Exhibit 10.2  
  
  
  
  
LICENSE AGREEMENT  
by and between  
FLAME BIOSCIENCES, INC. and  
XXX XXXXX and COMPANY  
  
  
  
CERTAIN INFORMATION IDENTIFIED WITH THE MARK “(\*\*\*)” HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE SUCH INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.  
  
LICENSE AGREEMENT  
This License Agreement (the “Agreement”), is entered into as of November 25th, 2019 (the “Signing Date”), is entered into by and between FLAME BIOSCIENCES, INC., a Delaware corporation with a place of business at 000 Xxxxxxx Xxx, Xxxxx 0000, Xxx Xxxx, XX 00000 (“Flame”), and XXX XXXXX AND COMPANY, an Indiana corporation with a place of business at Lilly Corporate Center, Indianapolis, Indiana, 46285 (“Lilly”). Flame and Lilly may be referred to herein individually as a “Party” or collectively as the “Parties”.  
Recitals:  
X.Xxxxx has developed and controls certain technology, patent rights and proprietary materials related to a certain compound that is an anti IL-lb monospecific antibody known by Xxxxx as LY2189102.  
X.Xxxxx wishes to grant to Flame, and Flame wishes to receive, an exclusive license in the Field for the Territory to such technology, patent rights and proprietary materials under the terms and conditions set forth in this Agreement.  
Agreement:  
1.DEFINITIONS  
Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:  
B.1“Affiliate” means with respect to any Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Section 1.1, “control” shall mean (a) in the case of a corporate entity, direct or indirect ownership of (\*\*\*) or more of the stock or shares having the right to vote for the election of directors of such corporate entity and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.  
B.2“Applicable Laws” shall mean all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the activities references in the sentence where the term is used as contemplated by this Agreement.  
B.3“Biologics License Application” or “BLA” means an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce, or any similar application or submission for marketing authorization of a Licensed  
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Product filed with a Regulatory Authority to obtain Regulatory Approval for such product in a country or group of countries.  
B.4“Business Day” means any day other than a Saturday or a Sunday on which the banks in New York, New York are open for business.  
B.5“Calendar Quarter’’ means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.  
B.6“Calendar Year” means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.  
B.7“Combination(s)” means a Licensed Product containing the Licensed Compound and one or more additional active compounds or pharmaceutical ingredients not licensed hereunder (each such additional ingredient, an ‘‘Other Product”), whether co-formulated or co-packaged.  
B.8“Commercialization” or “Commercialize” means activities taken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sales force recruitment, pricing determination, manufacturing, importation, offering for sale, sale and distribution for commercial sale, of a pharmaceutical product and post-launch medical activities, including without limitation: (a) manufacturing, importation and distribution for commercial sale; (b) strategic marketing, sales force detailing, advertising, and market and product support; (c) medical education and liaison and any phase IV clinical trials; (d) all customer support and product distribution, invoicing and sales activities; (e) all post-approval regulatory activities, including those necessary to maintain Regulatory Approvals; (f) expanded target product profile activities after receipt of initial Regulatory Approval for the relevant product; and (g) pricing, formulary and reimbursement related activities, including pricing and reimbursement approvals.  
B.9“Commercially Reasonable Efforts” shall have the meaning provided in Section 2.4(b) of this Agreement.  
B.10“Confidential Information” means all confidential or proprietary information disclosed or made available by a Party (the “Disclosing Party”) or its Representatives to the other Party (the “Receiving Party”) or its Representatives pursuant to, or in connection with the purpose of, this Agreement or pursuant to the Confidentiality Agreement, in each case, whether in written, oral, graphic, electronic or other form. Notwithstanding the foregoing or any other provision of this Agreement to the contrary: (a) except as expressly set forth in clause (b) of this sentence, the Confidential Information identified on Exhibit C shall be deemed the Confidential Information of both Parties, and each Party shall be deemed the Receiving Party with respect thereto; and (b) solely in the event of termination of this Agreement by Flame pursuant to Section 9.3, or by Lilly pursuant to Section 9.4, the Confidential Information identified on Exhibit C shall be deemed the Confidential Information of Xxxxx, and Xxxxx shall be deemed the Disclosing Party and Flame the Receiving Party with respect thereto.  
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1.11 “Confidentiality Agreement” shall mean the Mutual Confidentiality Agreement between the Parties dated August 20, 2018.  
1.12“Control”, “Controls” or “Controlled by” means (except as used in Section 1.1, above), with respect to any item of or right under Patents or Know-How, the ability of the specified Party or any of its Affiliates, whether through ownership, license or other right (other than pursuant to this Agreement), to grant access to, license or sublicense such item or right without violating the terms of any agreement or other arrangement with any Third Party.  
1.13“Data Exclusivity Period” means the period during which any Regulatory Authority within the Territory prohibits reference for purposes of obtaining Regulatory Approval of a pharmaceutical product, without the consent of the owner of the regulatory submission materials, to the clinical and other data that is contained in such materials, and that is not published or publicly available outside of such submission.  
1.14“Develop” or “Development” or “Developing” means research, discovery, process development, manufacturing and importation for preclinical and clinical uses, and preclinical and clinical drug or biological development activities, including, without limitation, test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, in each case, of a Licensed Compound or Licensed Product for use in the Field, and to the extent normally undertaken during the development (as opposed to Commercialization) phase of such Licensed Compound or Licensed Product’s life cycle. Development shall exclude all Phase IV clinical trials.  
1.15“Effective Date” shall mean that certain date that Flame has satisfied both of the following requirements: (i) made the cash payment to Lilly required under Section 4.l(a) within the time period provided therein and (ii) signed the Equity Agreements and issued to Lilly the initial common stock in accordance under Section 4.1(b) within the time period provided therein.  
1.16 “EMA” means the European Medicines Agency or any successor agency thereto in the European Union having substantially the same function.  
1.17“Equity Agreements” shall mean the Common Stock Purchase Agreement in the form of Schedule 1 and the Investor Rights Agreement in the form of Schedule 2.  
1.18‘‘Equity Securities” means any and all shares of common stock or preferred stock of Flame, and any and all securities of Flame convertible into or exchangeable or exercisable for (whether or not subject to contingencies or the passage of time, or both), such shares, including, without limitation, options, warrants and other rights to acquire such shares.  
1.19“FDA” means the United States Food and Drug Administration or any successor agency thereto.  
1.20“Field” means any and all uses in human and animal diseases.  
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1.21“First Commercial Sale” means, with respect to any Licensed Product, the first sale to a Third Party for end use or consumption of such Licensed Product in a country after Regulatory Approval has been granted by the Regulatory Authority of such country, if such Regulatory Approval is required, or, if Regulatory Approval is not required, upon the first such sale.  
1.22“GAAP’’ means US Generally Accepted Accounting Principles as the same may be in effect from time to time.  
1.23“Good Clinical Practices” or “GCP” means all applicable current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) E6 and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50, 54, 56,312 and 314, as may be amended from time to time, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.  
l.24 “Generic Version” shall mean with respect to a particular Licensed Product sold by Flame or any of its Affiliates or Sublicensees in the Territory, a pharmaceutical product sold by a Third Party (other than a Sublicensee or any other Third Party in a chain of distribution originating from Flame or any of its Affiliates or Sub1icensees) in the Territory: (a) that contains Licensed Compound (and, if applicable, the same Other Product(s) as such Licensed Product) in the same dosage form as such Licensed Product; and (b) has received Regulatory Approval from the relevant Regulatory Authority in the Territory in reliance on the Regulatory Approval for such Licensed Product in the Territory.  
1.25“Good Laboratory Practices” or “GLP” means the then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58 and/or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (“OECD”), and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.  
1.26“Good Manufacturing Practices” or “cGMP” means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the WHO TRS 986 Annex 2, TRS 961 Annex 6 and TRS 957 Annex 2, (d) ICH Q7 guidelines, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.  
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1.27“Governmental Authority” shall mean any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, state or local authority or any political subdivision thereof, or any association of countries.  
1.28“Government or Public Official” means: (i) any officer or employee of: (a) a government, or any department or agency thereof; (b) a government-owned or controlled company, institution, or other entity, including a government-owned hospital or university; or (c) a public international organization (such as the United Nations, the International Monetary Fund, the International Committee of the Red Cross, and the World Health Organization), or any department or agency thereof; (ii) any political party or party official or candidate for public or political party office; and (iii) any person acting in an official capacity on behalf of any of the foregoing.  
1.29“IND” means a submission for approval in the Territory to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.  
1.30“Know-How” means any proprietary and confidential scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including any of the foregoing that are databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, manufacturing process and development information, results or data.  
1.31“Licensed Compound” means the certain compound that is an anti IL-1b monospecific antibody known by Xxxxx as LY2189102 with the structure set forth on Exhibit A. For clarity, notwithstanding anything to the contrary, the term “Licensed Compound” specifically excludes any other monospecific antibody (except for LY2189102) that may bind to the same or partially same epitope and; further, for clarity, since the Licensed Compound, by definition, is only an anti IL-lb monospecific antibody, the term “Licensed Compound” specifically excludes a bispecific antibody with any anti IL-Ib activity.  
1.32“Licensed Know-How” means solely the Know-How (excluding any Know-How covered by a claim of any published Licensed Patent) that is set forth on Exhibit C.  
1.33“Licensed Patents” means Patents Controlled by Xxxxx or any of its Affiliates as of the Effective Date that contain one or more claims covering the Licensed Compound or Licensed Product or the Manufacture of the Licensed Compound or Licensed Product (specifica1ly excluding any claim covering manufacturing for any Patents filed after the Effective Date but including Patents with a filing date prior to the Effective Date (the “Prior Manufacturing Patents”) including any Patents filed after the Effective Date that claim priority to the Prior Manufacturing Patents), or the composition of matter, or any method of use of the Licensed Compound or Licensed Product, including without limitation the Program-Specific Patents.  
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1.34“Licensed Product” means any pharmaceutical composition or preparation containing or comprising a Licensed Compound (whether or not as the sole active ingredient), including all formulations and dosage forms thereof.  
1.35“Licensed Technology” shall mean Licensed Patents and Licensed Know-How.  
1.36“Listed Patents” shall mean the patents and patent applications listed in Exhibit B hereto.  
1.37“Major Country” means each or any of the United States. (\*\*\*).  
a.38“Manufacture” and “Manufacturing” shall mean all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of Licensed Compound or Licensed Product, or any intermediate of either of the foregoing, including process development, process qualification and validation, scale-up, preclinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.  
a.39“Net Sales” shall mean, with respect to a Licensed Product, the gross amount invoiced by Flame (including a Licensee Affiliate) or any sublicensee thereof to unrelated Third Parties, excluding any sublicensee, for the Licensed Product (in final form for end use, but exclusive of inter-company transfers) in the Territory, less the following items consistent with U.S. Generally Accepted Accounting Principles consistently applied:  
(a)Trade, quantity and cash discounts allowed;  
(b)any tax imposed on the production, sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes;  
(c)allowance for distribution expenses not to exceed (\*\*\*) of gross sales;  
(d)Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances, not to exceed (\*\*\*) of gross sales, which effectively reduce the net selling price, including those granted to managed health care organizations, wholesalers, buying groups, retailers or to federal, state/provincial, local and other governments, their agencies and purchasers and reimbursers; and  
(e)Licensed Product returns and allowances not to exceed (\*\*\*) of gross sales.  
Such amounts shall be determined from the books and records of Flame, affiliates of Flame or any sublicensee maintained in accordance with GAAP, or in the case of sublicensees, such similar accounting principles, consistently applied. Flame further agrees in determining such amounts, it will use Flame’s then current standard procedures and methodology, including Flame’s then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars or, in the case of sublicensees, such similar methodology, consistently applied.  
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Sales between or among Flame and its Affiliates and its Sublicensees shall be excluded from the computation of Net Sales, but Net Sales shall include the first sales to Third Parties (other than Sublicensees) by Flame or any such Affiliates or Sublicensees. The supply (at no cost) of Licensed Product as samples, for use in non-clinical or clinical studies of Flame or any of its Affiliates or Sublicensees, or for use in any tests or studies of Flame or any of its Affiliates or Sublicensees reasonably necessary to comply with any Applicable Laws, regulation or request by a regulatory or governmental authority shall not be included within the computation of Net Sales.  
In the event that the Licensed Product is sold as part of a Combination Product (where Combination is defined above in § 1.7), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product by the fraction, A / (A+B) where A is the weighted average sale price of the Licensed Product when sold separately in finished form, and B is the weighted average sale price of the other product(s) sold separately in finished form.  
In the event that the weighted average sale price of the Licensed Product can be determined but the weighted average sale price of the other product(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A / C where A is the weighted average sale price of the Licensed Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.  
In the event that the weighted average sale price of the other product(s) can be determined but the weighted average sale price of the Licensed Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: one (l) minus (B / C) where B is the weighted average sale price of the other product(s) when sold separately in finished form and C is the weighted average sale price of the Combination Product.  
In the event that the weighted average sale price of both the Licensed Product and the other product(s) in the Combination Product cannot be determined, the Net Sales of the Licensed Product shall be deemed to be equal to (\*\*\*) of the Net Sales of the Combination Product.  
The weighted average sale price for a Licensed Product, other product(s), or Combination Product shall be calculated once each Calendar Year and such price shall be used during all applicable royalty reporting periods for the entire following Calendar Year. When determining the weighted average sale price of a Licensed Product, other product(s), or Combination Product, the weighted average sale price shall be calculated by dividing the sales dollars (translated into U.S. dollars) by the units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial calendar year) of the preceding Calendar Year for the respective Licensed Product, other product(s), or Combination Product. In the initial Calendar Year, a forecasted weighted average sale price will be used for the Licensed Product, other product(s), or Combination Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the following Calendar Year.  
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a.40“Other Licensed Patents” shall mean Licensed Patents that are not Program-Specific Patents.  
1.41“Patent(s)” means all patents and patent applications in any country or supranational jurisdiction, including any provisionals, substitutions, divisions, continuations, continuations-in part, reissues, renewals, registrations, confirmations, reexaminations, extensions, any other pre or post-grant forms of any of the foregoing, any confirmation patents or registration patents or patents of addition, utility models, patent term extensions or restorations, and supplementary protection certificates or requests for continued examinations and the like, including any and all foreign counterparts of any of the foregoing.  
