Exhibit 10.8  
[####] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.  
LICENSE AGREEMENT  
by and between  
WYETH,  
acting through its  
WYETH PHARMACEUTICALS DIVISION,  
And  
CARDIOKINE, INC.  
March 15, 2004  
LICENSE AGREEMENT  
This License Agreement (this “Agreement”) is entered into this 15th day of March, 2004 (the “Effective Date”), by and between Wyeth, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals Division, (“Wyeth”), and Cardiokine, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 0000 Xxxxxx Xx, 0xx Xxxxx, Xxxxxxxxxxxx, XX 00000 (“Cardiokine”). Wyeth and Cardiokine may each be referred to herein individually as a “Party” and collectively as the “Parties”.  
WHEREAS, Cardiokine is engaged in the research, development and commercialization of human pharmaceutical products;  
WHEREAS, Wyeth has developed and owns a vasopressin antagonist compound known as lixivaptan and patents and proprietary know-how relating to products including the Licensed Compound (as defined herein);  
WHEREAS, Cardiokine desires to obtain from Wyeth, and Wyeth desires to grant to Cardiokine, a license of such rights for the development and commercialization of pharmaceutical products for use in humans; and  
NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:  
1. DEFINITIONS.  
For purposes of this Agreement, the following terms shall have the following respective meanings:  
Affiliate(s). “Affiliate(s)” shall mean, with respect to any Person, any Person which directly or indirectly through the ownership of equity securities or through other arrangements either controls, or is controlled by or is under common control with, such Person. A Person shall be deemed to be in control of another entity if it owns or controls at least fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority); provided, however, that a Person shall not be deemed to be in control of an entity in which a Person owns a majority of the ordinary voting power to elect a majority of the board of directors or other governing board but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.  
Calendar Quarter. “Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.  
Cardiokine Know-How. “Cardiokine Know-How” shall mean all Know-How, whether patentable or not, owned or Controlled by Cardiokine as of the date of termination of this Agreement directed to the Licensed Compound, to Licensed Products, and to the Research, Development, Manufacture or Commercialization of the Licensed Compound and/or Licensed Products.  
Commercialization. “Commercialization” shall mean any and all activities of using, marketing, promoting, distributing, offering for sale, selling, importing and exporting Licensed Products. When used as a verb, “Commercialize” shall mean to engage in Commercialization.  
Commercially Reasonable Efforts. “Commercially Reasonable Efforts” shall mean efforts and resources normally used by a Party for a product or compound owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, and other relevant factors.  
Confidential Information. “Confidential Information” shall mean, with respect to each Party, confidential data or, information, which belong in whole or in part to such Party or its Affiliates and/or information designated as Confidential Information of such Party The term Confidential Information does not included information which (a) was generally available to the public or otherwise part of the public domain at the time of its receipt, (b) becomes generally available to the public or otherwise part of the public domain other than as a result of disclosure by the Receiving Party (as defined in Section 8 below) in breach of Section 8, (c) becomes available to the Receiving Party on a non-confidential basis from a source other than the Disclosing Party (as defined in Section 8 below) or its Affiliates, provided that, to the Receiving Party’s knowledge, such source is not bound by a confidentiality agreement with the Disclosing Party or its Affiliates, (d) is independently developed by the Receiving Party without use of the Confidential Information of the Disclosing Party, (e) is required to be disclosed pursuant to the order or requirement of a court or similarly empowered administrative or government agency provided that Receiving Party shall give Disclosing Party written notice of such order or requirement promptly upon receipt and prior to any disclosure and shall provide reasonable cooperation and assistance in opposing such order or requirement if requested by the Disclosing Party, or (f) was in Receiving Party’s possession prior to receipt from the Disclosing Party without any obligations of confidentiality.  
“Controls” or “Controlled” shall mean with respect to know-how and patent rights, the possession of the ability to grant licenses or sublicenses without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party.  
Development. “Development” shall mean all activities performed by or on behalf of Cardiokine, its Affiliates or sublicensees in a country or territory with respect to a Licensed Product from the Effective Date that are directly related to obtaining Regulatory Approval of such Licensed Product in such country or territory for the indication under study. When used as a verb, “Develop” shall mean to engage in Development.  
EMEA. “EMEA” shall mean the European Agency for the Evaluation of Medicinal Products or any successor agency thereto.  
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Europe. “Europe” shall mean the member states of the European Union including the new member states from time to time.  
FDA. “FDA” shall mean the United States Food and Drug Administration or any successor agency thereto.  
FD&C Act. “FD&C” Act shall mean the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.  
Field. “Field” means all fields other than Veterinary Use.  
First Commercial Sale. “First Commercial Sale” shall mean on a country-by-country basis, with respect to any Licensed Product, the first sale of such Licensed Product under this Agreement to a Third Party in a country in the Territory, after such Licensed Product has been granted Regulatory Approval in such country.  
Know-How. “Know-How” shall mean all proprietary and/or confidential information and data, including, with respect to a compound or a product containing such compound, manufacturing methodology, tangible biological materials, and other information including, for example, information regarding its stability, pharmacology, toxicology, clinical studies, compositions and formulations for administration.  
Licensed Compound. “Licensed Compound” shall mean lixivaptan, a vasopressin antagonist, with chemical name, [####], and any pharmaceutically acceptable salt or complex thereof.  
