any PFIZER Program Patent Rights without notifying PSIVIDA in a timely manner of PFIZER's intention and reason therefor and providing PSIVIDA with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of PFIZER Program Patent Rights at PSIVIDA's sole expense. The cancellation or amendment of a claim or claims during the prosecution of a patent application, or during a reissue or reexamination proceeding with respect to an issued patent, within the PFIZER Program Patent Rights shall not in and of itself constitute a discontinuance or abandonment under this Section.

8.4.3. Information Disclosure; Cooperation. Upon PSIVIDA's request, PFIZER shall disclose and make available to PSIVIDA all material information controlled by PFIZER or any of its Affiliates that is reasonably necessary for PSIVIDA to perform its obligations and to exercise its rights under this Section 8. PFIZER agrees to cooperate with PSIVIDA with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Section 8.

8.5. Enforcement of PFIZER Program Patent Rights.

8.5.1. Notification. During the Term, each of the Parties shall promptly notify the other in the event they learn of any known infringement or suspected infringement of any of the PFIZER Program Patent Rights that cover the

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Product and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

- 8.5.2. Enforcement. PFIZER shall have the initial right, but not the obligation, to initiate or prosecute an infringement or other appropriate suit or action against an Infringer of any of the PFIZER Program Patent Rights. PFIZER shall give PSIVIDA advance notice of its intent to file a suit against an Infringer of PFIZER Program Patent Rights relating to the Product, and shall provide PSIVIDA with an opportunity to make suggestions and comments regarding such filing; provided, however, that PSIVIDA shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by PFIZER, and further provided that it shall be within PFIZER's sole discretion whether to incorporate such suggestions or comments. PFIZER shall keep PSIVIDA reasonably informed of the status and progress of such litigation. PFIZER shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of the suit, including, but not limited to, attorneys' fees and court costs. With respect to PFIZER Program Patent Rights relating to the Product, if PFIZER has not taken legal action or been successful in obtaining cessation of the infringement within (a) ninety (90) days from the date of notice by either Party under Section 8.5.1; or (b) thirty (30) days after PSIVIDA notifies PFIZER that PSIVIDA would like to move for injunctive relief; or (c) ten (10) days before the expiration of a period of time set by applicable Law in which action must be taken with respect to the alleged infringement (e.g., as may be required under the Hatch-Waxman Act and 35 USC §271), then, PSIVIDA shall have the right to bring suit against an Infringer at PSIVIDA's own expense. This right of PSIVIDA to bring suit, as well as to continue an existing suit, is also conditioned on all of the following requirements:

[*]

- 8.5.3. Upon request of the other Party, either Party shall join as a party to or shall commence the suit on behalf of the other Party if required for standing, at the other Party's expense, and shall offer reasonable assistance to the other Party in connection therewith at its own expense. Any damages, royalties, settlement fees or other consideration for infringement resulting from the suit shall be distributed as follows: (i) first, each Party shall be reimbursed for its reasonable out-of-pocket costs paid in connection with the proceeding; and (ii) thereafter, PSIVIDA will receive [*] and PFIZER will receive [*] of any damages, royalties, settlement fees or other consideration.

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Neither Party shall settle any such suit or otherwise consent to an adverse judgment in any such suit that adversely affects the rights or interests of the other Party under this Agreement, including, issues of validity of the PFIZER Program Patent Rights, without the prior written consent of the other Party

- 8.6. Patent Term Extension. PFIZER shall have the exclusive right to seek, at PFIZER's expense, patent term extensions or supplemental patent protection, including supplementary protection certificates, in the Territory in relation to the Product under any of the PFIZER Patent Rights and PFIZER Program Patent Rights. PFIZER and PSIVIDA shall cooperate in connection with all such activities, and PFIZER, its agents and attorneys will give due consideration to all timely suggestions and comments of PSIVIDA regarding any such activities; provided that all final decisions shall be made by PFIZER.
- 8.7. Orange Book Listings. With respect to filings of patent information with FDA on Form 3542a or Form 3542 (and foreign equivalents) for issued patents for the Product for which PFIZER applies for or holds an NDA, PFIZER shall have the exclusive right and shall be solely responsible at its expense for fulfilling its obligations under applicable Laws to list any applicable PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. PFIZER will be solely responsible for any such filings and listings, and for any and all decisions with respect to such filings and listings. Notwithstanding the foregoing, with respect to any such form to be filed concerning any PSIVIDA Patent Rights, PFIZER shall provide PSIVIDA with the opportunity to comment on the filing of such form by providing a draft of such form to PSIVIDA at least five Business Days in advance of filing such form with FDA and by making a good faith effort to incorporate any comments received from PSIVIDA prior to filing such form with FDA.
- 8.8. Patent Invalidity Claim with Respect to PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. During the Term, each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a PSIVIDA Patent Right or a PSIVIDA Program Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. [*] shall have the first right, but not the obligation, to defend against any such action involving a PSIVIDA Patent Right or a PSIVIDA Program Patent Right, [*].

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- 8.9. Patent Invalidity Claim with Respect to PFIZER Program Patent Rights . During the Term, each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a PFIZER Program Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. PFIZER shall have the first right, but not the obligation, to defend against any such action involving PFIZER Program Patent Right, in its own name, and the costs of any such defense shall be at PFIZER's expense. PSIVIDA, upon request of PFIZER, agrees to join in any such action and to cooperate reasonably with PFIZER; provided that PFIZER shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by PSIVIDA in connection with such cooperation. [*] PFIZER, upon request of PSIVIDA, agrees to join in any such action and to cooperate reasonably with PSIVIDA; provided that PSIVIDA shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by PFIZER in connection with such cooperation.
- 8.10. Notification of Third Party Claim . Each Party shall promptly report in writing to the other Party during the Term of this Agreement any claim or allegation by any Third Party that the development or commercialization of the Product infringes the intellectual property rights of any Third Party and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.
- (a) PFIZER shall have the initial right, but not the obligation, to defend any suit or action initiated by any Third Party alleging solely that the Product has infringed, or is suspected of infringing any Third Party intellectual property rights in the Territory. Upon PFIZER's request, PSIVIDA shall join such suit or action and shall offer reasonable assistance to PFIZER in connection therewith at PFIZER's expense. PFIZER shall give PSIVIDA advance notice of its intent to defend any said suit and shall provide PSIVIDA with an opportunity to make suggestions and comments regarding such defense; provided, however, that PSIVIDA shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by PFIZER, and further provided that it shall be within PFIZER's sole discretion whether to incorporate such suggestions or comments. PFIZER shall keep PSIVIDA reasonably informed of the status and progress of the litigation. PFIZER shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of the suit, including, but not limited to, attorneys' fees and court costs. PFIZER shall have the right to settle any such litigation and shall specifically have the

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right, whether or not litigation commences, to negotiate a license or other rights from any Third Party authorizing the use of Third Party intellectual property rights in connection with the Product; provided, however, that PFIZER shall not settle any such action, or otherwise consent to an adverse judgment in any such action, or make any admission in any such license and negotiation that adversely affects the rights or interests of PSIVIDA under this Agreement, including, issues of validity of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights, without the prior written consent of PSIVIDA. Any such license shall be at arm's length and otherwise on terms and conditions as may be deemed appropriate in the reasonable business judgment of PFIZER. PFIZER shall provide PSIVIDA with a copy of any such license promptly after its execution.

