Licensing agreement for TransVax cytomegalovirus vaccine

Astellas Pharma
Vical

Jul 14 2011
Licensing agreement for TransVax cytomegalovirus vaccine

Companies: Astellas Pharma  Vical
Announcement date: Jul 14 2011
Deal value, US$m: 130.0 : sum of upfront and milestone payments

Details
Announcement date: Jul 14 2011
Start date: Jul 01 2011
Industry sectors: Bigpharma
Therapy areas: Infectives » Viral » Cytomegalovirus
Technology types: Recombinant DNA
Vaccines
Co-promotion
Deal components: Licensing
Option
Stages of development: Phase III
Geographic focus: Worldwide » North America » United States

Financials
Deal value, US$m: 130.0 : sum of upfront and milestone payments
Upfront, US$m: 25.0 : upfront payment
Milestones, US$m: 10.0 : upon finalization of Phase 3 trial design
95.0 : additional milestone payments through commercial launch
Royalty rates, %: n/d : double-digit royalties on net sales

Termsheet
4 April 2012

Vical announced that Astellas Pharma and Vical have finalized the general design of a pivotal, multinational Phase 3 trial of TransVax(TM), the companies' therapeutic cytomegalovirus (CMV) vaccine for transplant recipients.

This progress triggers a $10 million milestone payment to Vical. Based on guidance from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), the companies have confirmed that CMV disease will not be the primary endpoint in the Phase 3 trial.

The companies expect to initiate the Phase 3 trial of TransVax(TM) for hematopoietic stem cell transplant (HSCT) recipients in the second half of 2012, and initiate a Phase 2 efficacy trial of TransVax(TM) for solid organ transplant (SOT) recipients shortly thereafter.

Specific endpoints and trial design concepts will be announced when the trials begin. Vical and Astellas entered into exclusive worldwide license agreements in 2011 to develop and commercialize TransVax(TM).
Under the services and supply agreement, Vical will manufacture TransVax(TM) for Astellas through the remaining clinical development and commercial launch.

14 July 2011

Exclusive license agreements for the United States and for all territories in the rest of world outside the United States to develop and commercialize TransVax, Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients.

The companies expect to begin a multinational Phase 3 registration trial of TransVax in hematopoietic stem cell transplant (HSCT) recipients as well as a Phase 2 trial in solid organ transplant (SOT) recipients in the first half of 2012.

The agreements will become effective subject to the expiration or termination of the applicable 30-day waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

Astellas will be responsible for further development and commercialization, including all costs.

Vical will provide assistance to Astellas with TransVax-related manufacturing, regulatory and certain development activities, for which Astellas will reimburse all of Vical's future costs, including personnel and external expenses.

Vical will receive near-term payments of $35 million, including $25 million upon the effective date and $10 million upon finalization of the Phase 3 trial design.

Vical potentially will receive up to $130 million in total upfront and milestone payments through commercial launch and double-digit royalties on net sales.

Press Release

4 April 2012

Astellas Pharma Inc. (YPH.BE) and Vical Incorporated (VICL) Advance Toward Phase 3 Trial of TransVax(TM) CMV Vaccine Triggering $10 Million Milestone Payment to Vical

SAN DIEGO, April 2, 2012 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL - News) today announced that Astellas Pharma Inc. (Tokyo:4503) and Vical have finalized the general design of a pivotal, multinational Phase 3 trial of TransVax(TM), the companies' therapeutic cytomegalovirus (CMV) vaccine for transplant recipients. This progress triggers a $10 million milestone payment to Vical. Based on guidance from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), the companies have confirmed that CMV disease will not be the primary endpoint in the Phase 3 trial.

The companies expect to initiate the Phase 3 trial of TransVax(TM) for hematopoietic stem cell transplant (HSCT) recipients in the second half of 2012, and initiate a Phase 2 efficacy trial of TransVax(TM) for solid organ transplant (SOT) recipients shortly thereafter. Specific endpoints and trial design concepts will be announced when the trials begin. Vical and Astellas entered into exclusive worldwide license agreements in 2011 to develop and commercialize TransVax(TM). Under the services and supply agreement, Vical will manufacture TransVax(TM) for Astellas through the remaining clinical development and commercial launch.

25 July 2011

Vical Incorporated (VICL) Announces Early Termination of Hart-Scott-Rodino Waiting Period for TransVax(TM) License Agreements With Astellas Pharma Inc. (YPH.BE), Triggering an Upfront Payment of $25 Million from Astellas to Vical

7/25/2011 10:33:13 AM

SAN DIEGO, July 25, 2011 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced that the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 was terminated early on July 22, 2011, in connection with Vical's previously announced exclusive worldwide license agreements with Astellas Pharma Inc., (TOKYO:4503) for the development and commercialization of TransVax(TM), Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients. As a result, the agreements have become effective, triggering the initial upfront payment of $25 million from Astellas to Vical, which is expected within 30 days.

As previously disclosed, Astellas will be responsible for further development and commercialization, including all costs. Vical has an option to co-promote TransVax(TM) in the United States. Vical will provide assistance to Astellas with TransVax(TM)-related manufacturing, regulatory and certain development activities, for which Astellas will reimburse all of Vical's future costs, including personnel and external expenses. The companies expect to begin a multinational Phase 3 registration trial of TransVax(TM) in hematopoietic stem cell transplant (HSCT) recipients as well as a Phase 2 trial in solid organ transplant (SOT) recipients in the first half of 2012. Vical will receive an additional $10 million upon
Vical and Astellas Announce Worldwide License Agreements for TransVax™ Cytomegalovirus Vaccine

Vical Incorporated (Nasdaq: VICL) and Astellas Pharma Inc. (TOKYO: 4503) today announced that they have signed exclusive license agreements for the United States and for all territories in the rest of world outside the United States to develop and commercialize TransVax™. Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients.

The companies expect to begin a multinational Phase 3 registration trial of TransVax™ in hematopoietic stem cell transplant (HSCT) recipients as well as a Phase 2 trial in solid organ transplant (SOT) recipients in the first half of 2012. The agreements will become effective subject to the expiration or termination of the applicable 30-day waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

Under the agreements, Astellas will be responsible for further development and commercialization, including all costs. Vical has an option to co-promote TransVax™ in the United States. Vical will provide assistance to Astellas with TransVax™-related manufacturing, regulatory and certain development activities, for which Astellas will reimburse all of Vical's future costs, including personnel and external expenses. Vical will receive near-term payments of $35 million, including $25 million upon the effective date and $10 million upon finalization of the Phase 3 trial design. Vical potentially will receive up to $130 million in total upfront and milestone payments through commercial launch and double-digit royalties on net sales.

"We are very pleased to work with Vical on the development and commercialization of TransVax™ as Astellas is committed to reinforcing its vaccine business," said Yoshihiko Hatanaka, President and Chief Executive Officer of Astellas. "The impressive results from the TransVax™ Phase 2 trial provided evidence of safety, immunogenicity and efficacy in a highly challenging HSCT recipient patient population, and reinforce our confidence for future success. We are excited to advance this program toward commercialization to offer transplant recipients a vaccine option for potentially safe and effective control of CMV."

"We believe Astellas is ideally positioned to help us drive this key program toward its greatest potential success," said Vijay Samant, President and Chief Executive Officer of Vical. "Our first-in-class CMV vaccine would complement the existing Astellas franchise in the transplant market, a strategic focus area for Astellas. This program will bring together Astellas’ substantial resources and strong commercial presence in key world markets, and Vical’s development, regulatory and manufacturing expertise with DNA-based product candidates. We are excited to work with Astellas in advancing TransVax™ toward commercialization."

Conference Call

Vical will conduct a conference call and webcast on Friday, July 15, at 8:00 a.m. Eastern Time to discuss the TransVax™ agreements with invited analysts and institutional investors. The call and webcast are open on a listen-only basis to any interested parties. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (719) 457-2643 (preferred), or (888) 503-8163 (toll-free), and reference confirmation code 6648633. A replay of the call will be available for 48 hours beginning about two hours after the call. To listen to the replay, dial (719) 457-0820 (preferred) or (888) 203-1112 (toll-free) and enter replay passcode 6648633. The call also will be available live and archived through the events page at www.vical.com. For further information, contact Vical’s Investor Relations department by phone at (858) 646-1127 or by e-mail at http://www.globenewswire.com/newsroom/ctr?id=22651%26amp%3bl=7%26amp%3ba=ir%2540vical.com%26amp%3bu=mailto%253Air%2540vical.com.

About TransVax™

TransVax™ is a bivalent DNA vaccine containing plasmids (closed loops of DNA) encoding CMV pp65 and gB antigens for induction of both cellular and humoral immune responses. TransVax™ is formulated with a proprietary poloxamer-based delivery system. TransVax™ has received orphan drug designation in the United States for HSCT and SOT patients.
About CMV

CMV is a herpes virus that infects more than half of all adults in the United States by age 40, and is even more widespread in developing countries. While a healthy immune system typically protects an infected person against CMV disease, it rarely succeeds in eliminating the infection, and those whose immune systems are not fully functional are at high risk of CMV reactivation, potentially leading to severe illness or death. Those at greatest risk include transplant patients and infants born to mothers who first become infected during pregnancy. Vical is pursuing two different vaccine approaches for these distinct market segments: TransVax™ for the transplant market and CyMVectin™ for the congenital disease market.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 16,000 employees worldwide. The organization is committed to becoming a global category leader by rapidly establishing a business model in urology, immunology & infectious diseases, oncology, neuroscience, DM complications & metabolic diseases. For more information on Astellas Pharma Inc., please visit www.astellas.com/en.

The Astellas Pharma Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=10000

About Vical

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. The company is developing certain infectious disease vaccines and cancer therapeutics internally. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies that give it access to complementary technologies or greater resources. These strategic partnerships provide the company with mutually beneficial opportunities to expand its product pipeline and address significant unmet medical needs.

Additional information on Vical is available at www.vical.com.

Filing Data

Not available.

Contract

U.S. LICENSE AGREEMENT

THIS U.S. LICENSE AGREEMENT (the “Agreement”) is entered into as of the Effective Date (as defined below) by and between VICAL INCORPORATED, a Delaware corporation (“Vical”), having an address of 10390 Pacific Center Court, San Diego, California, 92121, USA, and ASTELLAS PHARMA INC., a company organized under the laws of Japan (“Astellas”), having an address of 3-11, Nihonbashi-Honcho 2-chome, Chuo-Ku, Tokyo 103-8411, Japan.

RECITALS

WHEREAS, Vical has developed expertise and owns proprietary rights related to Compounds and Products in the Field (each as defined below), as more fully described below;

WHEREAS, Astellas is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, Astellas wishes to obtain, and Vical is willing to grant to Astellas, an exclusive license under Vical Technology (as defined below) to develop and commercialize Products in the Field in the Territory (as defined below), subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. DEFINITIONS

1.1 “Affiliate” shall mean, with respect to a particular party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
1.2 “Astellas Indemnitee” shall have the meaning provided in Section 11.1.

1.3 “Astellas Reserved Product” shall have the meaning provided in Section 3.5(b).