Licensed Know-How. “Licensed Know-How” shall mean all Know-How, whether patentable or not, that (a) Wyeth or any of its Affiliates owns or Controls as of the Effective Date, (b) is related exclusively to the Licensed Compound, including the Manufacture or use thereof, and (c)is necessary or useful for the Manufacture, sale or use of the Licensed Compound. Licensed Know-How includes clinical information (including clinical data, files, protocols, and reports), as well as manufacturing information (including manufacturing batch records). The Licensed Know-How relating to clinical information is identified in Exhibit B to this Agreement. The Licensed Know-How relating to manufacturing information is not identified in any Exhibit to this Agreement.  
Licensed Patents. “Licensed Patents” shall mean all Patents owned or Controlled by Wyeth or any of its Affiliates that would, but for the license granted hereunder, be infringed by the manufacture, sale or use of the Licensed Compound. The Licensed Patents as of the Effective Date are listed on Exhibit A. Licensed Patents shall include, (a) all patents that issue from the patent applications listed on Exhibit A, and (b) any and all continuations, continuations- in-part, divisions, renewals, revivals, revalidations, substitutes, re-issues, extensions and reexaminations all U.S. and foreign counterpart applications and patents of any of the items described in (a).  
Licensed Product(s). “Licensed Product(s)” shall mean any and all pharmaceutical product(s) containing a Licensed Compound in any formulation or dosage form for any and all indications for use in the Field. For the avoidance of doubt, each formulation or dosage form of a pharmaceutical product containing a Licensed Compound shall be a separate Licensed Product.  
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Major European Market Countries. “Major European Market Countries” shall mean [####].  
Manufacture, Manufactured or Manufacturing. “Manufacture”, “Manufactured” or “Manufacturing” shall mean all activities undertaken by or on behalf of Cardiokine or its Affiliates or sublicensees that are involved in the production of a Licensed Compound or a Licensed Product.  
NDA. “NDA” shall mean a United States New Drug Application.  
Net Sales. “Net Sales” shall mean the gross amount invoiced by Cardiokine or its Affiliates or sublicensees in respect of sales of Licensed Compound or Licensed Products to Third Parties in the Territory, less returns and less the following amounts (a) customary quantity, trade and/or cash discounts, refunds, chargebacks, allowances, rebates (including any and all federal, state or local government rebates, e.g., Medicaid rebates) and any price adjustments allowed or given; (b) sales and other excise taxes and duties directly related to the sale, to the extent such items are included in the gross invoice price; (c) credits for returned goods; (d) transportation charges to the extent included in the gross invoice price; and (e) agents’ commissions. Sales of Licensed Product(s) by Cardiokine, or an Affiliate or sublicense of Cardiokine, to any Affiliate or sublicensee which is a reseller thereof shall be excluded, and only the subsequent sale of such Licensed Product(s) by Affiliates or sublicensees of Cardiokine to Third Parties shall be deemed Net Sales hereunder. Any transfer of Licensed Produces) by Cardiokine, or an Affiliate or sublicensee of Cardiokine, to any party in connection with the development, testing, marketing or promotion of any Licensed Produces) shall also be excluded from Net Sales.  
Patents. “Patents” shall mean (a) patents, patent applications and patents issuing from any such applications, and (b) any continuation, continuation-in-part, division, renewal, substitute, re-issue, extension, re-examination, revival or revalidation of any of the items in clause (a)/  
Person. “Person” shall mean an individual, a corporation, a limited liability company, a partnership, an association, a trust or other entity or organization, including a governmental entity.  
Regulatory Approval. “Regulatory Approval” shall mean the technical, medical and scientific licenses, registrations, authorizations and approvals of any national (e.g., the FDA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the Research, Development, Manufacture and Commercialization of Licensed Product(s) in the Territory, including, without limitation, INDs and other submissions and approvals necessary to conduct clinical studies, approvals of ND As, • supplements and amendments, pre- and post- approvals, and labeling approvals.  
Regulatory Approval Application. “Regulatory Approval Application” shall mean an application submitted to a Regulatory Authority seeking Regulatory Approval for a Licensed Product.  
Regulatory Authority. “Regulatory Authority” shall mean any national (e.g., the FDA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in the Territory involved in the granting of Regulatory Approval for a Licensed Product.  
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Research. “Research” shall mean those discovery and preclinical activities undertaken by or on behalf of Cardiokine, its Affiliates or sublicensees with respect to a Licensed Product prior to the Development of such Licensed Product, including, without limitation, medicinal chemistry, pharmacology, preclinical toxicology, and formulation of such Licensed Product. When used as a verb “Research” shall mean to engage in Research.  
Territory. “Territory” shall mean worldwide. No territories are reserved for Wyeth or any Third Party.  
Third Party(/ies). “Third Party(/ies)” shall mean any Person(s) other than Cardiokine, Wyeth or their respective Affiliates.  
Trademarks. “Trademarks” shall mean trademarks trade names brand names logos symbols, service marks, designs and the goodwill of the business symbolized thereby, and related registrations and applications for registration in the Unites States Patent and Trademark Office or in any similar office or agency in the Territory.  
Valid Claim. “Valid Claim” shall mean a claim of an issued patent within the Licensed Patents that has not lapsed, expired, been cancelled, or become abandoned, and has not been held invalid by a court or other appropriate body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.  
Veterinary Use. “Veterinary Use” shall mean the treatment of non-human animals.  
Wyeth Intellectual Property. “Wyeth Intellectual Property” shall mean the Licensed Patents and the Licensed Know-How.  
2. LICENSE.  
2.1 License to Cardiokine. Subject to the first negotiation rights of Wyeth pursuant to Article 6, Wyeth hereby grants to Cardiokine an exclusive license, including the exclusive right to sublicense, under the Wyeth Intellectual Property solely to Research, Develop, Manufacture and Commercialize Licensed Compounds and Licensed Products in the Field within the Territory.  
