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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)	March 5, 2015

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35076	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

5600 Blazer Parkway, Suite 200, Dublin, Ohio	43017
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code	(614) 793-7500

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On March 5, 2015, the Company and SpePharm AG (an affiliate of Norgine BV), a European specialist pharmaceutical company with an extensive pan-European presence ("SpePharm"), announced that they had entered into an exclusive sublicense agreement for the commercialization and distribution of Lymphoseek® 250 microgram kit for radiopharmaceutical preparation ("Product") in the European Union ("License Agreement"). Under the terms of the License Agreement, Navidea is entitled to receive an upfront payment of $2 million and is eligible to receive additional milestone payments up to $5 million, as well as royalties on European net sales.

The territory licensed to SpePharm initially consists of countries and territories included within the Company's marketing authorization by the European Medicines Agency, with an option to expand the territory to include additional countries. SpePharm will assume development and regulatory responsibilities for the Product in the territory, including conduct of market access clinical studies.

SpePharm is responsible for developing a commercial launch plan for the Product in the licensed territory, subject to review and comment by the Company, and to use commercially reasonable efforts to market and promote the Product. SpePharm may sell the Product at prices determined in its sole discretion. In addition to the upfront payment, SpePharm is required to make additional payments to the Company of up to $5 million on the achievement of defined milestones relating to the Product and achievement of net sales targets for the Product, as well as royalties on net sales of the Product.

The foregoing description of the terms of the License Agreement is qualified in its entirety by reference to the text of the License Agreement, a copy of which is attached hereto as Exhibit 10.1, and incorporated herein by reference.

Item 8.01 Other Events.

On March 5, 2015, the Company issued a press release regarding its entry into the License Agreement. A copy of the Company's March 5, 2015 press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 8.01 of this Current Report on Form 8-K, including exhibit 99.1 attached hereto, shall not be treated as "filed" for purposes of the Securities Exchange Act of 1934, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
10.1	Exclusive License Agreement, dated March 5, 2015 between the Company and SpePharm AG (portions of this Exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the United States Securities and Exchange Commission).
99.1	Press release, dated March 5, 2015, entitled "Navidea and Norgine Enter European Commercial Partnership for Lymphoseek®; Navidea to Receive $2 Million Upfront Payment."

Statements contained or incorporated by reference in this Current Report on Form 8-K which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, and markets for the Company's products, are forward-looking statements. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, and other risks detailed in the Company's most recent Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

SIGNATURES

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

Navidea Biopharmaceuticals, Inc.

Date: March 11, 2015

By: /s/ Brent L. Larson
Brent L. Larson, Executive Vice President and
Chief Financial Officer

CONFIDENTIAL TREATMENT REQUESTED PURSUANT TO RULE 24B-2 **Exhibit 10.1**

Certain confidential portions of this Exhibit, indicated by [*], have been omitted pursuant to Rule 24b-2 of the Securities Exchange Act of 1934. The omitted materials have been filed separately with the U.S. Securities and Exchange Commission.

EXCLUSIVE LICENSE AGREEMENT

This **Exclusive License Agreement** ("**Agreement**") is entered into and effective as of March 5, 2015 ("**Effective Date**"), by and between **Navidea Biopharmaceuticals, Inc.**, a company organized and existing under the laws of Delaware, with its principal place of business located at 5600 Blazer Parkway, Suite 200, Dublin, OH 43017, ("**Company**"); **SpePharm AG**, a company organized and existing under the laws of Switzerland, with offices located at Kapellplatz 1, 6004 Luzern, Switzerland ("**SpePharm**") and, solely for the purposes of Section 2.6 and Articles 14, 16 and 17, Norgine BV, a company organized and existing under the laws of The Netherlands, with offices located at Hogehilweg 7, 1101 CA Amsterdam Zuid-Oost, The Netherlands ("**Norgine**"). Company and SpePharm are each referred to herein by name or as a "**Party**" or, collectively, as the "**Parties**."

RECITALS

Whereas, Company is engaged in the development, manufacturing and commercialization of the Product (as defined below);

Whereas, SpePharm and its Affiliates (as defined below) have the capability and resources to develop, market, sell and commercialize the Product in the Licensed Territory (as defined below) and to fulfill the needs and requirements of customers who purchase the Product in the Licensed Territory; and

Whereas, Company desires to grant an exclusive license to and appoint SpePharm with the right, and SpePharm desires to accept from Company such exclusive license and the right, to develop, market, promote, sell, offer for sale, use, distribute and otherwise commercialize the Product in the Licensed Territory, all on the terms and subject to the conditions stated herein.

AGREEMENT

Now, Therefore, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

ARTICLE I – DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout this Agreement.

1.1 "**Accounting Standards**" shall mean Generally Accepted Accounting Principles (GAAP) or International Financial Reporting Standards (IFRS), as designated and used by the applicable Person.

[*] - indicates deleted language

1.2 "**Additional Indication**" shall have the meaning set forth in Section 2.9(a).

1.3 **"Additional Products**" shall have the meaning set forth in Section 2.8.

1.4 **"Additional Product License**" shall have the meaning set forth in Section 2.8.

1.5 **"Affiliate"** shall mean any Person, *whether de jure or de facto*, that directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.

1.6 **"AI Notice Period"** shall have the meaning set forth in Section 2.9(a).

1.7 **"Agreement"** shall have the meaning set forth in the introductory paragraph hereof.

1.8 **"Applicable Laws"** shall mean any and all laws, rules, regulations, directives, and guidance of any governmental authority pertaining to the development, manufacture, extrusion, packaging, labeling, storage, marketing, sale, distribution or intended use of a Product, as amended from time-to-time.

1 . 9 "**Business Combination**" means with respect to a Party, any of the following events: (i) any Third Party (or group of Third Parties acting in concert as a "group" within the meaning of Section 13(d) of the U.S. Securities Exchange Act of 1934) acquires (including by way of a tender or exchange offer or issuance by such Party), directly or indirectly, beneficial ownership or a right to acquire beneficial ownership of shares of such Party representing fifty percent (50%) or more of the voting shares (where voting refers to being entitled to vote for the election of directors) then outstanding of such Party, but excluding for such purposes any transaction or series of transactions with Financial Investors (as defined below) made for bona fide equity financing purposes in which cash is received by a Party or indebtedness of such Party is cancelled or converted or a combination thereof; (ii) such Party consolidates with or merges into another corporation or entity which is a Third Party, or any corporation or entity which is a Third Party consolidates with or merges into such Party, in either event pursuant to a transaction in which more than fifty percent (50%) of the voting shares of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting shares of such Party immediately preceding such consolidation or merger; or (iii) such Party sells, transfers, leases or otherwise disposes of all or substantially all of its assets to a Third Party.

1.10 **"Business Program**" shall have the meaning set forth in Section 2.6(c).

1.11 "**Calendar Year**" shall mean a twelve (12) month period commencing on January 1 and ending on December 31.

1.12 "**Commercialization**", with a correlative meaning for "**Commercialize**" and "**Commercializing**", means all activities undertaken relating specifically to the pre-launch, launch, promotion, market access, detailing, pricing, reimbursement, marketing, sale, and distribution of the Product in the Licensed Territory, including: (a) strategic marketing, sales force detailing, advertising, and medical education and liaison; (b) market access studies for use in generating pricing and reimbursement data in the Licensed Territory; and (c) all Product distribution, importation, exportation, invoicing and sales activities.

1.13 "**Commercialization Plan**" shall have the meaning set forth in Section 7.2.

1.14 **"Commercially Reasonable Efforts**" shall mean those efforts and resources that a similarly situated pharmaceutical company would reasonably devote in the exercise of its commercially reasonable practices relating to a product owned by it or to which it has rights of the type licensed hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account the competitiveness of the global and local marketplace, the pricing and launching strategy for the respective product, the proprietary position of the product, the profitability (but not considering any payments due to either Party pursuant to this Agreement) and the relative potential safety and efficacy of the product and other relevant factors, including technical, legal, scientific, regulatory or medical factors. "Commercially Reasonable" as used herein shall be interpreted in a corresponding manner.

1.15 **"Company"** shall have the meaning set forth in the introductory paragraph hereof.

1.16 "**Company Development Plan**" shall have the meaning set forth in Section 4.2.

1.17 "**Company Indemnitees**" shall have the meaning set forth in Section 13.1.

1.18 **"Company Know-How"** shall mean all Information Controlled (subject to Sections 2.9 and 4.6) by Company or any of its Affiliates as of the Effective Date or thereafter during the Term (as defined below), in each case to the extent related to, or necessary or useful for, the development, manufacture, use, sale and/or Commercialization of the Product. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate after the Effective Date due to a Business Combination of Company, provided that (a) any Information Controlled by Company or any of its Affiliates immediately prior to the Business Combination of Company shall continue to be Controlled by Company and its Affiliates after such Business Combination; and (b) any Information made, developed, conceived, or reduced to practice by, or otherwise owned by, such Third Party or any of its Affiliates (including Company), whether solely or jointly, in connection with the research, development, use, sale, offer for sale, manufacture, or other Commercialization of the Product, shall be deemed Controlled by Company and its Affiliates for purposes of this Agreement.

1.19 **"Company Marks"** shall have the meaning set forth in Section 11.3(b).

1.20 **"Company Patents"** shall mean any Patent Rights in the Licensed Territory (a) Controlled by Company or any of its Affiliates as of the Effective Date or thereafter during the Term and (b) that would, but for the licenses granted herein, be infringed by the development, manufacture, use, sale, offer for sale, keeping (whether for sale or otherwise), importation and/or Commercialization of the Product. Company Patents existing as of the Effective Date are, without limitation, set forth on Exhibit A.

1.21 "**Company Territory**" means worldwide except the Licensed Territory.

1.22 "**Competitive Infringement**" shall have the meaning set forth in Section 11.4(a).

1.23 **"Confidential Information"** shall have the meaning set forth in Section 14.1.

1.24 **"Control"** or **"Controlled"** shall mean, with respect to any Information, Patent Rights, other intellectual property rights, or any proprietary or trade secret information, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense under such Information, Patent Rights or intellectual property rights to another Person, or to otherwise disclose such proprietary or trade secret information to another Person, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.25 **"Days"** or **"days"** shall mean calendar days unless otherwise specified.

1.26 "**Developing Party**" shall have the meaning set forth in Section 2.9(b)(ii).

1.27 "**Disclosing Party**" shall have the meaning set forth in Section 14.1.

1.28 "**Divest**" or "**Divestiture**" means the divestiture of a Business Program through (a) an outright sale or assignment of all or substantially all rights in such Business Program to a Third Party or (b) an exclusive (even with respect to a Party and its Affiliates) out-license of all rights and obligations, including all research, development, manufacture and commercialization rights and obligations, with respect to such Business Program with no further material role, influence or authority of a Party or any of its Affiliates with respect to such Business Program.

1.29 "**Dollar**" or "**$**" shall mean the legal tender of the United States.

1.30 **"Effective Date"** shall have the meaning set forth in the introductory paragraph hereof.

1.31 "**Euro**" or "**€**"shall mean the currency of participating member states of the European Union.

1.32 "**Excluded Information**" shall have the meaning set forth in Section 2.9(b)(ii).

1.33 "**Excluded Regulatory Materials**" shall have the meaning set forth in Section 2.9(b)(iii)

1.34 **"Expanded Territory"** shall mean those countries and territories listed on Exhibit E attached hereto.

1.35 **"Field"** shall mean [*].

1.36 **"Financial Investor"** means any investor or series of Affiliated investors whose primary business is the investment of capital for financial gain (including venture capital funds, private equity funds, pension funds and so-called "angel investors"), but in all cases excluding so-called "strategic investors" such as biotechnology companies, specialty pharmaceutical companies, pharmaceutical companies, generic pharmaceutical companies, and medical device companies and their Affiliates such as strategic venture arms.

1.37 "**First Commercial Sale**" means, in a particular country, the first commercial sale for which revenue has been recognized of [*] by SpePharm, its Affiliates or Sublicensees, to any Third Party for end use in such country in the Licensed Territory, after obtaining Product Approval (including pricing and reimbursement approvals as applicable), as is required in order to sell such Product in such country.

1.38 **"Fiscal Year"** shall mean SpePharm's fiscal year beginning on January 1 of each year.

1.39 "**Force Majeure Events**" shall have the meaning set forth in Section 17.1.

1.40 "**General IP**" shall have the meaning set forth in Section 11.1(b).

1.41 "**Generic Product**" means any pharmaceutical product in the same dosage form sold by a Third Party not authorized by or on behalf of SpePharm, its Affiliates or Sublicensees, that (a) is approved as interchangeable with Product through an abbreviated route of approval by a Regulatory Authority, which approval references the Product, or (b) is approved for the same indication for use through a regulatory pathway referencing clinical data first submitted by Company or its Affiliates or licensees or SpePharm or its Affiliates or Sublicensees for obtaining Product Approval for the Product.

1.42 "**Improvement**" means any enhancement or modification of the Product's dose, dosage form, strength, presentation, preparation, packaging (including volume) or formulation.

1.43 "**Indemnification Claim Notice**" shall have the meaning set forth in Section 13.3.

1.44 "**Indemnified Party**" shall have the meaning set forth in Section 13.3.

1.45 "**Indemnifying Party**" shall have the meaning set forth in Section 13.3.

1.46 **"Information"** shall mean any and all data, results, technology and information of any type whatsoever, in any tangible or intangible form, including trade secrets, scientific, technical or regulatory information, processes, methods, techniques, materials, technology, results, analyses, laboratory, pre-clinical and clinical data, and other know-how, whether or not patentable, including pharmacology, toxicology, drug stability, manufacturing and formulation data, methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies, absorption, distribution, metabolism and excretion studies, but excluding any Patent Rights.

1.47 "**Initial Indication**" means imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

1.48 **"Initial Territory"** shall mean all countries and territories included within Company's EMA (European Medicines Agency) marketing authorization as of the Effective Date for Product 1, which are Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

1.49 "**Inventions**" shall have the meaning set forth in Section 11.1(a).

1.50 **"JMC"** shall have the meaning set forth in Section 3.1(a).

1.51 "**Joint IP**" shall have the meaning set forth in Section 11.1(b).

1.52 "**Jointly Funded Data**" shall have the meaning set forth in Section 11.1(e).

1.53 **"Licensed Territory"** shall mean the Initial Territory and the Expanded Territory.

1.54 "**Litigation Conditions**" shall have the meaning set forth in Section 13.3.

1.55 **"Losses**" shall have the meaning set forth in Section 13.1.

1.56 "**Major EU Market Countries**" means [*].

1.57 "**Marketing Materials**" shall have the meaning set forth in Section 9.1.

1.58 "**Negotiation Period**" shall have the meaning set forth in Section 2.9(a).

1 . 5 9 "**Net Sales**" shall mean on a country-by-country and Product-by-Product basis, with respect to any period for each country in the Licensed Territory, [*];

1.60 "**Non-Developing Party**" shall have the meaning set forth in Section 2.9(b)(ii).

1.61 **"Norgine"** shall have the meaning set forth in the introductory paragraph hereof.

1.62 **"Party"** and **"Parties"** shall have the meaning set forth in the introductory paragraph hereof.

1.63 "**Patent Challenge**" shall have the meaning set forth in Section 15.7.

1.64 **"Patent Rights"** shall mean all patents and patent applications (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations, pediatric exclusivity periods, supplemental protection certificates and the like of any such patents and patent applications, any and all utility models and short term patents, and any and all foreign equivalents of the foregoing.

1.65 **"Person"** shall mean any natural person or any corporation, partnership, limited liability company, business association, joint venture or other entity.

1.66 "**PV Agreement**" shall have the meaning specified in Section 5.5.

1.67 "**PIP Trials**" shall have the meaning set forth in Section 4.2(b).

1.68 **"Product"** shall mean [*] (with and without labeling). For clarity, any references in this Agreement to the Product shall always mean [*], unless otherwise expressly stated to refer to only one of [*].

1.69 **"Product 1"** shall mean any product approved for radiolabeling with technetium 99m, containing Lymphoseek® (or any alternative or replacement name), with the chemical name tilmanocept, in its current 250µg, multi-dose volume packaging configuration as of the Effective Date and any other multi-dose volume packaging configuration, and any Improvements thereto or thereof.

1.70 **[*].**

1.71 **"Product Approval"** shall mean all authorizations, permits and approvals that are issued by a Regulatory Authority and necessary for the use, distribution, promotion and/or sale of a Product in a particular country or jurisdiction, including pricing and reimbursement approval.

1.72 **"Product IP"** shall have the meaning set forth in Section 11.1(a).

1.73 **"Product Marks"** shall mean the Product -related trademarks used by Company in the Company Territory for the Product, including those listed in Part II of Exhibit C and as may be updated from time-to-time by the Company.

1.74 "**RA Field**" shall mean any and all drugs for the diagnosis of rheumatologic conditions in humans, including rheumatoid arthritis, psoriatic arthritis, osteo-arthritis, ankylosing spondylitis, and further including manifestations of such diseases in the joint, cartilage, synovium or entheses.

1.75 "**RA Field License Agreement**" shall mean that certain license agreement by and between Company and TcRA Imaging, Inc. ("TcRA"), wholly-owned subsidiary of R-NAV, LLC ("R-NAV"), dated June 15, 2014.

1.76 "**RA Field Licensee**" shall mean TcRA and its affiliates, or any licensee, sublicense, assignee or successor (whether by operation of law, merger or otherwise) thereof.

1.77 [*].

1.78 [*]

1.79 "**RA Field Rights**" shall have the meaning set forth in Section 2.10(a).

1.80 "**Receiving Party**" shall have the meaning set forth in Section 14.1.

1.81 **"Regulatory Authority"** shall mean any applicable government regulatory authority involved in granting approvals for the promotion, sale, distribution, import/export, use, handling, reimbursement and/or pricing of a Product.

1.82 **"Regulatory Data"** shall mean all regulatory information, data and results relating to the Product which are necessary for Product Approvals, including in-vitro Product testing data and study data, data queries, data tables reports and case report forms generated during any pre-clinical or clinical study or registry study, for the Product.

1.83 **"Regulatory Materials"** shall mean all regulatory applications, submissions, notifications, communications, correspondence, registrations, Product Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority for the use, distribution, promotion, importation, exportation, pricing, reimbursement, marketing and sale of the Product in a particular country or jurisdiction.