1.4 “BLA” shall mean a Biologics License Application as described in Title 21 of the U.S. Code of Federal Regulations, Part 601, et seq., that is filed with the FDA in order to gain the FDA’s approval to commercialize a biologic pharmaceutical product in the Territory.

1.5 “Calendar Quarter” shall mean each respective period of three consecutive months ending on March 31, June 30, September 30 and December 31.

1.6 “Calendar Year” shall mean each respective period of twelve (12) consecutive months beginning on January 1.

1.7 “City of Hope” shall mean City of Hope, a California nonprofit public benefit corporation located at 1500 East Duarte Road, Duarte, California 91010, USA.

1.8 “City of Hope Agreement” shall mean that certain Exclusive License Agreement, dated February 3, 2003, by and between Vical and City of Hope concerning […]***…, and any amendments made in accordance with its terms. A copy of the City of Hope Agreement has been provided to Astellas under separate cover.

1.9 “CMC” shall mean chemistry, manufacturing and controls.

1.10 “CMV” shall mean cytomegalovirus.

1.11 “Combination Product” shall mean any pharmaceutical product that contains one or more Compound(s) in combination with one or more other therapeutically and/or prophylactically active ingredient(s), whether packaged together or included in a prime-boost regimen or in the same therapeutic formulation, including, in each case, all formulations, line extensions and modes of administration, but excluding, in each case, any formulation with the Vaxfectin Adjuvant. For clarification, poloxamers, other delivery systems and adjuvants shall not be considered therapeutically and/or prophylactically active ingredients.

1.12 “Commercialization Plan” shall have the meaning provided in Section 4.2.

1.13 “Commercially Reasonable Efforts” shall mean that level of efforts and resources consistent with commercially reasonable practices of a company in the pharmaceutical industry with respect to the research, development or commercialization of a pharmaceutical product at a similar stage of research, development or commercialization, taking into account relevant factors including, without limitation, measures of patent coverage, relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of such product, the regulatory structure involved, the market potential of such product and other relevant factors, including comparative technical, legal, scientific and/or medical factors, all as measured by the facts and circumstances in effect at the time when the carrying out of such obligations is due.

1.14 “Committees” shall mean the JDC and JSC, collectively, and “Committee” shall mean the JDC or JSC, as applicable.

1.15 “Competitive Product” shall have the meaning provided in Section 3.5(c).

1.16 “Compound” shall mean […]***… plasmid that encodes […]***… of glycoprotein B and/or phosphoprotein 65 […]***….

1.17 “Confidential Information” shall mean all Information and other proprietary scientific, marketing, financial or commercial information or data, which one party or any of its Affiliates has furnished or otherwise made available to the other party or its Affiliates, whether ***Confidential Treatment Requested

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made available orally, in writing, or in electronic form. Confidential Information shall include all such information provided or made available pursuant to the Confidentiality Agreement. All Vical Technology shall be Confidential Information of Vical. All Confidential Information shall be subject to the Article 9.

1.18 “Confidentiality Agreement” shall mean that certain Confidentiality Agreement […]***….

1.19 “Control” shall mean, with respect to any Information, Patent or other intellectual property right, possession by a party of the ability (whether by ownership, license or otherwise, but without taking into account any rights granted by one party to the other party under the terms of this Agreement) to grant access, a right to use, a license, or a sublicense (as applicable) to such Information, Patent or other intellectual property
1.20 “CytRx” shall mean CytRx Corporation, a Delaware corporation located at 154 Technology Parkway, Technology Park/Atlanta, Norcross, GA 30092, USA.

1.21 “CytRx Agreement” shall mean that certain License Agreement, dated December 7, 2001, by and between Vical and CytRx, and any amendments made in accordance with its terms. A copy of the CytRx Agreement has been provided to Astellas under separate cover.

1.22 “Development Plan” shall mean the annual plan for preclinical and clinical development of Products in the Field, including the budget for such activities to be performed by Vical, and any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the JDC and approved by the JSC.

1.23 “Effective Date” shall have the meaning provided in Section 12.15.

1.24 “Excluded Claim” shall have the meaning provided in Section 12.3(c)(vi).

1.25 “Excluded Product” shall have the meaning provided in Section 3.5(a).

1.26 “Executives” shall have the meaning provided in Section 2.1(d).

1.27 “Existing IND” shall mean the existing Investigational New Drug Application (including any amendments thereto) for Product in the Field in the Territory, as filed by Vical with the FDA pursuant to 21 C.F.R. §312 and Controlled by Vical on the Effective Date.

1.28 “Ex-U.S. Agreement” shall mean that certain Ex-U.S. License Agreement of even date herewith by and between Vical and Astellas, as amended in accordance with its terms.

1.29 “FDA” shall mean the United States Food and Drug Administration, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the Territory.

1.30 “Field” shall mean all therapeutic and prophylactic use to control or prevent CMV infection in (a) Immunocompromised Patients, including HSCT Recipients and SOT Recipients, and (b) human transplant donors, but excluding, in each case, any therapeutic or prophylactic use to control or prevent CMV infection other than as expressly described in clauses (a) and (b).

1.31 “First Commercial Sale” shall mean, with respect to a Product, the first sale for end use to a Third Party in the Territory after the Regulatory Authority has granted Regulatory Approval in the Territory.

1.32 “FTE” shall mean the equivalent of the work time of a full-time employee or contractor of Vical or its Affiliate for a twelve (12) month period ([***...***]) based on ([***...***]) hours worked per 12-month period.

1.33 “Generic Product” shall mean a product that is introduced in the Territory by an entity other than Astellas or a Sublicensee or their respective Affiliates, which contains the same or equivalent (by FDA standards) therapeutically and/or prophylactically active ingredient(s) and is approved in reliance, in whole or in part, on a prior Regulatory Approval of a Product by the FDA.

1.34 “HSCT” shall mean transplantation of hematopoietic stem cells, including peripheral blood stem cells, cord blood stem cells and bone marrow.

1.35 “HSCT Recipient” shall mean a human recipient in a HSCT.

1.36 “HSCT Study” shall have the meaning set forth in Section 5.1.

1.37 “HSR Act” shall have the meaning provided in Section 12.15.

1.38 “HSR Filing Date” shall have the meaning provided in Section 12.15.

1.39 “ICC” shall have the meaning set forth in Section 12.3(c)(i).

1.40 “ICC Rules” shall have the meaning set forth in Section 12.3(c)(i).

1.41 “IFRS” shall mean the International Financial Reporting Standards.
1.42 “Immunocompromised Patients” shall mean human patients whose immune system is not functioning normally because of an immunodeficiency disorder or other disease, or as the result of the administration of immunosuppressive drugs or other drugs that may indirectly cause a reduction of the immune system function. For the avoidance of doubt, elderly patients and pregnant women shall not be deemed Immunocompromised Patients solely because such patients are elderly or pregnant, respectively.

1.43 “Information” shall mean all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, protocols, processes, knowledge, know-how, skill, experience, information, data and results (including pharmacological, toxicological, clinical, analytical and quality control data and results), regulatory filings, marketing reports, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.

1.44 “[…***…]” shall have the meaning set forth in Section […***…].

1.45 “JDC” shall have the meaning set forth in Section 2.2.

1.46 “JSC” shall have the meaning set forth in Section 2.1.

1.47 “Losses” shall have the meaning provided in Section 11.1.

1.48 “[…***…]” shall have the meaning set forth in Section […***…].

1.49 “Manufacturing Coordinators” shall have the meaning set forth in Section 2.7.

1.50 “Manufacturing Plan” shall mean (a) the annual plan for (i) CMC activities (including, without limitation, formulation, analytical and process development, and scale-up, stability, packaging and shipping studies) with respect to Compound and Products in the Field and (ii) the manufacture of Compound and Products in the Field and (b) any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the Manufacturing Coordinators and approved by the JSC during the term of the Services Agreement.

1.51 “Net Sales” shall mean the gross amounts invoiced by Astellas and/or its Sublicensees for sales or other dispositions of Products to Third Parties in the Territory, less the following items, as allocable to such Products (if not previously deducted from the amount invoiced): (a) trade, quantity and cash discounts, credits or allowances; (b) credits or allowances additionally granted upon returns, rejections or recalls or for retroactive price reductions and billing errors; (c) rebates, discounts and chargeback payments in any form granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers; (d) freight, shipping and insurance charges directly related to the distribution of Products; and (e) taxes, duties or other governmental tariffs (other than income taxes).

Upon any sale or other disposition of any Product for any consideration other than exclusively monetary consideration on bona fide arm’s-length terms, for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Product when such Product is sold alone and not as part of a Combination Product.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales. Sales of a Product between Astellas and its Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of Net Sales. Any free-of-charge disposal or use of a Product for development, regulatory or marketing purposes, such as clinical trials, compassionate use or indigent patient programs, shall not be deemed a sale or disposition for purposes of calculating Net Sales.

In the case of a Combination Product, Net Sales for such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where A is the invoice price of the Product that contains one or more Compound(s) as the sole active ingredient(s), if sold separately, and B is the total invoice price of the other active ingredient(s) in the Combination Product, if sold separately. If the other active ingredient(s) in the Combination Product is not sold separately in the Territory, Net Sales for the purpose of determining royalties of the Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction.
A/D, where A is the average invoice price of the Product that contains one or more Compound(s) as the sole active ingredient(s), if sold separately in such country, and D is the average invoice price of the Combination Product in such country. If the Product that contains one or more Compound(s) as the sole active ingredient(s) is not sold separately in the Territory, the parties shall determine Net Sales for such Combination Product by mutual agreement based on the relative contribution of the Product that contains one or more Compound(s) as the sole active ingredient(s) and the other active ingredient(s) in the Combination Product.

Net Sales will be calculated in accordance with this definition and Astellas’ accounting policies generally consistent with IFRS on an accrual basis, as consistently applied. To the extent any accrued amounts used in the calculation of Net Sales are estimates, such estimates shall be trued-up in accordance with Astellas’ accounting policies generally consistent with IFRS, as consistently applied, and Net Sales and related payments under this Agreement shall be reconciled as appropriate.

1.52 “Option” shall have the meaning provided in Section 4.3.

1.53 “Patent Term Extension” shall have the meaning provided in Section 7.3.

1.54 “Patents” shall mean (a) all patents, including design patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, including provisional patent applications and design patent applications, and (b) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.55 “Phase 3 Clinical Trial” shall mean a pivotal clinical trial of a Product conducted in human patients in any country designed to ascertain efficacy and safety of such Product for the purpose of submitting an application for Regulatory Approval to the competent Regulatory Authority in the Territory, including any human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. 312.21(c) or its successor regulation.

1.56 “[…***…]” shall have the meaning set forth in Section […***…].

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1.57 “Product” shall mean any pharmaceutical product that contains one or more Compound(s), alone or as a Combination Product, including, in each case, all formulations, line extensions and modes of administration, including any pharmaceutical product containing any formulation of one or more Compound(s) with poloxamer CRL1005, but excluding, in each case, any formulation with the Vaxfectin Adjuvant.

1.58 “Regulatory Approval” shall mean any and all approvals (including individual and national price and reimbursement approvals, as applicable), licenses, registrations, or authorizations of any country, federal, supra-national, state or local regulatory agency, department, bureau or other governmental entity that are necessary to market and sell a Product in the Field in the Territory.