1.42“Patent Files” shall mean: (a) the complete file histories for the Program-Specific Patents in the possession of Lilly or any of its Affiliates; and (b) all files relating to the Program Specific Patents that are held or maintained on Lilly’s or its Affiliate’s behalf by Xxxxx’x or its Affiliate’s outside patent counsel, including all contents of such files.  
1.43“Patent Prosecution” or “Prosecution” means, with respect to a Patent, (a) preparing, filing and prosecuting applications (of all types) for such Patent, (b) paying filing, issuance and maintenance fees relating to such Patent, (c) managing and conducting any interference, opposition, invalidation, re-issue, reexamination, revocation, nullification, post-grant review, inter partes review, derivation proceeding, cancellation proceeding or other similar administrative proceeding or administrative appeal thereof with respect to such Patent, and (d) settling any interference, opposition, revocation, nullification or cancellation proceeding.  
1.44“Phase III Clinical Study” means a human clinical trial designed as a pivotal study to confirm, with statistical significance, the efficacy and safety of a Licensed Product with respect to a particular indication, which trial is performed for purposes of filing an BLA or similar application to obtain Regulatory Approval for such Licensed Product in any country or regulatory jurisdiction, as defined in 21 C.F.R. § 312.2l(c), as may be amended from time to time, or any analogous clinical trial described or defined in Applicable Laws and guidelines in the Territory.  
l.45 “Program” shall mean all of Lilly’s and its Affiliates’ activities (including activities performed by any Third Party on behalf of Lilly or any of its Affiliates) directed to the Development, Manufacture, use, offer for sale, sale or import of Licensed Compounds and Licensed Products up to the Effective Date.  
1.46“Program-Specific Patents” shall mean the Listed Patents and any and all Patents corresponding to the Listed Patents throughout the world, whether now existing or hereafter filed or issued.  
1.47“Regulatory Applications” means any and all applications that are necessary and appropriate to obtain a Regulatory Approval with respect to a Licensed Product, including, without limitation, all required documents, data and information concerning a Licensed Product, filed or required to be filed with or, otherwise submitted to, a Regulatory Authority.  
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1.48“Regulatory Approval” means all approvals from the relevant Regulatory Authority to market and sell a Licensed Product (or for purposes of Sections 1.12 and 1.20, a pharmaceutical product) in the Territory (including all applicable pricing and reimbursement approvals).  
1.49“Regulatory Authority” means any applicable government regulatory authority involved in granting approvals for the conduct of clinical trials or the manufacturing, marketing, sale, reimbursement or pricing of a Licensed Product in the Territory.  
1.50“Regulatory Materials” shall mean all Regulatory Approvals, Regulatory Applications and other regulatory submissions in the Territory for any Licensed Compound or Licensed Product, and all correspondence with such Regulatory Authorities relating to any Licensed Compound or Licensed Product; that, in each case, are in the possession of or controlled by, or held by or for, Lilly or any of its Affiliates at the Effective Date, whether generated, filed or held by or for Lilly or its Affiliates.  
1.51“Related Party” means, with respect to Flame, its Affiliates and Sublicensees.  
1.52“Representatives” shall mean, with respect to a Party, such Party’s Affiliates, and such Party’s and its Affiliates’ directors, officers, employees, consultants, contractors, licensees, sublicensees, agents and other representatives.  
1.53“Sublicense Agreement” means any agreement entered into by Flame with a Sublicensee.  
1.54“Sublicensee” means any Third Party to which Flame or a Sublicensee grants a sublicense of the rights granted to Flame under the Licensed Patents or Licensed Know-How.  
1.55“Territory” means worldwide.  
1.56“Third Party” means an entity other than (a) Lilly and its Affiliates, and (b) Flame and its Affiliates.  
1.57‘‘Valid Claim” means, with respect to a country, a claim of an issued and unexpired Patent included within the Licensed Patents in such country which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise in such country.  
2.LICENSE  
B.1License to Flame  
As of the Effective Date, Xxxxx, on behalf of itself and its Affiliates, hereby grants to Flame an exclusive (even as to Lilly and its Affiliates, except for research purposes as described below), worldwide, royalty bearing license, with the right to grant sublicenses (subject to Section 2.2), under the Licensed Patents and Licensed Know-How to research, Develop, Commercialize,  
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Manufacture, make, have made, use, sell, have sold, offer to sell, and import the Licensed Compound and Licensed Product in the Field. Lilly and its Affiliates retain a non-exclusive license, (\*\*\*). The Parties acknowledge that the license grant above is, by definition, limited to the Licensed Compound and Licensed Product in its monospecific form and, therefore, such license grant specifically excludes and Lilly and its Affiliates retain any and all rights to research and develop and commercialize antibodies (other than the monospecific form of LY2189102) that may bind to the same or partially same epitope, including a bispecific antibody with anti IL-lb activity and containing the same complementarity determining regions as LY2189102.  
B.2Sublicenses  
The rights and licenses granted in Section 2.1 include the right to grant sublicenses, directly or through multiple tiers to Affiliates or Third Parties, provided that: (a) any sublicense granted by Flame under this Agreement (directly or indirectly through its Affiliate) to a Third Party shall be (i) in writing and (ii) subject in applicable respects to the provisions contained in this Agreement. Flame shall be responsible for the compliance of its Sublicensees with the applicable provisions contained in this Agreement.  
B.3Third Party Contractors  
Flame shall have the right to retain a Third Party contractor to perform any activity in connection with Flame’s exercise of any of its rights granted under Section 2.1, where such activity is to be performed at the direction and control and for the sole benefit of Flame or its Affiliates. Such retention of the Third Party contractor is not a sublicense within the meaning of Section 2.2 but is considered an activity of Flame under the license granted under Section 2.1.  
B.4Regulatory Interactions And Responsibility to Develop and Commercialize  
(a)Regulatory Interactions. Subject to the terms of this Agreement, Flame, its Affiliates or Sublicensees, or its or their designees will have the right to conduct, and shall be responsible for, all regulatory activities and interactions, at their cost, for the Licensed Products and will hold its own master file and be the liaison with regulatory agencies.  
(b)Responsibility to Develop and Commercialize. Flame, itself or through its Affiliates and Sublicensees, will use Commercially Reasonable Efforts to Develop and Commercialize one or more Licensed Products for therapeutic uses in the Field in the Territory. For clarity, development and commercialization of a Product as a diagnostic product is not sufficient to comply with the diligence obligations. Flame will be responsible for all its costs and expenses associated with development, regulatory and commercialization activities. The term “Commercially Reasonable Efforts” means, with respect to Flame, those efforts and resources commensurate with those efforts commonly used in the biotechnology or pharmaceutical industry by a company of comparable size in connection with the development or commercialization of pharmaceutical products that are of similar status, stage of development, life cycle and commercial potential, including issues of safety and efficacy, the patent or proprietary position of the product, the regulatory status and approval process, the probable  
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profitability of the applicable product, and other relevant factors such as technical, legal, scientific or medical factors.  
(c)GCP and GLP Compliance. The Development of the Licensed Product shall be conducted by Flame using GCP and good laboratory practices (“GLP”). GLP means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time. GCP means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 3 I 2 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.  
(d)Compliance with Animal Care and Use Requirements. Flame shall comply with all Applicable Laws pertaining to the care and use of experimental animals and that all animals used in experiments with Licensed Compound shall be provided with humane care and treatment in accordance with the current applicable veterinary practices. Company shall also comply with Lilly animal care and use requirements referenced in the attached Exhibit D.  
B.5Progress Reports. During the Term of the Agreement, Flame shall keep Xxxxx regularly informed of the progress of its efforts to Develop the Licensed Compound and/or the Licensed Product, including providing (\*\*\*) written updates to Lilly within thirty (30) days of (\*\*\*) of each year during the Term of this Agreement, including a summary of (\*\*\*). In addition, during the Term of the Agreement, upon the reasonable request of Xxxxx, but no more frequently than one time in each Calendar Year, Xxxxx and Flame shall meet by telephone, videoconference, or in-person at a mutually agreeable location to discuss the topics described in the progress reports. Notwithstanding anything to the contrary in this Section 2.5 or elsewhere in this Agreement, if at any point Lilly or its Affiliate, directly or indirectly, has (\*\*\*) one or more molecule(s) utilizing the same mechanism of action and targeting the same indications, as the Licensed Compound and/or Licensed Product, the reports, information and meetings required under this Section 2.5 and elsewhere in this Agreement shall no longer apply and Flame shall in lieu thereof provide to Lilly only a high level summary of development activities (\*\*\*) within thirty (30) days (\*\*\*) of each year.  
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B.6If at any time Flame or its Affiliates receive written term sheet (or similar written expression of interest) from a Third Party for any rights in the Licensed Compound/Product or acquisition of Flame, unless prohibited by Applicable Law, Flame will notify Lilly of the same promptly thereafter but in no event less than (\*\*\*) days after receipt of such written terms.  
3.TECHNOLOGY TRANSFER  
(a)General. Within (\*\*\*) of the Effective Date, the Parties will coordinate and agree to a technology transfer plan for Xxxxx to provide and transfer to Flame the Lilly Know-How but only to the extent as set forth on Exhibit C and was not previously provided to Flame (the “Technology Transfer Plan”), which may be updated or amended by the mutual agreement by the Parties from time to time as needed. For purposes of clarity, Xxxxx will transfer only the Lilly Know-How referenced in Exhibit C to Flame in accordance with the Technology Transfer Plan, and Flame will cooperate to facilitate the receipt of such transfer of Xxxxx Know How. Unless Lilly otherwise agrees, all Licensed Know-How will be transferred in its current form and will not be re-formatted or otherwise modified for Flame’s benefit. If in the future the parties mutually agree (such agreement will not be unreasonably withheld) that Xxxxx possessed data as of the Effective Date (and Xxxxx still possesses at the time of such request) that is (\*\*\*) to develop the Licensed Compound or Licensed Product, Flame will have the right to request such data and Lilly (subject to the mutual agreement of the Parties as referred to above) will provide such data to Flame. Xxxxx will be compensated at the rate of (\*\*\*) per hour for such activities payable within (\*\*\*) days after receipt of such data.  
(b)Only Exhibit C Know How. Notwithstanding anything to the contrary in this Agreement, Xxxxx will have no obligation under this this Agreement to transfer any Lilly Know How or material other than the items specifically described in the attached Exhibit C to Flame in accordance with the Technology Transfer Plan, and Flame will cooperate to facilitate such transfer.  
(c)Tech-Transfer Assistance. Xxxxx will provide written or verbal responses to reasonable questions relating to the Licensed Compound or Licensed Product for a period of (\*\*\*) days following the Effective Date provided under no circumstance shall such assistance exceed (\*\*\*) hours. For clarity, except as specifically provided in this Article 3, Xxxxx shall have no other obligations to provide any assistance in connection with technology transfer under this Agreement.  
4.PAYMENTS  
4. l Upfront Payments and Equity  
(a)Upfront. In consideration for the exclusive license rights granted by Xxxxx to Flame hereunder, Xxxxx will pay Xxxxx a nonrefundable and non-creditable upfront payment of (\*\*\*) within (\*\*\*) calendar days of the Signing Date.  
(b)Equity. Also in consideration for the exclusive license rights granted by Xxxxx to Flame hereunder, within (\*\*\*) calendar days of the Signing Date Flame shall enter into and  
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deliver the Common Stock Purchase Agreement in the form of Schedule I and will issue to Lilly the number of shares of common stock of Flame pursuant to the terms set forth in the Common Stock Purchase Agreement (such agreement, the “Stock Purchase Agreement” and such shares, the “License Shares”). The License Shares will represent (\*\*\*) of Flame’s fully diluted capital stock as of the date of execution of the Stock Purchase Agreement. Contemporaneous with the execution of the Stock Purchase Agreement, Xxxxx and Xxxxx will enter into an Investor Rights Agreement in the form of Schedule 2 (the “Investor Rights Agreement”). If as of the initial common stock issuance to Lilly under the Stock Purchase Agreement at the Closing, Flame has not yet issued and sold Equity Securities in a bona fide equity financing, in a single transaction or series of related transactions, resulting in gross proceeds to Flame of not less than (\*\*\*), then the Investor Rights Agreement will include Article IV which will provide Lilly with the right to receive additional shares of Flame common stock, for no additional consideration, in order to ensure that Xxxxx continues to own (\*\*\*) of Flame’s fully diluted capital stock following each issuance of capital stock by Flame after the date of the Investor Rights Agreement until (and including) Flame’s issuance of capital stock for proceeds of not less than (\*\*\*) in a bona fide equity financing, all on the terms and subject to the conditions set forth in the Investor Rights Agreement. The parties agree that a breach by Flame of such Article IV of the Investor Rights Agreement, and a failure of Flame to cure within thirty (30) days following receipt of written notice from Xxxxx made within thirty (30) days after Xxxxx first becomes aware of such breach, will entitle Xxxxx to terminate this Agreement and the Investor Rights Agreement and to seek all rights and remedies available hereunder and thereunder in connection with such breach.  
(c)Closing. This Agreement shall come into effect as of the date that Flame has satisfied its obligations under Section 4.1(a) and 4.1(b) within the time period specified therein (the “Closing”). Upon Flame’s delivery of the cash payment required under Section 4.1(a) within the time period required therein and Flame’s delivery of the Equity Agreements executed by Flame and issuance of the shares of common stock to Lilly under the Stock Purchase Agreement within the time period required under Section 4.l(b), this License Agreement shall automatically come into effect without the need for further action on the part of either party. If on or before the (\*\*\*) calendar day following the Signing Date Flame has not (i) made the cash payment to Lilly required by Section 4.1(a); or has not (ii) delivered to Lilly the Equity Agreements executed by Flame and issued the shares of common stock to Lilly under the Stock Purchase Agreement, then this Agreement shall not come into effect and shall automatically be null and void and of no force and effect.  
1.2Regulatory and Commercial Milestone Payments  
(a)Initial Regulatory Milestone. Flame will make a one-time non-refundable and noncreditable payment to Lilly in the amount of (\*\*\*) as follows: (i) If the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration trial occurs as evidenced by written documentation from the Regulatory Authority of a Major Country (\*\*\*) shall be tolled for a period equal to the time that Flame (or its Affiliate or its or their Sublicensee) is unable to undertake development activities due to a delay caused by a Regulatory Authority), Flame will make the payment upon the first submission by Flame, its Affiliate or Sublicensee of a BLA or equivalent in any Major Country for the Licensed Product; and (ii) If the first dosing of the first  
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patient in a Phase III Clinical Trial or an equivalent registration trial occurs (\*\*\*) shall be tolled for a period equal to the time that Flame (or its Affiliate or its or their Sublicensee) is unable to undertake development activities due to a delay caused by a Regulatory Authority), Flame will make the payment upon the first dosing of the first patient in a Phase III Clinical Trial or an equivalent registration for the Licensed Product by Flame, its Affiliate or Sublicensee. Such payment will be made within (\*\*\*) days after the first achievement, whether by Flame, its Affiliate or Sublicensee.  
(b)Subsequent Regulatory Milestones. Within (\*\*\*) days after the first achievement, whether by Flame, its Affiliate or Sublicensee, of each of the milestone events set forth in the table below (each, a “Regulatory Milestone Event”) by the Licensed Product, Flame will make the corresponding one-time non-refundable and noncreditable payment to Lilly.  
Regulatory Milestones for  
the Licensed Product  
Milestone Payment (U.S. dollars)  
1.  
First Regulatory Approval of an BLA or equivalent in the (\*\*\*) for the Licensed Product  
(\*\*\*)  
2.  
First Regulatory Approval of an BLA or equivalent in (\*\*\*) for the Licensed Product  
(\*\*\*)  
3.  
First Regulatory Approval of an BLA or equivalent for the Licensed Product in any (\*\*\*).  
(\*\*\*)  
Total Regulatory Milestones  
(\*\*\*)  
  