2.2 Sublicensing. Subject to the rights of Wyeth pursuant to Article 6, Cardiokine may grant to any Third Party sublicenses of the rights granted to it under Section 2.2.  
2.3 Technology Transfer and Assistance. For [####]following the Effective Date, Wyeth shall provide, at its cost, reasonable assistance to Cardiokine to effect the orderly transfer to Cardiokine of the Licensed Know-How. For this purpose, Wyeth will deliver to Cardiokine the Wyeth materials listed on Exhibit B within [####]after the Effective Date. The Parties will have telephone conferences and, upon mutual agreement, meetings at Wyeth as often as reasonably necessary to review the status of the transfer. The Parties shall have a one (1) day meeting [####]after the Effective Date at Wyeth in which Cardiokine and Wyeth shall review the status of the transfer of the Licensed Know-How.  
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2.4 Noncompetition Within The Field. During the term of this Agreement, Wyeth and its Affiliates shall take all reasonable measures to prevent any and all off-label uses of any vasopressin antagonist sold by it for Veterinary Use.  
3. DILIGENCE AND DEVELOPMENT.  
3.1 Diligence. Cardiokine shall use Commercially Reasonable Efforts to Research Develop, Manufacture and Commercialize Products in the United States, Canada, and the Major European Market Countries. Without limiting the generality of the foregoing, Cardiokine shall) use Commercially Reasonable Efforts to file an NDA in the United States as soon as reasonably practicable. Cardiokine shall have sole responsibility for all expenses it incurs in connection with the performance of its obligations under this Agreement.  
3.2 Reports. On a semiannual basis but no later than June 30 and December 31 of each calendar year, Cardiokine shall provide Wyeth with a written report summarizing its Research, Development (including the status of any Regulatory Approval process) and Commercialization activities, with respect to Licensed Compounds and Licensed Products during the just-ended semiannual period. Such report and all information contained therein shall be deemed to be Confidential Information of Cardiokine.  
4. MANUFACTURE AND COMMERCIALIZATION OF PRODUCTS; REGULATORY MATTERS.  
4.1 Manufacture. Pursuant to the licenses granted to Cardiokine in Section 2, Cardiokine shall have the sole right and responsibility (subject to Section 4.2), at its own expense, itself and/or through Affiliates and/or sublicensees, to Manufacture or have Manufactured Licensed Compound and Licensed Products in order to perform its obligations under this Agreement.  
4.2 Supply by Wyeth. Notwithstanding Section 4.1, within [####]after the Effective Date Wyeth shall provide to Cardiokine, FOB Wyeth shipment site, with Wyeth’s existing (as of the Effective Date) inventory of Licensed Compounds, formulated clinical supplies of Licensed Compounds, if any, and Licensed Product, if any, in “AS IS” condition. Wyeth shall have no obligation to requalify, repurify or certify any such inventory of Licensed Compounds, formulated clinical supplies of Licensed Compounds or Licensed Product; provided, however, that Wyeth shall provide all available documentation relating to the manufacture and testing of said inventory and formulated clinical supplies of Licensed Compounds and Licensed Product.  
4.3 Regulatory Approvals. As between the Parties, Cardiokine (and/or its designee) shall have the sole right and responsibility, at its own expense, for preparing and filing, in its (and/or its designee’s) own name, all Regulatory Approval Applications. Cardiokine (and/or its designee) shall have the sole right and responsibility, at its own expense, for communicating with any Regulatory Authority, and preparing and filing any submissions which may be necessary or appropriate, regarding any Regulatory Approval Application in order to obtain the corresponding Regulatory Approval or with respect to making any supplements or modifications thereto.  
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4.4 Regulatory Reporting. As between the Parties, Cardiokine (and/or its designee) shall have sole right and responsibility, at its own expense, for filing all reports required to be filed, and for responding to all correspondence from any Regulatory Authority which may be required, in order to maintain any Regulatory Approvals granted for Licensed Products within the Territory, including, without limitation, adverse drug experience reports.  
4.5 Use of and Reference to Regulatory Approval Applications. Wyeth shall have, and Cardiokine hereby grants to Wyeth, the right to use and make reference to the Regulator Approval Applications filed by Cardiokine or any of its Affiliates or sublicensees in any jurisdiction m the Territory (and all data included therewith, which data shall be provided to Wyeth upon Wyeth’s written request) for the sole purpose of Developing, Manufacturing and Commercializing a product containing Licensed Compounds solely for Veterinary Use and for no other purpose whatsoever shall be without any charge or royalty payable to Cardiokine. Cardiokine shall have, and Wyeth hereby grants to Cardiokine, the right to use and make reference to the Regulatory Approval Applications filed by Wyeth or any of its Affiliates or sublicensees in any jurisdiction in the Territory (and all data included therewith, which data shall be provided to Cardiokine upon Cardiokine’s written request) for the sole purpose of Developing, Manufacturing and Commercializing a product containing Licensed Compounds for use in the Field. Such right shall be without any charge or royalty payable to Wyeth.  