1.59 “Regulatory Authority” shall mean any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity whose review and/or approval is necessary for the manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a Product in the Field in the Territory.

1.60 “Representatives” shall have the meaning provided in Section 12.1.

1.61 “Reserved Product” shall have the meaning provided in Section 3.5(b).

1.62 “Restricted Period” shall have the meaning provided in Section 3.5(c).

1.63 “Royalty Term” shall have the meaning provided in Section 5.3(b).

1.64 “Sale” shall have the meaning provided in Section 12.7(a).

1.65 “Services Agreement” shall mean that certain Supply and Services Agreement of even date herewith by and between Vical and Astellas, as amended in accordance with its terms.

1.66 “SOT” shall mean solid organ transplantation.

1.67 “SOT Recipient” shall mean a human recipient in a SOT.

1.68 “SPA” shall have the meaning set forth in Section 5.1.

1.69 “Standstill Period” shall have the meaning provided in Section 12.1.
1.70 “[…***…]” shall have the meaning set forth in Section […***…].

1.71 “Sublicense Agreement” shall have the meaning provided in Section 3.2.

1.72 “Sublicensee” shall mean a Third Party or Affiliate to whom Astellas has granted a sublicense of the right to research, develop, make, have made, use, sell, offer for sale, have sold or import a Product in the Field in the Territory, beyond the mere right to purchase such Product.

1.73 “Term” shall have the meaning provided in Section 10.1.

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1.74 “Territory” shall mean the United States of America and its territories and possessions, including Puerto Rico and the District of Columbia.

1.75 “Third Party” shall mean any entity other than Vical or Astellas or an Affiliate of Vical or Astellas.

1.76 “Valid Claim” shall mean a claim of an issued patent or pending patent application within the Vical Primary Patents that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been abandoned, claimed or admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise.

1.77 “Vaxfectin Adjuvant” shall mean Vical’s proprietary cationic lipid-based system known as Vaxfectin® comprising (+)-N-(3-aminopropyl)-N,N-dimethyl-2,3-bis(syn-9-tetradeceneyloxy)-1-propanaminium bromide (GAP-DMORIE) or derivatives thereof and one or more co-lipid(s), including 1,2-diphytanoyl-sn-glycero-3-phosphoethanolamine (DPyPE), which is claimed or disclosed in a Patent Controlled by Vical.

1.78 “Vical Indemnitee” shall have the meaning provided in Section 11.2.

1.79 “Vical Know-How” shall mean Information not included in the Vical Patents that Vical Controls on the Effective Date or during the Term, which Information is necessary or useful for the development, registration, manufacture, use, promotion, distribution, offer for sale, sale, import or export of Compounds or Products in the Field in the Territory, including any Information Controlled by Vical regarding poloxamer CRL1005 under which Vical has an exclusive license pursuant to the CytRx Agreement, and any replication or any part of any of the foregoing. For clarification, in the case of a Combination Product, Vical Know-How does not include any Information Controlled by Vical relating to any therapeutically and/or prophylactically active ingredient in such Combination Product other than a Compound.

1.80 “Vical Patents” shall mean all Patents that Vical Controls as of the Effective Date or during the Term, which Patents claim the composition of matter of, or any method of making or using, Compounds or Products in the Field in the Territory, including the Vical Primary Patents, but excluding […***…]. For clarification, in the case of a Combination Product, Vical Patents do not include any Patents Controlled by Vical, which Patents relate to any therapeutically and/or prophylactically active ingredient in such Combination Product other than a Compound. The Vical Patents as of the Effective Date are listed on EXHIBIT A.

1.81 “Vical Primary Patents” shall mean (a) […***…], and such other Vical Patents as the parties agree to include in this subsection (a) pursuant to the last sentence of this Section 1.81, and (b) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, including provisional patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or

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1.82 “Vical Reserved Product” shall have the meaning provided in Section 3.5(b).

1.83 “Vical Retained Product” shall have the meaning provided in Section 3.5(a).
2. GOVERNANCE

2.1 Joint Steering Committee. For purposes of this Agreement and the Ex-U.S. Agreement, the parties will establish one joint steering committee (the “JSC”) to oversee the activities of the parties with respect to development, regulatory, manufacturing and commercialization matters relating to Products in the Field.

(a) Composition. The JSC will be comprised of three (3) members appointed by Astellas and three (3) members appointed by Vical, or such other equal number of members of each party agreed by Astellas and Vical. Each party will notify the other party of its initial JSC members within thirty (30) days after the Effective Date. Any party may change its JSC members at any time by written notice to the other party, which may be delivered at a scheduled meeting of the JSC. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC. The JSC shall appoint for each meeting a Vical member or an Astellas member, on an alternating basis, as chairman for such meeting, whose role shall be to (i) provide written notice to the JSC members of agenda items proposed for discussion or decision at such meeting at least ten (10) days prior to such JSC meeting, together with appropriate information related thereto, and (ii) convene and preside at such meeting of the JSC; provided, however, that the chairman shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Each party may, with the consent of the other party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such party to attend meetings of the JSC.

(b) Responsibilities. The JSC shall be responsible for monitoring and providing strategic oversight of the parties’ activities with respect to development, regulatory, manufacturing and commercialization matters relating to Products in the Field. Without limiting the foregoing, the JSC shall:

(i) review and approve the Development Plan and the Manufacturing Plan (including any amendments thereto);

(ii) review (but not approve) the Commercialization Plan (including any amendments thereto);

(iii) provide a forum in which Astellas updates Vical, and Vical provides input, with regard to development, regulatory, manufacturing and commercialization matters relating to Products in the Field;

(iv) facilitate the exchange of data and other information between the parties with regard to development, regulatory, manufacturing and commercialization matters relating to Products in the Field; and

(v) perform such other duties as are specifically assigned by the parties to the JSC in this Agreement or any other written agreement between the parties.

(c) Meetings. The JSC will hold meetings at such frequency as determined by the JSC members, but no less than once every six (6) months. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person JSC meetings will alternate between Vical’s offices in San Diego, California and Astellas’ offices in Deerfield, Illinois unless the parties otherwise agree.

(d) Decision-Making. The JSC may make decisions with respect to any subject matter that is within the JSC’s decision-making authority. Subject to this Section 2.1(d), all decisions of the JSC shall be made by unanimous vote, with the representatives of Vical on the JSC collectively having one vote and the representatives of Astellas on the JSC collectively having one vote in all such decisions. If the JSC cannot make a decision with regard to any matter to be decided by the JSC within fifteen (15) days after such matter has been brought to the JSC’s attention, then such matter shall be referred to the Chief Executive Officer of Vical and a senior executive of Astellas who reports directly to the Chief Executive Officer of Astellas (the Chief Executive Officer of Vical and such senior executive of Astellas, collectively, the “Executives”) for resolution. If the Executives cannot resolve the issue within thirty (30) days after the matter has been brought to their attention then, subject to good faith consideration of the views of Vical, and subject to Section 2.4, Astellas’ Executive shall have the tie-breaking vote on such matter.

2.2 Joint Development Committee. For purposes of this Agreement and the Ex-U.S. Agreement, the parties will establish one joint development committee (the “JDC”) with respect to development of Products in the Field.

(a) Composition. The JDC will be comprised of three (3) members appointed by Astellas and three (3) members appointed by Vical, or such other equal number of members of each party agreed by Astellas and Vical. Each party will notify the other party of its initial JDC members within thirty (30) days after the Effective Date. Each party may change its JDC members at any time by written notice to the other party, which may be delivered at a scheduled meeting of the JDC. Any member of the JDC may designate a substitute to attend and perform the functions of that member at any meeting of the JDC. The JDC shall appoint for each meeting a Vical member or an Astellas member, on an alternating basis, as chairman for such meeting, whose role shall be to (i) provide written notice to the JDC members of agenda items...
proposed for discussion or decision at such meeting at least ten (10) days prior to such JDC meeting, together with appropriate information related thereto, and (ii) convene and preside at such meeting of the JDC; provided, however, that the chairman shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Each party may, with the consent of the other party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such party to attend meetings of the JDC.

(b) Responsibilities. The JDC shall be responsible for oversight of the progress of the parties’ activities with respect to development of Compounds and Products in the Field. Without limiting the foregoing, the JDC shall:

(i) draft the Development Plan (including any amendments thereto) for approval by the JSC, and provide a forum for review and discussion of the Development Plan;

(ii) provide a forum for review and discussion of the results of the development of Compounds and Products in the Field;

(iii) facilitate the exchange of Information between the parties regarding the development of Compounds and Products in the Field; and

(iv) perform such other duties as are specifically assigned by the JSC to the JDC.

(c) Meetings. The JDC will hold meetings at such frequency as determined by the JDC members, but no less than once each Calendar Quarter. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person JDC meetings will alternate between Vical’s offices in San Diego, California and Astellas’ offices in Deerfield, Illinois unless the parties otherwise agree.

(d) Decision-Making. The JDC may make decisions with respect to any subject matter that is within the JDC’s decision-making authority. Subject to this Section 2.2(d), all decisions of the JDC shall be made by unanimous vote, with the representatives of Vical on the JDC collectively having one vote and the representatives of Astellas on the JDC collectively having one vote in all such decisions. If the JDC cannot make a decision with regard to any matter to be decided by the JDC within fifteen (15) days after such matter has been brought to the JDC’s attention, then such matter shall be referred to the JSC for resolution in accordance with Section 2.1(d).

2.3 Minutes. Reasonably detailed written minutes will be kept of all Committee meetings and will reflect material decisions made at such meetings. Minutes for each meeting of each Committee will be prepared by the chairman of such meeting and such minutes shall be sent to each member of the respective Committee for review and approval within ten (10) days after the meeting. Minutes will be deemed approved unless a member of the respective Committee objects to the accuracy of such minutes within fifteen (15) days of receipt.

2.4 Scope of Decision-Making. Neither Committee nor any Executive in the course of resolving any dispute of the JSC shall have any right or power to amend this Agreement, to decide any matter in contravention of any terms of this Agreement or to change any rights or obligations of either party under this Agreement. Without limiting the foregoing, neither Committee nor any Executive in the course of resolving any dispute of the JSC shall have the right or power to (a) require Vical to perform studies or other development work that is not expressly agreed in writing by Vical and Astellas, or (b) require Vical to incur expenses other than as set forth in this Agreement or otherwise expressly agreed in writing by Vical and Astellas.

2.5 Expenses. Each party shall bear all its own costs in connection with its participation in the Committees, including expenses incurred by the members that it appoints to the Committees in connection with their activities as members of the Committees.