- (b) If PFIZER does not defend a claim, suit or proceeding as set forth above within ninety (90) days of the date PFIZER was reasonably aware or notified of the Third Party claim alleging infringement (or within such shorter period as may be necessary for submitting or filing a response), then PSIVIDA may, in its sole discretion, elect to defend such claim, suit or proceeding, using counsel of its own choice and the provisions of Section 8.10(a) shall apply as if the term "PSIVIDA" were changed to "PFIZER" and the term "PFIZER" were changed to "PSIVIDA".

- 8.11. Third Party Royalty Obligations. If PFIZER reasonably determines in good faith that, in order to exercise the license granted by PSIVIDA in this Agreement without infringing the Patent Rights of a Third Party, it is necessary to obtain a license of Patent Rights from such Third Party (excluding any license that is required to make, use, sell, offer for sale, supply, cause to be supplied, or import the Compound in such country or to practice PFIZER Technology or PFIZER Patent Rights), then the amount of PFIZER's royalty payments under Section 6.4 with respect to Net Sales for the Product in such country shall be reduced by [*] of the amount of royalties on Net Sales payable by PFIZER to such Third Party [*].

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9. **Confidentiality; Publication**

9.1. **Confidential Information**

- 9.1.1. PFIZER and PSIVIDA each agree that, except as permitted in this Agreement, during the Term and for five (5) years after the Term, it will keep confidential, and will cause its Affiliates to keep confidential, all of the other Party's Confidential Information that is disclosed to it, or to any of its Affiliates. PFIZER and PSIVIDA each agree to take such action, and to cause its Affiliates to take such action, to preserve the confidentiality of PSIVIDA Confidential Information and PFIZER Confidential Information, respectively, as it would customarily take to preserve the confidentiality of its own similar types of confidential information.
- 9.1.2. Each of PFIZER and PSIVIDA, agree, and agree to cause their respective Affiliates, (i) to use PSIVIDA Confidential Information and PFIZER Confidential Information, respectively, only as expressly permitted in this Agreement and (ii) not to disclose PSIVIDA Confidential Information and PFIZER Confidential Information, respectively, to any Third Parties under any circumstance without the prior consent of the other Party, except as expressly permitted in this Agreement.
- 9.1.3. Notwithstanding anything to the contrary in this Section 9, each Party or any of its Affiliates may disclose the other Party's Confidential Information (i) to Governmental Authorities (a) to the extent desirable to obtain or maintain INDs or Regulatory Approvals, and (b) in order to respond to inquiries, requests or investigations relating to this Agreement; (ii) to such Party's attorneys and accountants; (iii) to other outside consultants, contractors, advisory boards, managed care or other health care providers or organizations, and non-clinical and clinical investigators, in each case to the extent desirable to develop, register or market any Compound or Product pursuant to this Agreement or in connection with the exercise of rights or performance of obligations under this Agreement, provided that such Party shall obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information; (iv) in connection with filing or prosecuting Patent Rights or trademark rights as permitted by this Agreement, (v) in connection with prosecuting or defending litigation as permitted by this Agreement, (vi) in connection with or included in scientific presentations and publications relating to Compounds or Products, including abstracts, posters, journal articles and the like, and (vii) to the extent necessary or desirable in order to enforce its rights under

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this Agreement.

- 9.2. Disclosure of Agreement Terms. PSIVIDA or any of its Affiliates may issue mutually acceptable press releases in connection with the execution of this Agreement. Disclosure of the financial terms of this Agreement shall be made in the form of a mutually acceptable press release on the Effective Date. Neither Party nor any of its Affiliates shall disclose or describe the financial terms of this Agreement in any way that is contrary to or inconsistent with the substance of such press release or the Agreement, and neither Party nor any of its Affiliates shall otherwise publically disclose any other terms of this Agreement except as expressly set forth herein. Notwithstanding the foregoing and notwithstanding Section 9.1, each Party or any of its Affiliates may disclose this Agreement or its terms (a) to the extent required by Law, provided that the disclosing Party provides the other Party notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of the other Party, with the other Party's efforts to preserve the confidentiality of such information and (b) to any investors or potential investors, lenders, and other potential financing sources, or to a Third Party in connection with an investment or proposed investment, financing or proposed financing, merger or acquisition, proposed merger or acquisition, a license or proposed license of the technology or intellectual property licensed hereunder and not prohibited hereunder, sale of assets or other similar transaction, and to Affiliates, attorneys, accountants, stockholders, investment bankers, advisers or other consultants in connection with the foregoing permitted disclosures, in each case provided that the Person to which such disclosure is made agrees to keep such information confidential on essentially the same terms as set forth herein and to use such Confidential Information solely to evaluate such investment, financing, acquisition, merger, license, sale or other transaction, (c) to any stock exchange on which its stock is then listed to the extent required by such exchange, provided that the disclosing Party shall notify the other Party in advance of such disclosure to the extent reasonably possible and otherwise complies with the provisions of Section 9.4, (d) to its attorneys and accountants, and (e) to its consultants, advisers, contractors and agents in connection with any of the foregoing permitted purposes, provided that the Person to which such disclosure is made agrees, or is otherwise bound by professional standards of conduct, to keep such information confidential on essentially the same terms as set forth herein.

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- 9.3. **Other Disclosures** . Notwithstanding anything else herein but subject to Section 3.5, both Parties and their respective Affiliates shall be entitled to publicly disclose significant Product achievements of the type and by the means customary for similarly situated companies. For the purpose of clarity, such public disclosures with respect to a Product by PSIVIDA or any of its Affiliates may include, (i) prior to the Pfizer Option Date, Commencement of Clinical Trials, significant factual information with respect to Clinical Trials including numbers of patients, centers, investigators, descriptions of protocols, completion of enrollment and of treatment under Clinical Trials, safety and efficacy data and other results of Clinical Trials, and filings with and actions by Regulatory Authorities, and (ii) following the Pfizer Option Date, Commencement of Clinical Trials, significant factual information with respect to Clinical Trials including numbers of patients, number of centers, number of investigators, high level descriptions of study design, completion of enrollment and of treatment under Clinical Trials, top line safety and efficacy data, and significant actions by Regulatory Authorities. For the purpose of clarity, such public disclosures described in the first sentence of this Section with respect to a Product by PFIZER or any of its Affiliates following the PFIZER Option Date may include any of the disclosures described in the preceding sentence. Prior to making public disclosure of the achievement of any such event relating to a Product, including any results of Clinical Trials, the disclosing Party will provide the other Party with a copy of such disclosure five (5) Business Days in advance, or if such advance notice is not practicable under the circumstances, as much advance notice as the disclosing Party practicably can provide and shall take into account the good faith and reasonable comments made by the other Party within such five (5) day period. Subject to the foregoing provisions of this Section 9.3, and without limiting any rights under Sections 9.2 and 9.4, each Party shall submit to the other Party for review and approval (such approval not to be unreasonably withheld or delayed) any proposed academic, scientific or medical publication or public presentation (for the purpose of clarity, not including public disclosures as described in the first three sentences of this Section or filings with a Governmental Authority) which contains the other Party's Confidential Information. Such review and approval will be conducted for the purposes of preserving the value of intellectual property rights and determining whether any portion of the proposed publication or presentation containing the other Party's Confidential Information should be modified or deleted for such purpose. Written copies of such proposed publication or presentation required to be submitted hereunder shall be submitted to the other Party no later than twenty (20) days before submission for publication or presentation. The non-disclosing Party shall provide its comments with respect to such publications and presentations within fifteen (15) days of its receipt of such written copy. The review period may be extended for an additional fifteen (15) days in the event the non-disclosing Party can demonstrate reasonable need for such extension including for the preparation and filing of patent applications. PSIVIDA and PFIZER will each comply with standard academic practice regarding authorship of

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scientific publications and recognition of contribution of other parties in any publication.