5. CONSIDERATION.  
5.1 Payments. Subject to the terms and conditions, and during the term of this Agreement, Cardiokine shall make the following payments to Wyeth:  
Within [####]after the Effective Date (the “Signing $[####] Fee”)  
And within [####]after the first occurrence of each of the following events with respect to the first Licensed Product to achieve such milestone;  
 [####] $[####]  
[####] $[####]  
[####] $[####]  
Total of Signing Fee and Milestone Payments: $[####]  
Each of the foregoing payments shall be non-refundable and not creditable against any other payments required by tin’s Agreement. Each of the foregoing payments shall be made only once for the first Licensed Product. Thereafter, no additional Milestone Payments shall be due or payable by Cardiokine to Wyeth under this Agreement or for other Licensed Products.  
5.2 Royalties. Cardiokine shall pay Wyeth royalties on Net Sales on Licensed Products at the rates set forth m the below table. Royalty payments shall be made by Cardiokine to Wyeth on a [####] for Net Sales of Licensed Product(s) that are manufactured or sold in such country and (i) such manufacture or sale is covered by one or more Valid Claims of an issued patent within the Licensed Patents or (ii) until the [####] anniversary of the First Commercial Sale of said Licensed Product(s) in such country, whichever is latest; provided however that in the event that no Valid  
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Claim of a patent within the Licensed Patents covers the manufacture or sale of a Licensed Product(s) within a particular country and a Licensed Compound (or other compound previously within the scope of a Valid Claim) is being marketed by one or more Third Parties in such country at a level equal to [####] or more of the market for such compounds based on volume of units sold in such country, the applicable royalty rates with respect to Net Sales of such Licensed Produces) in such country shall be reduced by [####]:  
 On that Portion of  
Net Sales in the Territory during a  
Calendar Year: Royalty Rate (% of  
Net Sales)  
[####]  
 [####]  
[####]  
 [####]  
[####]  
 [####]  
[####]  
 [####]  
[####]  
 [####]  
Generally, Net Sales shall be computed on the basis of sales of Licensed Products as set forth above. However, if Cardiokine sells a Licensed Compound and knows or reasonably should know that some or all of such Licensed Compound subject to such sale will be Manufactured into Licensed Product intended for commercial sale or commercial distribution, then Cardiokine shall pay royalties as set forth in this Section 5.2 on the Net Sales generated from such sale of Licensed Compound and submit reports and payments as set forth in Section 5.3; provided that to the extent some or all of such Licensed Compound subject to such sale is subsequently Manufactured into Licensed Product intended for commercial sale or commercial distribution, then Cardiokine shall also pay royalties as set forth in this Section 5.2 on the difference between the Net Sales from the sale of Licensed Products Manufactured from such Licensed Compound and the Net Sales from the sale of such Licensed Compound.  
5.3 Reports and Payments.  
5.3.1 Statements and Payments. Cardiokine, within [####]after the end of each Calendar Quarter, shall deliver to Wyeth a report in form and substance reasonably acceptable to Wyeth setting forth for such Calendar Quarter the following information, on a Licensed Product by Licensed Product basis, the Net Sales of each Licensed Product (and supporting schedules showing the information from which Cardiokine calculated Net Sales). No such reports shall be due for any Licensed Product before the First Commercial Sale of such Licensed Product. Cardiokine shall remit the total amount due under Section 5.2 in respect of each Calendar Quarter at the time as it delivers the report required by this Section 5.3.1 for such Calendar Quarter but in no event later than [####]after the completion of such Calendar Quarter.  
5.3.2 Currency. All amounts payable hereunder shall be in United States dollars. To the extent that Cardiokine or its Affiliates or sublicensees invoice Products in currency other than United States for purposes of calculating Net Sales, the invoiced amounts shall be converted to United States dollars at the rate of exchange quoted in the Wall Street Journal on the last business day of the Calendar Quarter in which the applicable invoice was invoiced.  
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5.3.3 Reimbursements; Interest. To the extent this Agreement requires a Party (the “Paying Party”) to reimburse the other Party (the “Paid Party”) for an expense, the Paying Party will so reimburse the Paid Party no later than [####]after receipt of the invoice from the Paid Party and receipts and bills supporting the amount of the reimbursable expense. Overdue amounts under this Agreement shall bear interest at the lower of [####]  
5.3.4 Taxes and Withholding. All payments under this Agreement will be made without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by applicable United States laws or regulations. If Cardiokine or any of its Affiliates or sublicensees so required to deduct or withhold any such amount, Cardiokine (and/or its Affiliates or sublicensees, as applicable) will (a) promptly notify Wyeth of such requirement, (b) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against Wyeth, and (c) promptly forward to Wyeth an official receipt (or certified copy) or other documentation reasonably acceptable to Wyeth evidencing such payment to such authorities. The foregoing shall not be construed to permit Cardiokine to reduce the royalties payable to Wyeth as a result of any currency control measures or withholding obligations imposed by any governmental authority, foreign or domestic, in respect of its transactions with its Affiliates or sublicensees or with Third Parties. Notwithstanding the above, in each country where the local currency is blocked and cannot be removed from the country, at the election of Cardiokine, royalties accrued in that country shall be paid to Wyeth in the country in local currency by deposit in a local bank designated by Wyeth.  
5.4 Maintenance of Records; Audits.  
5.4.1 Record Keeping. Cardiokine shall keep and shall cause its Affiliates and sublicensees to keep accurate books and accounts of record in connection with die sale of Licensed Products during the term of this Agreement, in sufficient detail to permit accurate determination of all figures, including Net Sales, necessary for verification of amounts to be paid hereunder. Cardiokine and its sublicensees shall maintain such records for a period of at least three (3) years after the end of the calendar year in which they were generated.  