2.6 Withdrawal. At any time during the Term and for any reason, Vical shall have the right to withdraw from participation in either Committee or both Committees upon written notice to Astellas, which notice shall be effective immediately upon receipt ("Withdrawal Notice"). Following the issuance of a Withdrawal Notice and subject to this Section 2.6, Vical’s representatives on the applicable Committee(s) shall not participate in any meetings of the applicable Committee(s), nor shall Vical have any right to vote on decisions within the authority of the applicable Committee(s). If, at any time, following the issuance of a Withdrawal Notice, Vical wishes to resume participation in the applicable Committee(s), Vical shall notify Astellas in writing and, thereafter, Vical’s representatives on the applicable Committee(s) shall be entitled to attend any subsequent meeting of the applicable Committee(s) as if a Withdrawal Notice had not been issued by Vical. Following Vical’s issuance of a Withdrawal Notice, unless and until Vical resumes participation in the applicable Committee(s) in accordance with this Section 2.6: (a) all meetings of the Committee(s) shall be held at Astellas’ facilities; (b) Astellas shall have the right to make the final decision on all matters within the scope of authority of the Committee(s); and (c) Vical shall have the right to continue to receive the minutes of the Committee(s) meetings, but shall not have the right to approve the minutes for any meeting of the applicable Committee(s) held after Vical’s issuance of a Withdrawal Notice. For clarity, if Vical withdraws and then resumes participation in a Committee, it shall not have any right to retroactively review or modify any decision made by the Committee during Vical’s withdrawal period.
3. LICENSES AND OTHER RIGHTS

3.1 License and Sublicense Grant. Subject to the terms and conditions of this Agreement, Vical hereby grants to Astellas an exclusive (even as to Vical and its Affiliates, but subject to the Option, to Vical’s performance of such development, regulatory and manufacturing activities as agreed in writing by the parties), royalty-bearing license and sublicense, with the right to sublicense in accordance with Section 3.2, under the Vical Technology, to research, develop, register, make, have made, use, promote, distribute, sell, offer for sale, have sold, import and export Products in the Field in the Territory; provided that the sublicense with respect to any Vical Patents licensed to Vical under the City of Hope Agreement shall be non-exclusive.

3.2 Sublicensing. Astellas shall have the right to grant sublicenses under the license granted in Section 3.1 to one or more Third Parties or Affiliates subject to the provisions of this Section 3.2. Each agreement under which Astellas grants a sublicense under the license granted in Section 3.1 (each, a “Sublicense Agreement”) shall (a) be in writing and (b) be consistent with, and subject to the terms and conditions of, this Agreement (including the terms relating to sublicenses of Vical Technology licensed or conveyed to Vical under the City of Hope Agreement and CytrRx Agreement, as applicable). Astellas acknowledges and agrees that the right to grant sublicenses under the rights granted to Vical with respect to Vical Technology licensed or otherwise conveyed to Vical under the City of Hope Agreement is limited to sublicenses granted to Astellas’ Affiliate(s) (for so long as each Affiliate sublicensee remains an Affiliate) and such Affiliate sublicensees shall not have the right to grant further sublicenses to any Third Party. Astellas shall be responsible for compliance of any Sublicensee with this Agreement. Any breach of this Agreement by the acts or omissions of a Sublicensee shall be a breach of this Agreement by Astellas. Astellas shall provide Vical with a full and complete copy of each Sublicense Agreement with a Third Party (and if required by the CytRx Agreement and/or the City of Hope Agreement, each Sublicense Agreement with an Affiliate) within […] days after execution thereof; provided, that Vical may redact any confidential information contained therein that is not necessary to disclose to ensure compliance with this Agreement.

3.3 In-License Agreements. Astellas acknowledges that the Vical Technology licensed or otherwise conveyed to Vical under the City of Hope Agreement or the CytrRx Agreement is subject to the applicable terms and conditions of the City of Hope Agreement or the CytrRx Agreement. In the event that City of Hope or CytrRx notifies Vical of a default or breach under the City of Hope Agreement or the CytrRx Agreement, respectively, related to any failure by Astellas or any Sublicensee to perform any obligation or covenant under this Agreement, the parties will discuss how to resolve the matter and, if the parties agree to a proposed resolution of the matter, they will cooperate in responding to City of Hope or CytrRx, as applicable. If Astellas does not resolve such matter as agreed by the parties, or if the parties do not agree to a resolution of the matter, then Vical shall have the right, but not the obligation, to take such actions as reasonably necessary or appropriate to cure such default or breach and shall keep Astellas reasonably informed regarding such actions, and Astellas shall promptly reimburse Vical for all reasonable costs and expenses actually incurred by Vical solely as a result of such default or breach by Astellas or any Sublicensee. In the event Vical receives from CytrRx or City of Hope notice of termination of the CytrRx Agreement or the City of Hope Agreement,

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respectively, Vical shall notify Astellas thereof within […] days after receipt by Vical of such notice. Vical shall have no liability to Astellas for any termination or modification of the City of Hope Agreement or the CytrRx Agreement arising out of or resulting from the failure of Astellas or any Sublicensee to abide by, comply with or perform under the terms, conditions or obligations of this Agreement. In addition, in the event the rights to the Vical Technology licensed to Vical under the CytrRx Agreement cease to be licensed to Vical under the CytrRx Agreement and Astellas obtains a license with respect to such Vical Technology directly from CytrRx, then Astellas may deduct from the applicable payments owed to Vical hereunder the amount actually paid by Astellas to CytrRx for such license with respect to such Vical Technology up to the amount that Vical would have been obligated to pay to CytrRx under the CytrRx Agreement with respect to such payment.

3.4 Disclosure of Vical Know-How. Upon Astellas’ request, Vical shall make available to Astellas Vical Know-How in Vical’s possession that has not previously been provided to Astellas, including any raw data and/or original data relating to Compounds and Products in the Field; provided that any Vical Know-How relating to the manufacture of Compounds and Products in the Field shall be made available through a technology transfer arrangement as provided in the Services Agreement. Vical shall not destroy, discard or otherwise dispose of or shall have not destroyed, discarded or otherwise disposed of any Vical Know-How without prior written approval of Astellas, which approval shall not be unreasonably
3.5 Agreements.

(a) By Vical. During the Term, Vical shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, any Product that contains any formulation of one or more Compound(s) with poloxamer CRL1005 (an “Excluded Product”) outside the Field in the Territory or (ii) any pharmaceutical product that contains any formulation of one or more Compound(s) with the Vaxfectin Adjuvant, alone or in combination with one or more other therapeutically and/or prophylactically active ingredients, in any dosage form or mode of administration (a “Vical Retained Product”) in the Field in the Territory, provided, however, that nothing shall prevent Vical from, directly or indirectly through any Affiliate or Third Party, marketing, promoting, distributing, offering for sale or selling, or granting any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, any Vical Retained Product so long as Vical or such Affiliate or Third Party does not market or promote the Vical Retained Product for use in the Field in the Territory.

(b) Reserved Products. The provisions of this Section 3.5(b) shall apply with respect to any Product other than an Excluded Product (a “Reserved Product”) outside the Field in the Territory. Vical retains all rights, directly or indirectly through any Affiliate or Third Party, to research, develop, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to research, develop, market, promote, distribute, offer for sale or sell, any Reserved Product outside the Field in the Territory, subject to this Section 3.5(b) (any such Reserved Product with respect to which Vical has retained rights, a “Vical Reserved Product”). Astellas may notify Vical in writing that it proposes to designate

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any Reserved Product as an “Astellas Reserved Product,” specifying whether such Reserved Product would contain a Compound alone, a Compound formulated with an adjuvant (identifying the adjuvant) or a Compound administered through a delivery system (identifying the delivery system). Astellas may provide such written request at any time after it or its Sublicensee has initiated good laboratory practices preclinical studies of such Reserved Product. The Reserved Product specified in such written notice from Astellas shall be deemed an Astellas Reserved Product unless Vical provides written notice to Astellas within thirty (30) days after Vical’s receipt of such written notice from Astellas that Vical has granted a license or similar rights with respect to such Product to a Third Party or has initiated good laboratory practices preclinical studies of such Reserved Product, in which case such Reserved Product shall not be an Astellas Reserved Product and shall remain a Vical Reserved Product. During the Term for so long as Astellas uses Commercially Reasonable Efforts to develop, manufacture and commercialize an Astellas Reserved Product, Vical shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, any Astellas Reserved Product outside the Field in the Territory.

(c) By Astellas. During the Term, Astellas shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense to market, promote, distribute, offer for sale or sell, any DNA vaccine product for use in the Field in the Territory, other than Products in the Field in the Territory (a “Competitive Product”). Further, Astellas agrees not to practice any Vical Technology except to develop, register, make, have made, use, promote, distribute, sell, offer for sale, have sold, import and export Products in the Field in the Territory during the Term in accordance with the terms of this Agreement and any other written agreement between the parties. If Astellas or any of its respective Affiliates signs a definitive agreement whereby it would acquire a license to or ownership of a Competitive Product, acquire ownership or control of or otherwise merge with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product or be acquired by or otherwise merged with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product, in all such cases that would result in a violation of this Section 3.5(c), then Astellas or its Affiliate shall promptly notify Vical in writing and, as promptly as reasonably possible but in no event later than [***] months after the signing date of such definitive agreement (“Restricted Period”), either (i) divest itself of such Competitive Product and notify Vical in writing of such divestiture, or (ii) notify Vical in writing that such Competitive Product shall be incorporated into this Agreement and thereafter such Competitive Product shall be a Product subject to the terms and conditions of this Agreement. If Astellas or its Affiliate elects to divest itself of such Competitive Product, such divestiture shall occur by an outright sale to a Third Party of all of Astellas’ and its Affiliate’s rights to such Competitive Product. For clarity, the commercialization of such Competitive Product during the Restricted Period shall not constitute a violation of Section 3.5(c).

3.6 Retained Rights; No Implied Licenses. Except for the rights and licenses expressly granted in this Agreement, Vical retains all rights under the Vical Technology, and no rights shall be deemed granted by Vical to Astellas by implication, estoppel or otherwise.

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4. DEVELOPMENT AND COMMERCIALIZATION OF PRODUCTS

4.1 Development of Products in the Field in the Territory. Subject to the terms and conditions of this Agreement, during the Term, Astellas shall be solely responsible for the development of and obtaining Regulatory Approvals for Products in the Field in the Territory, including all costs associated with such activities, subject to the terms of any written agreement between the parties providing for Vical to perform any such activities. Without limiting the foregoing, Astellas shall have sole responsibility, at Astellas’ cost and expense, for conducting clinical and non-clinical studies of Products in the Field in the Territory and for preparing, filing, obtaining and maintaining the appropriate applications with Regulatory Authorities, and for all contacts with Regulatory Authorities, regarding Products in the Field in the Territory. Vical will transfer the Existing IND to Astellas, the timing of such transfer to be discussed in good faith by Vical and Astellas, provided, that such transfer shall be completed by the date of commencement of the first Phase 3 Clinical Trial of a Product in the Field in the Territory. Astellas shall use Commercially Reasonable Efforts to develop, and to file for, obtain and maintain Regulatory Approvals for, at least one Product [***] and at least one Product [***] in the Field in the Territory. Astellas shall perform all development and regulatory activities with respect to Products in the Field in the Territory in compliance with the Development Plan and all applicable laws, rules and regulations. Furthermore, Astellas shall be solely responsible for the timely reporting of all relevant adverse drug reactions/experiences, Product quality, Product complaints and safety data relating to Compounds and Products, in each case in the Field in the Territory, to the appropriate Regulatory Authorities in accordance with the applicable laws, rules and regulations of the Regulatory Authorities in the Territory. Prior to commencement of the first Phase 3 Clinical Trial, Vical shall complete transfer from Vical to Astellas of the global safety database with respect to Compounds and Products in the Field. In addition, each party shall cooperate, and shall cause its Affiliates, licensees and Sublicensees to cooperate, in implementing and adhering to a safety data exchange arrangement with respect to Compounds and Products in the Territory that shall be set forth in a safety data exchange agreement executed by the parties.