- 9.4. **Filing, Registration or Notification of the Agreement.** If a Party or any of its Affiliates determines that it is required by Law to publicly file, register or notify this Agreement with a Governmental Authority (it being agreed that PSIVIDA or any of its Affiliates may file this Agreement with the Securities & Exchange Commission), such Party or such Affiliate shall (i) initially file a copy of this Agreement in form redacting the financial terms and such other terms as are reasonably requested by the other Party (the “**Redacted Agreement**”), (ii) request, and use Commercially Reasonable Efforts to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in the Redacted Agreement, for a period of at least ten (10) years, (iii) permit the other Party to review and comment upon such request for confidential treatment and any subsequent correspondence with respect thereto at least five (5) Business Days prior to its submission to such Governmental Authority, provided that any comments shall be made within three (3) Business Days of receipt, (iv) promptly deliver to the other Party any written correspondence received by it or its representatives from such Governmental Authority with respect to such confidential treatment request and promptly advise the other Party of any other communications between it or its representatives with such Governmental Authority with respect to such confidential treatment request, (v) upon the written request of the other Party, request an appropriate extension of the term of the confidential treatment period, and (vi) if such Governmental Authority requests any changes to the redactions set forth in the Redacted Agreement, use Commercially Reasonable Efforts to support the redactions in the Redacted Agreement as originally filed and shall not agree to any changes to the Redacted Agreement without first discussing such changes with the other Party and taking the other Party’s comments into consideration when deciding whether to agree to such changes. Each Party and its Affiliates shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

10. **Representations and Warranties.**

- 10.1. **PSIVIDA Representations and Warranties.** As of the Effective Date, PSIVIDA hereby represents and warrants to PFIZER as follows:
- 10.1.1. PSIVIDA has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by PSIVIDA have been duly and validly authorized and approved by proper

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corporate action on the part of PSIVIDA, and PSIVIDA has taken all other action required by Law, its certificate of incorporation, by-laws or other organizational documents or any agreement to which it is a party or to which it may be subject required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of PFIZER, this Agreement constitutes a legal, valid and binding obligation of PSIVIDA, enforceable against PSIVIDA in accordance with its terms.

- 10.1.2. The execution and delivery of this Agreement by PSIVIDA and the performance by PSIVIDA contemplated hereunder does not and will not violate any Laws or any order of any court or Governmental Authority.
- 10.1.3. Neither the execution and delivery of this Agreement nor the performance hereof by PSIVIDA requires PSIVIDA to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to performance of the Development Plan or the manufacture, use, importation or sale of the Product) or from any other person, firm or corporation, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination under any agreement or contract to which PSIVIDA or any of its Affiliates is a party or to which it may be subject, except for those breaches or rights that would not adversely affect the ability of PSIVIDA to perform its obligations under this Agreement.
- 10.1.4. [*], the patents encompassed within the PSIVIDA Patent Rights and the PSIVIDA Program Patent Rights as of the Effective Date, are, or, upon issuance, will be, valid and enforceable patents and no Third Party is (i) infringing any such Patent Rights relating to the Device as of the Effective Date or (ii) has challenged the extent, validity or enforceability of such Patent Rights (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign entity).
- 10.1.5. Schedule 10.1.5 contains a complete and correct list of all patents and patent applications owned by or otherwise Controlled by PSIVIDA or any of its Affiliates (and indicating which entity owns or Controls each patent and patent application and which are owned and which are Controlled) that are included within PSIVIDA Patent Rights and PSIVIDA Program Patent Rights.

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- 10.1.6. To the knowledge of PSIVIDA, PSIVIDA or its relevant Affiliate is the sole legal and beneficial owner of all the PSIVIDA Patent Rights and PSIVIDA Technology, free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and no person, firm, corporation, governmental agency, or other entity (including any Affiliate of PSIVIDA) has any right, interest or claim in or to, and neither PSIVIDA nor any of its Affiliates has entered into any agreement granting to any Third Party (including any academic, governmental organization or agency) any right, interest or claim in or to, any PSIVIDA Patent Rights or PSIVIDA Technology, which would conflict with the licenses and rights granted to Pfizer hereunder.
- 10.1.7. Neither PSIVIDA nor any of its respective employees nor, to the best knowledge of PSIVIDA, its agents, in their capacity as such, have been debarred by the FDA, pursuant to 21 U.S.C. §§ 335(a) or (b), or been charged with or convicted under United States law for conduct relating to the development or approval, or otherwise relating to the regulation of Product under the Generic Drug Enforcement Act of 1992, disqualified from receiving investigational new drugs or devices under 21 CFR 312.70 or 812.119, or debarred, disqualified, or convicted under or for any equivalent or similar applicable foreign law, rule, or regulation.
- 10.1.8. 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 PSIVIDA, threatened against PSIVIDA or any of its Affiliates in connection with the PSIVIDA Patent Rights, PSIVIDA Technology, PSIVIDA Program Patent Rights or PSIVIDA Program Technology or relating to the transactions contemplated by this Agreement.
- 10.1.9. PSIVIDA has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value to improperly seek, or corruptly seek to influence any Government Official, and, if PSIVIDA is itself a Government Official, has not accepted, and will not accept in the future, such a payment. Further, PSIVIDA undertakes to update the representations and warranties herein if (during the term of this Agreement) PSIVIDA, or any of the employees, individuals, or subcontractors who will be primarily responsible for performing under this Agreement, or a relative of such an employee or individual or subcontractor, becomes a Government Official. PSIVIDA will comply with Pfizer Inc.'s Anti-Bribery and Anti-Corruption Principles as set out in Exhibit A attached hereto in connection with its activities pursuant to this Agreement. For purposes of this Agreement, a "Government Official" is defined as: (i) any elected or appointed Government Official (e.g., a member of a

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ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization; where "government" is meant to include all levels and subdivisions of non-US governments (i.e., local, regional, or national and administrative, legislative, or executive).