1.84 "**Relevant Executive Member**" shall have the meaning set forth in Section 3.1(f).

1.85 "**Repurchase Price**" shall have the meaning set forth in Section 15.8(b)(xi).

1.86 "**Right of Reference**" has the meaning assigned to such term in 21 C.F.R. §314.3(b) (or any analogous Applicable Laws recognized outside the United States).

1.87 **"ROFN**" shall have the meaning set forth in Section 2.8.

1.88 **"ROFN Notice**" shall have the meaning set forth in Section 2.8.

1.89 "**Royalty Term**" shall have the meaning set forth in Section 10.4(b).

1.90 "**Segregate**" means, with respect to a Business Program, to use Commercially Reasonable Efforts to segregate the development, manufacture and Commercialization activities relating to such Business Program from development, manufacture and Commercialization activities with respect to any Products licensed under this Agreement, including ensuring that: (a) personnel involved in performing the development, manufacture or Commercialization of such Business Program do have access to any material non-public plans or information relating to the development, manufacture or Commercialization of any Products; (b) personnel involved in materially performing the development, manufacture or Commercialization of any Products in the Field under this Agreement have access to non-public plans or information relating to the development, manufacture or Commercialization of such Business Program; provided, that, in either case of (a) or (b), management personnel may review and evaluate plans and information regarding the development, manufacture and Commercialization of such Business Program solely in connection with portfolio decision-making among product opportunities; and (c) no Product IP, General IP or Joint IP is practiced or used in the development, manufacture or commercialization of the Business Program.

1.91 **"SpePharm"** shall have the meaning set forth in the introductory paragraph hereof.

1.92 "**SpePharm Development Plan**" shall have the meaning set forth in Section 4.3.

1.93 "**SpePharm Excluded Rights**" shall have the meaning set forth in Section 2.10(b)(i).

1.94 "**SpePharm Indemnitees**" shall have the meaning set forth in Section 13.1.

1.95 "**SpePharm IP**" means all Patent Rights and Information Controlled by SpePharm, its Affiliates or Sublicensees (to the extent SpePharm receives rights from its Sublicensees) as of the date of termination of this Agreement, that is necessary, or uniquely specific, for development, marketing, promotion, importation, use, sale, offer for sale, distribution, manufacture, having manufactured and otherwise commercializing the Product, but excludes General IP and Joint IP.

1.96 "**SpePharm Witholding Tax Action**" shall have the meaning set forth in Section 10.8(c).

1.97 **"Sublicensee"** shall have the meaning set forth in Section 2.2(a).

1.98 **"Successor Entity"** shall have the meaning set forth in Section 15.9(a)(viii).

1.99 "**Supply Agreement**" shall have the meaning set forth in Section 6.1.

1.100 **"Term"** shall have the meaning set forth in Section 15.1.

1.101 "**Territory**" shall mean, with respect to Company, the Company Territory, and with respect to SpePharm, the Licensed Territory.

1.102 "**Third Party**" shall mean any entity other than Company, SpePharm, Norgine or their respective Affiliates.

1.103 "**Third Party Claims**" shall have the meaning set forth in Section 13.1.

1.104 "**Upstream Agreements**" shall mean (i) that certain License Agreement by and between Company and The Regents of the University of California effective as of July 14, 2014, and (ii) that certain Amended and Restated License Agreement by and between Company and The Regents of the University of California effective as of July 14, 2014.

1.105 "U.S." shall mean the United States of America, including all possessions and territories thereof.

1.106 "**U.S. Export Control Laws**" shall mean all applicable U.S. laws and regulations relating to the export or re-export of commodities, technologies, or services, including, but not limited to, the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 *et seq.*, the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986.

1.107 "Valid Claim" shall mean, with respect to any country, a claim of a pending patent application (which has been pending for five (5) years or less from the date of filing of the earliest priority patent application to which such pending patent application is entitled to claim benefit) or issued and unexpired Patent Right (including any supplementary protection certificate or patent term extension or the like), to the extent such claim has not been (a) rejected, revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) or (b) abandoned, surrendered, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

1.108 "Weighted Average Price" shall mean total Net Sales of [*] divided by the number of units of [*] sold, in each case across the referenced set of Major EU Market Countries over the three (3) month period prior to the date of calculation.

1.109 Interpretation. In this Agreement, unless otherwise specified:

(a) "includes" and "including" shall mean respectively includes and including without limitation;

(b) unless the context otherwise requires, the word "or" shall be deemed to include the word "and" (*i.e.*, shall mean "and/or");

(c) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(d) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and

(e) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibits and attachments.

ARTICLE II – GRANT OF RIGHTS: LICENSE AND EXCLUSIVITY

2.1 License to SpePharm; Retained Rights

(a) License Grant. Subject to the terms and conditions of this Agreement (including Section 2.9), Company hereby grants to SpePharm and its Affiliates (i) an exclusive (even as to Company and its Affiliates) right and license, with the right to grant sublicenses in accordance with Section 2.2, under the Company Patents, Company Know-How, Joint IP and Joint Study Data to develop, market, promote, import, use, sell, offer for sale, keep (whether for sale or otherwise), distribute and otherwise Commercialize the Product, in each case in the Field and in the Licensed Territory, and (ii) a co-exclusive (with Company and its Affiliates) right and license in the Licensed Territory, and non-exclusive right and license outside of the Licensed Territory, with the right to grant sublicenses in accordance with Section 2.2, under the Company Patents, Company Know-How, Joint IP and Joint Study Data to, manufacture and have manufactured the Product for the Field for the Licensed Territory. The license granted to SpePharm's Affiliates under this Section 2.1(a) shall terminate when and if such entity is no longer an Affiliate of SpePharm.

(b) Company Retained Rights. Notwithstanding the rights granted to SpePharm and its Affiliates in Section 2.1(a), Company retains all rights and interests other than expressly granted under this Agreement, including without limitation, rights to: (i) manufacture and have manufactured the Product worldwide; (ii) conduct the activities specified in Section 4.2 hereunder; (iii) subject to Section 4.4, conduct or have conducted clinical trials and other studies in the Licensed Territory for the generation of data in support of regulatory submissions to the Regulatory Authorities in the Company Territory; and (iv) subject to Section 4.4, conduct activities in the Licensed Territory with respect to the research, development, and manufacture of the Product, for use and commercialization in the Company Territory.

2.2 Sublicense Rights. [*].

2.3 Negative Covenant. SpePharm covenants that it will not, and it will not grant a license to or otherwise authorize any of its Affiliates or Sublicensees to, use or practice any Company Patents and Company Know-How outside the scope of the license granted to it under Section 2.1(a) above.

2.4 No Implied Rights. Except for the licenses and rights expressly granted under this Agreement, no right, title or interest with respect to the Product or any other intellectual property interest, by implication or otherwise, under any trademarks, Information and/or Patent Rights owned or Controlled by Company is granted by Company to SpePharm hereunder.

2.5 Upstream Agreement. The Company Patents sublicensed under Section 2.1 are licensed to Company pursuant to the Upstream Agreements. SpePharm covenants to comply and cause its Sublicensees to comply with the material terms of the Upstream Agreements as applicable to Sublicensees in all material respects, current copies of which have been provided to SpePharm as of the Effective Date. Company acknowledges that SpePharm's and its Sublicensees' compliance with its diligence obligations expressly set forth in this Agreement shall satisfy the requirements of the preceding sentence with respect to diligence obligations applicable to Sublicensees under the Upstream Agreements, if any. SpePharm acknowledges and agrees that its sublicense rights with respect to such Company Patents under this Agreement are at all times subject to, and limited by, the applicable terms of the Upstream Agreements (including the scope of the licenses granted to Company) and in the event of any inconsistency between this Agreement and the applicable Upstream Agreement, the Upstream Agreements shall control (without limitation of the preceding sentence). Company shall not amend or agree to amend any terms or conditions of the Upstream Agreements in any manner that would adversely affect the rights granted to SpePharm in the Licensed Territory under this Agreement without the prior written consent of SpePharm. Company further agrees that it shall not terminate either Upstream Agreement, without the prior written consent of SpePharm. Company shall comply with all material terms of the Upstream Agreements in all material respects, and shall timely make all payments required to be made thereunder, provided that Company shall not be in breach of the foregoing obligations to the extent that Company's failure to comply results from SpePharm's non-compliance with the terms of the Upstream Agreements as required under this Section 2.5. For avoidance of doubt, Company is solely responsible for any payment obligations under the Upstream Agreements. Company shall notify SpePharm when it has received any notice from any Third Party that is a party to the Upstream Agreements stating that such Third Party intends to terminate or is terminating any of the Upstream Agreements. Company shall further notify SpePharm of any issue of which Company is aware that has given or could reasonably be expected to give rise to a material dispute under either Upstream Agreement. [*].

2.6 Exclusivity.

(a) During the Term, SpePharm shall not, and shall cause its Affiliates not to, directly or indirectly, by itself or with a Third Party, develop, promote, market, import, use, sell, offer for sale, distribute or otherwise commercialize anywhere in the Licensed Territory any product for [*] (except for any Product under this Agreement).

(b) During the Term, Company shall not, and shall cause its Affiliates not to, directly or indirectly, by itself or with a Third Party, develop, promote, market, import, use, sell, offer for sale, distribute or otherwise commercialize anywhere in the Licensed Territory any product for [*]; provided that the foregoing restriction shall not apply to any development of the Product under this Agreement (to the extent permitted hereunder) or product that was offered and not licensed to SpePharm under Section 2.8.

(c) Notwithstanding this Section 2.6, if a Business Combination occurs with respect to SpePharm or any of its Affiliates, and the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates immediately prior to such Business Combination) has a program that existed prior to, or was planned prior to and is demonstrably to be implemented shortly after, or would be developed independently of any intellectual property licensed hereunder after, the Business Combination that would otherwise violate this Section 2.6 (a "**Business Program**"), then such Third Party or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, including SpePharm and its Affiliates as of the Business Combination, as applicable, will be permitted to continue such Business Program after such Business Combination and such continuation will not constitute a violation of this Section 2.6 so long as such Third Party acquirer or the Third Party acquirer's Affiliate Segregates the Business Program. [*].

(d) Notwithstanding this Section 2.6, if a Business Combination occurs with respect to Company and the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates immediately prior to such Business Combination) has a Business Program that existed prior to, or was planned prior to and is demonstrably to be implemented shortly after the Business Combination, or would be developed independently of any intellectual property licensed hereunder after, then such Third Party or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, including Company and its Affiliates as of the Business Combination, as applicable, will be permitted to continue such Business Program after such Business Combination and such continuation will not constitute a violation of this Section 2.6 so long as such Third Party acquirer or the Third Party acquirer's Affiliate Segregates the Business Program; provided that, at SpePharm's election, the JMC shall be dissolved and/or SpePharm shall have final decision making authority with respect to all matters for which the JMC had review rights or responsibility, provided that the last paragraph of Section 3.1 shall continue to apply.

(e) If SpePharm or any of its Affiliates acquires a Third Party (including by merger or consolidation) so that such Third Party becomes an Affiliate over which SpePharm or such Affiliate has control (as defined in Section 1.5), or SpePharm or any of its Affiliates acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof), and the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates immediately prior to such Business Combination) has, or the acquired assets contain, as applicable, a Business Program, then SpePharm shall promptly notify Company of such Business Program within five (5) days after such Business Combination and SpePharm and/or such Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates), as applicable, will [*].

(f) If Company or any of its Affiliates acquires a Third Party (including by merger or consolidation) so that such Third Party becomes an Affiliate over which Company or such Affiliate has control (as defined in Section 1.5), or Company or any of its Affiliates acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof), and the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates immediately prior to such Business Combination) has, or the acquired assets contain, as applicable, a Business Program, then Company shall promptly notify SpePharm of such Business Program within five (5) days after such Business Combination and Company and/or such Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates) will [*].

(g) Each Party acknowledges and agrees that the restrictions set forth in this Section 2.6 are considered by the Parties to be reasonable for the purposes of protecting the goodwill and value of the other Party's business. Each Party acknowledges that the other Party may be irreparably harmed and that monetary damages may not provide an adequate remedy to the other Party in the event the covenants contained in this Section 2.6 were not complied with in accordance with their terms. Accordingly, each Party agrees that any breach by it of any provision of this Section 2.6 shall entitle the other Party to, without limit any other rights it may have, injunctive and other equitable relief to secure the enforcement of these provisions, in addition to any other remedies (including damages) which may be available to the other Party.

(h) It is the desire and intent of the Parties that the provisions of this Section 2.6 be enforced to the fullest extent permissible under the laws and public policies of each jurisdiction in which enforcement is sought. If any provisions of this Section 2.6 relating to the time period, scope of activities or geographic area of restrictions is declared by a court of competent jurisdiction to exceed the maximum permissible time period, scope of activities or geographic area, as the case may be, the time period, scope of activities or geographic area shall be reduced to the maximum which such court deems enforceable. If any provisions of this Section 2.6 other than those described in the preceding sentence are adjudicated to be invalid or unenforceable, the invalid or unenforceable provisions shall be deemed amended (with respect only to the jurisdiction in which such adjudication is made) in such manner as to render them enforceable and to effectuate as nearly as possible the original intentions and agreement of the Parties.

2.7 Cross-Territorial Restrictions.

(a) Unless otherwise expressly authorized by Company in writing, SpePharm shall not (i) actively seek prospective purchasers for the Product for use in the Company Territory; (ii) engage in any advertising or promotional activities relating to the Product directed primarily to prospective purchasers for use in the Company Territory; or (iii) solicit orders from any prospective purchaser for sale and use in the Company Territory. If SpePharm receives any order from a prospective purchaser in the Company Territory, SpePharm shall promptly refer that order to Company and shall not accept any such orders. SpePharm shall not sell any Product to a purchaser if SpePharm knows that such purchaser intends to resell or otherwise distribute or provide such Product to a prospective purchaser for use in the Company Territory.

(b) Unless otherwise expressly authorized by SpePharm in writing, Company shall not (i) actively seek prospective purchasers for the Product for use in the Licensed Territory; (ii) engage in any advertising or promotional activities relating to the Product directed primarily to prospective purchasers for use in the Licensed Territory; or (iii) solicit orders from any prospective purchaser for sale and use in the Licensed Territory. If Company receives any order from a prospective purchaser in the Licensed Territory, Company shall promptly refer that order to SpePharm and shall not accept any such orders. Company shall not sell any Product to a purchaser if Company knows that such purchaser intends to resell or otherwise distribute or provide such Product to a prospective purchaser for use in the Licensed Territory.

2.8 ROFN for Additional Products. Company hereby grants to SpePharm the first right to negotiate for the exclusive rights to market, sell, distribute and commercialize in the Licensed Territory any imaging agent for [*] Controlled by Company or any of its Affiliates during the Term (the "**Additional Products**") (the "**ROFN**") in accordance with this Section 2.8. In the event that Company or any of its Affiliates proposes to, directly or indirectly, enter into, a license or other arrangement with a Third Party at any time during the Term pursuant to which such Third Party would receive rights to market, sell, distribute and/or commercialize any Additional Product (an **"Additional Product License**"), then Company shall so notify SpePharm in writing (the "**ROFN Notice**") prior to engaging in any such activities. For clarity, Company shall notify SpePharm upon receipt of, or prior to entering into discussions or a binding commitment with respect to, an unsolicited offer or proposal for an Additional Product License from a Third Party. If within thirty (30) days of receiving the ROFN Notice, SpePharm notifies Company in writing that it wishes to exercise its ROFN, the Parties shall negotiate in good faith on an exclusive basis for a period not to exceed ninety (90) days after Company's receipt of such written notification. If the Parties reach agreement on the terms to include such Additional Product under this Agreement, the Parties shall amend this Agreement based upon the agreed upon terms. If, at the end of the 90-day period, Company and SpePharm are unable to reach agreement on such terms, Company shall be free to enter into an Additional Product License for such Additional Product and Company shall have no further obligation to SpePharm with respect to such Additional Product. For clarity, (a) an agreement with a contractor, contract research organization, contract manufacturer or other Third Party which agreement provides solely for the performance of contract services on behalf of Company, shall not be subject to this Section 2.8; and (b) this Section 2.8 shall not be triggered by a Business Combination of Company, or an assignment or transfer of this Agreement or any right or obligation hereunder to a Third Party pursuant to Section 17.8. In the event Company is acquired by a Third Party in connection with a Business Combination, the terms of this Section 2.8 will no longer apply.

2.9 Additional Indications.

(a) In the event that either Party or its Affiliates is interested in developing a Product for an indication other than the Initial Indication (each an "**Additional Indication**"), it shall propose such development to the JMC for discussion by the Parties. If the other Party indicates, within sixty (60) business days of such proposal for development by the other Party (the "**AI Notice Period**"), it is interested in jointly developing the Product for the Additional Indication with the first Party, the Parties agree to negotiate the terms of such development, including a development plan that would satisfy the requirements of the FDA and EMA for such Additional Indication, the roles and responsibilities of the Parties in such development and the sharing of costs and expenses that would be incurred by the Parties in developing the Product for such Additional Indication. The Parties agree that such negotiations shall occur for at least sixty (60) days after the other Party referenced above has indicated its interest in the Additional Indication, or for such other period of time mutually agreed by the Parties ("**Negotiation Period**"). If the Parties reach mutual agreement on such terms, the Parties shall document such agreement in writing.