4.2 Commercialization of Products in the Field in the Territory. Subject to the terms and conditions of this Agreement (including the Option), during the Term, Astellas shall be solely responsible for the commercialization of Products in the Field in the Territory, including any post-marketing studies of Products in the Field in the Territory, including all costs associated with such activities. Astellas shall use Commercially Reasonable Efforts to commercialize at least one Product [***] and at least one Product [***] in the Field in the Territory. Within a reasonable time prior to anticipated commercial launch of a Product, Astellas shall prepare a plan for the marketing, promotion and commercialization of such Product in the Field in the Territory, which plan shall be in reasonable scope and detail and may be amended by Astellas (the “Commercialization Plan”). Astellas shall provide, or cause to be provided, the Commercialization Plan to the JSC for review on an annual basis and shall provide, or cause to be provided, any material amendments to the Commercialization Plan to the JSC for review. Astellas shall perform all commercialization activities with respect to Products in the Field in the Territory in compliance with the Commercialization Plan and all applicable laws, rules and regulations. Without limiting the foregoing, Astellas shall have the sole right and responsibility for all commercial and medical affairs matters with respect to Products in the Field in the Territory.

4.3 Commercialization Option. Astellas hereby grants to Vical an exclusive option to co-promote and/or collaborate in medical affairs activities with respect to Products in the Field in the Territory (the “Option”). Vical may exercise the Option by providing written notice to Astellas no later than [***] days after Astellas provides written notice to Vical of [***]. For clarification, Vical shall in no event be obligated to make any payment to Astellas in connection with exercising the Option. Upon timely exercise by Vical of the Option, the parties shall engage in good faith negotiations to conclude a separate written agreement within [***] days after exercise of the Option (or such longer period as agreed by the parties), which agreement would provide for mutually agreeable terms pursuant to which Vical would co-promote and/or collaborate in medical affairs activities with respect to Products in the Field in the Territory in accordance with the Commercialization Plan and would provide for Astellas [***] provided, however, that Vical’s activities thereunder shall not exceed [***] percent ([***]% of the total activities of the parties in each of the co-promotion and the medical affairs. Notwithstanding the exercise of the Option or the execution of an agreement as set forth in the immediately preceding sentence, Astellas shall at all times remain obligated to pay the applicable amounts specified under Article 5 with respect to Products.

4.4 Manufacture and Supply of Products. Subject to the terms and conditions of this Agreement and the Services Agreement, during the Term, Astellas shall be solely responsible for the manufacture and supply of Products in the Field in the Territory, including CMC-related work necessary for obtaining Regulatory Approval for Products in the Field in the Territory, including all costs associated with such activities. Astellas shall perform all manufacturing activities with respect to Products in the Field in the Territory in compliance with the Manufacturing Plan and all applicable laws, rules and regulations.

4.5 Disclosure Regarding Astellas’ Efforts. Astellas shall keep Vical regularly and fully informed regarding development, regulatory, manufacturing and commercialization activities of Astellas and its Sublicensees with respect to Products in the Field in the Territory. Without limiting the foregoing, Astellas shall keep Vical reasonably informed of the progress of such activities, through the JSC, the JDC and directly, and shall, within [***] after the end of each Calendar Year during the Term, provide Vical a report setting forth a reasonably detailed description of the progress and status of development, manufacture and commercialization of, and regulatory strategy and filings made and Regulatory Approvals obtained for, Products in the Field in the Territory, and a reasonably detailed description of the development, manufacture, commercialization and regulatory activities that Astellas plans to undertake during the subsequent Calendar Year.
4.6 Subcontractors. Astellas may perform some or all of its obligations under this Article 4 through one or more subcontractors (which may include Vical). Astellas shall remain responsible for the performance by any Third Party subcontractors and the compliance of such Third Party subcontractors with the provisions of this Agreement in connection with such performance.

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5. FEES AND PAYMENTS

5.1 Upfront Fee. Astellas shall make a non-refundable, non-creditable payment to Vical of US$[...***...], payable as follows: (a) US$[...***...]
shall be paid to Vical within thirty (30) days after the Effective Date; and (b) US$[...***...]
shall be paid to Vical within thirty (30) days after the earliest of (i) agreement by the FDA in a special protocol assessment ("SPA") on a protocol with the primary endpoint of [...***...]
for a Phase 3 Clinical Trial of a Product for use in HSCT Recipients in the Field (an "HSCT Study"); (ii) agreement by Astellas and Vical to go forward with an HSCT Study without a SPA or (iii) initiation (enrollment of first patient) of an HSCT Study.

5.2 Milestone Payments. Within thirty (30) days after the occurrence of each of the following milestone events, Astellas shall pay to Vical the corresponding non-refundable, non-creditable milestone payment set forth below (whether such milestone event is achieved by Astellas or any Sublicensor):

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Each of the milestone payments described in this Section 5.2 shall be payable one time for the first achievement of such milestone event by any applicable Product, regardless of the number of other Products that subsequently achieve such milestone event. For clarification, in the event two or more milestone events are achieved at the same time, the milestone payments for both milestone events shall be due.

5.3 Royalties.

(a) Royalty Rate. Astellas shall pay Vical royalties equal to [⋯***…] percent ([⋯***…]%) of Net Sales of Products in the Field in the Territory.

(b) Royalty Term. Royalties under this Section 5.3 shall be payable on a Product-by-Product basis during the period of time commencing on the First Commercial Sale of such Product in the Territory and ending upon the latest to occur of (i) expiration of the last to expire Valid Claim with respect to such Product (or any Compound therein), (ii) expiration of any data or other regulatory exclusivity period for such Product in the Territory or (iii) ten (10) years after the earliest date of First Commercial Sale of such Product for any indication in the Field in the Territory (the "Royalty Term").

(c) Royalty Reduction. During any portion of the Royalty Term for a Product in which (i) there is no Valid Claim with respect to such Product (or any Compound therein), (ii) a Generic Product(s) is marketed in the Territory, and (iii) unit share of the Generic Product(s) in the Territory are equal to or greater than [⋯***…] percent ([⋯***…]%) of total unit number of such Product and the Generic Product(s) sold in the Territory for at least [⋯***…] ([⋯***…]) ([⋯***…]) Calendar Quarters, the royalty rate payable under Section 5.3(a) on Net Sales of such Product in the Territory during such portion of the Royalty Term shall be reduced by [⋯***…] percent ([⋯***…]%) (i.e., from [⋯***…]% to [⋯***…]%); provided, however, that during any such portion of the Royalty Term for such Product that Vical owes royalties on Net Sales of such Product in the Territory under both of the City of Hope Agreement and the CytRx Agreement, the royalty rate payable under Section 5.3(a) on Net Sales of such Product in the Territory during such portion of the Royalty Term shall instead be reduced to [⋯***…] percent ([⋯***…]%).

5.4 Payments to Third Parties. Vical shall be responsible for any fees, milestone and royalty payments owed to City of Hope and CytRx under the City of Hope Agreement and CytRx Agreement, respectively. Except as provided in the preceding sentence, Astellas (or its Sublicensee) shall be responsible for any and all payments owed to any Third Party for any Patents, Information or other intellectual property rights licensed or acquired by Astellas (or its Sublicensee) after the Effective Date in order to develop, make, have made, use, promote, distribute, sell, offer for sale, have sold or import any Product in the Field in the Territory (it being understood that the decision to license or acquire any such Patents, Information or other intellectual property rights shall be at Astellas’ (or its Sublicensee’s) discretion).

6. PAYMENT; RECORDS; AUDITS

6.1 Payment; Reports. All payments due under this Agreement shall be paid within [⋯***…] ([⋯***…]) days of the end of each Calendar Quarter, unless otherwise specifically provided herein. Royalty payments shall be calculated and reported for each Calendar Quarter. Each royalty payment due to Vical shall be accompanied by a report of Net Sales by Astellas and its Sublicensees, each in sufficient detail to permit confirmation of the accuracy of the payment.

6.2 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in U.S. dollars. When conversion of payments from any foreign currency is required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange (i.e., the average of TTS rate and TTB rate) for the currency of the country from which the royalties are payable as published by the Bank of Tokyo Mitsubishi UFJ, Ltd. in Japan (or such other bank or source agreed in writing by the parties), during the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank account designated in writing by Vical, unless otherwise specified in writing by Vical.

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6.3 Income Tax Withholding. Each party will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by the paying party, the paying party will (a) deduct such taxes from the payment made to the other party, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to the other party and certify its receipt by the taxing authority within thirty (30) days following such payment. For purposes of this Section, each party agrees to provide the other with reasonable assistance to enable the due deduction by the paying party and appropriate recovery by the other party, which assistance includes, but is not limited to, provision of any tax forms and other information that may be reasonably necessary in order for the paying party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.

6.4 Records; Audits. Astellas shall keep, and require its Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Vical pursuant to this Agreement, as well as the expenses of any [...***...]. Such books and records shall be kept for such period of time required by law, but no less than [...***...][(...***...)] years following the end of the Calendar Quarter to which they pertain. Vical (or City of Hope or CytRx, as applicable) shall have the right to cause an independent, certified public accountant, reasonably acceptable to Astellas, to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than the preceding [...***...][(...***...)] years. Except for any audits of the expenses of any [...***...], for-cause audits or as otherwise permitted under the City of Hope Agreement or CytRx Agreement, as applicable, audits may be exercised not more often than [...***...][(...***...)] each year, [...***...][(...***...)] for each relevant record, and during normal business hours upon reasonable prior written notice to Astellas. Any such auditor shall not disclose Astellas' Confidential Information to Vical, except to the extent such disclosure is necessary to verify the accuracy of such records. Prompt adjustments shall be made by the parties to reflect the results of such audit. Vical (or City of Hope or CytRx, as applicable) shall bear the full cost of such audit unless such audit discloses an underpayment by Astellas of more than [...***...][(...***...)] percent of [...***...][(...***...)] of the amount of royalties or other payment due under this Agreement or an overstatement by more than [...***...][(...***...)] percent of [...***...][(...***...)] of the expenses of any [...***...], in which case, Astellas shall bear the full cost of such audit and shall promptly remit to Vical the amount of any underpayment.

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6.5 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of [...***...][(...***...)] above the U.S. Prime Rate (as set forth by Bloomberg (Ticker symbol PRIME index)); provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Vical from exercising any other rights it may have as a consequence of the lateness of any payment.

7. INTELLECTUAL PROPERTY

7.1 Ownership. Vical has, and shall retain, all right, title and interest in and to, the Vical Patents and Vical Know-How. [...***...].