10.1.10. PSIVIDA is not a healthcare professional and is not an appointed agent or expert of any public authority.

10.2. PFIZER Representations and Warranties. As of the Effective Date, PFIZER hereby represents and warrants to PSIVIDA as follows:

10.2.1. PFIZER has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by PFIZER have been duly and validly authorized and approved by proper corporate action on the part of PFIZER, and PFIZER 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 to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of PSIVIDA, this Agreement constitutes a legal, valid and binding obligation of PFIZER, enforceable against PFIZER in accordance with its terms.

10.2.2. The execution and delivery of this Agreement by PFIZER and the performance by PFIZER contemplated hereunder does not and will not violate any Laws or any order of any court or Governmental Authority.

10.2.3. Neither the execution and delivery of this Agreement nor the performance hereof by PFIZER requires PFIZER to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to the manufacture, use, importation or sale of the Product) or from any other person, firm or corporation, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination under any agreement or contract to which PFIZER or any of its Affiliates is a party or to which it may be subject, except for those breaches or rights that would not adversely affect the ability of PFIZER to perform its obligations under this Agreement.

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- 10.2.4. [*], the patents encompassed within the PFIZER Program Patent Rights are, or upon issuance will be, valid and enforceable patents and no Third Party (i) is infringing any such Patent Rights relating to the Device as of the Effective Date or (ii) has challenged the extent, validity or enforceability of such Patent Rights (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous or foreign entity).
- 10.2.5. To the knowledge of PFIZER, PFIZER or its relevant Affiliate is the sole legal and beneficial owner of all the PFIZER Patent Rights and PFIZER Technology, free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and no person, firm, corporation, governmental agency, or other entity (including any Affiliate of PFIZER) has any ownership right, interest or claim in or to, any PFIZER Patent Rights or PFIZER Technology.
- 10.2.6. Neither PFIZER nor any of its respective employees nor, to the best knowledge of PFIZER, its agents, in their capacity as such, have been debarred by the FDA, pursuant to 21 U.S.C. §§ 335(a) or (b), or been charged with or convicted under United States law for conduct relating to the development or approval, or otherwise relating to the regulation of Product under the Generic Drug Enforcement Act of 1992, disqualified from receiving investigational new drugs or devices under 21 CFR 312.70 or 812.119, or debarred, disqualified, or convicted under or for any equivalent or similar applicable foreign law, rule, or regulation.
- 10.2.7. 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 PFIZER threatened against PFIZER or any of its Affiliates (except to the extent disclosed pursuant to Section 10.2.4) relating to the PFIZER Program Patent Rights, PFIZER Program Technology, PFIZER Technology or transactions contemplated by this Agreement.
- 10.2.8. PFIZER has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value to improperly seek, or corruptly seek to influence any Government Official, and, if PFIZER is itself a Government Official, has not accepted, and will not accept in the future, such a payment. Further, PFIZER undertakes to update the representations and warranties herein

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if (during the term of this Agreement) PFIZER, or any of the employees, individuals, or subcontractors who will be primarily responsible for performing under this Agreement, or a relative of such an employee or individual or subcontractor, becomes a Government Official. PFIZER will comply with its Anti-Bribery and Anti-Corruption Principles as set out in Exhibit A attached hereto in connection with its activities pursuant to this Agreement.

10.3. Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO COMPOUNDS, DEVICES, FORMULATIONS, PRODUCTS, PATENT RIGHTS, OR TECHNOLOGY. EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION 10, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

11. Additional Covenants.

11.1. Each of PSIVIDA and PFIZER shall conduct, and shall use Commercially Reasonable Efforts to cause its Affiliates to conduct, all its activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted.

11.2. [*]

11.3. Non-Compete. Subject to the BMP Agreement, the B&L Agreement, the Alimera Agreement, and Section 13.5, during the Royalty Term in any country, PSIVIDA shall not, and shall cause its Affiliates not to, alone or in collaboration with any Third Party, promote, sell, distribute or otherwise commercialize in such country (a) any bioerodible Device delivering by subconjunctival implant or injection the Compound, alone or together with another active ingredient, in humans, (b) any bioerodible Device for the treatment of Glaucoma in humans by a subconjunctival implant or injection that contains a prostaglandin, or (c) any Product for uveitis, or grant any Third Party the right to do any of the foregoing; provided, however, that the foregoing shall not apply to prevent a Person that first becomes an Affiliate of PSIVIDA after the Effective Date from developing, promoting, selling, distributing or otherwise commercializing such a Device as long as such developing, promoting, selling, distributing or otherwise commercializing does not infringe PSIVIDA Patent Rights or PSIVIDA Program Patent Rights.

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- 11.4. Kentucky Study Agreement . As soon as practicable after the Effective Date, (a) PFIZER shall assign to PSIVIDA and PSIVIDA shall accept and assume all of the rights and obligations of PFIZER under the Kentucky Study Agreement with effect from and after the Effective Date and (b) the Parties shall take such actions and execute such documents as are necessary to carry out such assignment and assumption.
12. Term . This Agreement shall be effective as of the Effective Date and shall, unless earlier terminated in accordance with Section 13, remain in effect until the expiration of the Royalty Term.
13. Termination .
- 13.1. Termination Rights . This Agreement may be terminated as follows:
- 13.1.1. If either PFIZER or PSIVIDA materially breaches or materially defaults in the performance or observance of any of its respective obligations under this Agreement, and such breach or default is not cured within (a) in the event of a failure of a Party to make a required payment under this Agreement, thirty (30) days and (b) for all other breaches or defaults, sixty (60) days after the giving of written notice by the other Party specifying such breach or default, then such other Party shall have the right to terminate this Agreement by providing the breaching Party written notice within thirty (30) days following the expiration of such period (such termination to be effective upon receipt of such termination notice). For the purpose of this Section 13.1.1, a material breach or material default shall include a material inaccuracy in any warranty or representation contained herein. In addition, PSIVIDA may terminate this Agreement pursuant to Section 11.2.
- 13.1.2. PFIZER may terminate this Agreement effective immediately upon notice to PSIVIDA, if PSIVIDA breaches any of the representations and warranties set forth in Section 10.1.9 or if PFIZER learns that improper payments are being or have been made to Government Officials (as defined in Section 10.1.9) by PSIVIDA with respect to services performed or activities undertaken either on behalf of PSIVIDA or in connection with PSIVIDA's provision of services to any other party. Further, in the event of any termination referred to in the preceding sentence, PSIVIDA shall not be entitled to any further payment, regardless of any activities undertaken or agreements with additional Third Parties entered into prior to termination, and PSIVIDA shall be liable for damages or remedies as provided by law.