For each of Regulatory Milestone only one payment shall ever be due and payable with respect to the occurrence of each milestone by the Licensed Product containing the Licensed Compound.  
(c)Commercial Milestones. Within (\*\*\*) days after the first achievement, whether by Flame, its Affiliate or Sublicensee, of each of the milestone events set forth in the table below (each, a “Commercial Milestone Event”) for the Licensed Product, Flame will make the corresponding one-time non-refundable and noncreditable payment to Lilly.  
  
Commercial Milestones for  
the Licensed Product  
Milestone Payment (U.S. dollars)  
1.  
At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (\*\*\*)  
(\*\*\*)  
2.  
At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (\*\*\*)  
(\*\*\*)  
3.  
At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (\*\*\*)  
(\*\*\*)  
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4.  
At the end of the first calendar year in which aggregate worldwide sales for the Licensed Product in such calendar year exceeds (\*\*\*)  
(\*\*\*)  
Total Commercial Milestones  
(\*\*\*)  
  
For each of Commercial Milestone only one payment shall ever be due and payable with respect to the occurrence of each milestone.  
1.3Royalties  
Subject to Section 4.5, Flame will pay Xxxxx a tiered royalty on the Calendar Year Net Sales of the Licensed Product as follows:  
  
Portion of Calendar Year Net Sales  
of the Licensed Product (U.S. dollars)  
Royalty rate  
applicable to such portion  
  
(\*\*\*)  
(\*\*\*)  
  
More than (\*\*\*) to (\*\*\*)  
(\*\*\*)  
  
More than (\*\*\*) (i.e., (\*\*\*))  
(\*\*\*)  
  