5.4.2 Audits. Upon [####]prior written notice from Wyeth, Cardiokine shall permit and shall cause its Affiliates and sublicensees to permit an independent certified public accounting firm selected by Wyeth to examine the relevant books and records of Cardiokine and its Affiliates as may be reasonably necessary to verify the accuracy of the reports submitted in accordance with Section 5.3.1 and the payment of all amounts hereunder. Such audits shall be conducted no more than [####]. Cardiokine shall have the right to approve the auditor selected by Wyeth, such approval not to be unreasonably withheld. The accounting firm shall be provided access to such books and records at Cardiokine’s facility(ies) where such books and records are normally kept and such examination shall be conducted during Cardiokine’s normal business hours. Cardiokine may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to Cardiokine’s facilities or records. Upon completion  
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of the audit, the accounting firm shall provide to Cardiokine and Wyeth a written report disclosing whether the reports submitted by Cardiokine are correct or incorrect, whether the royalties paid are correct or incorrect, and, in each case, the specific details concerning any discrepancies. Any sublicense by Cardiokine of its rights under this Agreement shall contain an audit provision that permits Wyeth to audit the books and records of die sublicensee to the same extent and using file same procedures as that set forth in this Section 5.4.2,  
5.4.3 Underpayments/Overpayments. If such accounting firm concludes that additional royalties were due to Wyeth, Cardiokine shall pay to Wyeth the additional royalties within [####]of the date Cardiokine receives such accountant’s written report so concluding. If such underpayment exceeds [####]of the royalties that should have been paid to Wyeth in respect of the period covered by such audit, Cardiokine also shall reimburse Wyeth for the reasonable out-of-pocket expenses incurred by Wyeth in conducting the audit. If such accounting firm correctly concludes that Cardiokine overpaid royalties to Wyeth, Wyeth will refund such overpayments to Cardiokine within [####]after the date Wyeth receives such accountant’s report so correctly concluding.  
6. MARKETING PARTNERSHIP.  
6.1 Right of First Negotiation. In the event Cardiokine at any time seeks or determines to enter into a marketing partnership, co-promotion or other equivalent or similar arrangement (a “Marketing Partnership”) for a Licensed Product within the Territory, Cardiokine shall provide Wyeth with written notice thereof (the “Initial Notice”) and comply with this Section 6.1 prior to negotiating with any Third Party for such Marketing Partnership. Cardiokine shall also provide to Wyeth, together with such written notice, an electronic copy of the ND A submitted to the FDA for such Licensed Product (if one has been submitted at the time of such Initial Notice) as well as the market studies and reports and other similar or related information and data in respect of such Licensed Product in Cardiokine’s or its Affiliates’ possession or control in order for Wyeth to determine its interest in entering into a Marketing Partnership with Cardiokine. All such information provided to Wyeth hereunder shall be deemed to be Confidential Information of Cardiokine. Wyeth shall have [####]from the date of its receipt of the Initial Notice to give Cardiokine written notice that it is exercising its right to negotiate with Cardiokine regarding a Marketing Partnership (such notice being an “Exercise Notice”). If Wyeth gives Cardiokine an Exercise Notice within the foregoing [####] period, then during the period beginning on the date of the Exercise Notice and ending on the date that is [####] after the date of the Exercise Notice, the Parties shall promptly and diligently negotiate, on an exclusive basis and in good faith, to enter into a Marketing Partnership for such Licensed Product on commercially reasonable terms. If (i) Wyeth fails to give an Exercise Notice within the foregoing [####]day period or (ii) if the Parties are unable, within the foregoing [####]period, to enter into a term sheet or letter of intent setting forth the principal terms of the Marketing Partnership to be entered into, or (iii) if the Parties are unable to enter into a definitive agreement setting forth all the terms and conditions of the Marketing Partnership within [####]after entering into said term sheet or letter of intent, then Cardiokine shall be free to negotiate and enter into an agreement for a Marketing Partnership for such Licensed Product (the “Marketing Partnership Agreement”) with any Third Party; provided that the terms of the Marketing Partnership Agreement with the Third Party, taken as a whole, may not be less favorable to Cardiokine than those last offered to Wyeth or proposed by Wyeth; and provided, further, that the Marketing Partnership Agreement must comply with the terms and conditions of this Agreement. The provisions applicable to Cardiokine under this Article 6 shall also apply to any Affiliate of Cardiokine to which Cardiokine has granted or otherwise extended its rights hereunder.  
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7. INTELLECTUAL PROPERTY.  
7.1 Filing, Prosecution and Maintenance of Licensed Patents.  
7.1.1 Patent Prosecution and Maintenance. From and after the date of this Agreement, the provisions of this Section 7 shall control the preparation, filing, prosecution and maintenance of all patent applications and patents included within the Licensed Patents. Subject to the requirements, limitations and conditions set forth in this Agreement, Wyeth shall direct and control (i) the preparation, filing and prosecution of the United States and foreign patent applications within Licensed Patents (including any interferences and foreign oppositions) and (ii) maintain the patents issuing therefrom. Wyeth shall select the patent attorney, subject to Cardiokine’s written approval, which approval shall not be unreasonably withheld. Both Parties hereto agree that Wyeth may at its sole discretion, utilize Wyeth in-house counsel in lieu of independent counsel for patent prosecution and maintenance described herein, and the fees and expenses incurred by Wyeth with respect to work done by such Office of Patent Counsel shall be paid as set forth below. Cardiokine shah have full rights of consultation with the patent attorney so selected on all matters relating to Licensed Patents. Wyeth shall keep Cardiokine timely and fully informed of the progress of all matters relating to the Licensed Patents, and give Cardiokine and Cardiokine s counsel reasonable opportunity to comment on the preparation and prosecution of all patent applications within the Licensed Patents, including but not limited to the type and scope of useful claims and the nature of supporting disclosures. Wyeth shall use reasonable efforts to implement all reasonable requests made by Cardiokine with regard to the preparation, filing, prosecution and/or maintenance of the patent applications and/or patents within Licensed Patents. Prior to abandoning any Licensed Patent, Wyeth shall consult with Cardiokine. If Wyeth decides to abandon any Licensed Patent, then Wyeth shall give Cardiokine reasonable notice to this effect and thereafter Cardiokine may (but shall not have the obligation to) upon written notice to Wyeth, take responsibility for prosecuting or maintaining the Licensed Patent that Wyeth has decided to abandon at Cardiokine’s sole cost and expense, and Wyeth shall assign ownership of such Licensed Patent to Cardiokine.  