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- 13.1.3. PSIVIDA may terminate this Agreement effective immediately upon notice to PFIZER, if PFIZER breaches any of the representations and warranties set forth in Section 10.2.8 or if PSIVIDA learns that improper payments are being or have been made to Government Officials (as defined in Section 10.2.8) by PFIZER with respect to services performed or activities undertaken either on behalf of PFIZER or in connection with PFIZER's provision of services to any other party. Further, in the event of any termination referred to in the preceding sentence, PFIZER shall not be entitled to any further payment, regardless of any activities undertaken or agreements with additional Third Parties entered into prior to termination, and PFIZER shall be liable for damages or remedies as provided by law.
- 13.1.4. If either Party is generally unable to meet its debts when due, or makes a general assignment for the benefit of its creditors, or there shall have been appointed a receiver, trustee or other custodian for such Party for all or a substantial part of its assets, or any case or proceeding shall have been commenced or other action taken by or against such Party in bankruptcy or seeking the reorganization, liquidation, dissolution or winding-up of such Party or any other relief under any bankruptcy, insolvency, reorganization or other similar act or Law, and any such event shall have continued for sixty (60) days undismissed, unstayed, unbonded and undischarged, then the other Party may, upon notice to such Party, terminate this Agreement, such termination to be effective upon such Party's receipt of such notice.
- 13.1.5. PFIZER, upon sixty (60) days' written notice to PSIVIDA, shall have the right, at PFIZER's sole discretion, to terminate this Agreement.
- 13.1.6. This Agreement shall terminate under the circumstances set forth in Section 3.3 or Section 3.5
- 13.1.7. In the event that the Parties make an HSR Filing under Section 3.6.5 hereof, this Agreement shall terminate (a) at the election of either Party immediately upon notice to the other Party, in the event that the United States Federal Trade Commission and/or the United States Department of Justice shall seek or threaten or shall obtain a preliminary injunction under the HSR Act against PFIZER and PSIVIDA to enjoin the transactions contemplated by this Agreement, or (b) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to ninety (90) days after the effective date of the HSR Filing. Notwithstanding the foregoing, this Section 13.1.7 shall not apply in the event that an HSR Filing is not required.
- 13.2. Accrued Obligations. Expiration or termination of this

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Agreement for any reason (x) shall be without prejudice to a Party's right to receive all royalties accrued under Section 6 prior to the effective date of such termination and to any other remedies that either Party may otherwise have and (y) shall not release a Party hereto from any indebtedness, liability or other obligation incurred hereunder by such Party prior to the date of termination or expiration.

13.3. Effect of Termination .

- 13.3.1. Upon any termination of this Agreement pursuant to Section 13.1.1, 13.1.3, 13.1.4, 13.1.5, 13.1.6 or 13.1.7, all licenses granted herein to PFIZER shall terminate. Upon any termination of this Agreement by PFIZER pursuant to Section 13.1.1, 13.1.2 or 13.1.4 or upon any termination of this Agreement pursuant to Section 13.1.6 or 13.1.7, all licenses granted herein to PSIVIDA shall terminate, except for such licenses that survive as provided by Section 16.7, and except as expressly set forth in Section 13.3.2.
- 13.3.2. If PFIZER terminates this Agreement pursuant to Section 13.1.5 (other than in the event (A) of any safety issue that would reasonably be expected to have a material adverse effect on PFIZER's ability to develop, manufacture or commercialize the Product, as determined in good faith in the reasonable judgment of PFIZER's internal safety committee in accordance with PFIZER's standard internal procedures for evaluating such safety issues or (B) that a Regulatory Authority or data monitoring review board has required termination or suspension of a Clinical Trial for the Product or withdrawal of the Product from any market on account of a safety issue), or this Agreement terminates pursuant Section 13.1.6 or 13.1.7, or PSIVIDA terminates this Agreement pursuant to Section 13.1.1 or 13.1.3 (but in no event if (x) any such termination results, arises from or relates to, or is deemed to result, arise from or relate to, by operation of law or otherwise, any termination or deemed termination hereof that occurs during the course of any bankruptcy or other insolvency proceeding involving PSIVIDA or (y) PSIVIDA rejects this Agreement pursuant to Sections 363, 365 or 1123 of Title 11 of the United States Code, as amended):
- (a) PFIZER shall at PSIVIDA's request, (i) use Commercially Reasonable Efforts to transfer ownership of all regulatory filings and Regulatory Approvals that relate solely to the Product to PSIVIDA or its designee; (ii) deliver to PSIVIDA a copy of all Clinical IP in PFIZER's or any of its Affiliates' possession and Control (including Clinical IP generated by Third Parties under any services arrangement) related to the Product (and that does not relate solely to the Compound), if any, in the same form in which PFIZER or such Affiliate maintains such data; (iii) provide

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PSIVIDA with copies of any then-existing documentation and technical information, in the form and format in which such materials are maintained by PFIZER or any of its Affiliates in the ordinary course of its business, that are necessary for the manufacture of the Product, which documentation and technical information shall include (A) [*], (B) [*], (C) [*], (D) [*], (E) [*] and (F) such other documentation as the Parties may mutually agree, in each case of the foregoing subsections (iii) and (A) through (F), that are in PFIZER's or any of its Affiliates' possession and Control (including any of the foregoing that are generated by Third Parties under any services arrangement) and are necessary to manufacture Products; and (iv) deliver to PSIVIDA, in the same form in which PFIZER or any of its Affiliates maintains such items, copies of all regulatory reports, records, correspondence and other regulatory materials in PFIZER's or any of its Affiliates' possession and Control related solely to such Product (and not related solely to the Compound) and any Regulatory Approval therefor (including any of the foregoing that are generated by Third Parties under any services arrangement), including, if applicable, any information contained in the global safety database established and maintained by PFIZER or any of its Affiliates (provided that any good faith failure by PFIZER to provide immaterial data, information, reports, records, correspondence or other materials to PSIVIDA shall not be a breach of PFIZER's obligations under this Section 13.3.2).

- (b) PFIZER shall and hereby does grant to PSIVIDA (i) a non-exclusive, royalty-free (except as set forth below in this paragraph), perpetual, irrevocable, world-wide license, with the right to sublicense, under and to the Clinical IP Controlled by PFIZER or any of its Affiliates, the PFIZER Patent Rights, the PFIZER Technology, the PFIZER Program Technology and the PFIZER Program Patent Rights, and (ii) the non-exclusive right to [*], in the case of (i) and (ii) solely to develop, make, have made, sell, offer for sale, use and import the Product. It is understood that

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upon any termination, PSIVIDA will not obtain any rights to PFIZER Compounds, PFIZER Patent Rights, PFIZER Technology, PFIZER Program Patent Rights or PFIZER Program Technology except as expressly set forth in this Agreement. If any of the foregoing are licensed to Pfizer from a Third Party (“Third Party Licensor”), [*]. Without limiting the foregoing [*].

- (c) PFIZER shall and hereby does grant to PSIVIDA a non-exclusive, royalty-free (except as set forth below in this paragraph), perpetual, irrevocable, world-wide license, with the right to sublicense, under and to all PFIZER Controlled Intellectual Property, solely to develop, make, have made, sell, offer for sale, use and import the Product; provided that such license shall continue only so long as (a) PSIVIDA elects to accept such license, and (b) [*]

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[*]. Without limiting the foregoing, [*].

13.3.3. Following any termination of this Agreement but subject to the foregoing provisions of Section 13.3.2 each Party shall, upon request of the other Party, return or destroy all Confidential Information

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disclosed to it by the other Party pursuant to this Agreement or the Prior Agreement, including all copies and extracts of documents, as promptly as practicable following receipt of such request, except that one (1) copy may be kept for the purpose of complying with continuing obligations under this Agreement.