  
1.4Royalty Payments  
Royalty obligations under Sections 4.3 (subject to adjustment pursuant to Section 4.5) shall commence on the date of First Commercial Sale of the Licensed Product in the Territory, and expire on a country-by-country basis, on the latest of the following dates (the “Royalty Term”):  
(a)the (\*\*\*) anniversary of the date of First Commercial Sale of the Licensed Product in such country;  
(b)the expiration of the last-to-expire Licensed Patent having a Valid Claim covering the (\*\*\*) of the Licensed Product as Commercialized in the country at issue; and  
(c)the expiration of any Data Exclusivity Period for the Licensed Product in the country at issue.  
Following the expiration of the Royalty Term with respect to the Licensed Product in a country, the licenses and rights granted to Flame hereunder with respect to the Licensed Product in the Territory shall become fully paid-up, royalty-free non-exclusive license. Notwithstanding  
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anything herein to the contrary, with respect to the Licensed Product only a single royalty payment shall be due and payable, regardless if such Licensed Product is covered by more than one Valid Claim or its distribution involves more than one country.  
1.5Royalty Reductions  
(a)Step-Down for Generic Version Provided No Valid Claim and No Data Package Exclusivity. On a country-by-country basis in the event that a Generic Version of the Licensed Product is commercially launched in a particular country and the Net Sales of such Licensed Product in such country subsequently decreases for (\*\*\*) by more than (\*\*\*) from the level of Net Sales in such country for such Licensed Product for the calendar quarter immediate( y prior to the entry of such Generic Version of such Licensed Product then the royalty owed to Xxxxx associated with such Net Sales for such Licensed Product in such country commencing on such date for the remainder of the Royalty Term shall be reduced by (\*\*\*).  
(b)Third Party Licenses. If Flame or any of its Related Parties (i) determines in good faith, and after consultation with Xxxxx, that it is reasonably necessary to obtain a license or other right from a Third Party under any Patent with one or more Valid Claims covering any Licensed Product or the Licensed Compound, or the composition of matter, method of use or manufacture thereof (including in connection with the settlement of a patent infringement claim), (in each case, “Third Party IP Payments”), then Flame may deduct (\*\*\*) of the Third Party IP Payments payable by Flame or any of its Related Parties to such Third Party from the (\*\*\*) otherwise payable by Flame to Lilly under Section 4.3.  
(c)Royalty Reduction Cap. Notwithstanding anything in this Section 4.5 to the contrary, in no case shall the royalties payable by Flame to Lilly under Section 4.3 with respect to Net Sales of such Licensed Product in such country be reduced by more than an aggregate of (\*\*\*) in any Calendar Quarter as a result of any and all reductions or offsets under this Section 4.5 of this Agreement. Any portion of the Third Party IP Payments payable to such Third Party with respect to such Licensed Product in such country that Flame would, but for the foregoing limitation on royalty reductions, be entitled to deduct under Section 4.5 shall be (\*\*\*).  
1.6Reports; Payment of Royalty  
During the Term, following the First Commercial Sale of the Licensed Product by Flame, Flame shall furnish to Lilly a (\*\*\*) written report for the Calendar Quarter showing the Net Sales of the Licensed Product subject to royalty payments sold by Flame and its Related Parties and broken down between Flame and any Sublicensees during the reporting period and the royalties payable under this Agreement. Flame shall also cooperate with Xxxxx to provide Xxxxx with such information that Xxxxx may reasonably request so as to enable Xxxxx to make quarterly accruals regarding royalties hereunder for financial reporting purposes. Reports shall be due thirty (30) days following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Flame will mail such reports to the attention of: Xxx Xxxxx and Company, Xxxxx Xxxxxxx Administration in Finance, Drop Code 1064, Lilly Corporate Center, Indianapolis, Indiana, 46285.  
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1.7Financial Audits  
Flame will keep and maintain (and to the extent applicable, will cause its Affiliates and Sublicensees to keep and maintain) proper and complete records and books of account in such form and detail as is necessary for the determination and verification of the royalty amounts payable by Flame (on behalf of itself and its Affiliates and Sublicensees) to Lilly under this Agreement and for the purposes of this Agreement. Such records need only be kept and maintained for up to (\*\*\*) months after the end of any Calendar Year.  
Within the term of this agreement and within (\*\*\*) years after its termination/expiration, Xxxxx shall not more than once each year have the right to have Xxxxx’x independent certified public accountants inspect Flame’s records for (\*\*\*) preceding years for the purpose of determining the accuracy of royalty payments. The independent certified public accountants shal1 keep confidential any information obtained during such inspection and shall report to Flame and Lilly only the amounts of net sales and royalties due and payable. If determined that additional royalties are owed, or that royalties were overpaid, during such period, Flame will pay Lilly the additional royalties, or Xxxxx will pay Flame the overpaid royalties within thirty (30) days of the date the independent certified public accountants written report is received by the paying party. The fees charged by such accounting firm will be paid by Xxxxx unless any additional royalties owed are at least (\*\*\*) and also exceed (\*\*\*) of the royalty obligation for the royalty period subject to the audit, in which case Flame will pay the reasonable fees of the accounting firm.  
Flame shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Xxxxx’x independent accountant to the same extent required of Flame under this Agreement.  
Xxxxx shall treat all financial information subject to review as Flame’s Confidential Information in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firms to enter into an acceptable confidentiality agreement with Flame, its Affiliate or Sublicensee, as applicable, obligating them to retain all such information in confidence pursuant to such confidentiality agreement.  
1.8Payment Method  
All payments to be made by Flame to Lilly under this Agreement shall be made in United States dollars by bank wire transfer in immediately available funds to a bank account designated in writing by Xxxxx.  
1.9Late Payment  
All late payments under the Agreement shall bear interest at the rate of (\*\*\*) for United States dollars as of the date such payment was due, taken from a widely accepted source of published interest rates, plus (\*\*\*) percentage points, or, if lower, the highest rate permitted by Applicable Law, until the date such payment is made.  
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1.10Tax Withholding If laws, rules or regulations require Flame or any Related Party to withhold income taxes or other taxes imposed upon payments due hereunder, Flame or such Related Party shall promptly notify Lilly of such requirement and shall make such withholding payments as required and subtract such withholding payments from the payments due. Flame shall, or shall require its Related Party to, submit any original receipts or other evidence of payment of any such withholding taxes to Lilly within (\*\*\*) days to allow Lilly to document such tax withholdings for purposes of claiming foreign tax credits and similar benefits and shall cooperate with reasonable requests of Xxxxx and at Xxxxx’x expense (without acting to the detriment of Flame or any Related Party) to the extent necessary for Xxxxx obtaining such credits and benefits. Notwithstanding the foregoing, if Flame sublicenses or assigns its payment obligations to an Affiliate or to a Third Party, and such sublicense or assignment results in a greater amount of withholding tax which may be subtracted from payments to Lilly than if Flame had fulfilled its payment obligations to Lilly directly, such Affiliate or Third Party shall increase the payment to Lilly as necessary such that the amount received by Xxxxx after such required income tax withholding is equal to the amount Lilly would have received if Flame had fulfilled such payment obligations to Lilly directly. If Xxxxx subsequently becomes aware that it recoups through foreign lax credits and similar benefits the incremental increase in payment described in the preceding sentence, Xxxxx will bring this to the attention of Flame and will extend a credit applicable to subsequent payments due to Xxxxx hereunder in amounts and on terms acceptable to Xxxxx such that Xxxxx receives the equal amount that would have been received by Xxxxx pursuant to this Agreement had such sublicense or assignment not occurred.. For clarity, Flame (including its Affiliates, assignees and sublicensees) is solely responsible for any income tax due in connection with its income under this Agreement.  
5.CONFIDENTIALITY; PUBLICATION  
B.1Nondisclosure Obligation  
Except to the extent expressly authorized by this Agreement, during the Term and for (\*\*\*) years thereafter, 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, the Confidential Information of the Disclosing Party. The Receiving Party may use Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than (\*\*\*)) to ensure that its Representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or unauthorized disclosure of the Disclosing Party’s Confidential Information by the Receiving Party or any of its Representatives.  
B.2Exceptions  
The Receiving Party’s obligations under Section 5.1 shall not apply to any information that the Receiving Party can show by competent evidence: (i) is already known to it or its Affiliates at the time it is disclosed to any of them, as evidenced by the Receiving Party’s written records, provided that Xxxxx shall not have the right to avail itself of the exception set forth in this  
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clause (i) with respect to Licensed Know-How listed on Exhibit C for so long Lilly is deemed the Receiving Party with respect thereto; (ii) is or becomes generally known to the public through no act or omission of the Receiving Party or any of its Affiliates in violation of the terms of this Agreement; (iii) has been lawfully received by the Receiving Party or any of its Affiliates from a Third Party without restriction on its disclosure and without, to the knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party or any of its Affiliates; or (iv) has been independently developed by the Receiving Party or any of its Affiliates without use of or reference to the Confidential Information of the Disclosing Party or any of its Affiliates, provided that Xxxxx shall not have the right to avail itself of the exception set forth in this clause (iv) with respect to Licensed Know-How set forth on Exhibit C for so long Lilly is deemed the Receiving Party with respect thereto.  
B.3Authorized Disclosure  
Notwithstanding the provisions of Section 5.1, 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)filing or prosecuting Patents as permitted by this Agreement;  
(b)enforcing the Receiving Party’s rights under this Agreement and performing the Receiving Party’s obligations under this Agreement;  
(c)prosecuting or defending litigation as permitted by this Agreement;  
(d)complying with applicable court orders, applicable laws, rules or regulations, or the listing rules of any exchange on which the Receiving Party’s or any of its Affiliates’ securities are traded;  
(e)in the case of Flame as the Receiving Party during the Term or after expiration (but not earlier termination) of this Agreement, disclosure in submissions to or filings with any Regulatory Authority (including, without limitation, in INDs and BLAs) with respect to any Licensed Compound or Licensed Product, and in correspondence with any Regulatory Authority in the Territory regarding any Licensed Compound or Licensed Product or any of the foregoing submissions or filings in the Territory;  
(f)disclosure to the Receiving Party’s Affiliates, to actual or potential Sublicensees (in the case of Flame as the Receiving Party during the Term or after expiration, but not earlier termination, of this Agreement), and to the Receiving Party’s Representatives who, in each case, have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential Sublicensee, or Representative agrees to be bound by terms of confidentiality and non use at least as restrictive as those set forth in this Section 5; and  