(b) If the Parties do not reach agreement on terms for developing the Product for the Additional Indication within the Negotiation Period, or if a Party has indicated it is not interested in, or has failed to indicate (within the AI Notice Period) it is interested in, jointly developing with the other Party the Product for the Additional Indication, then each Party shall have the right to independently develop the Product for such Additional Indication for its respective Territory, provided that, notwithstanding anything to the contrary in this Agreement (including Sections 2.1 and 11.1(f)):

(i) such right to independently develop the Product is subject to, and without limitation of, Section 4.4;

(ii) any and all Information (including raw clinical data and manufacturing information) generated by or on behalf of such Party (the "**Developing Party**") or its Affiliates or licensees or sublicensees in the conduct of the development and commercialization of the Product in and for the Additional Indication ("**Excluded Information**") shall be excluded from any and all licenses and other rights granted to the other Party (the "**Non-Developing Party**") under this Agreement, provided that if such Excluded Information was generated in the conduct of development and/or commercialization of the Product in and for (A) the Additional Indication and (B) either (1) the Initial Indication or (2) a different Additional Indication which the Parties have mutually agreed to develop pursuant to Section 2.9(a) above, then the Excluded Information shall not be excluded from the license and other rights granted to the Non-Developing Party with respect to the Initial Indication and such different Additional Indication;

(iii) the Non-Developing Party and its Affiliates and licensees and sublicensees shall have no right to, and shall not, refer to, rely upon or otherwise make any use of any Excluded Information, or any Regulatory Materials for the Product for the Additional Indication that are Controlled by the Developing Party or its Affiliates or licensees or sublicensees ("**Excluded Regulatory Materials**"), other than (A) solely as necessary to comply with any safety reporting obligations of a Regulatory Authority and (B) with respect to the Initial Indication and any different Additional Indications which the Parties have mutually agreed to develop pursuant to Section 2.9(a) above;

(iv) subject to the RA Field Licensee's rights in the RA Field under the RA Field License Agreement, neither Party nor any of its Affiliates or licensees or sublicensees shall seek or obtain any Product Approval for the Product for the Additional Indication in the Developing Party's Territory; and

(v) for avoidance of doubt, subject to clauses (ii) and (iii) above, the Field shall continue to include the Additional Indication, including for purposes of the licenses granted to SpePharm and its Affiliates under Section 2.1 for the Licensed Territory.

If a Non-Developing Party desires to obtain access to any Excluded Information or Excluded Regulatory Materials, the Developing Party agrees to negotiate in good faith the terms of such access, including the consideration to be paid by the Non-Developing Party for such access.

For purposes of this Section 2.9(b), references to "licensees," when referring to Company's licensees, shall not include SpePharm or its Affiliates.

2.10 RA Field.

(a) [*].

(b) Notwithstanding anything to the contrary herein:

(i) RA Field Licensee shall not have, and Company and its Affiliates and other licensees (excluding SpePharm and its Affiliates) shall not have in the RA Field, any license, sublicense or other rights (including any right to reference or rely upon) to or under, directly or indirectly, any (A) Information, Confidential Information or Patent Rights Controlled (other than where Controlled as a result of the licenses granted under Section 2.1) by SpePharm or any of its Affiliates or licensees or sublicensees (including any General IP), (B) any Product IP, (C) any Information generated under this Agreement from clinical studies funded (in whole or in part) by SpePharm or any of its Affiliates), (D) any Regulatory Materials owned, held or possessed by SpePharm or any of its Affiliates or licensees or sublicensees, including any Product Approvals for any Product in the Licensed Territory, but excluding Product Approvals, Regulatory Data and Regulatory Materials assigned or licensed by Company to SpePharm under this Agreement, ((A) through (D) collectively, the "**SpePharm Excluded Rights**"); or (E) the Product Marks;

(ii) neither Company nor any of its Affiliates or any other Person acting by, for or through them, shall, directly or indirectly, (A) grant or otherwise convey to the RA Field Licensee any license, sublicense or other rights (including any right to reference or rely upon) to or under any SpePharm Excluded Rights or any Product Marks, or (B) disclose or otherwise make available any SpePharm Excluded Rights to the RA Field Licensee;

(iii) neither Company nor any of its Affiliates or licensees or sublicensees (other than the RA Field Licensee pursuant to the RA Field License Agreement) shall, directly or indirectly, sell, distribute or otherwise Commercialize the Product in or for the RA Field in the Licensed Territory;

(iv) if the RA Field Licensee, directly or indirectly, sells, distributes or otherwise Commercializes the Product in any country of the Initial Territory, such Product shall be deemed a Generic Product for each and every country of the Initial Territory, and Section 10.4(c) shall apply for as long as such sale, distribution or Commercialization continues;

(v) if the RA Field Licensee, directly or indirectly, sells, distributes or otherwise Commercializes the Product in any country of the Expanded Territory, such Product shall be deemed a Generic Product for such country of the Expanded Territory, and Section 10.4(c) shall apply for as long as such sale, distribution or Commercialization continues; and

(vi) if the RA Field Licensee, directly or indirectly, sells, distributes or otherwise Commercializes the Product in any country of the Licensed Territory, SpePharm's obligation to pay any milestone payments under Sections 10.2 and 10.3 that come due after the first date of such sale, distribution or Commercialization, shall terminate.

2.11 Expanded Territory. [*] after the Effective Date, SpePharm shall provide Company with a development plan for each of [*]. Each such plan shall include those activities designed to obtain Product Approval in a timely manner consistent with the exercise of Commercially Reasonable Efforts and will include the initiation of material development activities, consistent with Commercially Reasonable Efforts, not later than [*] from the date of such plan. From time to time during the Term, SpePharm shall have the right to make Commercially Reasonable amendments to such development plans. SpePharm will provide any proposed amendments to the JMC for its review, and will reasonably consider any comments from the JMC with respect to such amendments. SpePharm will update the JMC from time to time on its plans to develop the Product in the Expanded Territory countries aside from [*]. The Licensed Territory shall be redefined to exclude [*] where SpePharm does not provide a development plan for such country in accordance with this Section 2.11, and such redefinition of the Licensed Territory shall constitute Company's sole remedy for such non-provision of such development plan.

ARTICLE III – GOVERNANCE

3.1 Joint Management Committee.

(a) Promptly after the Effective Date the Parties will establish a joint management committee ("**JMC**") composed of at least three (3) representatives from each Party, that number not necessarily required to be the same for each Party. Each Party may change its representatives on the JMC from time to time, in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate experience and knowledge. The JMC shall coordinate the activities of the Parties under this Agreement and discuss measures facilitating the Product's successful development and Commercialization in the Licensed Territory. Upon written notice to the other Party, either Party may invite a reasonable number of non-member representatives (including, without limitation, its employees or non-employee professional representatives), who have a reasonable purpose for attending such meeting or portion of such meeting and are bound to obligations of confidentiality at least as protective as those set forth in this Agreement.

(b) Meetings. The JMC shall meet at least on a semi-annual basis and at such other times as the Parties may agree. Meetings shall be held at such dates and locations as are mutually agreed, and may be held in person, by teleconference or videoconference. The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Section 3.1 shall be borne solely by such Party.

(c) Role of the JMC. Subject to the foregoing, the JMC shall be responsible for:

(i) reviewing and discussing the strategy for obtaining Product Approval and for reviewing strategic Regulatory Materials, as needed, including Product Approval filings, for the Product in the Licensed Territory;

(i i) reviewing and discussing the development, manufacturing, marketing, distribution and Commercialization of the Product in the Licensed Territory, including (A) any Chemistry, Manufacturing and Controls (" **CMC**") work which may be required or necessary for the approval of [*] by the EMA and (B) the Commercialization Plan;

(iii) reviewing and discussing progress of the clinical trials required to fulfill Paediatric Investigation Plans agreed with the FDA and EMA;

(iv) reviewing and discussing clinical trials involving the Product (including market access trials) conducted in the Licensed Territory;

(v) reviewing and discussing the Company Development Plan and SpePharm Development Plan;

(vi) establishing such joint subcommittees or committees as the Parties may agree in writing as necessary to achieve the objectives and intent of this Agreement; and

(vii) performing such other functions as agreed by the Parties in writing.

Notwithstanding any other provision of this Section 3.1, the JMC shall have only the powers assigned expressly to it in this Section 3.1 and elsewhere in this Agreement.

(d) Quorum and Decision-Making. The quorum for meetings of the JMC shall be two (2) representatives from each Party. At any meeting, the JMC members from each respective Party shall have one (1) aggregate vote, irrespective of the number of representatives from each Party actually in attendance of the meeting. No decision of the JMC shall be made unless both Parties have voted in favor thereof.

(e) Chair. Unless otherwise mutually agreed between the Parties, the chair of the JMC shall alternate between representatives of each of the Parties at each meeting of the JMC. The first chair of the JMC shall be a representative of SpePharm.

(f) Decision-Making. If the JMC cannot unanimously resolve a disagreement within thirty (30) days after first addressing such a matter, either Party may, by written notice to the other Party, have such dispute referred to the Chief Operating Officer or closest equivalent ("**Relevant Executive Member**") of each Party or their designees for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. If the Relevant Executive Members are unable to agree on any matter or resolve any issue referred to it within fifteen (15) days after such matter was referred to them, or in such longer period as the Parties may agree, such dispute shall be referred to the Chief Executive Officer of each Party or their designees for attempted resolution by good faith negotiations within fifteen (15) days after such notice is received; *provided*, *however*, that each of the Parties shall have the final decision-making authority and discretion with respect to the following matters, as and to the extent set forth in this Agreement:

(i) SpePharm's Decision. SpePharm shall have the authority and discretion to decide any matter (A) related to (i) except as provided in Section 3.1(f)(ii)(B), development of the Product in the Licensed Territory, and Regulatory Materials, Product Approvals and regulatory matters concerning the Product in the Licensed Territory, (ii) conduct of any clinical trials involving the Product to be conducted in the Licensed Territory (including any clinical trials which may be done for market access and pricing and reimbursement purposes for the Products in the Licensed Territory); and (iii) the Commercialization of the Product within the Licensed Territory, including the Commercialization Plan (but excluding the training to be provided pursuant to Section 9.2(a), which shall require mutual agreement of the Parties); (B) related to CMC work which may be required or necessary for Product Approval of the Product in the Licensed Territory after the first Product Approval of [*] in the Licensed Territory by the EMA; and (C) related to seeking Product Approval for [*] in the Expanded Territory and maintaining Product Approvals for the Product, in the Licensed Territory; and (D) related to activities in the Licensed Territory that could reasonably be deemed to have a material adverse effect on the Commercialization of the Product in the Field, in the Licensed Territory.

(ii) Company's Decision. Company shall have the authority and discretion to decide (A) any matter relating to the development, manufacture or commercialization of the Product in the Company Territory; and/or (B) the conduct of CMC work which may be required or necessary for the first Product Approval of [*] in the Licensed Territory by the EMA.

Notwithstanding the foregoing, the Party having final decision-making authority under this Section 3.1(f) shall not have the right to exercise its final decision-making authority to unilaterally: (1) determine that it has fulfilled any obligations under this Agreement or that the other Party has breached any obligation under this Agreement, (2) determine that a milestone event required for the payment of a milestone payment has or has not occurred, (3) make a decision that is expressly stated to require the mutual agreement of the Parties (which, for clarity, does not encompass matters to be approved by the JMC), (4) otherwise expand its rights or reduce its obligations under this Agreement, (5) determine any issue in a manner that would conflict with the terms and conditions of this Agreement, or (6) require Company to make any expenditures or conduct any activities not otherwise specified in the Company Development Plan or require SpePharm to make any expenditures or conduct any activities not otherwise specified in the SpePharm Development Plan.

ARTICLE IV – PRODUCT DEVELOPMENT

4.1 Product Development. Subject to the terms of this Agreement, SpePharm will be responsible for the development of the Product in the Licensed Territory except as expressly assigned to Company.

4.2 Development Responsibilities of Company. Company shall be responsible, at its sole cost and expense (except as provided in Section 4.2(b)), for the following activities for the Product for the Licensed Territory:

(a) designing and conducting, in accordance with Applicable Laws and protocols mutually agreed by the Parties, any non-clinical and clinical trials which may be required for Product Approval (excluding pricing and reimbursement approval) of the Products in the Initial Territory by any Regulatory Authorities;

(b) designing and conducting, in accordance with Applicable Laws and protocols mutually agreed by the Parties, any clinical trials which may be required to fulfill Paediatric Investigation Plans agreed with the EMA ("**PIP Trials**"); provided that Company and SpePharm will share equally in the out-of-pocket costs and expenses of any such PIP Trials, as will be mutually agreed by the Parties in writing prior to the commencement of such PIP Trials, with SpePharm's share not to exceed [*]; and

(c) conducting any CMC work which may be required or necessary for the first Product Approval of [*] by the EMA in the Licensed Territory and as may be required or necessary in connection with the supply of Product to SpePharm under the Supply Agreement;

in each case subject to review by and discussion at the JMC.

The development plan detailing the foregoing development activities is attached hereto as Exhibit G (the "**Company Development Plan**"). From time to time during the Term, Company shall have the right to amend the then-current Company Development Plan. Company will provide any proposed amendments to the JMC for its review, and will reasonably consider any comments from the JMC with respect to such amendments. Company shall use Commercially Reasonable Efforts to conduct the development activities set forth in the Company Development Plan.

4.3 Development Responsibilities of SpePharm. SpePharm shall be responsible, at its sole cost and expense, for:

(a) designing and conducting any clinical trials required or necessary for market access and pricing and reimbursement purposes for the Products in the Licensed Territory;

(b) providing reasonable requested advice and expertise to Company with respect to CMC work conducted by Company which may be required or necessary for the first Product Approval of [*] by the EMA in the Licensed Territory;

(c) conducting any CMC work which may be required or necessary for Product Approvals after the first Product Approval of [*] by the EMA in the Licensed Territory, except as provided in Section 4.2(c); and

(d) using Commercially Reasonable Efforts to conduct other Commercially Reasonable development activities (other than those that are Company's responsibility pursuant to Section 4.2) that may be required or necessary to obtain Product Approvals for [*] in the Licensed Territory.

[*], SpePharm shall prepare a plan setting forth the development activities (including any market access or other studies) that will be conducted by SpePharm for the Initial Territory pursuant to this Section 4.3 (the "**SpePharm Development Plan**"). From time to time during the Term, SpePharm shall have the right to amend the then-current SpePharm Development Plan. SpePharm will provide any proposed amendments to the JMC for its review, and will reasonably consider any comments from the JMC with respect to such amendments. SpePharm shall use Commercially Reasonable Efforts to conduct the development activities set forth in the SpePharm Development Plan. Without limiting the generality of the foregoing, the Parties shall review and discuss, through the JMC, a schedule for filing of regulatory applications for such Product Approvals in such countries.

In the event that SpePharm determines that it is not Commercially Reasonable to file a regulatory application for Product Approval for the Product or Commercialize the Product, in any particular country in the Licensed Territory, then SpePharm shall promptly discuss such matter with the JMC.

4.4 Clinical Trials.

(a) The Parties shall discuss, at the JMC, the conduct by SpePharm of market access studies for use in generating pricing and reimbursement data for the Product in the Licensed Territory.

(b) If SpePharm intends to initiate and conduct any investigator led trials or clinical trials necessary or desirable to seek and maintain Product Approvals for the Product in the Licensed Territory, SpePharm shall discuss such trials with Company reasonably in advance of their initiation and shall in good faith consider Company's reasonable comments and suggestions in respect thereof.

(c) Except for any clinical trials required to be conducted by Company pursuant to Section 4.2, neither Company nor its Affiliates or licensees may sponsor or conduct any investigator led trials or clinical trials involving the Product in the Licensed Territory without SpePharm's prior written approval (such approval not to be unreasonably withheld, delayed or conditioned).

(d) If Company or its Affiliates or licensees sponsor or conduct any investigator led trials or clinical trials involving the Product in the Company Territory, Company agrees to discuss and review such trials at the JMC (provided that neither SpePharm nor the JMC shall have any approval rights, and all decisions regarding such trials shall be in Company's sole discretion).

4.5 Product Development Activities. Each Party agrees that it shall consult with and keep the other Party reasonably apprised of the developing Party's conduct, directly or indirectly, of any clinical development activity using the Product in its respective Territory, including the evaluation of the Product for use in additional fields or applications.

4.6 Records; Information Sharing; Right of Reference.

(a) Records, Data and Information. Each Party shall maintain complete, current and accurate records of all work conducted by it under this Agreement and all data and other Information resulting from the performance of such activities in sufficient detail and in a good scientific manner appropriate for patent and regulatory purposes.

(b) Data Generated by SpePharm. Subject to Sections 2.9 and 2.10, SpePharm shall promptly provide Company with copies of final reports and of all Information (including raw clinical data) generated by or on behalf of SpePharm or its Affiliates or Sublicensees in conducting any activities under this Agreement that are Controlled by SpePharm and are necessary or useful for the development, manufacture or Commercialization of the Product. SpePharm shall provide such Information to Company as soon as reasonably practical and through information sharing procedures to be established by mutual agreement of the Parties. Notwithstanding any other provision of this Agreement to the contrary, SpePharm acknowledges and agrees that, subject to Sections 2.9 and 2.10, Company may disclose any and all such Information to Company's Affiliates and licensees and that Company and such Affiliates and licensees may use, free of charge, any such Information solely for (i) the research, development, manufacture and commercialization of the Product in the Company Territory, and (ii) the research, development, manufacture and commercialization of any product controlled by Company (other than the Product in the Licensed Territory) as of the Effective Date or during the Term.

(c) Data Generated by Company. Subject to Section 2.9, Company shall promptly provide SpePharm with copies of final reports and of all Information (including raw clinical data and manufacturing information) generated by or on behalf of Company or its Affiliates or licensees prior to the Effective Date as well as during the Term in the conduct of the development and commercialization of the Product that are necessary or useful for the development, Product Approval or Commercialization of the Product in the Field by SpePharm for the Licensed Territory. Company shall provide such Information to SpePharm as soon as reasonably practical and through information sharing procedures to be established by mutual agreement of the Parties. Notwithstanding any other provision of this Agreement to the contrary, Company acknowledges and agrees that, subject to Section 2.9, SpePharm may disclose any and all such Information with SpePharm's Affiliates and Sublicensees and that SpePharm and such Affiliates and Sublicensees may use, free of charge, any such Information solely for the research, development, manufacture and commercialization of the Product in the Licensed Territory.

(d) Right of Reference. Subject to Section 2.9, Company hereby grants to SpePharm, its Affiliates and Sublicensees a Right of Reference to all Regulatory Data and all Regulatory Materials Controlled by Company or its Affiliates relating to the Product solely to the extent necessary or useful to develop, manufacture, market, promote, use, sell, distribute and Commercialize the Product in the Field in or for the Licensed Territory, consistent with the terms of this Agreement. Subject to Sections 2.9 and 2.10, SpePharm hereby grants to Company, its Affiliates and licensees a Right of Reference to all Regulatory Data and Regulatory Materials Controlled by SpePharm or its Affiliates relating to the Product solely to the extent necessary or useful to develop, manufacture, market, promote, use, sell, distribute and Commercialize the Product in or for the Company Territory. Each Party shall provide a signed statement regarding the foregoing, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Applicable Laws recognized outside of the United States).