7.1.2 Information to Cardiokine. Wyeth shall promptly deliver to Cardiokine copies of (a) all file histories of all patents within the Licensed Patents, (b) all patent application files for patent applications within the Licensed Patent, (c) copies of all communications and documents received by Wyeth that relate to such patents and patent applications, and (d) copies of all filings or submissions made or to be made by Wyeth that relate to such patents and patent applications.  
7.1.3 Patent Costs. Wyeth shall pay for all patent costs and expenses as described in this Section 7.1.  
7.1.4 Wyeth Right to Pursue Patent. If at any time during the term of this Agreement, Cardiokine’s rights with respect to one or more Licensed Patents are terminated, Wyeth shall have the right to take whatever action Wyeth deems appropriate to obtain or maintain the corresponding patent protection.  
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7.2 Enforcement of Licensed Patents.  
7.2.1 Notice. Each Party shall promptly inform the other Party of any suspected infringement or violation of any of the Licensed Patents by a Third Party and provide such other Party with any available evidence of such suspected infringement  
7.2.2 Enforcement.  
7.2.2.1 During the term of this Agreement, the Parties shall consult with each other regarding the infringement of any patent within Licensed Patents. During or following said consultation, Cardiokine shall have the right, but shall not be obligated, to take steps to xxxxx the infringement and/or to institute, prosecute and control at its own expense any action or proceeding with respect to any infringement of such patent by a Third Party and, in furtherance of such right, Wyeth hereby agrees that Cardiokine may include and join Wyeth as a party plaintiff in any such suit, without expense to Wyeth.  
In the event that Cardiokine determines to bring suit against an alleged Third Party infringer, the total cost of any such infringement action commenced solely by Cardiokine shall be borne by Cardiokine, provided that Wyeth may elect to fund up to [####]of the out-of-pocket expenses and legal fees in return for up to [####]of the recoveries as set forth below. Cardiokine shall keep any recovery or damages for past infringement derived therefrom, except that, Cardiokine shall share such balance in proportion to each Party’s share of such expenses and legal fees, said balance to be calculated following, and subject to, reimbursement of expenses as described in Section 7.2.2.3 below. Ln the event such infringement adversely affects the scope or validity of the Licensed Patents, no settlement, consent judgment or other voluntary disposition of any such suit may be entered into without the consent of Wyeth, which consent shall not be unreasonably withheld or delayed. Wyeth shall have [####]from the date of Cardiokine’s written notice to Wyeth either to consent or to object in writing, stating in reasonable detail the reasons for withholding consent. No response within such period shall be deemed to constitute Wyeth’s consent. Notwithstanding the foregoing, Wyeth may elect at its option to participate in the prosecution of any such infringement action through counsel of its own choice at its own expense.  
7.2.2.2 If within [####]after having been notified of any alleged infringement of the Licensed Patents by a Third Party, Cardiokine shall have been unsuccessful in persuading the alleged infringer to cease and desist or shall not have brought and shall not be diligently prosecuting an infringement action, or if Cardiokine shall notify Wyeth at any time prior thereto of its intention not to bring suit against any alleged infringer then, and in those events only, Wyeth shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents covering the Licensed Products, and Wyeth may, for such purposes, include and join Cardiokine as party plaintiff in any such suit, without expense to Cardiokine. In such event, the total cost of any such infringement action commenced solely by Wyeth shall be borne by Wyeth, provided that Cardiokine may elect to fund up to [####]of the out-of-pocket expenses and legal fees in return for up to [####] of the recoveries as set forth below. Wyeth shall keep any recovery or damages for past infringement derived therefrom, except that,  
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Wyeth shall share such balance in proportion to each Party’s share of such expenses and legal fees, said balance to be calculated following, and subject to, reimbursement of expenses and legal fees as described in Section 7.2.23 below. In the event such infringement adversely affects the scope or validity of the Licensed Patents, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Cardiokine, which consent shall not be unreasonably withheld or delayed. Cardiokine shall have [####]from the date of Wyeth’s written notice to Cardiokine either to consent or to object in writing, stating in reasonable detail the reasons for withholding consent. No response within such period shall be deemed to constitute Cardiokine’s consent. Notwithstanding the foregoing, Cardiokine may elect at its option to participate in the prosecution of any such infringement action through counsel of its own choice at its own expense.  
7.2.2.3 In the event either Party shall undertake die enforcement of the Licensed Patents covering the Licensed Products, any recovery of damages by such Party for such suit shall be applied first in satisfaction of any expenses and legal fees of such Party (and, if applicable, the expenses and legal fees of the other Party that has elected to and has paid up to [####]of the out-of-pocket expenses and legal fees associated with said enforcement) relating to such enforcement and the balance remaining from any such recovery distributed as set forth in Section 7.2.2.1 or Section 7.2.2.2, as the case may be.  