- 13.3.4. In order to ensure the smooth transition of the development and/or commercialization of the Product from PFIZER to PSIVIDA or a Third Party designated by PSIVIDA, at PSIVIDA's request, representatives of PFIZER and PSIVIDA will meet to discuss in good faith a transition plan with respect to all then-current as well as planned activities relating to the Product, consistent with Section 13.3.2.
- 13.4. Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by PSIVIDA are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101 of the U.S. Bankruptcy Code. The Parties agree that PFIZER, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of any proceeding by or against PSIVIDA or any of its Affiliates under the U.S. Bankruptcy Code, PFIZER shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and, if not already in its possession, PSIVIDA shall promptly deliver to PFIZER all such intellectual property and all embodiments of such intellectual property (a) upon PFIZER's request any time following commencement of any such proceeding, unless PSIVIDA elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon PFIZER's request any time following the rejection of this Agreement by or on behalf of PSIVIDA.
- 13.5. Change of Control. PSIVIDA shall notify PFIZER promptly, but in no event later than five (5) Business Days, following approval by PSIVIDA's (or its parent corporation's) board of directors of any transaction that constitutes a Change of Control; provided, however, that in the event such disclosure is prohibited by applicable Law or PSIVIDA's contractual obligations to a Third Party, PSIVIDA shall have the right to delay such notification until five (5) Business Days following the consummation of the applicable Change of Control. Effective upon the consummation of such Change of Control, Section 3.4(e) shall be automatically deleted from this Agreement and shall cease to be of any further force or effect. PFIZER shall have the right upon sixty (60) days' notice following any such Change of Control, to elect that any one or more of the following shall be deleted, in

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whole or in part, from this Agreement: Sections 2.1 through 2.6 and 3.6.4, and PFIZER's obligations under Sections 3.9, 3.10, 5.2.3, 5.2.4, and 5.5.1. If PFIZER makes any election as provided in this Section 13.5 to delete any Section, each of the Parties hereto will enter into an appropriate and customary written amendment and no Party shall have any further obligations with respect to any such deleted Section. In the event that a transaction that constitutes a Change of Control is approved by PSIVIDA's board of directors but is not consummated, any Section deleted by PFIZER pursuant to the foregoing shall immediately and automatically be reinstated upon notice thereof by PSIVIDA to PFIZER. For the avoidance of doubt, PFIZER shall be entitled, in its sole discretion, to make the elections provided for in this Section 13.5 upon each occurrence of a Change of Control.

13.6. Breach Remedy. If an event occurs that gives rise to a right of termination by PFIZER under Section 13.1.1 (as a result of an uncured breach by PSIVIDA) and if PFIZER elects not to terminate this Agreement, any amounts payable by PFIZER to PSIVIDA pursuant to Section 3.6.1 or Section 6 shall be reduced to seventy percent (70%) (i.e., a thirty percent (30%) reduction) of the amount that would otherwise have been payable under the terms of the Agreement during the Term and PFIZER may elect that any one or more of the following shall be deleted, in whole or in part, from this Agreement: Sections 2.1 through 2.6, 3.6.3 and 3.10, and PFIZER's obligations under Sections 3.9, 5.2.3, 5.2.4 and 5.5.1. If PFIZER makes any election as provided in this Section 13.6 to delete any Section, each of the Parties hereto will enter into an appropriate and customary written amendment and no Party shall have any further obligations with respect to any such deleted Section.

14. **Indemnification and Insurance** .

14.1. Indemnification .

14.1.1. PSIVIDA will indemnify, defend and hold PFIZER and PFIZER's Affiliates, and their respective directors, officers and employees (collectively, "Representatives"), harmless from any and all Losses (as defined below) incurred by any of them and which are not covered by an insurance policy that result from:

- (a) the breach of any covenant, warranty or representation made by PSIVIDA under this Agreement;
- (b) the negligence, recklessness, or willful misconduct of PSIVIDA or any of its Affiliates; or

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- (c) any acts or omissions of PSIVIDA or any of its Affiliates, agents or licensees in connection with the research, development or commercialization of the Product.

PSIVIDA shall only be obligated to so indemnify, defend and hold PFIZER harmless to the extent that such Losses do not result from the negligence, recklessness or willful misconduct of PFIZER or its Affiliates, agents or licensees.

- 14.1.2. PFIZER will indemnify, defend and hold PSIVIDA and PSIVIDA's Representatives, harmless from any and all Losses incurred by any of them and which are not covered by an insurance policy that result from:

- (a) the breach of any covenant, warranty or representation made by PFIZER under this Agreement;
- (b) the negligence, recklessness, or willful misconduct of PFIZER or any of its Affiliates;
- (c) any acts or omissions of PFIZER or any of its Affiliates, agents or licensees in connection with the research, development or commercialization of the Product.

PFIZER shall only be obligated to so indemnify, defend and hold PSIVIDA harmless to the extent that such Losses do not result from the negligence, recklessness or willful misconduct of PSIVIDA or its Affiliates, agents or licensees.

- 14.2. Losses. For purposes of this Agreement, "Losses" means any and all costs, expenses, claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, settlement amounts, awards, and judgments, including any and all reasonable, out-of-pocket costs and expenses properly incurred, as a result of a Third Party claim (including reasonable, out-of-pocket attorneys' fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened), in each case, net of any insurance recovery received as a result of such Loss.
- 14.3. Insurance. Each Party shall maintain, and shall cause its Affiliates and each sublicensee conducting activities under this Agreement to maintain, at such Party's, an Affiliate's, or sublicensee's sole expense, appropriate product liability insurance coverage in amounts reasonably determined by the Party from time to time but at least sufficient to insure against claims which may arise from the performance of obligations or exercise of rights granted under this Agreement or from indemnification obligations under this Section 14, but

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in no event shall a Party's insurance coverage be in an amount less than \$5,000,000 per occurrence and \$10,000,000 annual aggregate (provided that (i) in the case of PFIZER such coverage may be pursuant to a program of self-insurance and (ii) in the case of an Affiliate that becomes an Affiliate of PSIVIDA following the Effective Date, such Affiliate may (a) continue to operate under a self-insurance plan that was in place at the time it became an Affiliate or (b) adopt a self-insurance plan to the extent such plan is reasonable in light of industry practices of Persons similarly situated to such Affiliate). The policy of insurance shall contain a provision of non-cancellation except upon the provision of thirty (30) days notice to the other Party. Each Party shall maintain such insurance commencing on the Effective Date and for so long as it continues to research, produce, develop, manufacture, distribute, sell or use the Products, and thereafter for so long as each Party maintains insurance for itself covering such manufacture or sales.

- 14.4. Defense Procedures; Procedures for Third Party Claims . In the event that any Third Party (in no event to include any Affiliate of any of the Parties) asserts a claim with respect to any matter for which a Party (the "Indemnified Party") is entitled to indemnification hereunder (a "Third Party Claim"), then the Indemnified Party shall promptly notify the Party obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.
- 14.4.1. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within ten (10) 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 (i) 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, (ii) the Third Party Claim seeks solely monetary damages and (iii) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (i), (ii) and (iii) above are collectively referred to as the "Litigation Conditions").
- 14.4.2. Within ten (10) Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a

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Third Party Claim, the Indemnified Party shall 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 shall 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 shall 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 shall cooperate, and shall 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 (10) 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, shall 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.