ARTICLE V – REGULATORY MATTERS; PHARMACOVIGILANCE

5.1 Transfer of Existing Product Approvals. The Parties shall take, and shall cause their Affiliates to take, such actions as are reasonably necessary to transfer Product Approvals for Product 1 [*] to SpePharm or an Affiliate designated by SpePharm within three (3) months after the receipt of Product Approval for [*] in the Initial Territory, including Company providing all Regulatory Data to SpePharm that is required to be submitted to Regulatory Authorities in connection with SpePharm's or its designated Affiliate's application to assume such Product Approvals. Each Party shall be responsible for its own costs and expenses incurred in connection with such transfer, provided that SpePharm shall be responsible for any fees payable to Regulatory Authorities in connection with such transfer. Until transfer of the Product Approvals for Product 1 to SpePharm, or in the event of failure to transfer such Product Approvals to SpePharm or its designated Affiliate, Company hereby consents and grants to SpePharm and its Affiliates the right to access and reference (without any further action required on the part of Company, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such Product Approval.

5.2 Preparation and Filing of Product Approvals for [*].

(a) Product Approval for Product 1 has been obtained as of the Effective Date in the Initial Territory. Subject to SpePharm's input and final approval (not to be unreasonably withheld), Company shall, at its expense, prepare submission-ready Regulatory Materials to obtain Product Approvals for the Initial Indication for [*] in the Initial Territory and file all such Regulatory Materials to obtain such Product Approvals in the Initial Territory. SpePharm shall provide Company with such advice and reasonable consultation and assistance as may be requested by Company in connection with the foregoing activities.

(b) SpePharm, at its expense, shall be responsible for preparing and filing all Regulatory Approvals to obtain Product Approvals for the Initial Indication for [*] in the Expanded Territory. Company shall provide SpePharm with such advice and reasonable consultation and assistance as may be requested by SpePharm in connection with the foregoing activities, including supplying to SpePharm copies of all Regulatory Data and Regulatory Materials possessed by Company and its Affiliates and licensees.

(c) SpePharm shall, at its expense, use Commercially Reasonable Efforts to obtain, in consultation with Company through the JMC, Product Approvals for the Initial Indication for [*] in the Expanded Territory in those countries of the Expanded Territory where it is Commercially Reasonable to do so (subject to Section 2.11).

5.3 Maintenance of Product Approvals.

(a) After transfer of each Product Approval in the Licensed Territory to SpePharm or its designated Affiliate, or obtaining of each Product Approval in the Licensed Territory by SpePharm or its designated Affiliate, SpePharm or such designated Affiliate shall use Commercially Reasonable Efforts to maintain, in consultation with Company through the JMC, such Product Approvals. SpePharm shall be responsible for all costs and expenses incurred in maintaining such Product Approvals, including amounts required to be paid to Regulatory Authorities, but excluding any costs and expenses incurred by Company or its Affiliates.

(b) As between the Parties, all Product Approvals for the Product in the Licensed Territory shall be in the name of SpePharm or its designated Affiliate, and shall indicate SpePharm or such designated Affiliate is the holder of such Product Approvals. SpePharm shall be responsible for obtaining and maintaining any other approvals, permits or licenses necessary for its distribution, promotion, and sale of the Product in the Licensed Territory.

5.4 Review of Regulatory Materials; Communications with Regulatory Authorities.

(a) Company shall provide to SpePharm for its review and comment any proposed material Regulatory Materials to be submitted (other than routine correspondence) to a Regulatory Authority in the Licensed Territory relating to the Product at least ten (10) business days in advance of submission, and Company shall reasonably consider and incorporate such comments. From and after such time that Product Approvals for Product 1 [*] are held in the name of SpePharm, Company shall not submit any Regulatory Materials to a Regulatory Authority in the Licensed Territory relating to the Product. SpePharm shall furnish to Company copies of material Regulatory Materials (other than routine correspondence) in advance of submission where practical that SpePharm submits to or receives from any Regulatory Authority in the Licensed Territory relating to the Product (and consider Company's comments in good faith), as well as contact reports concerning substantive conversations or substantive meetings with any such Regulatory Authority, in each case relating to any such material Regulatory Materials.

(b) Each Party shall provide the other Party with prior written notice, to the extent the Party has advance knowledge, of any meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the Licensed Territory relating to the Product, within two (2) business days after the Party or its Affiliate, licensee or Sublicensee first receives notice of the scheduling of such meeting, conference, or discussion (or within such shorter period as may be necessary in order to give the other Party a reasonable opportunity to attend such meeting, conference, or discussion). To the extent permitted by the Regulatory Authority, the other Party shall have the right to attend as an observer (but not participate in unless otherwise agreed in advance) all such meetings, conferences, and discussions.

5.5 Pharmacovigilance. The responsibilities of each Party in regards to pharmacovigilance activities, including the exchange of safety information, adverse event reporting, governmental reporting and related follow-up, to the extent they relate to the Product, shall be set forth in a separate Pharmacovigilance Agreement (**"PV Agreement**") between the Parties (or, as the case may be, Affiliates or experienced Third Parties acting on their behalf) for such Product, which shall be entered into within ninety (90) days after the Effective Date and attached hereto as Exhibit D. Company shall maintain and will be the recognized holder of a global safety database for adverse event reports related to the Product received by either Party or their Affiliates, licensees and Sublicensees, and SpePharm shall have access thereto, as shall be further specified in the PV Agreement.

5.6 Product Recalls.

(a) SpePharm has the sole discretion to make a decision for recalling, or issuing an advisory letter or other safety-related communication with respect to, Product in the Licensed Territory and handling such recalls. SpePharm shall bear all costs associated with such recalls, except to the extent that any recall is attributable to a breach of this Agreement by, or the gross negligence or willful misconduct of, Company or its Affiliates or to the manufacture of the Product by or on behalf of Company. SpePharm shall notify Company in a timely manner in connection with any such action. Each Party agrees to provide reasonable assistance to the other Party in the event of any recall or issuance of any advisory letter. In the event that Company has determined to initiate a recall of the Product outside the Licensed Territory, it shall so notify SpePharm and the Parties shall immediately discuss the cause of such action and whether to initiate a recall or take other action in the Licensed Territory.

(b) If and when SpePharm becomes aware of any information that reasonably suggests that a Product sold in the Licensed Territory may have caused or contributed to a death or serious injury or has malfunctioned and that the Product would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, SpePharm agrees to furnish such information to Company within the time periods specified in the PV Agreement.

(c) If and when Company becomes aware of any information that reasonably suggests that a Product sold in the Company Territory may have caused or contributed to a death or serious injury or has malfunctioned and that the Product would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, Company agrees to furnish such information to SpePharm within the time periods specified in the PV Agreement.

5.7 No Harmful Actions . If either Party reasonably believes that the other Party is taking or intends to take any action with respect to the Product that could reasonably be expected to have a material adverse impact upon the regulatory status of the Product in the Licensed Territory (in the case of SpePharm) or the Company Territory (in the case of Company), such Party shall have the right to bring the matter to the attention of such other Party and the Parties shall meet and discuss the impact of such action.

ARTICLE VI – PRODUCT MANUFACTURING AND SUPPLY

6.1 Product Manufacturing and Supply. The Parties shall negotiate in good faith and enter into a definitive supply agreement governing the clinical and commercial supply of Product by Company to SpePharm and SpePharm's purchase of Product from Company, consistent with the terms and conditions of the term sheet attached hereto as Exhibit F, within ninety (90) days of the Effective Date.

ARTICLE VII – COMMERCIALIZATION

7.1 Product Commercialization. Subject to the terms and conditions of this Article 7, SpePharm shall be the responsible Party for the Commercialization of the Product in the Field in the Licensed Territory. Without limiting the foregoing, SpePharm shall be responsible for: (a) developing and using its Commercially Reasonable Efforts in executing a commercial launch and pre-launch plan, (b) negotiating with applicable Regulatory Authorities regarding price and reimbursement, (c) using its Commercially Reasonable Efforts in marketing and promotion of the Product in the Licensed Territory, and (d) except where Company has such responsibility under the Supply Agreement, manufacture, storage, shipment, transportation, distribution and invoicing in the Licensed Territory.

7.2 Commercialization Plans. [*] prior to the anticipated commercial launch by SpePharm or its Affiliates or Sublicensees of the Product in the Licensed Territory, SpePharm shall provide to Company for review and comment, a commercialization plan outlining SpePharm's good faith plan for the Commercialization of Product in the Licensed Territory (the "**Commercialization Plan**"). The Commercialization Plan will, in reasonable detail, include information, sales forecasts and timelines regarding SpePharm's Commercialization activities.

7.3 Commercialization Diligence.

(a) General. SpePharm shall use Commercially Reasonable Efforts to Commercialize [*] in the Initial Territory in those countries in which it receives Product Approval and in which it is Commercially Reasonable to Commercialize the Product. Without limiting any of the foregoing, SpePharm shall use its Commercially Reasonable Efforts to: (i) develop marketing and market access dossiers (including pricing and reimbursement where applicable) as may be required in SpePharm's sole determination; (ii) diligently promote the sale of [*] in the countries of the Licensed Territory in which it receives Product Approvals in accordance with Applicable Laws; and (iii) be responsible for all medical education programs with professional clinical liaisons within the Licensed Territory.

(b) Major EU Market Countries. [*]:

(i) if, during such ninety (90) day period, SpePharm (or its Affiliates or Sublicensees) has commercially launched [*] in [*] of the Major EU Market Countries, such termination shall be deemed withdrawn and of no further force or effect; or

(ii) to the extent that SpePharm (or its Affiliates or Sublicensees) has not commercially launched [*] in at least [*] of the Major EU Market Countries in accordance with the terms of this Section 7.3(b) above due to (A) the occurrence of adverse events that raise serious safety issues with respect to the Product; (B) any regulatory hold, constraint or material restriction imposed or raised by a Regulatory Authority with respect to the Product; (C) manufacture or supply delays or failures with respect to the Product; (D) any Force Majeure Event; or (E) a Third Party alleges in writing that the manufacture, use or sale of the Product infringes its intellectual property or there is a pending infringement action, or decision of a court or a settlement relating to an infringement action that prevents SpePharm from commercially launching the Product, then in each of (A) through (E) to the extent that (1) such event occurs within the applicable Major EU Market Country, (2) such event would have a materially, adverse impact on a Commercially Reasonable launch of such Product therein, and (3) SpePharm is using Commercially Reasonable Efforts to remove the existence of such event, then the foregoing termination right shall be tolled during the pendency of such event and the material adverse impact thereof.

The foregoing termination right shall cease to apply after [*] has been commercially launched in [*] of the Major EU Market Countries. After [*] has been commercially launched in a Major EU Market Country, SpePharm shall use Commercially Reasonable Efforts to Commercialize [*] in each such Major EU Market Country.

(c) Expanded Territory. SpePharm shall use Commercially Reasonable Efforts to Commercialize [*] in those countries of the Expanded Territory in which it receives Product Approval and in which it is Commercially Reasonable to Commercialize the Product.

(d) JMC Review. At Company's request, SpePharm shall discuss at the JMC meeting following such request the basis on which SpePharm has determined it is not Commercially Reasonable to Commercialize the Product in a country in which it has received Product Approval.

7.4 Price. SpePharm may sell the Product in the Licensed Territory at prices determined by it in its sole discretion.

7.5 Company Support. Upon SpePharm's request, Company will use Commercially Reasonable Efforts to support SpePharm in its pre-launch and launch activities, as set forth in the Commercialization Plan, and at SpePharm's cost and expense, to the extent provided in the Commercialization Plan. Upon SpePharm's request and at SpePharm's cost and expense, Company may provide direct support to SpePharm's customers and in such case SpePharm shall provide Company with SpePharm's customers' names and information that Company may reasonably request in order for Company to provide such support to such customers.

7.6 Commercialization Reports. SpePharm shall update the JMC periodically at each regularly scheduled JMC meeting regarding SpePharm's Commercialization activities with respect to the Product in the Licensed Territory, which update shall summarize SpePharm's significant Commercialization activities with respect to each Product on a country-by-country basis in the Licensed Territory pursuant to this Agreement, covering subject matter at a level of detail sufficient to enable Company to determine SpePharm's compliance with its diligence obligations pursuant to Section 7.3 above.

ARTICLE VIII – CERTAIN OBLIGATIONS OF THE PARTIES

8.1 Compliance with Laws. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in compliance in all material respects with all Applicable Laws.

8.2 Insurance.

(a) Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this Agreement (including coverages, deductible limits and self-insured retentions) as are customary in the pharmaceutical industry for the activities to be conducted by such Party under this Agreement.

(b) The insurance required herein shall be maintained during the term of this Agreement and, if on a "claims made" basis, for a period of at least five (5) years thereafter. Each Party shall be solely responsible for the payment of any deductible under any such policies maintained by it.

ARTICLE IX – PROMOTIONAL MATERIALS; TRAINING

9.1 Promotional Materials. During the Term, SpePharm shall at its expense be responsible for the creation of all marketing and technical information concerning the Product in the Licensed Territory that are necessary or helpful for the promotion of Product in the Licensed Territory, including but not limited to brochures, instructional material, advertising literature and other Product data (the "**Marketing Materials**"). All Marketing Materials created by SpePharm shall remain the property of SpePharm. Any liability or consumer claim arising from any inaccurate Marketing Materials or translation provided by SpePharm or the creation of such Marketing Materials shall be the sole responsibility of SpePharm, except that Company shall be solely responsible for any such liability or consumer claim to the extent attributable to any Information (including Regulatory Data) or Regulatory Materials licensed or otherwise provided by Company to SpePharm for use in Marketing Materials. To assist SpePharm with the creation of Marketing Materials, Company shall provide SpePharm with sample branding and marketing information and/or brochures (in English) utilized by Company in the Company Territory. All such information and materials provided by Company shall remain the property of Company, and SpePharm shall return the same to Company upon termination of this Agreement, to the extent they are then in SpePharm's possession or control.

9.2 Training.

(a) Company shall provide to SpePharm a reasonable level of Product-specific training on a planned and periodic basis for SpePharm personnel (*e.g.*, sales force, medical liaisons or marketing personnel) at a mutually agreed upon facility, as mutually agreed by the Parties at the JMC.

(b) Subject to Company providing training pursuant to Section 9.2(a), SpePharm shall ensure that all of its employees and agents who are engaged in the promotion and sales of the Product under this Agreement are adequately trained with respect to the Product.

ARTICLE X – FINANCIAL PROVISIONS

10.1 Upfront License Payment. In partial consideration of the licenses and rights granted to SpePharm hereunder, SpePharm shall pay to Company a non-refundable, non-creditable payment of two million U.S. dollars (U.S. $2,000,000) within ten (10) days after the Effective Date.

10.2 [*] Milestone Payments. SpePharm shall pay to Company the following non-refundable, non-creditable (except as set forth in Section 10.9), one-time milestone payments upon first achievement of such milestone for [*]:

Milestone	Milestone Payment
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

SpePharm shall notify Company in writing within thirty (30) days following the achievement of each milestone event above, and shall make the applicable milestone payment within forty-five (45) days after the achievement of such milestone event.

10.3 Sales Milestone Payments. SpePharm shall pay to Company the following non-refundable, non-creditable (except as set forth in Section 10.9), one-time milestone payments upon first achievement of such milestone for [*]:

Milestone	Milestone Payment
[*]	[*]
[*]	[*]

10.4 Royalties.

(a) SpePharm shall pay to Company royalties on aggregate Net Sales of the Product in the Licensed Territory for each Calendar Year as set forth below:

Calendar Year Net Sales in the Licensed Territory	Royalty Rate
Portion of aggregate Net Sales in the Licensed Territory less than or equal [*] in any Calendar Year	[*]
Portion of aggregate Net Sales in the Licensed Territory greater [*] in any Calendar Year	[*]

(b) The royalties payable under Section 10.4 shall apply, on a country-by-country basis, on Net Sales of the Product in each country in the Licensed Territory commencing on the date of the First Commercial Sale of the Product in such country and continuing until the later of [*] (such period, the "**Royalty Term**").

(c) If, on a country-by-country and calendar quarter-by-calendar quarter basis, a Generic Product is sold in such country during such calendar quarter, then following the date of first commercial launch of such Generic Product in such country, the royalties payable with respect to Net Sales of the Product pursuant to Section 8.4(a) in such country thereafter shall be reduced by [*] of the royalties otherwise payable pursuant to Section 8.4(a).

(d) If SpePharm or any of its Affiliates or Sublicensees enters into an agreement with a Third Party to obtain a license under a patent right or other right that is deemed by its counsel to be necessary to use, sell or otherwise Commercialize the Product in the Licensed Territory or otherwise to practice the rights under the Company Patents or Company Know-How granted to SpePharm in Section 2.1, or if SpePharm or any of its Affiliates or Sublicensees shall be subject to a final court or other binding order or ruling or settlement agreement requiring any payments in respect of the use, sale or other Commercialization of any Product in a country in the Licensed Territory, SpePharm may deduct from royalties due to Company [*] of any payments actually paid to such Third Party for such license, or pursuant to such final court or other binding order or ruling or settlement agreement, with respect to such Product in such country; provided that the royalties payable to Company for any particular calendar quarter for such Product in such country shall not be reduced by more than [*] by reason of this Section 10.4(d), provided further that any such payments to Third Parties not applied to reduce royalties as a result of the forgoing proviso may be carried over to subsequent calendar quarters and applied to reduce royalties (subject to the aforementioned [*] limitation) in such subsequent calendar quarters.

(e) Within forty-five (45) days after the end of each calendar quarter, SpePharm shall provide a royalty report showing, on a country-by-country basis:

(i) the number of units of the Product sold by SpePharm and its Affiliates and Sublicensees during such calendar quarter reporting period;

(ii) The gross sales associated with each Product sold by SpePharm and its Affiliates and Sublicensees during such calendar quarter;

(iii) the Net Sales of the Product sold by SpePharm and its Affiliates and Sublicensees during such calendar quarter reporting period (together with reasonable supporting information underlying the calculation of Net Sales in such period);

(iv) the royalties payable in Euros which shall have accrued hereunder with respect to such Net Sales; and

(v) details of any corrections or true-ups from previously reported Net Sales amounts;

(vi) withholding taxes, if any, required by Applicable Laws to be deducted with respect to such royalties; and

(vii) the rate of exchange used by SpePharm under Section 10.5.