7.2.2.4 In any infringement suit which either Party may institute to enforce the Licensed Patents pursuant to this Agreement, or in a suit for patent infringement which is brought by a Third Party against Wyeth or Cardiokine, which either Party or both Parties are required or elect to defend, the other Party hereto shall, at the request and the expense of the Party initiating or defending such suit, cooperate in all reasonable respects and, to the extent reasonably possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.  
7.2.2.5 Cardiokine shall have the sole right subject to the terms and conditions hereof to sublicense any alleged infringer for future use of the Licensed Patents for Licensed Products. Any upfront fees paid to Cardiokine as part of a sublicense agreement made in settlement of the infringement action shall be applied first in satisfaction of any expenses and legal fees of Cardiokine relating to such suit and the balance remaining from any such recovery distributed as set forth in Section 7.2.2.1 above.  
7.3 Infringement Defense. Cardiokine shall have the right, but not the obligation, to defend and control any suit against any of Cardiokine, Cardiokine’s Affiliates or sublicensees, alleging infringement of any patent or other intellectual property right of a Third Party arising out of the manufacture, use, sale offer to sell or importation of a Licensed Compound or Licensed Product by Cardiokine, Cardiokine’s Affiliates or sublicensees. Cardiokine shall be responsible for the costs and expenses, including lawyer’s fees and costs, associated with any suit or action, Cardiokine and Wyeth will consult with one another and cooperate in the defense of any such action. If Cardiokine finds it necessary or desirable to join Wyeth as a party to any such action, Wyeth will execute all papers and perform such acts as shall be reasonably required, at Cardiokine’s expense. In the event the patent claim of any Third Party is held in a final and unappealable order of a court to be valid and infringed, or if Cardiokine enters into a settlement of such proceedings, Cardiokine shall pay the foil amount of any damages and/or settlement amounts due to such Third Party.  
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7.4 Patent Certifications. Wyeth shall immediately give written notice to Cardiokine, and Cardiokine shall immediately give written notice to Wyeth, of any certification of which it becomes aware filed pursuant to 21 U.S.C. § 355(b)(2)(A), or § 355(j)(2)(A)(vii) (or any amendment or successor statute thereto) claiming that a Licensed Patent covering any Licensed Product is invalid or that infringement of such Licensed Patent will not arise from the development, manufacture, use or sale of any product by a Third Party. The provisions of Section 7.2.2 shall thereafter apply as if such Third Party were an infringer or suspected infringer.  
7.5 Patent Term Restoration. Cardiokine and Wyeth shall cooperate in obtaining patent term restoration or any similar benefit for the Licensed Patents. Wyeth and Cardiokine shall discuss which countries in which such patent term restoration or similar benefits are to be sought and Wyeth shall seek such restoration in any country selected by Cardiokine. Cardiokine shall, at Wyeth’s reasonable request and at Wyeth’s expense, take all actions and execute all documents as reasonably necessary or appropriate to accomplish same. In the event that Wyeth elects not to seek restoration in a country selected by Cardiokine, Wyeth shall cooperate with Cardiokine in securing restoration in such country by taking all actions and executing all documents as reasonably necessary or appropriate to accomplish same. In such event, Cardiokine shall apply the cost for seeking such restoration as an advance on royalties to be paid to Wyeth.  
7.6 Trademarks. Cardiokine may, at its own expense, select, use, apply and seek to register in the Territory (and maintain such registration once obtained), one or more Trademarks for use in connection with Commercializing the Licensed Products; provided, that if Wyeth and Cardiokine enter into a Marketing Partnership pursuant to Section 6, Wyeth shall be entitled to participate in selection of a trademark that is reasonably acceptable to both Parties.  
8. CONFIDENTIALITY AND PUBLIC ANNOUNCEMENTS.  
8.1 Confidentiality. Except to the extent expressly authorized by this Agreement, each Party (the “Receiving Party”) receiving any Confidential Information of the other Party (the “Disclosing Party”) agrees for the term of this Agreement and for [####]thereafter to, and shall cause its applicable Affiliates and its own and its applicable Affiliates’ employees and agents to, do the following: (a) keep in strictest confidence, the existence, source, content and substance of the Disclosing Party’s Confidential Information, (b) employ at least the same methods and degree of care (but no less than a reasonable degree of care) to prevent disclosure of the Disclosing Party’s Confidential Information as such Receiving Party employs with respect to its own Confidential Information, and (c) disclose the Disclosing Party’s Confidential Information to employees and agents solely on a need-to-know basis, and only if such employee or agent has executed a confidentiality agreement which imposes on such employee or agent a duty to maintain the confidentiality of the Disclosing Party’s Confidential Information and only after informing the employee or agent of the confidential and/or proprietary nature of the Disclosing Party’s Confidential Information.  