(g)disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in  
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confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use.  
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 5.3(c) or Section 5.3(d), each party (except in the case of Xxxxx, where Xxxxx may disclose a copy of the agreement in response to a valid request from a (\*\*\*) without complying with (i) or (ii) below) will (i) give reasonable advance notice to the Disclosing Party of such required disclosure, and (ii) at the Disclosing Party’s request and expense, shall cooperate with the Disclosing Party’s efforts to contest such requirement, to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the order was issued or the law or regulation required, and/or to obtain other confidential treatment of such Confidential Information.  
B.4Publication  
Lilly and its Affiliates shall not have the right to publish or present, and to authorize any Third Party to publish or present, the results of any study or clinical trial, or other development activities with respect to any Licensed Compound or Licensed Product, without the prior review or approval of Flame. Flame shall have the right in the future to issue a press release or other public statement describing Xxxxx’s progress or activities in developing the Licensed Product.  
B.5Publicity and Filing of this Agreement.  
Flame shall have the right in the future to issue a press release or other public statement relating to this Agreement and the transactions contemplated hereunder, subject to Xxxxx’x review and approval of such press release, approval not to be unreasonably withheld. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with any securities authority or with any stock exchange on which securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential treatment for the terms proposed to be redacted: provided that each Party shall ultimately retain control over what information to disclose to any securities authority or stock exchange, as the case may be, and provided further that the Parties shall 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 (nor any of its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings to any securities authority or stock exchange.  
B.6Prior Confidentiality Agreement  
As of the Effective Date, the terms of this Article 5 shall supersede the Confidentiality Agreement, and any information disclosed by a Party pursuant to the Confidentiality Agreement shall be deemed Confidential Information of such Party for purposes of this Agreement, except as expressly provided in Section 1.10.  
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6.REPRESENTATIONS AND WARRANTIES  
B.1Mutual Representations and Warranties  
Each party represents and warrants to the other that, as of the Effective Date:  
(a)it has the full right, power and authority to enter into this Agreement, and its execution of this Agreement, the fulfillment of its obligations and performance of its activities hereunder do not conflict with, violate, or breach, or constitute a default under, any material 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;  
(b)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;  
(c)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;  
(d)this Agreement is legally binding upon it, enforceable in accordance with its terms; and  
(e)all necessary consents, approvals and authorizations of all Governmental Authorities and other persons required to be obtained by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained.  
B.2Representations and Warranties of Flame  
Flame represents and warrants to Lilly that, as of the Effective Date:  
(a)neither Flame nor any of its Affiliates is debarred or disqualified under the Act or comparable Applicable Laws outside of the United States; and  
(b)no current employee of Flame or any of its Affiliates is debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof.  
B.3Representations and Warranties of Xxxxx  
Xxxxx represents and warrants to Flame that, as of the Effective Date:  
(a)the Listed Patents constitute all Patents owned or Controlled by Xxxxx or any of its Affiliates as of the Effective Date in the Territory that contain one or more claims covering any Licensed Compound or Licensed Product, or the composition of matter or formulation, or any method of use or manufacture, of any Licensed Compound or Licensed Product;  
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(b)Lilly has provided or otherwise made available to Flame current, true and complete copies of all unpublished Listed Patents;  
(c)all documents required to be filed and all payments required to be made in order to prosecute and maintain each Patent in the Listed Patents prior to the Effective Date in the Territory have been filed or made, as the case may be, in a timely manner, and no action has been taken that would constitute waiver, abandonment or any similar relinquishment of such rights;  
(d)no Listed Patent in the Territory is or has been involved in any interference, opposition, reissue, reexamination, revocation, inter partes review, post-grant review, post-grant proceeding, or equivalent proceeding in which the scope, validity or enforceability of any such Listed Patent is being or has been contested or challenged, and to Xxxxx’x knowledge, no such proceeding has been threatened with respect to any Listed Patent in the Territory;  
(e)no Listed Patent in the Territory has been adjudged invalid or unenforceable in whole or part, or, in the case of pending patent applications within the Listed Patents in the Territory, has been the subject of a final and non-appealable finding of unpatentability;  
(f)Xxxxx has the ful1 right, power and authority to grant the rights and licenses it purports to grant hereunder, and neither Xxxxx nor any of its Affiliates has granted any Third Party any rights or licenses that would interfere or be inconsistent with Flame’s rights and licenses hereunder;  
(g)to the knowledge of Lilly, there are no legal claims, judgments or settlements against or owed by Xxxxx or any of its Affiliates, threatened or pending legal claims or litigation, in each case relating to the Licensed Technology;  
(h)neither Xxxxx nor any of its Affiliates has received written notice from any Third Party claiming that the manufacture, use, sale, offer for sale or import of any Licensed Compound or Licensed Product infringes or misappropriates, or would infringe or misappropriate, the Patents or other intellectual property rights of any Third Party, and, to Lilly’s knowledge, none of the manufacture, use, sale, offer for sale and import of Licensed Compounds and Licensed Products infringes the Patents or misappropriates any other intellectual property rights of any Third Party;  
B.4Covenants.  
Each Party shall inform the other Party in writing immediately upon learning that it or any person or entity who has performed activities with respect to the Licensed Compound or a Licensed Product prior to the Effective Date is debarred or is the subject of a conviction described in Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or upon learning that any action is pending or threatened relating to the debarment or conviction of such Party or any person or entity used in any capacity by such Party or any of its Affiliates in connection with the Development or Commercialization of the Licensed Compounds or Products.  
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B.5No Other Representations or Warranties  
EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY AND ALL SUCH OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.  
B.6Limitation of Liability  
NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, OR LOST PROFITS, ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 6.6 (\*\*\*).  
7.INDEMNIFICATION  
B.1By Xxxxx  
Xxxxx agrees to indemnify, defend and hold harmless Flame, its Affiliates, and their respective Representatives (individually and collectively, the “Flame Indemnitee(s)”) from and against all losses, liabilities, damages and expenses, including reasonable attorneys’ fees and costs (individually and collectively, “Losses”), to which any Flame Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a “Claim”), to the extent such Losses arise out of (a) the gross negligence, illegal conduct or willful misconduct of Lilly or any Lilly lndemnitee or (b) Xxxxx’x material breach of this Agreement; except, in each case, to the extent such Losses arise out of any Flame lndemnitee’s gross negligence, illegal conduct or willful misconduct or Flame’s breach of this Agreement.  
B.2By Flame  
Xxxxx agrees to indemnify, defend and hold harmless Lilly, its Affiliates, and their respective Representatives (individually and collectively, the “Lilly Indemnitee(s)”) from and against all Losses to which any Lilly lndemnitee may become subject as a result of any Claim, to the extent such Losses arise out of (a) the gross negligence, illegal conduct or willful misconduct of Flame or any Flame lndemnitee, (b) the use, Development, Manufacture, Commercialization, handling, storage or other disposition of the Licensed Compound or Licensed Product by or on behalf of Flame or any of its Related Parties, including without limitation any product liability claim, or (c) Flame’s material breach of this Agreement; except, in each case, to the extent such Losses arise out of any Lilly lndemnitee’s gross negligence, illegal conduct or willful misconduct or Lilly’s breach of this Agreement.  
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B.3Defined Indemnification Terms  
Either the Lilly lndemnitee or the Flame lndemnitee shall be an “Indemnitee” for the purpose of this Article 7, and the Party that is obligated to indemnify the lndemnitee under Section 7.1 or Section 7.2 shall be the “Indemnifying Party”.  
B.4Defense  
The Indemnifying Party shall have the right to assume direction and control of the defense of the Claim at the Indemnifying Party’s sole expense by counsel selected by Indemnifying Party and reasonably acceptable to the lndemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such Claim subject to the terms of this Article 7, but shall consider in good faith all suggestions of the lndemnitee. Notwithstanding the foregoing, if the Indemnifying Party does not assume direction and control of the defense of the Claim within thirty (30) days after receiving notice of the Claim from the Indemnitee, the lndemnitee shall have the right to assume direction and control of such defense by counsel selected by the lndemnitee, and, without limiting the Indemnifying Party’s indemnification obligations, the Indemnifying Party shall reimburse the lndemnitee for all reasonable and documented costs, including reasonable attorney fees, incurred by the Indemnitee in defending itself within 30 days after receipt of any invoice therefor from the lndemnitee. If the lndemnitee assumes direction and control of the defense of such Claim in accordance with the preceding sentence, the Indemnifying Party may, at its own expense, participate in and monitor such defense with counsel of its own choosing.  
B.5Settlement  
The Indemnifying Party may settle any such Claim or otherwise consent to an adverse judgment with respect to such Claim (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where (i) there is no admission of legal wrongdoing on the part of the lndemnitee, and (ii) the only liability or other obligation imposed on the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld.  
B.6Notice  
The Indemnitee shall notify the Indemnifying Party promptly of any Claim for which the Indemnitee seeks indemnification under Section 7.1 or Section 7.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect to such Claim and the defense thereof.  
B.7Permission by Indemnifying Party  
The lndemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any  
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admission as to liability or fault without the express written permission of the Indemnifying Party.  
B.8Flame’s Insurance  
Flame, at its own expense, shall maintain liability insurance in an amount adequate to cover its obligations under this Agreement during the Term. Flame shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to Lilly upon request.  
8.INVENTIONS; PATENT PROVISIONS  
B.1Ownership of Inventions  
As between the Parties, Flame shall own the entire right, title and interest in and to any and all information and inventions, whether or not patentable, discovered, created, identified or made solely by Flame or any of its Representatives in the course of performing its obligations or exercising its rights under this Agreement, and all intellectual property rights in any of the foregoing. Inventorship shall be determined in accordance with U.S. patent laws.  
B.2Patent Filing, Prosecution and Maintenance  