Concurrent with these reports, SpePharm shall remit to Company all payment due for the applicable calendar quarter. If no royalty or payment is due for any royalty period hereunder, SpePharm shall so report.

10.5 Manner of Payment and Exchange Rate. All milestone payments to be made by SpePharm to Company under this Agreement shall be made in United States Dollars, and all royalty payments to be made by SpePharm to Company under this Agreement shall be made in Euros, and shall be paid by electronic transfer in immediately available funds to a bank account in the United States designated in writing by Company. If any Net Sales are made in a currency other than Euros and currency conversion is required, the rate of exchange shall be calculated using the arithmetic daily average of the relevant published currency exchange rate from the European Central Bank from the source http://fxtop.com, across the calendar quarter for which the relevant royalty payment is due pursuant to Section 10.4.

10.6 Late Payments. Any amount due not received by the due date may, at the billing Party's sole discretion, be subject to a charge equal to the lesser of (i) an annual rate of [*] above EURIBOR (one month) per annum, and (ii) the maximum rate permitted by Applicable Law governing this Agreement. Interest shall be calculated daily on the basis of a year of 365 days and the actual number of days for which interest is due.

10.7 Records and Audits. SpePharm shall maintain complete and accurate books and records with respect to the sale and distribution of the Product in accordance with Accounting Standards. Company shall have the right, during reasonable business hours and with reasonable prior notice, but not more than once per calendar year, to inspect such books and records for purposes of verifying SpePharm's payments under this Agreement. SpePharm shall maintain all records and reports required under this Agreement relating to the Product for a period of five (5) years or longer as required by Applicable Law. Company shall make inspections permitted hereunder at its sole cost and expense; *provided*, *however*, that in the event such audit reveals an underpayment of the annual royalties by more than [*] SpePharm shall bear the reasonable out-of-pocket costs and expenses of the audit. If, as a result of any audit performed pursuant to this Section 10.7, it is determined that SpePharm under-reported any information necessary to calculate royalties for Product, and as a result Company received less than it should have under this Agreement, SpePharm shall, no later than thirty (30) days after receiving notice of such underpayment, remit to Company the amount of the underpayment. If as a result of the audit performed pursuant to this Section 10.7, it is determined that SpePharm over-reported any information used to calculate the royalties for the Product and as a result Company has received more than it should have under this Agreement, SpePharm shall be entitled to a credit against the royalties due to Company in the next applicable period in the amount of such excess.

10.8 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

(b) Tax Cooperation. To the extent SpePharm is required to deduct and withhold taxes on any payment to Company, SpePharm shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to Company an official tax certificate or other evidence of such withholding sufficient to enable Company to claim such payment of taxes. Company shall provide SpePharm any tax forms that may be reasonably necessary in order for SpePharm to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Company shall use reasonable efforts to provide any such tax forms to SpePharm at least thirty (30) days prior to the due date for any payment for which Company desires that SpePharm apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

(c) Taxes Resulting From SpePharm Action. If SpePharm is required by any taxing authority outside of the United States to make a payment to Company subject to a deduction of tax or withholding tax, then (i) if such withholding or deduction obligation arises as a result of any action by SpePharm, including any assignment or sublicense, or any failure on the part of SpePharm to comply with applicable laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (an **"SpePharm Withholding Tax Action"**), then the sum payable by SpePharm (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Company receives a sum equal to the sum which it would have received had no such SpePharm Withholding Tax Action occurred, and (ii) otherwise, the sum payable by SpePharm (in respect of which such deduction or withholding is required to be made) shall be made to Company after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable law; provided, however, that SpePharm shall have no obligation to pay any additional amount to the extent that the deduction of tax or withholding tax would not have been imposed but for (A) the failure by Company to qualify for an exemption from or reduction in the rate of withholding tax under any applicable income tax convention between the United States and Switzerland, (B) the assignment by Company of its rights under this Agreement or any redomiciliation of Company outside of the United States, or (C) the assertion by a taxing authority in a jurisdiction other than the United States or Switzerland that a payment by SpePharm to Company hereunder is derived from sources within such other jurisdiction and therefore is subject to withholding tax in such other jurisdiction.

10.9 Right to Set-off. SpePharm shall have the right at all times to retain and set-off against all amounts due and owing to Company any damages recovered by SpePharm for any Losses incurred by SpePharm as determined in a final judgment.

ARTICLE XI – INTELLECTUAL PROPERTY

11.1 Intellectual Property Ownership.

(a) The Parties acknowledge and agree that, as between the Parties, except for the licenses and rights granted to SpePharm hereunder, all right, title and interest in and to the Company Patents and Company Know-How shall reside solely in Company. Subject to Sections 11.1(c) and 11.1(e), any inventions made, developed, conceived, or reduced to practice by or on behalf of SpePharm or its Affiliates, solely or jointly, in the performance of this Agreement (collectively " **Inventions**"), to the extent solely related to the composition of matter, use, manufacture or development of the Product, and any data and other Information generated by or on behalf of SpePharm or its Affiliates, solely or jointly, in the performance of this Agreement that solely relate to the Product, and any intellectual property rights in any of the foregoing (including Information and Patent Rights), shall be owned by Company (collectively, "**Product IP**"). SpePharm hereby assigns and transfers to Company all right, title and interest it may have in and to such Product IP and agrees to take all further acts reasonably required to evidence such assignment and transfer to Company, at Company's cost and expense.

(b) Subject to Sections 11.1(c) and 11.1(e), any Inventions that are not Product IP, and any data and other Information generated by or on behalf of SpePharm or its Affiliates, solely or jointly, in the performance of this Agreement that do not solely relate to the Product, and any intellectual property rights in any of the foregoing (including Information and Patent Rights) shall be owned by SpePharm (collectively "**General IP**"). Company hereby assigns and transfers to SpePharm all right, title and interest it may have in and to such General IP and agrees to take all further acts reasonably required to evidence such assignment and transfer to SpePharm, at SpePharm's cost and expense.

(c) Notwithstanding Sections 11.1(a) and (b), but subject to Section 11.1(e), any inventions made, developed, conceived, or reduced to practice jointly by SpePharm (including its Affiliates) and Company (including its Affiliates) in the performance of this Agreement, and any data and other Information jointly generated by SpePharm (including its Affiliates) and Company (including its Affiliates) in the performance of this Agreement, and any intellectual property rights in any of the foregoing (including Information and Patent Rights), shall be owned jointly by SpePharm and the Company (collectively, "**Joint IP**"). Each Party will have an undivided one-half interest in and to such Joint IP. Each Party will exercise its ownership rights in and to such Joint IP, including the right to license and sublicense or otherwise to exploit, transfer or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the licenses hereunder and the other terms and conditions of this Agreement. Each Party hereby assigns to the other Party a joint and undivided interest in and to all Joint IP.

(d) Each Party shall promptly disclose to the other Party any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing Inventions and all Information relating to such Inventions to the extent necessary for the preparation, filing and maintenance of any Patent with respect to such invention.

(e) Notwithstanding Sections 11.1(a), 11.1(b) and 11.1(c), and subject to Sections 2.9 and 2.10, (i) each Party will solely own all data generated from clinical studies conducted pursuant to this Agreement that are funded solely by such Party or its Affiliates, and (ii) Company will solely own all data generated from clinical studies conducted pursuant to this Agreement that are funded jointly by the Parties or their respective Affiliates ("**Jointly Funded Data**"). SpePharm hereby assigns and transfers to Company all right, title and interest it may have in and to such Jointly Funded Data and agrees to take all further acts reasonably required to evidence such assignment and transfer to Company, at Company's cost and expense.

(f) Subject to the terms and conditions of this Agreement (including Sections 2.9 and 2.10), SpePharm hereby grants to Company an exclusive (even as to SpePharm and its Affiliates) right and license, with the right to grant sublicenses in accordance with Section 2.2 (*mutatis mutandis*), under the General IP and Joint IP to the extent necessary or useful to develop, market, promote, import, use, sell, offer for sale, distribute, manufacture, have manufactured and otherwise commercialize the Product in the Field in the Company Territory. Notwithstanding the foregoing, SpePharm retains all rights and interests in and to the General IP and joint ownership rights in the Joint IP other than expressly granted under this Section 11.1(f), including the right to use and practice the General IP and Joint IP in connection with the exercise of the rights granted to it under Section 2.1.

11.2 Patent Prosecution and Maintenance.

(a) Company shall have the first right, but not the obligation, to be responsible for the preparation, filing, prosecution, maintenance and extension of the Company Patents and the Patent Rights within the Product IP in the Licensed Territory, at its expense. Company shall keep SpePharm advised on the status of preparation, filing and prosecution of all patent applications included within the Company Patents in the Licensed Territory and the maintenance and extension of any issued patents within the Company Patents in the Licensed Territory, and shall allow SpePharm a reasonable opportunity and reasonable time to review and comment regarding relevant material communications and drafts of any material responses or proposed filings by Company before any applicable filings are submitted to any relevant patent office or government authority, and incorporate any reasonable comments offered by SpePharm in any final filings submitted by Company to any relevant patent office or government authority in the Licensed Territory.

(b) If Company decides not to file, prosecute, maintain or extend a Company Patent or Patent Rights within the Product IP, in each case, in the Licensed Territory, it shall give SpePharm reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Patent Right to permit SpePharm to carry out such activity. After such notice, SpePharm may file, prosecute, maintain and extend such Patent Right, and perform such acts as may be reasonably necessary for it to file, prosecute, maintain or extend such Patent Right, at its sole cost and expense, provided that SpePharm may deduct one hundred percent (100%) of its costs and expenses incurred in such filing, prosecution, maintenance and extension of such Patent Rights from the royalties or any other amounts payable by SpePharm to Company under this Agreement, provided that the royalties payable to Company shall not be reduced by more than fifty percent (50%) by reason of this Section 11.2(b), and any such payments to Third Parties not applied to reduce royalties as a result of the forgoing proviso may be carried over to subsequent calendar quarters and applied to reduce royalties (subject to the aforementioned fifty percent (50%) limitation) in such subsequent calendar quarters. If SpePharm does so elect, then Company shall provide such cooperation to the SpePharm, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such patent activities.

(c) The filing, prosecution, maintenance and extension of any Patent Rights within Joint IP will be jointly managed by the Parties on mutually agreeable terms (including as to costs and expenses) to be entered into by the Parties at the time any such Patent Rights are first filed. The filing, prosecution, maintenance and extension of any Patent Rights within General IP will be managed by SpePharm, at its cost and expense.

(d) The Parties shall cooperate, if necessary and appropriate, with each other in gaining patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future wherever applicable to Patent Rights that are applicable to the Product in the Licensed Territory. The Parties shall, if necessary and appropriate, use reasonable efforts to agree upon a joint strategy relating to patent term extensions, but, in the absence of mutual agreement with respect to any extension issue, a Patent Right shall be extended in the Licensed Territory only as and if SpePharm elects in writing to extend such Patent Right.

11.3 Trademark License; Trademark Prosecution, Maintenance and Enforcement.

(a) Product Marks. Subject to Applicable Law and the requirements of applicable Regulatory Authorities, the Product shall be marketed and sold in the Licensed Territory using the Company Marks, Product Marks and other trade dress and logos as mutually agreed by the Parties (in accordance with Section 11.3). In the event that SpePharm provides Company with written notice indicating good commercial reason for the removal of a Company Mark or Product Mark from the Product, or association therewith, the Parties shall discuss in good faith such removal, and mutually agree upon an alternative mark as set forth in Section 11.3(c). Such use shall be conducted in accordance with the license rights granted hereunder and Company's trademark usage policies provided from time to time in writing to SpePharm as available, provided that SpePharm shall not be required to implement any changes arising from modified trademark usage policies provided by Company if SpePharm would incur any additional costs as a result thereof without SpePharm's consent (not to be unreasonably withheld), other than such changes required by a Regulatory Authority in the Licensed Territory, or with respect to any written Third Party claim that a Company Mark and/or Product Mark infringes the intellectual property rights of such Third Party in the Licensed Territory. SpePharm is not authorized to use the Company Marks in any manner except as expressly authorized herein. SpePharm shall acquire no right (except as expressly set forth below), title, or interest in or to the Company Marks or Product Marks, or any other trademarks, trade names, or service mark owned by Company. SpePharm understands and agrees that it is not authorized to use the name "Navidea" in connection with its general business or to imply to Third Parties that its relationship with Company is other than a licensee under this Agreement.

(b) License and Usage. Subject to the terms and conditions of this Agreement, Company hereby grants to SpePharm and its Affiliates (i) the limited, non-exclusive, royalty-free (except as provided in Section 15.1) right and license to use Company's trademarks, trade names and logos that are listed in Part I of Exhibit C (including any replacements or successors thereof, the **"Company Marks"**), and (ii) the limited, exclusive, royalty-free (except as provided in Section 15.1) right and license, to use any of the Product Marks that are listed in Part II of Exhibit C, including additional trademark applications and registrations for any of the Product Marks, anywhere in the Licensed Territory, in each case solely in connection with its manufacture, use, sale, offer for sale, keeping (whether for sale or otherwise), importation and Commercialization of the Product hereunder, including in each case with respect to the Company Marks, to indicate that it is a licensee of Company for the Product in the Licensed Territory, and only during the Term of this Agreement and only in the Licensed Territory. The foregoing license shall be sublicensable by SpePharm to its Affiliates and Sublicensees pursuant to, and in accordance with, Section 2.2, solely in accordance with the Products, provided that the rights granted to SpePharm pursuant to Section 11.3(c) shall not apply to Sublicensees. SpePharm recognizes Company's exclusive ownership or control of the Company Marks and Product Marks and agrees to comply with any reasonable usage requirements and/or quality control guidelines with respect to the Company Marks and Product Marks as Company may reasonably prescribe in writing from time to time. All goodwill resulting from the use of the Company Marks and Product Marks by SpePharm shall belong to and inure solely to the benefit of Company. SpePharm shall not knowingly undertake any act that would impair the Company Marks or Product Marks or the goodwill associated therewith. SpePharm shall promptly notify Company in writing of any actual or suspected infringement of the Company Marks or Product Marks by a Third Party of which SpePharm becomes aware. SpePharm shall not make or permit alteration or removal of any tags, labels, or other identifying marks placed, in accordance with Applicable Law, by Company on the Product.

(c) SpePharm House Marks; Alternative Product Marks. At SpePharm's option, the Product packaging, Marketing Materials and Product labeling for use in the Licensed Territory may, in addition to the Company Marks and Product Marks, carry house marks of SpePharm or its Affiliates as may be chosen by SpePharm in its sole discretion. In the event that the Product Marks are not available or suitable (due to, for example, translation or other reasons) for registration in any particular jurisdiction within the Licensed Territory, SpePharm shall have the right, in consultation with and subject to Company's written approval (not to be unreasonably withheld), to select an alternative trademark for use with the Product in such jurisdiction in addition to the Company Marks. Such alternative trademark shall be deemed a Product Mark and subject to the terms of this Section 11.3.

(d) Prosecution and Maintenance.

(i) Company shall have the first right, but not the obligation, to be responsible for the clearance, preparation, filing, prosecution and maintenance of the Product Marks in the Licensed Territory, at its expense. Company shall keep SpePharm advised on the status of preparation, filing and prosecution of all applications for Product Marks in the Licensed Territory and the maintenance of any registered Product Marks in the Licensed Territory, and shall allow SpePharm a reasonable opportunity and reasonable time to review and comment regarding relevant material communications and drafts of any material responses or proposed filings by Company before any applicable filings are submitted to any relevant trademark office or government authority, and incorporate any reasonable comments offered by SpePharm in any final filings submitted by Company to any relevant trademark office or government authority in the Licensed Territory.

(ii) If Company decides not to clear, prepare, file, prosecute or maintain a Product Mark in the Licensed Territory, it shall give SpePharm reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Product Mark to permit SpePharm to carry out such activity. After such notice, SpePharm may clear, prepare, file, prosecute and maintain such Product Mark, and perform such acts as may be reasonably necessary for it to clear, prepare, file, prosecute and maintain such Product Mark, at its sole cost and expense, provided that SpePharm may deduct one hundred percent (100%) of its costs and expenses incurred in such filing, prosecution and maintenance of such Product Mark from the royalties or any other amounts payable by SpePharm to Company under this Agreement, provided that the royalties payable to Company shall not be reduced by more than fifty percent (50%) by reason of this Section 11.3(c), and any such payments to Third Parties not applied to reduce royalties as a result of the forgoing proviso may be carried over to subsequent calendar quarters and applied to reduce royalties (subject to the aforementioned fifty percent (50%) limitation) in such subsequent calendar quarters. If SpePharm does so elect, then Company shall provide such cooperation to SpePharm, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such trademark activities.

(e) Enforcement.

(i) Each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected infringement of the Product Marks by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of the Product Marks, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto.

(ii) As between the Parties, SpePharm will have the first right, but not the obligation, to seek to abate any infringement of the Product Marks in the Licensed Territory, including to file suit against any such Third Party for such infringement. If SpePharm does not take steps to abate such infringement, or file suit to enforce the Product Marks against such Third Party, within ninety (90) days after the first notice under Section 11.3(d)(i), Company will have the right (but not the obligation) to take action to enforce the Product Marks against such Third Party for such infringement. The controlling Party will pay all its costs and expenses incurred for such enforcement.

(iii) With respect to any infringement or defensive action identified above in this Section 11.3(d):

(A) If a controlling Party ceases to pursue or withdraws from such action, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may continue or may substitute itself for the withdrawing Party and proceed under the terms and conditions of this Section 11.3(d).

(B) The Parties will reasonably cooperate with each other, whether or not controlling any such action, including (1) providing access to relevant documents and other evidence, (2) making its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (3) if necessary, by being joined as a party, subject for this clause (3) if and when the joined Party is not controlling such action, the controlling Party agreeing to indemnify such non-controlling Party for its involvement as a named party in such action and paying those reasonable costs and expenses incurred by such Party in connection with such joinder. If only one Party is controlling any such action, the Party controlling any such action will keep the non-controlling Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

(C) If only one Party is controlling any such action, the non-controlling Party will have the right to participate or otherwise be involved in any such action, in each case at the participating Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will take into account reasonable requests of the participating Party regarding such enforcement or defense.