7.2 Patent Prosecution and Maintenance. As between the parties, Vical (or its licensor, as applicable) shall have the sole right, but not the obligation, to prepare, file, prosecute (including any interferences, extensions, reissue proceedings and reexaminations) and maintain the Vical Patents, at its sole cost (subject to Section 7.3) and by counsel of its own choice. Vical shall provide Astellas with reasonable opportunity to review and comment on any material document that Vical intends to file or cause to be filed with the relevant intellectual property or patent office with respect to the Vical Patents in the Territory, and Vical shall give due consideration to such comments provided by Astellas. Astellas agrees to reasonably cooperate in the preparation, filing, and prosecution of any Vical Patents and in the obtaining and maintenance of any supplementary protection certificates and the like with respect to any Vical Patent claiming a Product being developed or commercialized by Astellas or Sublicensees in the Territory. Such cooperation includes, but is not limited to, promptly informing Vical of any matters coming to Astellas' attention that may affect the preparation, filing, prosecution or maintenance of any Vical Patents. In the event that Vical determines to abandon or cease prosecution or maintenance of any Vical Patent in the Territory, Vical shall provide reasonable prior written notice to Astellas of such intention to abandon or cease prosecution or maintenance. In such case, subject to the rights of Vical’s licensor with respect to any Vical Patent licensed to Vical by a Third Party, Astellas may elect, upon written notice by Astellas to Vical, to cause Vical to continue prosecution and/or maintenance of such Vical Patent in the Territory, at Vical’s sole cost and expense for any Vical Primary Patent, at Astellas’ sole cost and expense and in accordance with Astellas’ instructions for any such Vical Patent that is not a Vical Primary Patent. Astellas shall reimburse Vical for such costs and expenses incurred by Vical in connection with prosecuting and/or maintaining any such Vical Patent that is not a Vical Primary Patent within thirty (30) days from the date of invoice for such costs and expenses by Vical. In the event that Astellas desires to cease bearing the costs and expenses with respect to any such Vical Patent, Astellas shall provide reasonable prior written notice to Vical of such intention. In such case, Vical shall have the right, but not the obligation, to elect to continue prosecuting and maintaining any such Vical Patent at its own expense.

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7.3 Additional Patent Term Extension Obligations. Astellas shall keep Vical fully informed of the progress of Astellas (and, as applicable, its Sublicensee(s)) toward Regulatory Approval of the first Product in the Territory. Astellas shall assist Vical in determining with respect to such
Product if the Vical Patents would be eligible for patent term extension pursuant to 35 U.S.C. §§154–56 ("Patent Term Extension"). Astellas acknowledges that time is of the essence with respect to submission of any application for Patent Term Extension. Astellas shall give Vical notification in writing of its (or, as applicable, its Sublicensee(s)) first obtaining Regulatory Approval of a Product in the Territory within [...] days of receipt of written notice of such Regulatory Approval from the applicable Regulatory Authority. Vical shall apply for Patent Term Extension for any Vical Primary Patent as requested by Astellas, at Vical’s expense. At Vical’s request, Astellas shall, in a timely manner, reasonably assist Vical in preparing an application for Patent Term Extension. Astellas (and, as applicable, its Sublicensee(s)) shall reasonably cooperate with Vical in preparing the applications for Patent Term Extension. Astellas agrees to join in such applications at Vical’s request. Astellas shall reasonably support such applications and shall provide such information as may be requested by Vical or any Regulatory Authority in support of such applications.

7.4 Patent Enforcement. Each party shall promptly notify the other in writing of any alleged or threatened infringement of any Vical Patent in the Territory of which such party becomes aware. The following provisions shall apply with respect to any action or proceeding with respect to infringement by a Third Party of any Vical Patent in the Territory, subject to the terms of the City of Hope Agreement and CytRx Agreement with respect to Vical Patents licensed from City of Hope and CytRx, respectively.

(a) Enforcement.

(i) Astellas First Right. As between the parties, excepting Patents licensed to Vical under the CytRx Agreement and the City of Hope Agreement, Astellas shall have the first right to bring and control any action or proceeding with respect to infringement by a Third Party of any Vical Patent in the Field in the Territory, at its own expense and by counsel of its own choice, except as provided in this Section 7.4(a)(i) and except that Section 7.4(a)(ii) shall instead apply with respect to infringement by a Third Party of any Vical Patent both in the Field and outside the Field in the Territory. Vical shall have the right, at its own expense, to be represented in any such action with respect to infringement of any Vical Patents in the Field in the Territory by counsel of its own choice, and Astellas and its counsel shall reasonably cooperate with, and take into account the view of, Vical and its counsel in strategizing, preparing and presenting any such action or proceeding. If Astellas fails to bring an action or proceeding with respect to infringement of any Vical Patent in the Field in the Territory within (A) [...] days following the notice of alleged infringement or (B) [...] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Vical shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Astellas shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) Vical First Right. As between the parties, Vical shall have the first right to bring and control any action or proceeding with respect to infringement by a Third Party of any Vical Patent (including any Patents licensed to Vical under the CytRx Agreement

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and the City of Hope Agreement) in the Territory other than as set forth in Section 7.4(a)(i) at its own expense and by counsel of its own choice, except as provided in this Section 7.4(a)(ii). Astellas shall have the right, at its own expense, to be represented in any such action with respect to any such infringement of any Vical Patents in the Territory by counsel of its own choice, and Vical and its counsel shall reasonably cooperate with, and take into account the view of, Astellas and its counsel in strategizing, preparing and presenting any such action or proceeding. If Vical fails to bring an action or proceeding with respect to such infringement of any Vical Patent in the Territory within (A) [...] days following the notice of alleged infringement or (B) [...] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, such infringement of such Vical Patent would have a material adverse effect on Astellas’ rights with respect to any Product in the Field in the Territory, then Astellas shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Vical shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(b) Cooperation; Awards. In the event a party brings an infringement action in accordance with this Section 7.4, the other party shall reasonably cooperate, including if required to bring such action, joining such action as a necessary party or the furnishing of a power of attorney. Neither party shall have the right to settle any patent infringement litigation with respect to any Vical Patent under this Section 7.4 in a manner that diminishes the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld). Except as otherwise agreed to by the parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding shall be used first to reimburse the parties’ documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining damages relating to the Products (including lost sales or lost profits with respect to Products) shall be retained by the party that brought and controlled the action and, if Astellas brought and controlled such action, shall be deemed Net Sales subject to the royalty provisions of Section 5.3.

7.5 Third Party Infringement Claims. Each party shall promptly notify the other party in writing of any allegation by a Third Party that the activity of either party with respect to the development, manufacture or commercialization of any Product in the Field in the Territory infringes or may infringe the intellectual property rights of such Third Party. Vical shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Vical’s activities, at Vical’s sole cost and expense and by counsel of its own choice, and Astellas
shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Astellas shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Astellas’ activities, at Astellas’ sole cost and expense and by counsel of its own choice, and Vical shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Neither party shall enter into any settlement or compromise of any action under this Section 7.5 which would in any manner diminish the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld).

7.6 Orange Book Listing. Astellas shall have the sole right to make any filing with respect to any Vical Primary Patents in connection with the FDA’s Orange Book. Upon request of Astellas, Vical shall cooperate with Astellas to file appropriate information with the FDA listing any Vical Primary Patents in the Orange Book.

7.7 Patent Marking. Astellas shall mark all Products made, used or sold in the Territory, or their containers, if required under applicable laws, rules and regulations relating to patent marking.

7.8 Certification. Astellas and Vical each will immediately (and no later than five (5) days following the date when Astellas or Vical becomes aware the certification described in this Section), give notice to the other of any certification of which they become aware filed under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, as amended, arising from the filing of an application for the regulatory approval of a Generic Product claiming that Patents covering any Product are invalid or non-enforceable or that infringement will not arise from the manufacture, use or sale of any Product in the Field in the Territory by a Third Party. Any action based on such a certification shall be brought and controlled as provided in Section 7.4.

7.9 Trademarks. Astellas shall be responsible for selection, registration and maintenance of the trademark(s) for Products in the Field in the Territory, at its own cost, and all such trademark(s) shall be filed and exclusively owned by Astellas. At Astellas’ election, Vical shall grant to Astellas during the Term a royalty-free exclusive license with the right to sublicense under Vical’s interest in Vical’s common law trademark TransVax™ for use solely in connection with the sale and offer for sale of Products in the Field in the Territory. Such license shall become perpetual in the event Astellas obtains a perpetual and fully paid-up license and sublicense under the Vical Technology pursuant to Section 10.1. For clarity, Vical is and shall remain the owner of all right, title and interest in and to Vical’s common law trademark TransVax™ and the goodwill now and hereafter associated therewith shall at all times inure to the benefit of Vical.

8. REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each party represents and warrants to the other party as of the Effective Date that:

(a) Organization. It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Authorization. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action.

(c) Binding Agreement. This Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

(d) Agreements with Employees and Contractors. All of such party’s employees or contractors acting on its behalf pursuant to this Agreement or any other written agreement between the parties are and will be obligated under a binding written agreement to comply with obligations of confidentiality and non-use consistent with those set forth in Article 9.

(e) No Debarment. Such party is not debarred under the United States Federal Food, Drug and Cosmetic Act or comparable laws in any other country or jurisdiction, and it does not, and will not during the Term, employ or use the services of any person or entity who is debarred, in connection with the development, manufacture or commercialization of the Products. In the event that either party becomes aware of the debarment or threatened debarment of any person or entity providing services to such party, including the party itself and its Affiliates or Sublicensees, which directly or indirectly relate to activities under this Agreement, the other party shall be immediately notified in writing.

8.2 Vical Representations and Warranties. Vical represents, warrants and covenants to Astellas as of the Effective Date that:
(a) Control. Except for those rights in-licensed by Vical under the City of Hope Agreement and CytRx Agreement, Vical is the sole owner of all of the Vical Technology existing as of the Effective Date, free and clear of all liens.

(b) Right to Grant License. Vical has the right to grant the license and sublicenses it grants to Astellas under Section 3.1 of this Agreement.

(c) No Conflicting Grant of Rights. Vical and its Affiliates have not, and will not during the Term, grant any right to any Third Party that would conflict with the rights granted to Astellas hereunder or, except with Astellas’ prior written consent, allow a Third Party to create and maintain any security interest in (i) Vical Patents (excluding Patents licensed to Vical under the CytRx Agreement and the City of Hope Agreement) or (ii) any rights granted to Astellas hereunder, to secure third-party financing; provided that Vical may allow a Third Party to create and maintain such a security interest without Astellas’ prior written consent if such security interest is subject to the rights granted to Astellas under such Vical Patents or other rights as set forth in this Agreement.

(d) No Infringement. Vical has not received any notice alleging, and is not otherwise actually aware, that the practice of the Vical Patents infringes or may infringe any Patent(s) of any Third Party.

(e) No Legal Actions. As of the Effective Date, there are no pending legal actions, nor has Vical received any written notice regarding any pending legal actions, with respect to the Vical Technology, and no Vical Patent is the subject of any interference, opposition, cancellation or other protest proceeding.