- 14.4.3. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement or consent to the entry of any judgment with respect to any claim or Loss (a) that does not release Indemnified Party from all liability with respect to such claim or Loss or (b) which may materially adversely affect Indemnified Party or under which Indemnified Party would incur any obligation, commitment to act or forbear from taking any action, or liability, other than one as to which Indemnifying Party has an indemnity obligation hereunder. The Indemnified Party shall have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but shall not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party shall not make any

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admission of liability in respect of any Third Party Claim without the prior consent of the other Party, and the Indemnified Party shall use Commercially Reasonable Efforts to mitigate losses arising from the Third Party Claim.

- 14.5. Disclaimer of Liability for Consequential Damages . IN NO EVENT SHALL ANY PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE, SUFFERED BY PFIZER, PSIVIDA OR ANY OF THEIR RESPECTIVE REPRESENTATIVES, EXCEPT TO THE EXTENT OF ANY SUCH DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM; PROVIDED THAT THIS SECTION SHALL NOT RELIEVE EITHER PARTY FROM ITS PAYMENT OBLIGATIONS UNDER THIS AGREEMENT.
- 14.6. SOLE REMEDY . EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT AND EXCEPT FOR ANY EQUITABLE REMEDIES THAT MAY BE AVAILABLE TO A PARTY, INDEMNIFICATION PURSUANT TO THIS SECTION 14 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO PSIVIDA OR PFIZER FOR THE MATTERS COVERED THEREIN.

15. **Governing Law and Jurisdiction** .

- 15.1. Governing Law . This Agreement shall be governed by and construed in accordance with the substantive laws of the State of New York, without regard to conflicts of law rules.
- 15.2. Jurisdiction . With the exception of those matters referred for resolution by independent accountants under Section 7.5, in the event of any controversy, claim or counterclaim arising out of or relating to this Agreement, the Parties shall first attempt to resolve such controversy or claim through good faith negotiations for a period of not less than thirty (30) days following notification of such controversy or claim to the other Party. If such controversy or claim cannot be resolved by means of such negotiations during such period, then such controversy or claim shall be resolved by the United States District Court for the Southern District of New York or a local court sitting in New York, New York (collectively, the “Courts”). Each Party (a) irrevocably submits to

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the exclusive jurisdiction in the Courts for purposes of any action, suit or other proceeding relating to or 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. In the event of any action, suit or other proceeding pursuant to this Section 15.2, either Party may effect service of process by providing a complaint and/or summons or other court filing to the other Party pursuant to Section 16.10. Any defenses based on adequacy of service of process, other than breach of Section 16.10 are waived.

16. **Miscellaneous .**

- 16.1. **Termination of Prior Agreements .** The Parties agree that: (a) this Agreement shall supersede the Prior Agreement, which shall be and hereby is terminated as of the Effective Date; (b) notwithstanding any provisions of the Prior Agreement to the contrary, no rights, obligations or liabilities of the Parties under the Prior Agreement shall survive this termination except for rights, obligations and liabilities of both Parties under Section 9 (Confidentiality), Section 14 (Indemnification), and other sections, exhibits, or definitions referenced therein; and (c) as of the Effective Date, all payment and performance obligations, except for the assignment of rights from PSIVIDA to PFIZER related to United States Provisional Patent Application [*], owed by each Party under the Prior Agreement (including any payments that were due and payable prior to the Effective Date) to the other Party are hereby deemed fully paid and performed by such owing Party.
- 16.2. **Force Majeure .** Neither Party hereto shall be liable to the other Party (except for payment obligations set forth in this Agreement, each of which shall remain in effect) for any losses or damages attributable to a default in or breach of this Agreement that is the result of war (whether declared or undeclared), acts of God, revolution, acts of terror, fire, earthquake, flood, pestilence, riot, enactment or change of Law (following the Effective Date), accident(s), labor trouble, or shortage of or inability to obtain material equipment or transport or any other cause beyond the reasonable control of such Party; provided that if such a cause occurs, then the Party affected will promptly notify the other Party of the nature and likely result and duration (if known) of such cause and use Commercially Reasonable Efforts to reduce the

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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effect. If the event lasts for a period of longer than three (3) months, the Parties shall meet and discuss appropriate remedial measures.

16.3. Reserved Rights; Non-Exclusivity.

16.3.1. All rights and interests not expressly granted to PFIZER are reserved by PSIVIDA (the “PSIVIDA Reserved Interests”) for itself, its Affiliates and partners (other than PFIZER) and other licensees and sublicensees, including, but not limited to, the rights to use, enter into agreements or grant licenses under the PSIVIDA Patent Rights, PSIVIDA Program Patent Rights, PSIVIDA Technology, PSIVIDA Program Technology or any other technology owned, licensed or controlled by PSIVIDA or any of its Affiliates to make, have made, use, offer to sell, sell, have sold and import products (other than the Product in the Territory in the Field or for uveitis for so long as PFIZER has an exclusive license to the Product in the Field in the Territory under this Agreement). It shall not be a breach of this Agreement for PSIVIDA, acting directly or indirectly, to exploit the PSIVIDA Reserved Interests in any manner anywhere in or outside of the Territory, whether or not such activity is competitive with the activities of PFIZER, including the research, development and commercialization or licensing to others to research, develop and commercialize products (other than the Product in the Territory in the Field or for uveitis in the Territory for so long as PFIZER has an exclusive license to the Product in the Field in the Territory under this Agreement).

16.3.2. Subject to Section 13.3.3, except as otherwise expressly provided in this Agreement, for the avoidance of doubt, PFIZER shall be free to use, enter into an agreement with and grant licenses to any Third Party or Third Parties under the PFIZER Patent Rights, the PFIZER Program Patent Rights, the PFIZER Technology or the PFIZER Program Technology or any other technology owned, licensed or Controlled by PFIZER or any of its Affiliates to research, develop and commercialize any and all products, and it shall not be a breach of this Agreement for PFIZER, acting directly or indirectly, to engage in any activities competitive with the activities of PSIVIDA, including the research, development and commercialization of products and other drug delivery devices.

16.4. Severability. If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable, or shall render this entire Agreement to be unenforceable or invalid, such offending provision shall be of no effect and shall not affect the validity of the remainder of this Agreement or any of its provisions; provided, however, the Parties shall use their respective

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Commercially Reasonable Efforts to replace the invalid provisions in a manner that best accomplishes the original intentions of the Parties.