(iv) Neither Party will settle or consent to an adverse judgment in any action described in this Section 11.3(d), including any judgment which affects the scope, validity or enforcement of any Product Marks involved therewith, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

(v) Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in this Section 11.3(d) will be used first to reimburse each of the Parties, on a *pro rata* basis for each of their reasonable out-of-pocket costs and expenses relating to the action, with the balance of any such recovery being considered Net Sales.

11.4 Patent Enforcement and Defense.

(a) Each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected Competitive Infringement (defined below) of any Patent Right within the Company Patents, Product IP, General IP or Joint IP by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of any Patent Rights within the Company Patents, Product IP, General IP or Joint IP, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto. For purposes of this Agreement, "**Competitive Infringement**" means any allegedly infringing activity in the Field in the Licensed Territory with respect to a Patent Right within the Company IP, Product IP, General IP or Joint IP.

(b) As between the Parties, SpePharm will have the first right, but not the obligation, to seek to abate any Competitive Infringement of any Patent Rights within the Company Patents, Product IP, General IP or Joint IP in the Licensed Territory, or to file suit against any such Third Party for such Competitive Infringement. If SpePharm does not take steps to abate such Competitive Infringement, or file suit to enforce such Patent Rights against such Third Party with respect to such Competitive Infringement, within ninety (90) days after the first notice under Section 11.4(a), Company will have the right (but not the obligation) to take action to enforce such Patent Rights against such Third Party for such Competitive Infringement. The controlling Party will pay all its costs and expenses incurred for such enforcement.

(c) As between the Parties, Company will have the first right, but not the obligation, to defend against a declaratory judgment action or other action challenging any Patent Rights within the Company Patents and Product IP and any Patent Rights within the Joint IP in the Company Territory, and SpePharm will have the first right, but not the obligation, to defend against a declaratory judgment action or other action challenging any Patent Rights within the General IP and any Patent Rights within the Joint IP in the Licensed Territory, other than with respect to any action by a Third Party in response to an enforcement action brought pursuant to Section 11.4(b), which defense will be controlled by the Party or Parties controlling such enforcement action. If such Party does not take steps to defend within a commercially reasonably time, or elects not to continue any such defense (in which case it will promptly provide notice thereof to the other Party), then the other Party will have the right (but not the obligation) to defend any such Patent Right.

(d) With respect to any infringement or defensive action identified above in this Section 11.4:

(i) If a controlling Party ceases to pursue or withdraws from such action, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may continue or may substitute itself for the withdrawing Party and proceed under the terms and conditions of this Section 11.4.

(ii) The Parties will reasonably cooperate with each other, whether or not controlling any such action, including (1) providing access to relevant documents and other evidence, (2) making its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (3) if necessary, by being joined as a party, subject for this clause (3) if and when the joined Party is not controlling such action, the controlling Party agreeing to indemnify such non-controlling Party for its involvement as a named party in such action and paying those costs and expenses incurred by such Party in connection with such joinder. If only one Party is controlling any such action, the Party controlling any such action will keep the non-controlling Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

(iii) If only one Party is controlling any such action, the non-controlling Party will have the right to participate or otherwise be involved in any such action, in each case at the participating Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will take into account reasonable requests of the participating Party regarding such enforcement or defense.

(e) Neither Party will settle or consent to an adverse judgment in any action described in this Section 11.4 without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed), provided that with respect to any settlement that limits the scope, validity or enforcement of any Company Patents, Product IP or Joint IP involved therewith, Company's consent may be given or withheld in its sole discretion, and with respect to any settlement that limits the scope, validity or enforcement of any General IP or Joint IP involved therewith, SpePharm's consent may be given or withheld in its sole discretion.

(f) Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in this Section 11.4 will be used first to reimburse each of the Parties, on a *pro rata* basis for each of their reasonable out-of-pocket costs and expenses relating to the action, with the balance of any such recovery being considered Net Sales.

11.5 Third Party Licenses. Company shall have the right to obtain, subject to SpePharm's prior written approval (such approval not to be unreasonably withheld or delayed) rights or licenses to any Third Party intellectual property to the extent Company determines that it is Commercially Reasonable and necessary to enable the sale of the Product in the Field in the Licensed Territory. In the event of such approval, Company and SpePharm shall share all costs payable to such Third Party with respect to such license on a 50/50 basis. In the event SpePharm does approve such Third Party license, then Company shall be free to obtain such license in its sole discretion and such intellectual property rights shall not be deemed "Controlled" within the definition of the Company Know-How and Company Patents.

ARTICLE XII – REPRESENTATIONS AND WARRANTIES

12.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as of the Effective Date that:

(a) such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof; and

(d) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party.

12.2 Additional Company Representations and Warranties . Company hereby represents and warrants to SpePharm as of the Effective Date that:

(a) A true and complete copy of each of the Upstream Agreements, as each exists as of the Effective Date (including any amendments), has been provided to SpePharm prior to the Effective Date, and there are no oral or side agreements with respect thereto. Each of the Upstream Agreements is in full force and effect, all payments to date required to be made thereunder by Company have been made, and Company is in compliance in all material respects with its material obligations thereunder. Company has not received or provided any notice of termination of either of the Upstream Agreements, or any notices of material breach of either of the Upstream Agreements. Company has the right to sublicense its rights under the Upstream Agreements to SpePharm within the scope of the license granted in Section 2.1, and Company is not aware of any provision under either of the Upstream Agreement which is or could reasonably be expected to be inconsistent with the provisions of this Agreement in any material respect.

(b) The execution, delivery and performance of this Agreement by Company does not conflict with the RA Field License Agreement, the [*], any other agreement between Company or its Affiliates, R-NAV and/or TcRA, or any provision thereof. The RA Field License Agreement is the only agreement pursuant to which Company or any of its Affiliates has granted to the RA Field Licensee or any other Person any rights with respect to the RA Field. [*].

(c) Exhibit A sets forth a complete and correct list of all Company Patents owned by or licensed to Company and its Affiliates, and Company, together with its Affiliates, is the sole and exclusive owner or licensee of, and has the sole right, title and interest in and to, the Company Patents listed on Exhibit A as owned by the Company, and the Company Know-How, in each case free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien, lease, sublease, option, or charge of any kind, limitations on transfer or any subordination arrangement in favor of a Third Party that would preclude the grant of the licenses and rights hereunder.

(d) All of the Company Patents listed on Exhibit A, and the Product Marks in the Initial Territory, are in force or pending and have not been abandoned as of the Effective Date, and to Company's knowledge, all such Company Patents and Product Marks have been duly applied for and registered in accordance with Applicable Laws. Company is not aware of any facts or circumstances that could reasonably be expected to impair the validity or enforceability of any of the Company Patents or the Product Marks.

(e) Neither Company nor any of its Affiliates has granted any license, option or other rights of any kind to or in favor of a Third Party under the Company Patents or Company Know-How or Product Marks in the Licensed Territory that are inconsistent with this Agreement.

(f) Except for the Upstream Agreement, neither Company nor any of its Affiliates is party to any agreement pursuant to which Company or any of its Affiliates has been licensed or granted any rights in or to any Company Patents or Company Know-How or Product Marks for the Field and Licensed Territory.

(g) There is no intellectual property right, in particular no Patent Rights, owned by or licensed to Company or its Affiliates other than the Company Patents and Company Know-How, that are necessary for SpePharm or its Affiliates to develop and commercialize the Products as set forth herein.

(h) Company and its Affiliates have not received any written or oral claim, and to Company's knowledge no licensor of any Company Patents or Company Know-How has received any written or oral claim, of ownership, inventorship or patent infringement or trademark infringement, or any other claim of intellectual property misappropriation or violation, from any Third Party (including by current or former officers, directors, employees, consultants, or personnel of Company or any predecessor) with respect to the Company Patents or Company Know-How or Product Marks or the Product, and Company is not aware of any reasonable basis for any such claim.

(i) Neither Company nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that shall result in any person or entity obtaining any interest in, or that would give to any entity or person any right to assert any claim in or with respect to, any of SpePharm's rights granted under this Agreement.

(j) There are no claims, judgments or settlements pending against Company or its Affiliates, or to the knowledge of Company against any licensor of any Company Patents or Company Know-How, with respect to any Company Patents or Company Know-How or Product Marks or Product, and Company has not received notice that any such claims, judgments or settlements are threatened.

(k) Except as set forth on Schedule 12.2, no Company Patents are subject to, or were developed pursuant to any funding agreement with any government authority.

(l) To its knowledge, the research, development, manufacture, use, sale, offer for sale and import of the Products (in the form such Products exist as of the Effective Date) in the Field in the Licensed Territory does not infringe, misappropriate or violate any intellectual property rights of a Third Party, and Company and its Affiliates have not received any written or oral claim alleging such infringement, misappropriation or violation.

(m) To its knowledge, no Patent Rights or other intellectual property rights owned by a Third Party exist that are reasonably expected to serve as a basis for interferences, oppositions, invalidations or similar proceedings with respect to the Company Patents.

(n) Company has furnished or made available to SpePharm all material information that is in Company's possession and of which it is aware concerning the Products and relevant to the safety or efficacy of the Products, and all Regulatory Materials and other correspondence with Regulatory Authorities relating to the Products, and such information is accurate, complete and true in all material respects and has been prepared and filed in accordance with all Applicable Laws.

12.3 Warranty Disclaimer. THE FOREGOING WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF NONINFRINGEMENT, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE PRODUCTS UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

ARTICLE XIII – INDEMNIFICATION

13.1 Indemnification by SpePharm. SpePharm shall indemnify Company, its Affiliates, and their respective officers, directors, and employees and agents (the "**Company Indemnitees**"), for any reasonable out-of-pocket costs and expenses (including court and arbitration costs and reasonable attorneys' fees), non-appealed or non-appealable judicial or arbitration damage awards, and settlement payments (collectively, "**Losses**") payable or owed by such parties in connection with any demands, investigations, lawsuits and other legal actions of Third Parties ("**Third Party Claims**") to the extent arising from: (a) the development of the Product undertaken by SpePharm pursuant to the SpePharm Development Plan and those development plans for the Extended Territory contemplated by Section 2.11; (b) the Commercialization of the Product in the Licensed Territory, including, to the extent caused by SpePharm's or its Affiliates' or Sublicensees' off-label promotion of the Product or storage, handling or transportation of Product in a manner that is not compliant with applicable specifications therefrom, Third Party Claims based upon product liability; (c) any breach of any of SpePharm's obligations under this Agreement, including any representation, warranty, covenant or agreement on the part of SpePharm under this Agreement; or (d) the negligence or intentional misconduct of SpePharm, its Affiliates, or the officers, directors, employees, or agents of SpePharm or its Affiliates; except in each case, to the extent caused by the gross negligence or willful misconduct of Company or any of its Affiliates, or their respective officers, directors, and employees, or by breach of this Agreement by Company. The foregoing indemnity obligation shall not apply to the extent that any Third Party Claim arises from, is based on, or results from any activity set forth in Section 13.2 for which Company is obligated to indemnify the SpePharm Indemnitees.

13.2 Indemnification by Company. Company shall indemnify SpePharm and its Affiliates, and their respective officers, directors, and employees and agents (the "**SpePharm Indemnitees**"), for any Losses payable or owed by such parties in connection with any Third Party Claim to the extent arising from: (a) any breach of any of Company's obligations under this Agreement, including any representation, warranty, covenant or agreement on the part of Company under this Agreement; (b) the development of the Product undertaken by Company pursuant to the Company Development Plan; (c) subject to Section 13.3, a claim that the use, sale, offer for sale, or import of the Product (excluding any modifications to the Product made by SpePharm to the Product after the Effective Date to the extent such modifications are the basis for such Third Party Claim) in the Licensed Territory infringes, misappropriates or violates the intellectual property rights of a Third Party; (d) the Commercialization of the Product in the Company Territory, including Third Party Claims based upon product liability; or (e) the negligence or intentional misconduct of Company, its Affiliates, or the officers, directors, employees or agents of Company or its Affiliates; except in each case, to the extent caused by the gross negligence or willful misconduct of SpePharm or any of its Affiliates, or their respective officers, directors, and employees, or by breach of this Agreement by SpePharm. The foregoing indemnity obligation shall not apply to the extent that any Third Party Claim arises from, is based on, or results from any activity set forth in Section 13.1 for which SpePharm is obligated to indemnify the Company Indemnitees.

13.3 IP Infringement. If any Third Party Claim for which indemnity is or may be sought by SpePharm Indemnitees pursuant to Section 13.2(c), is made or appears reasonably possible, SpePharm agrees (i) promptly to notify Company in writing; (ii) to cooperate with Company, and to allow Company sole authority to control the defense and settlement of such Third Party Claim at Company's cost and expense (subject to Section 11.5); and (iii) to permit Company to take such actions necessary, as the Party's reasonably agree and in good faith and at the Party's equally shared cost and expense, to enable SpePharm to continue to use the allegedly infringing aspect of the Product or to obtain licenses (subject to Section 11.5) for, modify or replace any such infringing material to make it non-infringing (provided that such modifications or replacements do not require SpePharm to obtain approval from a Regulatory Authority in order to manufacture, sell or Commercialize the Product containing such modifications or replacements). In the event the Company desires to obtain any license for any Third Party intellectual property right for the Product in the Field and Territory, it shall first offer SpePharm the right to obtain such license (in which case the terms of Section 10.4(d) shall apply) or Company may take such license with prior notice to SpePharm (in which the terms of Section 11.5 shall apply). In no event shall Company be obligated to indemnify SpePharm for Third Party Claims for which indemnity is or may be sought by SpePharm Indemnitees pursuant to Section 13.2(c) in amounts in excess of fifty percent (50%) all amounts paid by SpePharm to Company hereunder as of the date of such Third Party Claim. If Company ceases to indemnify the SpePharm Indemnitees for such Third Party Claim, then SpePharm shall have the right, upon written notice to Company, to assume sole authority to control the defense and settlement of such Third Party Claim. Notwithstanding, if a Third Party Claim has been filed against a SpePharm Indemnitee in a court of competent jurisdiction for which indemnity is or may be sought by such SpePharm Indemnitee pursuant to Section 13.2(c), and Company determines that none of the foregoing alternatives is reasonably available and provides written notice of the same to SpePharm, SpePharm, its Affiliates and Sublicensees will have the option to, in SpePharm's sole discretion, either (a) cease sale, distribution and use of, and, if applicable, return, such materials as are the subject of the relevant infringement claim, or (b) continue the sale, distribution and use of such materials, in which case Company's obligation to indemnify the SpePharm Indemnitees pursuant to Section 13.2(c) in respect of such infringement claim shall be limited solely to liability resulting from sales, distributions and uses of such materials occurring prior to receipt of such notice from Company.

13.4 Conditions and Limitations of Indemnification Obligation. Each Party shall notify the other in the event it becomes aware of a claim for which indemnification may be sought hereunder pursuant to this Section 13. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Section 13, such Party (the "**Indemnified Party**") shall provide the other Party (the "**Indemnifying Party**") with prompt written notice of such proceeding (the "**Indemnification Claim Notice**"). Promptly after the Indemnifying Party receives the Indemnification Claim Notice, the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any claims that are the subject matter of such proceeding. At its option, the Indemnifying Party may assume the defense of any Third Party claim subject to indemnification as provided for in this Section 13 by giving written notice to the Indemnified Party within thirty (30) days (or within such time provided in any applicable extension to appropriately answer any complaint, if any, but no longer than seventy (70) days, provided that the Indemnified Party makes all reasonable efforts to obtain any such extension) after the Indemnifying Party's receipt of an Indemnification Claim Notice, provided that (a) the claim solely seeks monetary damages and (b) 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 claim in full (the matters described in (a) and (b), the "**Litigation Conditions**"). The Indemnified Party may, at any time, assume all such defense if the Litigation Conditions are not satisfied. Upon assuming the defense of a Third Party claim in accordance with this Section 13, the Indemnifying Party shall be entitled to appoint lead counsel in the defense of the Third Party claim. Should the Indemnifying Party assume and continue the defense of a Third Party Claim, except as otherwise set forth in this Section 13, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party claim. Without limiting this Section 13, any Indemnified Party shall be entitled to participate in, but not control, the defense of a Third Party Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing; (ii) the Indemnifying Party has failed to assume and actively further the defense and employ counsel in accordance with this Section 13.4 (in which case the Indemnified Party shall control the defense); or (iii) the Indemnifying Party no longer satisfies the Litigation Conditions. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim that shall not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, and subject to the Litigation Conditions being satisfied, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Losses, on such terms as the Indemnifying Party, in its reasonable discretion, shall deem appropriate (provided that such terms shall include a complete and unconditional release of the Indemnified Party from all liability with respect thereto), and shall transfer to the Indemnified Party all amounts which said Indemnified Party shall be liable to pay prior to the time of the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party claim in accordance with this Article 13, the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Liability, provided that it obtains the prior written consent of the Indemnified Party (which consent shall be at the Indemnified Party's reasonable discretion). The Indemnifying Party that has assumed the defense of the Third Party Claim in accordance with this Article 13 shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party (but in no event to include any court judgment or judicial or administrative order or disposition) that is reached without the written consent of such Indemnifying Party. No Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without first offering to the Indemnifying Party the opportunity to assume the defense of the Third Party Claim in accordance with this Article 13. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with such Third Party Claim. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses incurred in connection with such cooperation.

13.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 OR 13.2, OR DAMAGES AVAILABLE FOR A PARTY'S INFRINGEMENT OR MISAPPROPRIATION OF A PARTY'S INTELLECTUAL PROPERTY RIGHTS, OR BREACH OF (A) CONFIDENTIALITY OBLIGATIONS IN ARTICLE 14, OR (B) SECTIONS 2.6, 2.7 OR 2.8.