(a)Program-Specific Patents.  
(i)Within thirty (30) days after the Effective Date, Xxxxx shall inform in writing any outside patent counsel and all local patent representatives used by Xxxxx or any of its Affiliates to Prosecute any Program-Specific Patent, that (A) the Program-Specific Patents have been exclusively licensed to Flame, (B) Flame has the first right to Prosecute the Program-Specific Patents, and (C) a copy of all future correspondence regarding the Program-Specific Patents should be sent to both Flame and Lilly, and Xxxxx shall forward copies of any correspondence it or any of its Affiliates receives from any such outside patent counsel or local patent representative or any patent office or other governmental body regarding the Program-Specific Patents to Flame. Upon Flame’s written request, for a period of up to (\*\*\*) days following the Effective Date, Xxxxx will be responsible for Prosecuting the Program-Specific Patents on Flame’s behalf at Flame’s cost. For a period of (\*\*\*) after the Effective Date, at Flame’s reasonable request, Xxxxx will, subject to reimbursement of its costs, cooperate with and reasonably assist and provide support to Flame in relation to the Prosecution of the Program-Specific Patents.  
(ii)Flame shall have the first right, but not the obligation, to Prosecute the Program-Specific Patents, at its sole cost and expense using outside counsel mutually acceptable to the Parties (such acceptance not to be unreasonably withheld). In the event that Flame desires to abandon or cease Prosecution of any such Program-Specific Patent, Flame shall provide written notice to Lilly thereof at least (\*\*\*) days prior to the next deadline for any action that must be taken with respect to such Program-Specific Patent in the relevant patent office. In such case, Xxxxx shall have the right, in its discretion, exercisable upon written notice to Flame  
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delivered no later than (\*\*\*) days after receipt of notice from Flame, to assume responsibility for Prosecution of such Program-Specific Patent, at its sole cost and expense  
(iii)Flame shall keep Xxxxx reasonably informed regarding Xxxxx’s Prosecution activities with respect to Program Specific Patents, including periodic updates and advance notice of and reasonable opportunity to review material Patent filings prior to the time they are made. Flame shall consider in good faith any comments Xxxxx may make with respect to Flame’s Prosecution activities with respect to Program Specific Patents.  
(b)Other Licensed Patents. Xxxxx shall have the sole right, but not the obligation, to Prosecute the Other Licensed Patents, at its sole cost and expense.  
B.3Cooperation  
Each Party agrees to cooperate fully in the Prosecution of Licensed Patents under Section 8.2. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, that may be reasonably required so as to enable the other Party to Prosecute patent applications in any country as permitted by Section 8.2; and (b) promptly informing the other Party of any request for, or filing or declaration of, any interference, opposition, reissue, reexamination, revocation, inter partes review, post-grant review, post-grant proceeding or similar proceeding relating to any Licensed Patent received by the Party.  
B.4Enforcement and Defense of Patents  
(a)Notice. Each Party shall notify the other Party in writing within ten (10) Business Days (except as expressly set forth below) of becoming aware of any alleged or threatened infringement by a Third Party of a Licensed Patent (“Infringement”), including (x) any such alleged or threatened Infringement on account of a Third Party’s manufacture, use or sale of Licensed Compound or Licensed Product, (y) any certification filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions in connection with an ANDA (an Abbreviated New Drug Application in the United States or a comparable application for marketing approval under Applicable Law in any country other than the United States) or other BLA for a Licensed Product (a “Patent Certification”), and (z) any declaratory judgment action filed by a Third Party that is developing, manufacturing or commercializing Licensed Compound or Licensed Product alleging the invalidity, unenforceability or non infringement of any Licensed Patent ((x)-(z), collectively, “Competitive Infringement”); provided, however, that each Party shall notify the other Party of any Patent Certification regarding any Licensed Patent that it receives, and such Party shall provide the other Party with a copy of such Patent Certification, within five (5) days of receipt.  
(b)Right to Enforce and Defend.  
(i)Program-Specific Patents. Flame shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Competitive Infringement of a Program-Specific Patent, at Flame’s expense and by counsel of its choice, and  
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Xxxxx shall have the right to be represented in any such action or proceeding, at Xxxxx’x expense and by counsel of its choice. If Flame fails to bring any such action or proceeding with respect to Competitive Infringement of any Program-Specific Patent within ninety (90) days following the notice of alleged Competitive Infringement, Xxxxx shall have the right to bring (or defend) and control any such action at its expense and by counsel of its choice, and Flame shall have the right, at its own expense, to be represented in any such action at its expense and by counsel of its choice.  
(ii)Other Licensed Patents. Xxxxx shall have the sole right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Infringement of an Other Licensed Patent, at Xxxxx’x expense and by counsel of its choice; provided, however, that in the event of Competitive Infringement of an Other Licensed Patent, Xxxxx shall consider in good faith any request by Flame for consent to bring (or defend) and control any action or proceeding with respect to such Competitive Infringement.  
(c)Cooperation. In the event a Party brings (or defends) an infringement action in accordance with this Section 8.4, or in the event a Party is entitled to bring (or defend) an infringement action in accordance with this Section 8.4 but lacks standing to do so, the other Party shall cooperate fully, including, if required to bring (or defend) such action, the furnishing of a power of attorney or being named as a party. Neither Party shall enter into any settlement or compromise of any action under this Section 8.4 which would in any manner alter, diminish, or be in derogation of the other Party’s rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.  
(d)Recovery. Except as otherwise agreed by the Parties in connection with a cost- sharing arrangement, any recovery realized by a Party as a result of any action or proceeding pursuant to this Section 8.4 with respect to Competitive Infringement, whether by way of settlement or otherwise, shall be applied first to reimburse the documented out-of-pocket legal expenses of the Party that brought (or defended) and controlled such action or proceeding incurred in connection with such action or proceeding, and second to reimburse the documented out-of-pocket legal expenses of the other Party incurred in connection with such action or proceeding, and any remaining amounts shall be (\*\*\*).  
B.5Patent Term Extensions  
Flame shall have the right to determine the Program-Specific Patents for which it will apply for patent extension in any country for any Licensed Product. Flame shall file for any such extension at Flame’s cost and expense. Lilly shall provide (\*\*\*) assistance to Flame in connection with such filings, provided that Flame shall pay or reimburse any out-of-pocket costs incurred by Xxxxx in providing such assistance.  
B.6Infringement of Third Party Rights  
Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either Party pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Neither Party shall have the right to settle any  
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patent infringement litigation under this Section 8.6 in a manner that diminishes the rights or interests of the other Party without the written consent of such other Party (which shall not be unreasonably withheld).  
B.7Trademarks  
As between the Parties, Flame shall be responsible for selecting, in its sole discretion, and shall own all right, title and interest in and to any trademarks adopted by Flame for use with the Licensed Products anywhere in the world (including all goodwill accruing with respect to such use), and shall be responsible for the registration, filing, maintenance and enforcement thereof. Flame shall have no right to use any trademark, tradename, or corporate name of Lilly or any of its Affiliates with the Licensed Products.  
9.TERM AND TERMINATION  
B.1Term and Expiration  
This Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Sections 9.2, 9.3 or 9.4, the term of this Agreement (the “Term”) shall continue in effect until the expiration of the last-to-expire Royalty Term for any and all Licensed Products.  
B.2Termination On Mutual Agreement  
This Agreement may be terminated by the mutual written agreement of the Parties.  
B.3Unilateral Termination by Flame  
Flame shall have the right to terminate this Agreement, in its entirety, in its sole discretion by giving (\*\*\*) days’ advance written notice to Xxxxx.  
B.4Termination for Cause  
(a)Material Breach. This Agreement may be terminated by a Party at any time during the Term upon written notice to the other Party if such other Party is in material breach of its obligations under this Agreement and has not cured such breach within (i) (\*\*\*) days in the case of any failure to make when due any payment hereunder, (ii) in all other cases (\*\*\*) days. Any such termination shall become effective at the end of such (\*\*\*) or (\*\*\*) (as applicable) period unless the breaching Party has cured such breach prior to the end of such period or has commenced all actions reasonable to timely cure such breach and continues to work diligently to accomplish such cure within (\*\*\*) days. Any right to terminate under this Section 9.4 shall be stayed in the event that, during any cure period, the Party alleged to have been in material breach shall have in good faith initiated dispute resolution in accordance with Article 10 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Article 10.  
(b)Insolvency. Either Party will have the right to terminate this Agreement in the event of a general assignment for the benefit of creditors of the other Party, or if proceedings of a  
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case are commenced in any court of competent jurisdiction by or against such other Party seeking (i) such other Party’s reorganization, liquidation, dissolution, arrangement or winding up, or the composition or readjustment of its debts, (ii) the appointment of a receiver or trustee for or over such other Party’s property, or (iii) similar relief in respect of such other Party under any law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, and such proceedings shall continue undismissed, or an order with respect to the foregoing shall be entered and continue unabated, for a period of more than (\*\*\*) days.  
(c)Right of Reversion. Without limiting Flames’s obligations under this Agreement (including Section 2.4), or any other rights or remedies of Lilly under this Agreement, at any time prior to Flame’s (or its Affiliate’s or its or their Sublicensee’s) receipt of Regulatory Approval for the Licensed Product, in the event that Flame (or its Affiliate or its or their sublicensee) has not conducted any material development activities with respect to the Licensed Compound or Licensed Product for a period of (\*\*\*) consecutive months; provided, that such (\*\*\*) month period shall be tolled for a period equal to the time that Flame (or its Affiliate or its or their Sublicensee) is prohibited from undertaking development activities due to a clinical hold mandated by a Regulatory Authority, Flame will notify Lilly in writing of the same and the Parties will discuss in good faith the reasons for such lack of development and potential resolution(s) thereof; provided that in the event that Flame does not commence any material development activities within (\*\*\*) months of such written notice to Xxxxx, Xxxxx shall have the right to terminate this Agreement and have the rights to the Licensed Compound revert to Lilly, subject to Xxxxx’x payment of the Alternate Royalty Rate for Net Sales in accordance with Section 9.5(c) upon delivery of at least (\*\*\*) days’ prior written notice to Flame  
(d)Damages. If either Party has the right to terminate this Agreement under Section 9.4, it may at its sole option, elect either to (i) terminate this Agreement and pursue any legal or equitable remedy available to it or (ii) maintain the Agreement in effect and pursue any legal or equitable remedy available to it.  