- 16.5. Waivers. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party or Parties waiving such term or condition. Neither the waiver by any Party of any term or condition of this Agreement nor the failure on the part of any Party, in one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.
- 16.6. Entire Agreements; Amendments. This Agreement sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and supersedes all agreements or understandings, verbal or written, made between PSIVIDA and PFIZER before the date hereof with respect to the subject matter hereof, including the Confidentiality Agreement between the Parties, dated February 2, 2007, the Feasibility Study Agreement dated December 22, 2006 and the Collaborative Research and License Agreement dated April 3, 2007. All Confidential Information disclosed prior to the Effective Date will be deemed to have been disclosed pursuant to this Agreement. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by the Parties.
- 16.7. Survival. The provisions of Section 1 (Definitions), 4.2(b), 5.2 (Regulatory Affairs), 7.5 (Inspection of Records), 8.1 (Disclosure and Ownership of Program Technology and Program Patent Rights), 9.1 (Confidential Information), 9.2 (Disclosure of Agreement Terms), 9.4 (Filing, Registration or Notification of the Agreement), 13 (Termination), 14 (Indemnification and Insurance), 15 (Governing Law and Jurisdiction) and 16 (Miscellaneous), as well as any other Sections or defined terms referred to in such Sections or necessary to give them effect shall survive termination or expiration of this Agreement and remain in force until discharged in full. Furthermore, any other provisions required to interpret and enforce the Parties' rights and obligations or to wind up their outstanding obligations under this Agreement shall survive to the extent required.
- 16.8. Assignment. Neither this Agreement nor any rights or obligations of

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either Party to this Agreement may be assigned or otherwise transferred by either Party without the consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement, in whole or in part: (i) to any of its respective Affiliates; (ii) to any transferee of all or substantially all of such Party's assets or business or all or substantially all of such Party's ophthalmic assets or business, or (iii) in connection with a Change of Control of such Party; provided that such assigning Party shall remain jointly and severally liable with such assignee or transferee in respect of all obligations so assigned. Any purported assignment in violation of this Section 16.8 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

- 16.9. Independent Contractor. The relationship between PSIVIDA and PFIZER is that of independent contractors. PSIVIDA and PFIZER are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties.
- 16.10. Notices. Each communication and document made or delivered by one Party to another under this Agreement shall be made in the English language. All notices, consents, approvals, requests or other communications required hereunder given by one Party to the other hereunder shall be in writing and made by registered or certified air mail, facsimile, express overnight courier or delivered personally to the following addresses of the respective Parties:

If to PSIVIDA: PSIVIDA Inc.
400 Pleasant Street
Watertown, MA 02472
Attention: President
Fax: (617) 926-5050

with a copy to: PSIVIDA Inc.
400 Pleasant Street
Watertown, MA 02472
Attention: General Counsel
Fax: (617) 926-5050

with a copy to: Ropes & Gray LLP
800 Boylston Street
Boston, MA 02199
Attention: Susan Galli, Esq.

Invoices should be sent to PSIVIDA as directed by PSIVIDA.

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If to PFIZER: Pfizer Inc.
235 East 42nd Street
New York, New York 10017-5755
U.S.A.
Attention: Senior Vice President Worldwide Business Development

with a copy to: Pfizer Inc.
235 East 42nd Street
New York, New York 10017-5755
U.S.A.
Attention: General Counsel

Invoices should be sent to PFIZER as directed by PFIZER.

Notices hereunder shall be deemed to be effective (a) upon receipt if personally delivered, (b) on the tenth (10th) Business Day following the date of mailing if sent by registered or certified air mail; (c) on the second (2nd) Business Day following the date of transmission or delivery to the overnight courier if sent by facsimile or overnight courier. A Party may change its address listed above by sending notice to the other Party in accordance with this Section 16.10.

- 16.11. Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party. 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.
- 16.12. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, successors and permitted assigns.
- 16.13. Counterparts. This Agreement may be executed in any two or more counterparts, including by facsimile or by electronic scan copies delivered by email, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.
- 16.14. Headings. Headings in this Agreement are included herein for ease of reference only and shall have no legal effect. References to the parties, Sections, Schedules, and Exhibits are to the parties, Sections, Schedules and Exhibits to and of this Agreement unless otherwise specified.

[Signature page follows.]

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IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be executed by their duly authorized officers upon the date set out above.

PSIVIDA CORP.

PFIZER INC.

For itself and as successor to pSivida Limited

By: /s/ Paul Ashton
Name: Paul Ashton
Title: President and CEO

By: /s/ Adam Woodrow
Name: Adam Woodrow
Title: VP Commercial Development

PSIVIDA US, INC.

Formerly known as pSivida, Inc.

By: /s/ Paul Ashton
Name: Paul Ashton
Title: President and CEO

PSIMEDICA LIMITED

By: /s/ Paul Ashton
Name: Paul Ashton
Title: Director

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Schedule 1.65

PFIZER Patent Rights

[*]

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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Schedule 1.66

PFIZER Program Patent Rights

All right, title and interest to [*].

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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Schedule 1.74

Phase II Activities

[*]

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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Schedule 1.82

PSIVIDA Patent Rights

[*]

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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Schedule 1.83

PSIVIDA Program Patent Rights

All right, title and interest to [*].

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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Schedule 10.1.5

Scheduled PSIVIDA Patent Rights

[*]

pSivida US, Inc., owns all right, title and interest to [*].

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Exhibit A

FCPA

PFIZER ANTI-BRIBERY AND ANTI-CORRUPTION PRINCIPLES

Pfizer Corporate Policy # 201 (Lawful and Ethical Behavior) provides that Pfizer colleagues must conduct all Pfizer business in a lawful and ethical manner, in accordance with applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977 (the “FCPA”). The FCPA prohibits making, promising, or authorizing the making of a corrupt payment or providing anything of value to a government official to induce that official to make any governmental act or decision to assist a company in obtaining or retaining business. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Pfizer consultant, agent, or representative, or even by a company acting on behalf of Pfizer (“Business Associates”). Therefore, Pfizer requires all of its Business Associates to conduct their Pfizer-related work in accordance with these principles.

Definition of a Government Official

Under Pfizer’s policies, “government official” is broadly interpreted and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization (e.g., the United Nations). “Government” is meant to include all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive). Because this definition of “government official” is so broad, it is likely that Business Associates will interact with a government official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by state-owned hospitals could be considered “government officials” under Pfizer’s policies.

FCPA, Anti-Corruption and Anti-Bribery Principles

Business Associates may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help Pfizer obtain or retain business. Business Associates may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to

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approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or otherwise improperly to benefit Pfizer's business activities.

Understand and Follow Local Laws

Business Associates need to understand whether local laws, regulations, or operating procedures (including requirements imposed by government entities such as state-owned hospitals or research institutions) impose any limits, restrictions, or disclosure requirements on compensation, financial support, donations, or gifts that may be provided to government officials. Business Associates must take into account and comply with any applicable restrictions in conducting their Pfizer-related activities. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with government officials, that Business Associate should consult with his or her primary Pfizer contact before undertaking their activities.

Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, **Leonard S. Ross** , certify that:

1. I have reviewed this Annual Report on Form 10-K/A (Amendment No. 1) of **PSIVIDA CORP.** ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Date: December 27, 2011

/ s / L EONARD S. R OSS

Name:

Leonard S. Ross

Title:

Vice President, Finance
(Principal Financial and Accounting Officer)