ARTICLE XIV – CONFIDENTIALITY

14.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party (the "**Receiving Party**") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any information or other confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party (the "**Disclosing Party**") or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement, including but not limited to trade secrets, know-how, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to a Party's past, present and future marketing, financial, and research and development activities of any product or potential product or useful technology of the Disclosing Party and the pricing thereof (collectively, "**Confidential Information**"), except to the extent that it can be established by the Receiving Party that such Confidential Information: (a) was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party, or was otherwise developed independently by the Receiving Party, as evidenced by contemporaneous written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party hereunder; (c) became generally available to the public or otherwise part of the public domain after its disclosure hereunder and other than through any act or omission of the Receiving Party in breach of this Agreement; or (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others. All information disclosed under that certain Mutual Confidentiality/Non-Disclosure Agreement between the Parties dated as of May 24, 2013, as amended December 11, 2014, shall be deemed to be Confidential Information hereunder and such agreement shall be superseded by the terms hereof and terminated effective as of the Effective Date.

14.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows: (a) to the Receiving Party's Affiliates, potential and actual sublicensees or subdistributors, employees, officers, directors, agents, consultants, and/or other Third Parties under appropriate confidentiality provisions no less stringent than those in this Agreement, in connection with the performance of its obligations or exercise of its rights under this Agreement; or (b) to the extent such disclosure is reasonably necessary in defending litigation, complying with applicable governmental regulations or otherwise required by Applicable Law (including as required to seek, obtain and maintain Product Approvals); *provided, however*, that if a Receiving Party is required by Applicable Law to make any such disclosure of a Disclosing Party's Confidential Information it will, except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the Disclosing Party of such disclosure requirement and, except to the extent inappropriate in the case of patents, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; or (c) to potential or actual acquirers, merger candidates or investors or venture capital firms, investment bankers or other financial institutions or investors, provided that in connection with such disclosure, such Receiving Party shall inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; or (d) to the extent mutually agreed to in writing by the Parties; *provided*, *however*, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives the Confidential Information pursuant to this Section 14.2 to treat such Confidential Information as required under this Article 14.

14.3 Disclosure of Agreement. The Parties have agreed to jointly issue a public announcement of the execution of this Agreement, on or promptly after the Effective Date, and a draft of which is attached hereto as Exhibit B. Neither Party shall be free to issue any press release or other public disclosure regarding the Agreement or the other Parties' activities hereunder, except (a) with the other Party's prior written consent, or (b) for any disclosure that is reasonably necessary to comply with applicable national securities exchange listing requirements or Applicable Laws. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any such press releases prior to the issuance thereof, and a Party may not unreasonably withhold, delay or condition consent to such releases. Except to the extent required by Applicable Law or as otherwise permitted in accordance with this Section 14.3, neither Party shall make any public announcements concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, to the extent information regarding this Agreement has already been publicly disclosed in the same context, either Party may subsequently disclose the same information to the public without the consent of the other Party. Each Party shall be permitted to disclose the terms of this Agreement, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement, to any actual or potential investors, acquirers, merger partners, licensees or sublicensees, or purchasers of assets of such Party and to the professional advisors thereof. Each Party shall give the other Party a reasonable opportunity where practical to review all filings with the United States Securities and Exchange Commission describing the terms of this Agreement prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including without limitation the provisions of this Agreement for which confidential treatment should be sought; provided that no further review shall be provided for disclosures for which consent has been obtained. Notwithstanding, with respect to the filing of this Agreement by Company with the United States Securities and Exchange Commission, Company shall provide SpePharm with at least five (5) business days to review and comment on such proposed filing.

14.4 Publication. SpePharm recognizes that Company may wish to publish, report or present scientific information relating to the Product. All publications, reports and presentations involving the Product will first be submitted by Company to SpePharm. SpePharm will have fifteen (15) days to review the publication, report and/or presentation for potential patent right or other intellectual property rights protection. If SpePharm identifies subject matter in such publication, report and/or presentation which, if published would adversely affect either Party's patent rights, then upon SpePharm's written request, Company will delay submission of its publication, report and/or presentation for an additional period, not to exceed ninety (90) days, in order to allow for the filing of a patent application or other appropriate intellectual property protection.

ARTICLE XV – TERM AND TERMINATION

15.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 15, shall remain in effect on a Product-by-Product and country-by-country basis, until expiration of the Royalty Term in such Country (the "**Term**"). Upon expiration of this Agreement pursuant to this Section 15.1 with respect to a particular Product in a particular country, (a) the licenses granted to SpePharm pursuant to Section 2.1 with respect to such Product in such country shall become fully paid-up and non-terminable, and (b) if, with respect to a particular Product in a particular country, SpePharm or its Affiliates or Sublicensees elect to continue use of the Product Marks pursuant to Section 11.3(a) with respect to such Product in such country, SpePharm shall pay to Company a royalty equal to [*] of Net Sales of such Product in such country.

15.2 Termination by Company.

(a) For Breach. Company shall have the right to terminate this Agreement upon thirty (30) days' prior written notice if SpePharm materially breaches this Agreement and does not cure such breach within ninety (90) days (or thirty (30) days for non-payment) (except as otherwise provided in this Agreement) following written notice by Company, which notice shall specify the nature of the breach and demand its cure; provided, however, that a breach by SpePharm that relates to SpePharm's obligations under this Agreement with respect to one or more specific Product and/or one or more specific countries, where such breach does not materially adversely impact the performance by SpePharm of its obligations under this Agreement with respect to other Product and/or other countries, shall give Company a termination right only as to such affected Product(s) and/or countries.

(b) For Failure to Launch. Company shall have the right to terminate this Agreement pursuant to Section 7.3(b).

15.3 Termination by SpePharm for Breach. SpePharm shall have the right to terminate this Agreement as a whole upon thirty (30) days' prior written notice if Company materially breaches this Agreement and does not cure such breach within ninety (90) days following written notice by SpePharm, which notice shall specify the nature of the breach and demand its cure. Upon a final determination of Company's material breach under this Agreement, and exhaustion of Company's cure period, in lieu of termination, but not in lieu of any damages or other remedies arising from such breach, SpePharm shall have the right to continue with the Agreement in effect (including all payment obligations) and to assume those activities for which Company was determined to be in material breach and any activities necessary or reasonably required to perform such breached activities. Company and its Affiliates shall reasonably cooperate with SpePharm and its designees to facilitate a smooth, orderly and prompt transition to SpePharm or its designees of such activities.

15.4 Tolling. Notwithstanding Sections 15.2 and 15.3, if either Party is alleged to be in material breach and disputes in good faith such breach and/or termination through the dispute resolution procedures set forth in this Agreement, then the other Party's right to terminate this Agreement shall be tolled for so long as such dispute resolution procedures set forth in Article XVI are being pursued by the allegedly breaching Party in good faith and the Party is complying with its obligations under this Agreement, including payment, and if it is finally and conclusively determined that the allegedly breaching Party is in material breach, then the breaching Party shall have the right to cure such material breach after such determination within the cure period provided above in Section 15.2 or 15.3, as applicable.

15.5 Insolvency Event. Either Company or SpePharm may terminate this Agreement if the other Party, during the Term, shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make a general assignment for the benefit of its creditors. Termination under this Section 15.5 shall be effective upon twenty (20) days' prior written notice.

15.6 Termination by SpePharm for Convenience. Prior to its expiration, this Agreement may be terminated in its entirety or on a Product-by-Product and/or country-by-country basis, in its sole discretion, at any time by SpePharm effective upon at least one hundred and eighty (180) days' prior written notice to Company for any reason; provided however, if SpePharm terminates this Agreement, whether in whole or in part, in any of the Major EU Market Countries, such termination shall be deemed a termination of this Agreement in its entirety.

15.7 Termination for Patent Challenge. Company may terminate this Agreement in its entirety immediately upon written notice to SpePharm if SpePharm or its Affiliates or Sublicensees (directly or indirectly, individually or in association with any other person or entity) challenges in a legal or administrative proceeding the validity, enforceability or scope of any Company Patents anywhere in the world (except as a defense against a claim, action or proceeding asserted by Company or its Affiliates or licensees against SpePharm or its Affiliates or Sublicensees) (a "**Patent Challenge**"); provided that with respect to any such Patent Challenge by any Sublicensee of SpePharm, Company will not have the right to terminate this Agreement under this Section 15.7 if SpePharm (A) causes such Patent Challenge to be terminated or dismissed or (B) terminates such Sublicensee's sublicense to the Company Patents being challenged by the Sublicensee, in each case ((A) and (B)) within thirty (30) days of Company's notice to SpePharm under this Section 15.7. Notwithstanding the foregoing, Company's termination right under this Section 15.7 shall not apply to any Affiliate of SpePharm that first becomes an Affiliate of SpePharm after the Effective Date of this Agreement in connection with a Business Combination, where such Affiliate of SpePharm was undertaking activities in connection with a Patent Challenge prior to such Business Combination; provided however that SpePharm causes such Patent Challenge to terminate within forty-five (45) days after such Business Combination. For the avoidance of doubt, an action by SpePharm in accordance with Section 11.2 to amend claims within a pending patent application of the Company Patents during the course of SpePharm's prosecution and maintenance of such pending patent application or in defense of a Third Party proceeding, or to make a negative determination of patentability of claims of a patent application in the Company Patents or to abandon a patent application in the Company Patents during the course of SpePharm's prosecution and maintenance of such pending patent application, shall not constitute a Patent Challenge.

15.8 Termination for Pricing and Reimbursement Matters. SpePharm may terminate this Agreement on thirty (30) days' prior written notice if (a) the market access studies contemplated under Section 4.3(a) do not generate data adequate, in SpePharm's reasonable judgment, to support a level of pricing and reimbursement approvals in the Initial Territory that would make it Commercially Reasonable to Commercialize the Product in the Licensed Territory, or (b) achievement of pricing and reimbursement approval in the Major EU Market Countries is not feasible within the customary reimbursement timeframes in such countries, as reasonably determined by SpePharm.

15.9 Effect of Termination.

(a) Upon termination of this Agreement in its entirety, or with respect to a particular Product or a particular country in the Licensed Territory, then the following consequences shall apply:

(i) Each Party shall return to the other Party all Confidential Information of the other Party (except that each Party shall be permitted to retain, through its legal counsel, one (1) copy of the other Party's Confidential Information to the extent required under any Applicable Laws or to the extent necessary to exercise any rights surviving termination of this Agreement);

(ii) SpePharm's rights and each of SpePharm and Company's obligations under this Agreement with respect to the Licensed Territory, or such Product or country, as applicable, shall automatically terminate;

(iii) The JMC and all other committees shall be abolished and thereafter Company shall have the right to make the decisions and take the actions previously reserved to the JMC and such other committees;

(iv) All trademarks, marks, trade names, patents, copyrights, designs, drawings, formulas or other data, photographs, samples, literature, and sales and promotional aids of every kind (including Company Marks) of Company shall remain the sole and exclusive property of Company with respect to the particular Product, as applicable. Within thirty (30) days after the effective date of termination of this Agreement, but only if this Agreement is terminated in its entirety, SpePharm shall destroy all tangible items bearing, containing, or contained in, any of the foregoing, in its possession or control and provide written certification of such destruction, or prepare such tangible items for shipment to Company, as Company may direct, at Company's expense. SpePharm shall not make or retain any copies of any confidential or proprietary items or information, which may have been entrusted to it (except that SpePharm shall be permitted to retain, through its legal counsel, one (1) copy of such confidential or proprietary items or information to the extent required under any Applicable Laws or to the extent necessary to exercise any rights surviving termination of this Agreement). Effective upon the termination of this Agreement, SpePharm shall cease to use all Company Marks with respect to the particular Product and countries, as applicable. SpePharm shall transfer and assign to Company to the extent not already owned by Company, all right, title and interest in and to any trademarks, trade dress, and logos developed by SpePharm under this Agreement after the Effective Date solely for use in connection with Commercializing the Product in the Licensed Territory and all intellectual property rights in and to the Marketing Materials;

(v) SpePharm hereby grants to Company a worldwide, fully-paid, royalty-free, right and license, with the right to grant sublicenses (through multiple tiers) subject to subsection (xiii) below, under the General IP that, prior to termination, had been developed by Company and assigned to SpePharm and which is necessary or reasonably useful, to develop, market, promote, import, use, sell, offer for sale, distribute, manufacture, have manufactured and otherwise commercialize the Product, solely to develop, market, promote, import, use, sell, offer for sale, distribute, manufacture, have manufactured and otherwise commercialize the Products and other products. The foregoing license shall be exclusive with respect to Products, and non-exclusive with respect to other products.

(vi) If requested by Company, SpePharm shall grant to Company an exclusive (even as to SpePharm and its Affiliates), worldwide, royalty-bearing right and license, with the right to grant sublicenses (through multiple tiers) subject to subsection (xiii) below, under the General IP (to the extent not licensed under Section 15.9(a)(v) above), Joint IP and SpePharm IP which is necessary or reasonably useful, to develop, market, promote, import, use, sell, offer for sale, distribute, manufacture, have manufactured and otherwise commercialize the Product, solely to develop, market, promote, import, use, sell, offer for sale, distribute, manufacture, have manufactured and otherwise commercialize the Product. The Parties shall establish a commercially reasonable royalty rate and terms for such license prior to effective date of termination and in the event the Parties are unable to so agree, then the matter shall be decided by an independent industry expert selected by Company and reasonably acceptable to SpePharm. Until such matter is finally resolved, SpePharm will grant the license on a royalty-free basis with the finally determined royalty applying on a retroactive basis to the date of first sale of the Product by Company under the license granted hereunder. In addition, Company would to be responsible for its pro-rata share of costs and expenses owed by SpePharm to a third party pursuant to a license under which SpePharm has procured third party technology constituting SpePharm IP hereunder;

(vii) Neither Party shall be released from paying any amount which accrued prior to the effective date of such termination;

(viii) Company may, in its reasonable discretion in accordance with Applicable Laws, appoint itself as successor to SpePharm or appoint a Third Party that is located in the Licensed Territory, organized under the laws of the Licensed Territory and legally competent to hold and maintain the Product Approvals (with respect to the particular Product, as applicable) under the laws of the Licensed Territory, as successor to SpePharm solely for those Products and countries that have been terminated (the "**Successor Entity**"). SpePharm shall transfer and assign to Company or the Successor Entity, as applicable, all permits, filings and authorizations and Product Approvals (including reimbursement authorizations), if any, obtained, maintained or renewed that are under SpePharm's name that are held by SpePharm solely for the purpose of marketing, distributing and selling the terminated Products in the terminated countries of the Licensed Territory, as soon as practicable after this Agreement is terminated and at Company's expense. SpePharm shall reasonably cooperate, at Company's request and expense, in making any filings, executing any instruments, or taking other actions reasonably necessary to make such transfer of any Product Approvals (including pricing approvals) effective. In addition, SpePharm shall transfer and assign to Company all Regulatory Materials in the Licensed Territory that are Controlled by SpePharm;

(ix) SpePharm shall, at Company's request and expense, promptly assign to Company or the Successor Entity, as applicable, all of SpePharm's rights and obligations under all contracts, to the extent assignable, for such terminated Products in the terminated countries of the Territory with any Third Parties to the extent solely related to the development or Commercialization of the Product in the Licensed Territory.

(x) SpePharm shall provide Company with a complete inventory of Products in SpePharm's possession or in transit to SpePharm from Company or otherwise in SpePharm's control, within ten (10) days after the effective date of the termination. Company may inspect SpePharm's Product inventory and audit SpePharm's records in the manner provided hereinabove. Acceptance of any Product Order from, or sale or license of, any Product to SpePharm after the effective date of termination of this Agreement shall not be construed as a renewal or extension hereof, or as a waiver of termination of this Agreement.

(xi) Company shall, at its option, have the right to repurchase from SpePharm, and SpePharm shall sell to Company, all of the Products for the countries for which this Agreement has terminated, as applicable, and in SpePharm's stock at the applicable Repurchase Price actually paid by SpePharm for such Product(s). Any such repurchase shall be made within sixty (60) days after the effective date of termination, and SpePharm shall promptly ship such Products to a destination specified by Company in accordance with shipping instructions used by Company to SpePharm. Such Products and parts so delivered shall be subject to inspection by Company to be completed no later than ten (10) business days after receipt, and payment therefore shall be made within forty-five (45) days of final acceptance by Company of such Products so inspected. Company shall purchase from SpePharm, and SpePharm agrees to sell to Company, all of SpePharm's inventory of the terminated Products, as applicable, that are not obsolete, damaged or expired on the effective date of such termination. The price of such inventory shall be SpePharm's fully burdened cost of goods (the "**Repurchase Price**"). Products repurchased from SpePharm by Company pursuant to this Section 15.9(a)(x) shall be shipped promptly by SpePharm to a location specified by Company and Company shall reimburse SpePharm for all pre-approved reasonable out-of-pocket costs of shipment.

(xii) For a period not to exceed [*] following the effective date of termination of this Agreement, SpePharm and its Affiliates shall reasonably cooperate with Company and its designees to facilitate a smooth, orderly and prompt transition to Company or its designees of its activities with respect to Products, including any ongoing development, manufacturing and Commercialization of Products, and including any agreements related to the Product which SpePharm is unable to assign to Company or elects not to assign to Company due to such agreements not being solely related to the Product. During the pendency of any transition, SpePharm will not take any action that would reasonably be expected to have a material adverse effect on the Product. In connection with the transfer of activities under this Section 15.9(a)(xii), the Parties will develop and agree upon a written plan to effect such transition, and Company shall reimburse SpePharm for its reasonable costs and expenses incurred with such transfer.

(xiii) With respect to each sublicense granted by Company pursuant to subsections (v) or (vi) above, Company shall remain primarily responsible for all of its Affiliates' and sublicensees' activities and any and all failures by its Affiliates and sublicensees to comply with the applicable terms of this Agreement. The Parties agree that agreements with Third Parties acting only as distributors or wholesalers of Company or its Affiliates or providing products or services to Company or its Affiliates and which are not otherwise granted any sublicense of SpePharm's rights under this Agreement, shall not be deemed a sublicense. Within fifteen (15) days after entering into the sublicense agreement for the General IP or SpePharm Product IP with a non-Affiliated sublicensee, Company shall provide to SpePharm a copy of the executed sublicense agreement, which may be redacted as necessary to protect commercially sensitive information.