B.5Effect of Expiration or Termination  
(a)Expiration. Upon expiration (but not earlier termination) of this Agreement, the license and rights under Licensed Know-How granted by Xxxxx to Flame pursuant to this Agreement shall survive on a nonexclusive, royalty-free, fully-paid, irrevocable and perpetual basis.  
(b)Any Termination. Upon any termination of this Agreement prior to its expiration, all licenses and rights granted by Xxxxx to Flame pursuant to this Agreement shall automatically terminate and revert to Lilly, and all other rights and obligations of the Parties under this Agreement shall terminate, and any Sublicense shall automatically terminate; in each case, except as expressly provided elsewhere in this Article 9.  
(c)Termination by Flame Pursuant to Section 9.3 or by Xxxxx Xxxxxxxx to Section 9.4. In the event of termination of this Agreement by Flame pursuant to Section 9.3, or by Xxxxx pursuant to Section 9.4, the following provisions shall apply:  
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(i)Subject to Xxxxx’x payment of the Alternate Royalty Rate for Net Sales of Licensed Product made by Xxxxx or its Affiliates or licensees, effective as of such termination, Flame shall, and it hereby does, grant to Xxxxx:  
(1) Flame, effective as of such termination, hereby grants to Lilly an exclusive, worldwide (except as expressly set forth below), with the right to sublicense, under Flame Program-Specific Patents and Flame Know-How (each as defined below), to Develop, make, have made, use, sell, have sold, offer for sale and import Licensed Compounds and Licensed Products in the Field;  
(2)Flame, effective as of such termination, hereby grants to Lilly a non-exclusive, worldwide (except as expressly set forth below), with the right to sublicense, under Flame Blocking Patents (defined below), to Develop, make, have made, use, sell, have sold, offer for sale and import Licensed Compounds and Licensed Products in the Field; and  
(3)Flame, within ninety (90) days of the effective date of such termination (unless otherwise mutually agreed to by the Parties in writing), agrees to transfer and assign to Lilly of all Regulatory Applications and Regulatory Approvals for Licensed Products held in the name of Flame or any of its Affiliates (other than the Regulatory Materials, if any, previously transferred to Flame from Lilly, which will be transferred and assigned back to Lilly pursuant to Section 9.5(c)(ii)).  
For purposes of this Section 9.5(c)(i):  
a.“Alternate Royalty Rate” shall mean (i) (\*\*\*) if the Licensed Product as of the date of termination of the Agreement has not completed phase I clinical trial; (ii) (\*\*\*) if the Licensed Product as of the date of termination of the Agreement has completed a phase I clinical trial but has not yet completed phase II clinical trial; (iii) (\*\*\*) of the royalty rates set forth in Section 4.3 if the Licensed Product as of the date of termination of the Agreement has completed a phase II clinical trial but has not yet achieved Regulatory Approval; and (iv) (\*\*\*) royalty rates set forth in Section 4.3 if the Licensed Product as of the date of termination of the Agreement had achieved Regulatory Approval.  
b.“Flame Program-Specific Patents” means all Patents Controlled (other than pursuant to the license granted to Flame by Xxxxx under this Agreement) by Flame that, in each case, (A) claim only the composition of matter or formulation of, or any method of making or using, any Licensed Compound or Licensed Product (excluding any Other Product), and (B) do not claim the composition of matter or formulation of, or any method of making or using, any compound that is not a Licensed Compound or any product that is not a Licensed Product;  
c.“Flame Know-How” means all Know-How (excluding any Know-How covered by a claim of any published Flame Program-Specific Patent) that is (a) Controlled as of the effective date of termination of this Agreement by Flame or any of its Affiliates and (b) reasonably necessary or useful for, or was actually used or generated by or on behalf of Flame or any of its Affiliates in, the Manufacture, Development, Commercialization or  
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use of any Licensed Compound or Licensed Product; but excluding the Licensed Know-How; and  
d.“Flame Blocking Patents” means Patents Controlled (other than pursuant to the license granted to Flame by Xxxxx under this Agreement) by Flame, other than Flame Program-Specific Patents, that claim inventions actually practiced or generated by or on behalf of Flame in the development, manufacture, use, sale, offer for sale or import of any Licensed Compound or any Licensed Product (excluding any Other Product) prior to termination of this Agreement;  
(ii)As promptly as practicable (and in any event within ninety (90) days) after such termination, Flame shall, unless otherwise mutually agreed to by the Parties in writing: (A) transfer or assign, or cause to be transferred or assigned, back to Lilly or its designee all Regulatory Materials, if any, transferred by Xxxxx to Flame; and (B) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section 9.5(c)(ii) to Xxxxx;  
(iii)Flame shall reasonably cooperate with Lilly and its designee(s) to facilitate a smooth, orderly and prompt transition of any ongoing Licensed Product development activities being conducted by or on behalf of Flame or its Affiliates to Lilly or its designee(s), with due regard for patient safety and in compliance with all Applicable Laws and GCP;  
(iv)Flame shall return to Lilly, unless otherwise mutually agreed to by the Parties in writing, all Confidential Information of Xxxxx then in Flame’s possession except as necessary to exercise any licenses granted under Section 9.S(a) to Flame which are then irrevocable; and  
(v)any sublicense granted by Flame or its Affiliate to a Third Party under the license granted under Section 2.1 shall terminate as of the termination of this Agreement.  
B.6Accrued Obligations; Survival  
Neither expiration nor any termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. The following provisions shall survive the termination or expiration of this Agreement for any  
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reason: Articles 1, 4 (to the extent payments have accrued prior to termination), 5.1, 5.2, 5.3, 5.6, 6.5, 6.6, 7, 9.5, 9.6, 10 and 11.4 through 11.17.  
10.DISPUTE RESOLUTION  
B.1Disputes  
The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party’s rights and/or obligations hereunder. Subject to Section 10.2, any claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement (each, a “Dispute”) will be referred to the Chief Executive Officer of Flame and the Vice President (\*\*\*)of Xxxxx or their respective designees for attempted resolution. In the event such executives are unable to resolve such Dispute within thirty (30) days of such Dispute being referred to them, then, the Parties may, by mutual agreement, submit such Dispute to non-binding mediation, which non-binding mediation may be terminated by either Party at will. With respect to any Dispute not resolved under the above provisions of this Section 10.1, either Party may initiate litigation in accordance with Section 11.8 of this Agreement to seek relief from a court of competent jurisdiction.  
B.2Injunctive Relief and Patent Litigation  
Nothing contained in this Agreement (including Section 10.1) shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing nonbinding mediation proceeding. In addition, either Party may immediately bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to Section I0.1 of this Agreement.  
11.MISCELLANEOUS  
B.1Compliance with Applicable Laws.  
Each Party shall, and shall require its Affiliates, sublicensees, agents and subcontractors to comply in all material respects with all Applicable Laws in connection with the performance of their obligations and the exercise of their rights under this Agreement. Any internal compliance codes of a Party shall apply only to that Party, but the Parties agree to cooperate with each other to ensure that each Party is able to comply with the substance of its respective internal compliance codes and, to the extent practicable, to operate in a manner consistent with its usual compliance related processes.  
B.2Compliance with Anti-Corruption and Privacy Laws.  
(a)Anti-Corruption and Privacy. In connection with this Agreement, each Party and each of its Affiliates has complied and will comply with all applicable local, national, and  
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international laws, regulations, and industry codes dealing with data protection and privacy of personal information (“Privacy Laws”) and with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977 (“FCPA”), as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development (“OECD”) Convention on Combating Bribery of Foreign Officials in International Business Transactions.  
(b)No Bribery. In connection with this Agreement, neither Party, nor any of its Affiliates, has made, offered, given, promised to give, or authorized, nor will make, offer, give, promise to give, or authorize, in a manner that violates Applicable Laws, any bribe, kickback, payment or transfer of anything of value, directly or indirectly, to any person or to any Government or Public Official for the purpose of: (i) improperly influencing any act or decision of the person or Government or Public Official; (ii) inducing the person or Government or Public Official to do or omit to do an act in violation of a lawful or otherwise required duty; (iii) securing any improper advantage; or (iv) inducing the person or Government or Public Official to improperly influence the act or decision of any organization, including any government or government instrumentality, in order to assist Flame or Lilly in obtaining or retaining business.  
(c)Compliance in Development. In connection with this Agreement, Xxxxx specifically agrees that it will undertake all Development activities, in particular Development activities involving human subjects, in compliance with applicable GCPs, applicable Privacy Laws, and will utilize informed consent processes that permit the disclosure of such data in accordance with the terms of this Agreement.  
B.3Force Majeure  
Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.  
B.4Rights Upon Bankruptcy  
All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the US (collectively, the “Bankruptcy Laws”), licenses of rights to be “intellectual property” as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement  
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is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shal1 provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party’s written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.  
B.5Assignment  
Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, such consent not to unreasonably withheld, provided that either Party may assign this Agreement and its rights and obligations hereunder, without the other Party’s consent: (i) to any of its Affiliates, provided that the assigning Party shall remain liable and responsible to the non-assigning Party for the performance and observance of all such duties and obligations by such Affiliate; or (ii) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party (“Third Party Acquirer’’), whether by merger, sale of stock, sale of assets or otherwise (each, a “Sale Transaction”), provided that in the event of a Sale Transaction (whether this Agreement is actually assigned or is assumed by the Third Party Acquirer or the surviving corporation resulting from such Sale Transaction by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the Third Party Acquirer that existed prior to the Sale Transaction shall not be included in the technology licensed hereunder or otherwise subject to this Agreement. 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, and the name of a Party appearing herein will be deemed to include the name of such Party’s successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.  
B.6Severability  
If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.  
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B.7Notices  
All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:  
if to Flame, to:  
Flame Biosciences Inc.  
000 Xxxxxxx Xxxxxx  
Xxxxx 0000  
Xxx Xxxx, Xxx Xxxx 00000  
Attn: Chief Executive Officer  
with copy to:  
Torreya Partners LLC  
000 Xxxxxxx Xxxxxx  
Xxxxx 0000  
Xxx Xxxx, Xxx Xxxx 00000  
if to Lilly, to:  
Xxx Xxxxx and Company  
Lilly Corporate Center  
Indianapolis, IN 46285  
Attn: Office of Alliance Management  
with copy to:  
Xxx Xxxxx and Company  
Lilly Corporate Center  
Indianapolis, IN 46285  
Attn: General Patent Counsel  
  