(f) Disclosure. Up to and including the Effective Date, Vical has made available to Astellas (i) all material information (including without limitation pre-clinical and clinical data and the Existing IND) in its possession or Control relating to the Compound, the Product(s) and Vical Patents in the Field in the Territory, including material information in its possession or Control that is material to the utility or safety of the Compound and/or the Product(s) in the Field in the Territory, and (ii) all safety data in its possession or Control relating to the Compound and Product(s).

(g) Existing IND. Vical has sufficient legal and/or beneficial title and ownership in the Existing IND sufficient to transfer such Existing IND to Astellas in accordance with Section 4.1; no Regulatory Authority has, to Vical’s knowledge, commenced or threatened to initiate any action or proceeding to refuse to file, reject, not approve, or withdraw the Existing IND, nor has Vical received any notice to such effect; and to Vical’s knowledge, Vical is not in violation of any applicable laws that could reasonably be expected to form the basis for such an action.

8.3 Disclaimer. Except as expressly set forth herein, THE VICAL TECHNOLOGY IS PROVIDED “AS IS,” AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

8.4 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section 8.4 shall not be construed to limit either party’s indemnification obligations under Article 11 or its right to obtain recover damages for breach of Article 9. For clarification, payments under Article 5 shall not be considered special, incidental, consequential or punitive damages.

9. CONFIDENTIALITY

9.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and until the […***…] anniversary of the date of expiration or termination of the later to expire or terminate of this Agreement or the Ex-U.S. Agreement, each party (in such capacity, the “receiving party”) shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement or the Confidentiality Agreement any Confidential Information of the other party (in such capacity, the “disclosing party”). The receiving party may use Confidential Information of the other party only to the extent required to accomplish the purposes of this Agreement. The receiving party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but not less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information of the disclosing party. The receiving party will promptly notify the disclosing party upon discovery of any unauthorized use or disclosure of the Confidential Information of the disclosing party. Without limiting the foregoing, the parties acknowledge that Vical Know-How includes valuable trade secrets and that it is in the interests of both parties to

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9.2 Exceptions. Confidential Information shall not include any information which the receiving party can demonstrate by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available; (b) is known by the receiving party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the receiving party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the receiving party without the use of Confidential Information of the disclosing party.

9.3 Authorized Disclosure. The receiving party may disclose Confidential Information of the disclosing party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) prosecuting or defending litigation as permitted by this Agreement;
(b) complying with applicable court orders or governmental regulations;
(c) in the case of Astellas, conducting development, manufacturing and/or commercialization activities in accordance with the license granted in Section 3.1, including making regulatory filings with respect to Products;
(d) in the case of Vical, as reasonably necessary to fulfill its obligations under the City of Hope Agreement and CytRx Agreement; and
(e) disclosure to Affiliates, sublicensees, subcontractors, employees, consultants, agents or other Third Parties who need to know such information for the development, manufacture and commercialization of Products in accordance with this Agreement or in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Affiliate, sublicensee, subcontractor, employee, consultant, agent or Third Party agrees to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

Notwithstanding the foregoing, in the event the receiving party is required to make a disclosure of the disclosing party’s Confidential Information pursuant to Section 9.3(a) or (b), it will, except where impracticable, give reasonable advance notice to the disclosing party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as the receiving party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the receiving party agrees to take all reasonable action to avoid disclosure of Confidential Information of the disclosing party.

9.4 Confidentiality of this Agreement and its Terms. Except as otherwise provided in this Article 9, each party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other party.

9.5 Public Announcements.

(a) Press Releases. As soon as practicable following the date hereof, the parties shall each issue a mutually agreed press release announcing the existence of this Agreement. Except as required by applicable laws and regulations (including disclosure requirements of the U.S. Securities and Exchange Commission (“SEC”) or any stock exchange on which securities issued by a party or its Affiliates are traded), neither party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided that each party may make any public statement, including statements in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other party pursuant to this Section 9.5 and which do not reveal non-public information about the other party. For avoidance of doubt, Vical shall have the right, without the prior written consent of Astellas, to announce events such as achievement of milestones under this Agreement, and other events deemed material by its General Counsel; provided, however, that Vical shall consult with Astellas with regard thereto and provide reasonable opportunity for Astellas to review such announcement in advance. In the event of a required public announcement, to the extent practicable under the circumstances, the party making such announcement shall provide the other party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other party a reasonable opportunity to review and comment upon the proposed text.

(b) Filing of Agreement. The parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a party or its Affiliate are traded, and each party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the
case may be, and provided further that the parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither party (or its Affiliates) will be obligated to consult with or obtain approval from the other party with respect to any filings to the SEC or any stock exchange or other governmental agency.

(c) Publications.

(i) Except as otherwise set forth in Section 9.5(c)(ii) below, at least [...***…] ([...***…]) days prior to publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product in the Field that has not been previously published, each party shall provide to the other party a draft copy thereof for its review (unless such party is required by law to publish such Information sooner, in which case such party shall provide such draft copy to the other party as much in advance of such publication as possible). The publishing party shall consider in good faith any comments provided by the other party during such [...***…] ([...***…]) day period. In addition, the publishing party shall, at the other party's reasonable request, remove therefrom any Confidential Information of such other party, except each party shall have the right to publicly disclose any information, including Confidential Information, pertaining to safety or efficacy of the Product that such party believes in good faith it is obligated by applicable law or appropriate to conform to applicable regulatory requirements to disclose; provided that it shall delay publication for a period not to exceed [...***…] ([...***…]) days in order to allow the other party to file for patent protection as permitted by this Agreement in relation to its Confidential Information. The contribution of each party shall be noted in all publications or presentations by acknowledgment or co-authorship, as appropriate.

(ii) In the event Astellas desires to publish, publicly present, and/or submit for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product in the Field but that does not include any Confidential Information of Vical, Astellas shall provide to Vical a draft copy thereof for its review prior to the date of such publication, presentation or submission, and Astellas shall consider in good faith any comments provided by Vical with respect thereto.

(iii) Astellas shall, within a reasonable amount of time after the Effective Date and from time to time thereafter, provide to Vical a copy of its plan for publication regarding Compounds and Products in the Field, including all material updates and changes thereto.

9.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to the disclosing party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 9. In addition to all other remedies, the disclosing party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 9.

10. TERM AND TERMINATION

10.1 Term. The term of this Agreement shall commence on the Effective Date and continue until the expiration of the last Royalty Term, subject, in each case, to earlier termination pursuant to Section 10.2 (the "Term"). Upon expiration (but not early termination) of this Agreement [...***…] under this Agreement, the license and sublicense granted by Vical to Astellas under Section 3.1 shall remain in effect on a perpetual, fully paid-up and royalty-free basis, subject to the limits set forth in Article 3.

10.2 Early Termination.

(a) Termination for Cause.

(i) A party shall have the right to terminate this Agreement upon written notice to the other party if such other party is in material breach of this Agreement and has not cured such breach within sixty (60) days (thirty (30) days with respect to any payment breach) after written notice from the terminating party requesting cure of such breach. Any such termination shall become effective at the end of such sixty (60) day (thirty (30) day with respect to any payment breach) period unless the breaching party has cured any such breach prior to the end of such period. Furthermore, each party shall have the right to terminate this Agreement upon written notice to the other party if the Services Agreement is terminated by such party due to material breach by the other party.

(ii) A party shall have the right to terminate this Agreement upon written notice to the other party upon the bankruptcy, dissolution or winding up of such other party, or the making or seeking to make or arrange an assignment for the benefit of creditors of such other party, or the initiation of
proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such other party’s property that is not discharged within ninety (90) days.

(b) Other Astellas Termination Right. Astellas shall have the right to terminate this Agreement if Astellas reasonably determines that further development and/or commercialization of Products in the Field in the Territory will not be beneficial for Astellas for scientific, regulatory, commercial, financial, ethical or other fair reasons specified in reasonable detail in writing to Vical: (i) prior to completion of the technology transfer of Vical Know-How relating to the manufacture of Compounds and Products in the Field to Astellas or its designee, upon one hundred eighty (180) days’ prior written notice to Vical, and (ii) thereafter, upon ninety (90) days’ prior written notice to Vical.

(c) Other Vical Termination Rights. Vical shall have the right to terminate this Agreement immediately upon written notice to Astellas if Astellas or any of its Affiliates or Sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Vical Patent.

10.3 Effect of Termination or Expiration; Surviving Obligations.

(a) Effect of Any Termination. Upon any termination of this Agreement by either party:

(i) all rights and obligations of the parties under this Agreement shall terminate, except as provided in Sections 10.3, 10.4, 10.5 and, as applicable, 10.6;

(ii) Astellas shall perform its outstanding non-cancellable obligations with respect to Products in the Territory that existed or accrued prior to the notice date of termination; and

(iii) Astellas shall cooperate with and provide reasonable assistance to Vical with respect to any applications for Patent Term Extension, including providing such information as may be requested by Vical or any Regulatory Authority in support of such applications.

(b) Effect of Any Termination Other than Termination by Astellas for Cause. Upon any termination of this Agreement by Astellas under Section 10.2(b) or by Vical under Section 10.2(a) or (c):

(i) if, at the time of such termination, there are any ongoing clinical trials with respect to Products in the Field in the Territory, the parties shall, at Vical’s option, negotiate in good faith and adopt a plan to wind-down the development activities in an orderly fashion or, at Vical’s election, promptly transition such development activities to Vical or its designee, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of the Product and take any actions Vical deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable laws, rules and regulations; and

(ii) Astellas shall, and hereby does, grant to Vical:

(1) the unrestricted right to use and refer to all Information, including all data and regulatory documents, relating to any Compound or Product, in the Territory and also in any country or countries outside the Territory upon any termination of the Ex-U.S. Agreement in such country or countries;

(2) an exclusive, royalty-free, perpetual, irrevocable license, with the right to sublicense and further sublicense, under all Patents Controlled by Astellas or its Affiliates that claim or cover a Compound or Product specifically or its manufacture or use in the Territory, solely to research, develop, register, use, make, have made, promote, sell, offer for sale, distribute, import and export Compounds and Products in the Field in the Territory;

(3) a non-exclusive, royalty-free, perpetual, irrevocable license, with the right to sublicense and further sublicense, under all Patents Controlled by Astellas or its Affiliates other than those referenced in subsection (2) above, which Patents would, but for the license granted in this subsection (3), be infringed by the development, use, manufacture, promotion, sale, offer for sale, distribution, import or export of a Compound or Product in the Field in the Territory, solely to develop, use, make, have made, promote, sell, offer for sale, distribute, import and export Compounds and Products in the Field in the Territory; and

(4) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfers of rights as set forth in subsections (1), (2) and (3) above.

(c) Surviving Terms. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the obligations and rights of the parties under Sections 6.4 (for the period described therein), 7.1, 8.3, 8.4, 10.3, 10.4 and 10.5 and Articles 1, 9, 11 and 12 shall survive expiration or termination of this Agreement.