15.10 Survival. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration including the payment obligations hereunder and any and all damages or remedies arising from any breach hereunder. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement. The provisions of Articles I, XIII, XIV, XV, XVI and XVII, and Sections 8.2, 10.1-10.5 (as to any amounts accrued prior to the effective date of termination) 10.6, 10.7, 10.8, 11.1, 11.3 (for so long as Norgine elects its license under Section 15.1) and 12.3 shall survive the expiration or termination of this Agreement for any reason. All other rights and obligations of the Parties shall cease upon termination of this Agreement.

ARTICLE XVI – DISPUTES

16.1 Disputes. The Parties shall attempt to resolve all disputes between the Parties arising out of or relating to this Agreement and all related agreements, collectively or separately, amicably through good faith discussions upon the written request of any Party. In the event of a dispute arising out of or relating to this Agreement either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the executive officers designated below or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated officers are initially as follows:

For Company: its President

For SpePharm: its Managing Director

In the event the designated executive officers do not resolve such dispute within the allotted sixty (60) days, such dispute may be resolved by litigation pursuant to Section 16.2.

16.2 Venue; Jurisdiction. Each Party hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the federal courts located in the Southern District of New York, for any actions, suits or proceedings arising out of or relating to this Agreement and the transactions contemplated hereby. Each Party hereby irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Agreement and the transactions contemplated hereby in the federal courts located in the Southern District of New York, and waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in such court has been brought in an inconvenient forum. Notwithstanding the foregoing, a Party shall be entitled to seek enforcement of a judgment entered pursuant to this Section in any court having competent jurisdiction thereof where enforcement is deemed necessary.

16.3 Exclusions. Nothing in this Article 16 shall preclude a Party from seeking and obtaining in a court of competent jurisdiction injunctive or equitable relief to preserve the status quo or prevent immediate harm to the Party. The terms of this Article 16 shall not apply to any disputes relating to a material breach of Article 14 (Confidentiality) or any claim relating to the intellectual property rights of a Party, each of which may be brought in a court of competent jurisdiction.

ARTICLE XVII – MISCELLANEOUS

17.1 Force Majeure. Nonperformance by either Party shall be excused to the extent that performance is rendered beyond such Party's reasonable control by industrial conflicts, mobilization, requisition, embargo, currency restriction, insurrection, general shortage of transport, material or power supply, fire, flood, earthquake, explosion, stroke of lightning, other force majeure and similar casualties or other events beyond either Party's reasonable control ("**Force Majeure Events**"), as well as default in deliveries from subcontractors due to such circumstances as defined in this Section 17.1. If a Force Majeure Event exists for more than one hundred and eighty (180) days, then the affected Party shall have the right to terminate this Agreement upon written notice to the other Party and the terms of Section 15.9 shall apply. If either Party is affected by a Force Majeure Event, it shall promptly as soon as it is known that such circumstances are likely to have a detrimental impact on the performance of its obligations under the terms of this Agreement, immediately verbally notify the other Party and follow up in writing describing the nature and extent of the circumstances, the likely and potential duration and the foreseeable impact on its ability to perform any of its obligations under this Agreement. During the continuance of any Force Majeure Event, the affected Party shall use all reasonable efforts to overcome, remove or minimize the effects of such Force Majeure Event and to perform its obligations under this Agreement as soon as reasonably possible.

17.2 Performance by Affiliates. Each Party agrees to cause its Affiliates to comply with the provisions of this Agreement as applicable to such Affiliate and to guarantee the payment and performance thereof. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

17.3 Independent Contractors. It is understood that both Parties are independent contractors and are engaged in the operation of their own respective businesses. Neither Party is the agent of the other for any purpose whatsoever, and neither Party has any authority, express or implied, to enter into any contracts or assume any obligations for the other, to pledge the credit of the other or make any warranties or representations on behalf of the other, except where expressly authorized in writing to do so. Nothing in this Agreement or in the activities of either Party shall be deemed to create an agency, partnership or joint venture relationship.

17.4 No Partnership. The Parties agree and acknowledge that this Agreement is not intended to create, or be deemed to be or otherwise treated as, a partnership for United States federal, state or local income tax purposes or for purposes of the laws of any state of the United States or the District of Columbia. No Party shall file or cause to be filed any Internal Revenue Service Form 1065 (U.S. Return of Partnership Income), or any equivalent form for state or local tax purposes, with respect to the arrangements contemplated by this Agreement, and each Party agrees that any and all United States federal, state and local income tax returns it files will be consistent with the provisions of this Section 17.4. The transactions contemplated by this Agreement shall not be conducted under a joint or combined business name and no Party shall hold itself out to any person as being in a partnership, joint venture, or combined business with the other Party. The Parties shall not open any joint bank accounts or otherwise commingle their respective funds.

17.5 **Notices.** All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be given (and shall be deemed to have been duly given upon receipt) by delivery in person or via internationally recognized overnight delivery, or by registered or certified mail (postage prepaid, return receipt requested), or by facsimile or email with confirming letter sent by mail as provided above, to the following address (or at such other address for which such Party gives notice hereunder):

If to SpePharm:	SpePharm AG Kapellplatz 1 6004 Luzern, Switzerland Attention: Dr. Adrian von Segesser Fax: [*]

with a copy to Norgine.

If to Norgine:	Norgine BV Hogehilweg 7 1101 CA Amsterdam Zuid-Oost The Netherlands Attention: Managing Director Fax: [*]
If to Company:	Navidea Biopharmaceuticals, Inc. 5600 Blazer Parkway, Suite 200 Dublin, OH 43017 U.S.A. Attention: President Fax: [*]

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

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5656
United States of America
Attention: Ken Krisko

Notices shall be considered delivered when mailed or sent by confirmed email or facsimile in accordance with the provisions of this Section 17.5, subject to proof of receipt or facsimile confirmation or by mail receipt.

17.6 Governing Law. This Agreement, and the rights and obligations of the Parties hereunder, shall be governed, construed and interpreted in accordance with the laws of the State of New York, U.S.A., without reference to conflict of laws and choice of law principles and excluding the United Nations Convention on Contracts for the International Sale of Good.

17.7 Entire Agreement. This Agreement, including the Exhibits, sets forth the entire agreement and understanding of the Parties relating to the subject matter hereof, and supersedes all prior oral and written, and all contemporaneous oral, agreements, understandings and arrangements. No modification of or amendment to this Agreement shall be effective unless signed by the Parties.

17.8 Assignment. This Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned; provided that without consent (i) SpePharm may assign this Agreement to (x) an Affiliate, (y) Norgine (for so long as Norgine is an Affiliate of SpePharm) or (z) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, and (ii) Company may assign this Agreement to (x) an Affiliate or (y) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; provided however that, except in the case where a Party is involved in a merger or consolidation where it is the surviving entity and no assets of such Party have been transferred as a result of such merger or consolidation, that (A) such assigning Party provides the other Party to this Agreement with at least thirty (30) days advance written notice of such assignment(s), subject to any confidentiality obligations, and the assigning Party agrees in a written agreement delivered prior to such assignment(s) to the non-assigning Party (and upon which such non-assigning Party may rely) to remain fully liable for the performance of its obligations under this Agreement by its assignee(s), (B) the assignee(s) agree in a written agreement delivered prior to such assignment(s) to the non-assigning Party (and upon which such non-assigning Party may rely) to assume performance of all such assigned obligations, (C) in the case of any assignment(s) by Company, rights to all Company Patents and Company Know-How licensed to SpePharm for the Licensed Territory will be transferred to such assignee(s) effective as of such assignment(s), and (D) all of the matters referred to in clauses (A), (B) and (C), as applicable, will be set forth in documentation reasonably acceptable to the non-assigning Party prior to any such assignment(s) (and with such reasonable acceptance not to be unreasonably withheld, conditioned or delayed) and in all cases will provide the non-assigning Party with the full benefits of its rights under this Agreement (after taking into account all risks involving applicable counter-party performance and bankruptcy and insolvency risks, including those involving contractual rejection under 11 USC §365) as if no such assignment(s) had occurred. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 17.8 will be null and void *ab initio*.

17.9 **Guaranty**. In consideration of the rights granted hereunder, Norgine hereby guarantees in favor of Company the full payment and performance by SpePharm of all obligations of SpePharm under this Agreement, in accordance with the terms and conditions of this Agreement, including any applicable notice or cure periods. This guaranty shall be enforceable upon the failure by SpePharm to perform any obligation it may have under this Agreement in accordance with its terms, and shall be effective regardless of the solvency or insolvency of SpePharm at any time, the extension or modification of the obligations of this Agreement by operation of law, or the subsequent reorganization, merger, consolidation or other restructuring of SpePharm. Norgine hereby expressly waives any requirement that Company exhaust any right, power or remedy under this Agreement, or proceed against any other SpePharm entity under this Agreement, for any obligation or performance hereunder prior to proceeding directly against Norgine under this Section 17.9. In the event that this Agreement is transferred or assigned by SpePharm to a Third Party which is not an Affiliate of Norgine, or if a Business Combination occurs with respect to SpePharm and a Third Party which is not an Affiliate of Norgine, then Norgine's obligations under this Section 17.9 shall terminate, and the successor to SpePharm's rights in this Agreement or the successor to SpePharm, as the case maybe, shall assume such obligations under this Section 17.9.

17.10 **Severability.** If any provision of this Agreement is held to be invalid by a court of competent jurisdiction, then the remaining provisions shall remain, nevertheless, in full force and effect. The Parties agree to renegotiate in good faith any term held invalid and to be bound by the agreed substitute provision in order to give the most approximate effect intended by the Parties.

17.11 Headings. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. Any article, section, recital, exhibit, schedule or party references are to this Agreement unless otherwise stated. No Party or its counsel shall be deemed to be the drafter of this Agreement for purposes of construing the provisions hereof, and all provisions of this Agreement shall be construed in accordance with their fair meaning, and not strictly for or against any Party.

17.12 Export Control. SpePharm understands and acknowledges that Company is subject to regulation by agencies of the U.S. Government, including but not limited to, the FDA and the U.S. Department of Commerce, which prohibit and/or regulate export or diversion of certain products and technology to certain countries. Any and all obligations of Company to provide the Product as well as any other technical information and assistance shall be subject in all respects to such United States laws and regulations as shall from time to time govern the license and delivery of technology and products abroad by persons subject to the jurisdiction of the United States, including without limitation the Administration Act of 1979, as amended, any successor legislation, and the Export Administration Regulations issued by the Department of Commerce, Bureau of Import Administration. SpePharm agrees to cooperate with Company, including, without limitation, providing required documentation, in order to obtain export licenses or exemptions there from. Company warrants that it shall comply with the Export Administration Regulations and other United States laws and regulations governing exports in effect from time to time. Company further warrants that, as of the Effective Date, nothing in the Export Administration Regulations or other United States laws and regulations governing exports in any way restrict Company from providing the Product or any technical information or assistance relating thereto to SpePharm as required by this Agreement or from performing any of Company's obligations under this Agreement.

17.13 Waiver. No waiver of any term or condition of this Agreement shall be valid or binding on either Party unless agreed in writing by the Party to be charged. The failure of either Party to enforce at any time any of the provisions of the Agreement, or the failure to require at any time performance by the other Party of any of the provisions of this Agreement, shall in no way be construed to be a present or future waiver of such provisions, nor in any way affect the validity of either Party to enforce each and every such provision thereafter.

17.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in Adobe™ Portable Document Format ("**PDF**") sent by electronic mail. In addition, facsimile or PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a facsimile or PDF signature by any Party will constitute due execution and delivery of this Agreement.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Navidea Biopharmaceuticals, Inc.

By: _____

Name:

Title:

SpePharm AG

By: _____

Name:

Title:

Norgine BV (Solely for the purposes of Section 2.6 and Articles 14, 16 and 17)

By: _____

Name:

Title:

EXHIBIT A

Company Patents

Patents

"Compositions for radiolabeling DTPA dextran" (Lymphoseek - Formulation) US 8,545,808 [*]	Assigned to Navidea	Issued – U.S. (2029)
"Macromolecular Carrier for Drug and Diagnostic Agent Delivery" (Lymphoseek - Composition) US 6,409,990 [*]	Licensed from UCSD	Expiration 12 May 2020

EXHIBIT B

Press Release

Navidea and Norgine Enter European Commercial Partnership for Lymphoseek ®; Navidea to Receive $2 Million Upfront Payment

- Strategic partnership provides market development, sales and marketing infrastructure for Lymphoseek expansion into European marketplace –

DUBLIN OHIO March XX, 2015 — Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) and SpePharma AG (an affiliate of Norgine BV), a European specialist pharmaceutical company with an extensive pan-European presence, today entered into an exclusive sublicense agreement for the commercialization and distribution of Lymphoseek® 250 microgram kit for radiopharmaceutical preparation (tilmanocept) in the European Union. Under the terms of the agreement, Navidea will receive an upfront payment of $2 million and is eligible to receive additional milestone payments up to $5 million, as well as royalties on European net sales.

Lymphoseek is a receptor-targeted, radiopharmaceutical imaging agent approved by the U.S. Food and Drug Administration in 2013 and by the EU in November 2014. Lymphoseek is approved in Europe for imaging and intraoperative detection of sentinel lymph nodes in patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity. In these procedures, key lymph nodes adjacent to a primary tumor, that may contain tumor metastases, are identified and biopsied to determine if cancer has spread to these lymph nodes.

“Launching Lymphoseek in to new global markets is integral to Navidea’s corporate growth strategy. We believe that Norgine’s commercial, medical and development expertise, combined with its well-established infrastructure and strong presence in the European marketplace, make it an ideal commercialization partner to gain country-by-country reimbursement and drive Lymphoseek adoption,” said Rick Gonzalez, President and Chief Executive Officer of Navidea. “We anticipate a successful and mutually-beneficial partnership with Norgine based on synergistic core competencies, our shared vision for value creation and our strong commitment to providing highly-differentiated products that improve the diagnosis and treatment of disease for patients with unmet medical needs.”

“This agreement with Navidea underscores Norgine’s vision to be the partner of choice and facilitates the growth and expansion of our specialist product portfolio to help improve the treatment of patients throughout Europe,” said Peter Stein, Chief Executive Officer of Norgine. “We look forward to fully engaging our sales force to support commercial launch activities in a marketplace requiring a new alternative.”

“Securing a partner with the commitment to market access development was especially important to us since, unlike the United States where institutions typically rely on unit dose distribution of radiopharmaceutical products by specialized radio-pharmacy distributors, institutions in Europe purchase non-radiolabeled material and compound the finished product on-site,” added Mr. Gonzalez “As a specialist pharmaceutical company, Norgine is optimally positioned to interface directly with a targeted surgical oncologist customer base with a dedicated sales force. We expect Norgine to begin market access work immediately in the major markets in Europe with the goal of supporting commercial launch sometime in early 2016.”

Under terms of the exclusive license agreement, Navidea will supply packaged Lymphoseek product to Norgine; however, Navidea will transfer responsibility for regulatory maintenance of the Lymphoseek Marketing Authorization to Norgine. Norgine will also be responsible for pricing, reimbursement, sales, marketing, medical affairs, and regulatory. In connection with entering into the agreement, Navidea will be entitled to an upfront payment of $2 million, milestones totaling up to an additional $5 million, as well as royalties on European net sales. The initial territory covered by the agreement includes all 28 member states of the European Economic Community with the option to expand into additional geographical areas. Additional terms of the agreement were not disclosed.

About Lymphoseek
Lymphoseek® (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

EU Lymphoseek® 250 micrograms kit for radiopharmaceutical preparation (tilmanocept)
Indication and Important Safety Information
Radiolabelled Lymphoseek is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

External imaging and intraoperative evaluation may be performed using a gamma detection device.

Important Safety Information about Lymphoseek for EU & U.S. patients
In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers.
In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

Prescribing information and more information about Lymphoseek for EU patients will be available at: http://ec.europa.eu/health/documents/community-register/html/h955.htm

For full prescribing information and more information about Lymphoseek for U.S. patients, please visit: www.lymphoseek.com.

About Norgine
Norgine is a European specialist pharmaceutical company that has been established for over 100 years. Norgine provides expertise and 'know how' in Europe to develop, manufacture and market products that offer real value to healthcare professionals, payers and patients. Norgine's approach and infrastructure is integrated and focused upon ensuring that Norgine wins partnership opportunities for growth. Norgine is headquartered in the Netherlands and its global operations are based in Amsterdam and in Harefield, UK. Norgine owns an R&D site in Hengoed, Wales and two manufacturing sites, one in Hengoed, Wales and one in Dreux, France. For more information, please visit www.norgine.com. In 2012, Norgine established a complementary business Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit www.norgineventures.com.

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The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

Contact:

Source: Navidea Biopharmaceuticals, Inc.
Navidea Biopharmaceuticals

Brent Larson, 614-822-2330
Executive VP & CFO
Or
Sharon Correia, 978-655-2686
Associate Director, Corporate Communications

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EXHIBIT C

Company Marks; Product Marks

PART I – COMPANY MARKS

Navidea

"Navidea" US Trademark Reg. No. 4,514,173 CTM Trademark Reg. No.: 012204178 Canada Application No. 1647179 Japan Application Ser. No.: 2013-79448 China Application No. (tbd)	US Renewal-04/15/2024 CTM Renewal-10/31/2024
"Navidea Biopharmaceuticals" Design + Words Trademark Reg. No. 4,207,633	Renewal-09/11/2022

PART II – PRODUCT MARKS

Lymphoseek

"Lymphoseek" US Trademark Reg. No. 3,163,525 CTM Trademark Reg. No.: 012204202 Canada. Application No. 1647184 Japan Application Ser. No.: 2013-79449 China Application No. (tbd)	US Renewal-10/24/2016 CTM Renewal-10/31/2023
"Lymphoseek (technetium Tc 99m tilmanocept) injection" Design + Words Trademark Application Ser. No.: 86/055,675	Pending

EXHIBIT D

Pharmacovigilance Agreement

[To be attached within 90 days]

EXHIBIT E

Expanded Territory

[*]

EXHIBIT F

Summary of Supply Agreement Terms

[*]

EXHIBIT G

Company Development Plan

[to be supplied]

Exhibit 99.1

Navidea BIOPHARMACEUTICALS

Press Release

FOR IMMEDIATE RELEASE

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- more -

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Contact:

Source: Navidea Biopharmaceuticals, Inc.
Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
Executive VP & CFO
Or
Sharon Correia, 978-655-2686
Associate Director, Corporate Communications

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