Facsimile:  
or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a Business Day (provided that if given by facsimile, the transmitting Party received confirmation of complete transmission); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.  
B.8Applicable Law  
This Agreement shall be governed by and construed in accordance with the laws of the United States federal law and Delaware state law, without reference to any rules of conflict of laws.  
B.9Entire Agreement; Amendments  
The Agreement contains the entire understanding of the Parties with respect to the rights and licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the rights and licenses granted hereunder are superseded by the terms of this Agreement, including the prior Confidentiality Agreement. The Agreement may be  
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amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.  
B.10Headings  
The captions to the several Articles and Sections hereof are for convenience of reference only, are not a part of the Agreement, and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement.  
B.11Independent Contractors  
It is expressly agreed that Flame and Lilly shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Flame nor Lilly shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.  
B.12Waiver  
The failure by either Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement or any breach hereof by the other Party shall neither impair such provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or any other. No waiver by a Party of a particular provision or right shall be effective unless in writing, specific as to a particular matter and, if applicable, for a particular period of time, and signed by such Party.  
B.13Cumulative Remedies  
Except as expressly set forth herein, 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 at law or in equity.  
B.14Waiver of Rule of Construction  
Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.  
B.15Construction  
Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, and the use of any gender will be applicable to all genders. The term “including” as used herein means including, without limiting the generality of any description that precedes such term, and shall be deemed to be followed by the phrase “but not limited to,” “without limitation” or words of similar import regardless of whether such words are actually written there (and drawing no implication from the actual inclusion of such phrase in some instances after the word “including” but not others). References to “Article”, “Articles”,  
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“Section”, “Sections”, “Exhibit” or “Exhibits” are references to the numbered Article(s) or lettered Exhibit(s) of this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to a particular law, rule or regulation mean such law, rule or regulation as in effect as of the relevant time, including all rules and regulations thereunder and any successor law, rule or regulation in effect as of the relevant time, and including the then-current amendments thereto; the word “or” has the inclusive meaning that is typically associated with the phrase “and/or”; whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (d) references to a particular person or entity include such person’s or entity’s successors and assigns to the extent not prohibited by this Agreement; (e) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner; and (t) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits).  
B.16Use of Third Parties  
Notwithstanding any delegation of obligations under this Agreement by a Party or its Affiliates or to a Third Party, such Party shall remain primarily liable and responsible for the performance of all of its obligations under this Agreement and for causing such Affiliates or Third Parties to act in a manner consistent herewith, to the extent applicable. No Party contracting with any Third Party shall agree to any term that would make it unable to comply with its obligations under this Agreement.  
B.17Counterparts  
The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties. Signatures provided by facsimile transmission or in AdobeTM Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.  
Signature Page Follows.  
  
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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.  
FLAME BIOSCIENCES, INC.  
By: /s/ Xxx Xxxxx   
Name: Xxx Xxxxx  
Title: Chief Executive Officer  
Date: November 25, 2019  
XXX XXXXX AND COMPANY  
By: /s/ Xxxxxx X. Xxxxxxxxxx, M.D., Ph.D.   
Name: Xxxxxx X. Xxxxxxxxxx, M.D., Ph.D.  
Title: President, Lilly Research Laboratories  
 Chief Scientific Officer  
Date: November 21, 2019  
  
  
  
  
EXHIBIT A:  
Licensed Compound Structure  
  
  
EXHIBIT B:  
Listed Patents  
  
  
  
EXHIBIT C:  
Lilly Licensed Know How Materials and Related Documentation  
  
  
EXHIBIT D  
Lilly Animal Care and Use Requirements