(d) Return of Confidential Information. Within [...***...] days following the expiration or termination of this Agreement, each party shall deliver to the other party or destroy any and all Confidential Information of the other party in its possession, as per
11. INDEMNIFICATION

11.1 Indemnification by Vical. Vical hereby agrees to save, defend and hold Astellas, its Affiliates and its and their respective directors, officers, employees and agents and, with respect to the indemnification set forth in Section 11.1(c) only, also Astellas’ Sublicensees, subcontractors and distributors (each, a “Vical Indemnitee”) harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys’ fees (collectively, “Losses”), to which any Vical Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) the gross negligence or willful misconduct of any Vical Indemnitee with respect to any obligations or activities contemplated by this Agreement, (b) the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement, or (c) infringement or alleged infringement of any Patents co-owned by Vical and the Wisconsin Alumni Research Foundation as a result of the development, manufacture, use, handling, storage, sale or other disposition of any Product in the Territory by Astellas or any of its Sublicensees; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Vical Indemnitee or the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement.

11.2 Indemnification by Astellas. Astellas hereby agrees to save, defend and hold Vical and its Affiliates and its and their respective directors, officers, employees and agents (each, a “Vical Indemnitee”) harmless from and against any and all Losses to which any Vical Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, manufacture, use, handling, storage, sale or other disposition of any Product in the Territory by Astellas or any of its Sublicensees, (b) the gross negligence or willful misconduct of any Astellas Indemnitee with respect to any obligations or activities contemplated by this Agreement, or (c) the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Vical Indemnitee or the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement.

11.3 Control of Defense. Any person entitled to indemnification under this Article 11 shall give notice to the indemnifying party of any Losses that may be subject to indemnification, promptly after learning of such Losses, and the indemnifying party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified party. If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Losses made by the indemnified party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses.

11.4 Insurance. Each party shall, at its own expense, procure and maintain during the Term and for a period of three (3) years thereafter, insurance policies/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a party’s liability with respect to its obligations hereunder including the indemnification obligations under this Article 11. Each party shall provide the other party with written evidence of such insurance or self-insurance upon request. Each party shall provide the other party with written notice at least thirty (30)
days prior to the cancellation, non-renewal or material change in such insurance self-insurance which could materially adversely affect the rights of such other party hereunder.

12. GENERAL PROVISIONS

12.1 Standstill Agreement. For a period of […***…] […***…] years following the Effective Date (the “Standstill Period”), neither Astellas nor any of Astellas’ Representatives (as defined below) will, in any manner, directly or indirectly:

(a) make, effect, initiate, directly participate in or cause (i) any acquisition of beneficial ownership of any securities of Vical or any securities of any subsidiary or other Affiliate of Vical, if, after such acquisition, Astellas would beneficially own more than […***…] percent ([…***…]%) of the outstanding common stock of Vical, (ii) any acquisition of any assets of Vical or any assets of any subsidiary or other Affiliate of Vical, (iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving Vical or any subsidiary or other Affiliate of Vical, or

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involving any securities or assets of Vical or any securities or assets of any subsidiary or other affiliate of Vical, or (iv) any “solicitation” of “proxies” (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of Vical provided that nothing in this Section 12.1 shall preclude any activities of Astellas or its Representatives with respect to the grant by Vical or any Affiliate of Vical of any license, or the supply by Vical or any subsidiary or other Affiliate of Vical of any products, in each case to Astellas or any of its Affiliates as contemplated by this Agreement;

(b) form, join or participate in a group (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended) with respect to the beneficial ownership of any securities of Vical;

(c) act, alone or in concert with others, to seek to control the management, board of directors or policies of Vical;

(d) take any action that might require Vical to make a public announcement regarding any of the types of matters set forth in Section 12.1(a);

(e) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in Section 12.1(a), (b), (c) or (d);

(f) assist, induce or encourage any Third Party to take any action of the type referred to in Section 12.1(a), (b), (c), (d) or (e);

(g) enter into any discussions, negotiations, arrangement or agreement with any Third Party relating to any of the foregoing; or

(h) request or propose that Vical or any of Vical’s Representatives amend, waive or consider the amendment or waiver of any provision set forth in this Section 12.1.

For purposes of this Agreement, a party’s “Representatives” will be deemed to include each person or entity that is or becomes (i) an Affiliate of such party, or (ii) an officer, director, employee, partner, attorney, advisor, accountant, agent or representative of such party or of any of such party’s Affiliates, providing such person is acting on behalf of such party.

Notwithstanding the foregoing, Section 12.1 shall no longer apply (i) during a period commencing with Vical’s announcement in a filing with the Securities and Exchange Commission of a press release that (a) it is seeking purchaser for itself or (b) is otherwise exploring strategic options in this regard, and ending with Vical’s announcement in a filing with the Securities and Exchange Commission or a press release that is terminating such search or exploration; (ii) during the period beginning with the commencement by a Third Party of a publicly-announced tender or exchange offer for more than […***…] percent ([…***…]%) of voting power of the outstanding voting securities of Vical, and ending with the termination by such Third Party of such tender or exchange offer; or (iii) if Vical announces in a filing with the Securities and Exchange Commission a press release a transaction, or an intention to effect any transaction, which would result in (a) the sale by Vical or one or more Affiliate(s) of assets representing […***…] percent ([…***…]%) or more of the consolidated assets of Vical; or (b) the common shareholders of Vical immediately prior to such transaction owning less than […***…]

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percent ([…***…]%) of the outstanding common stock of the acquiring entity or, in case of a merger transaction, the surviving corporation (or, if the surviving corporation is an Affiliate of a parent company, the parent company); provide that, in the case of clause (ii) Astellas has not directly or indirectly taken any action prohibited under this Section 12.1.
12.2 Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

12.3 Dispute Resolution.

(a) Objective. The parties recognize that disputes as to matters arising under or relating to this Agreement or either party’s rights and/or obligations hereunder may arise from time to time. It is the objective of the parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the parties agree to follow the procedures set forth in this Section 12.3 to resolve any such dispute if and when it arises.

(b) Resolution by Executives. Except as otherwise provided in Section 2.1, if an unresolved dispute as to matters arising under or relating to this Agreement or either party’s rights and/or obligations hereunder arises, either party may refer such dispute to the Executives, who shall meet in person or by telephone within ten (10) days after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of the Executives within ten (10) days following such meeting (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with Section 12.3(c). For avoidance of doubt, any disputes, controversies or differences arising from the JSC pursuant to Article 2 shall be resolved solely in accordance with Section 2.1.

(c) Arbitration.

(i) If the parties do not resolve a dispute as provided in Section 12.3(b), and a party wishes to pursue the matter, each such dispute that is not an “Excluded Claim” shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce (“ICC”) as then in effect (the “ICC Rules”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The decision rendered in any such arbitration will be final and not appealable. If either party intends to commence binding arbitration of such dispute, such party will provide written notice to the other party informing the other party of such intention and the issues to be resolved. Within thirty (30) days after the receipt of such notice, the other party may by written notice to the party initiating binding arbitration, add additional issues to be resolved.

(ii) The arbitration shall be conducted by a panel of three (3) arbitrators experienced in the pharmaceutical business, none of whom shall be a current or former employee or director, or a then-current stockholder, of either party, their respective Affiliates or any Sublicensee. Within thirty (30) days after receipt of the original notice of binding arbitration, each party shall select one person to act as arbitrator and the two party-selected arbitrators shall select a third arbitrator within ten (10) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC in accordance with the ICC Rules. The place of arbitration shall be New York, New York and all proceedings and communications shall be in English.

(iii) It is the intention of the parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrators, the parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrators will design and the parties shall follow procedures to such effect.

(iv) Either party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages. The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a party in connection with the arbitration be paid by the other party. Subject to the preceding sentence, each party shall bear an equal share of the arbitrators’ and any administrative fees of arbitration.

(v) Except to the extent necessary to confirm or enforce an award or as may be required by applicable law, neither a party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(vi) As used in this Section, the term “Excluded Claim” shall mean a dispute, controversy or claim that concerns (A) the validity, enforceability or infringement of a patent, trademark, copyright or regulatory data exclusivity; or (B) any antitrust, anti-monopoly or competition law or regulation,
12.4 Entire Agreement; Modification. This Agreement, including the Exhibits hereto, is both a final expression of the parties' agreement and a complete and exclusive statement with respect to all of its terms. Except for the Ex-U.S. Agreement, the Services Agreement and the separate letter agreement between the parties, this Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein and therein, including the Confidentiality Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.

12.5 Relationship Between the Parties. The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

12.6 Non-Waiver. The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

12.7 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); provided, however, that either party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other party's consent:

(a) in connection with the transfer or sale of all or substantially all of the business or assets of such party relating to products for control or prevention of CMV infection to a Third Party, whether by merger, sale of stock, sale of assets or otherwise (a “Sale”), provided that in the event of a Sale (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the parties to this Agreement) shall not be included in the technology licensed hereunder; or

(b) to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

12.8 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except for City of Hope with respect to City of Hope's rights under the City of Hope Agreement and except as otherwise provided in this Agreement with respect to Astellas Indemnities under Section 11.1 and Vical Indemnities under Section 11.2.

12.9 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

12.10 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

12.11 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile or electronic mail (email) transmission confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, five (5) days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to Astellas, notices must be addressed to:
12.12 Force Majeure. Except for the obligation to make payment when due, each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party’s reasonable control including but not limited to
Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party’s failure or delay in performance due to force majeure must be given to the other party within ten (10) days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute.

12.13 Interpretation.

(a) Captions & Headings. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.

(b) Interpretation. All references in this Agreement to the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression. All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.

(c) Articles, Sections & Subsections. Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.

(d) Days. All references to days in this Agreement shall mean calendar days, unless otherwise specified.

12.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

12.15 HSR Filing. Each of Vical and Astellas agrees to prepare and make appropriate filings under the Hart-Scott-Rodino Anti-Trust Improvements Act of 1976, as amended (the “HSR Act”) and any analogous foreign laws and regulations, relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event within ten (10) days after the date of execution of this Agreement (the “HSR Filing Date”). The parties agree to cooperate in the antitrust clearance process and to furnish promptly to the Federal Trade Commission, the Antitrust Division of the Department of Justice and any other agency or authority, any information reasonably requested by them in connection with such filings. Other than the provisions of this Section 12.15, the rights and obligations of the parties under this Agreement shall not become effective until the waiting period provided by the HSR Act shall have terminated or expired without any action by any governmental agency or challenge to the transaction (the date of such termination or expiration shall be the “Effective Date” of this Agreement). Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the parties. In the event that antitrust clearance from the Federal Trade Commission and Antitrust Division of the Department of Justice is not obtained within ninety (90) days after the date of execution of this Agreement (or such later date as agreed in writing by the parties), this Agreement may be terminated by either party.

IN WITNESS WHEREOF, the parties hereto have duly executed this U.S. LICENSE AGREEMENT as of the date set forth below.

VICAL INCORPORATED

By:

ASTELLAS PHARMA INC.

By:
By:
Name: Vijay B. Samant Name: Yoshihiko Hatanaka
Title: President and CEO Title: President and CEO
Date: July, 2011 Date: July, 2011

SIGNATURE PAGE TO U.S. LICENSE AGREEMENT

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EXHIBIT A

Vical Patents in the Territory

Vical Primary Patents
1. [...***...]
   a. [...***...]
2. [...***...]
   a. [...***...]
   b. [...***...]
   c. [...***...]

Vical Patents
1. [...***...]
   a. [...***...]
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8. [...***...]
9. [...***...]
10. [...***...]