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8.2 Authorized Disclosure and Use. Notwithstanding the provisions of Section 8.1, each Party may use and disclose Confidential Information belonging to the other Party to the extent such use or disclosure is reasonably necessary to (a) prosecute or defend litigation provided that such Party shall provide the Disclosing Party with prompt notice of such request so that the Disclosing Party may seek an appropriate protective order or other remedy) or waiver of compliance therewith (and the Receiving Party shall cooperate reasonably with the Disclosing Party in all respects in seeking to obtain a protective order, waiver or other remedy and otherwise diligently contest or limit the required disclosure or (b) exercise rights hereunder; provided that any such disclosure is covered by terms of confidentiality similar to or more stringent than those set forth herein. In addition, Cardiokine may provide Confidential Information of Wyeth (i) to Cardiokine’s (sub)licensees, distributors, collaborators, investors and partners (and to any potential (sub)licensees, distributors, collaborators, investors and partners) and to Cardiokine’s legal and financial and other representatives and advisors in connection with the exercise of the license and other rights granted to Cardiokine and its Affiliates and sublicensees under this Agreement, and/or in connection with any due diligence in connection with any actual or potential acquisition of Cardiokine, including any sale, merger or transfer of any of the assets or business of Cardiokine, provided that any such disclosure is covered by terms of confidentiality similar to or more stringent than those set forth herein; and (ii) to any regulatory or other governmental agencies in connection with any filings with, or disclosures or submissions to, or any inspections or inquiries by, any regulatory or other governmental agencies in any country of the Territory and in connection with securing regulatory, pricing or other approvals in the Territory.  
8.3 Disclosures Required by Law. Notwithstanding the provisions of Section 8.1, a Receiving Party may make such disclosures of Confidential Information of the Disclosing Party to intended recipients (and no others) to the extent, and only to the extent, required, in the reasonable opinion of such Party’s counsel, to comply with applicable law or regulation or the requirements of a national securities exchange or another similar regulatory body. In the event that such Receiving Party is requested or required by applicable law or regulations to disclose any Confidential Information of the Disclosing Party, such Receiving Party shall provide the Disclosing Party with prompt notice of such request, requirement or other similar process so that the Disclosing Party may seek an appropriate protective order (or other remedy) or waiver of compliance therewith. The Receiving Party shall cooperate reasonably with the Disclosing Party in all respects in seeking to obtain a protective order, waiver or other remedy and otherwise diligently contest or limit the required disclosure.  
8.4 Public Announcements. Neither Party will make any public announcement regarding this Agreement without the prior written consent of the other Party; provided that upon execution of this Agreement, the Parties shall mutually agree to the terms of a press release, which shall be promptly issued by the Parties, and an accompanying “Q&A.”  
8.5 Equitable Remedies. The Parties acknowledge and agree that money damages may not be a sufficient remedy for any breach or threatened breach of this Section 8 and that the Parties shall be entitled, without the requirement of posting a bond or other security, to seek specific performance and injunctive or other equitable relief as a remedy for any such breach or threatened breach. Such remedies shall not be deemed to be the exclusive remedies for a breach or threatened breach of this Section 8 but shall be in addition to all other remedies available to the Parties at law or in equity.  
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9. REPRESENTATIONS AND WARRANTIES.  
9.1 Disclaimer. EXCEPT AS SET FORTH IN THIS SECTION 9, WYETH MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PURPOSE), AND ASSUMES NO LIABILITIES WHATSOEVER, WITH RESPECT TO THE INVENTORY OF COMPOUND, FORMULATED CLINICAL SUPPLIES OF COMPOUND AND PRODUCTS SUPPLIED TO CARDIOKINE PURSUANT TO SECTION 4.2. IN ADDITION, WYETH HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED BELOW IN THIS SECTION 9. WITHOUT LIMITATION OF THE FOREGOING GENERALITY, NOTHING CONTAINED HEREIN OR IN ANY DISCLOSURE MADE BY OR ON BEHALF OF WYETH SHALL BE CONSTRUED AS EXTENDING ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE WYETH INTELLECTUAL PROPERTY OR THE RESULTS TO BE OBTAINED BY THE USE OF THE WYETH INTELLECTUAL PROPERTY, OR THAT ANYTHING MADE, USED, OR SOLD BY USE OF THE WYETH INTELLECTUAL PROPERTY, OR ANY PART THEREOF, ALONE OR IN COMBINATION, WILL BE FREE FROM INFRINGEMENT OF PATENTS OF THIRD PARTIES. IN THE EVENT THAT WYETH RECEIVES ANY LICENSE RIGHTS’ PURSUANT TO SECTION 11.5, CARDIOKINE MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OR MERCHANTABILITY OR FITNESS FOR PURPOSE), AND ASSUME NO LIABILITIES WHATSOEVER WITH RESPECT TO THE INTELLECTUAL PROPERTY, CARDIOKINE KNOW-HOW, OR OTHER INFORMATION OR MATERIALS PROVIDED TO WYETH PURSUANT TO SECTION 11.5. EXCEPT FOR BREACH BY EITHER PARTY OF ITS OBLIGATIONS PURSUANT TO SECTION 8, AND EACH PARTY’S INDEMNIFICATION OBLIGATIONS PURSUANT TO SECTION 12, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY, ITS AFFILIATES, OR ANY OTHER PARTY, REGARDLESS OF THE FORM OR THEORY OF ACTION (WHETHER CONTRACT, TORT, INCLUDING NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE), FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR OTHER EXTRAORDINARY DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY THEREOF.  
9.2 Representations and Warranties of Each Party. Notwithstanding the first sentence of Section 9.1, each Party hereby represents and warrants to the other Party as follows:  
(i) it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;  
(ii) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;  
(iii) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and,  
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(iv) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) the provisions of its charter or operative documents or bylaws; (ii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; or (iii) violate, breach, cause a default under, or otherwise give rise to a right of termination, cancellation or acceleration with respect to (presently with the giving of nonce, or the passage or time) any agreement to which such Party or any of its Affiliates is a party, or by which any of us assets are bound.  
9.3 Additional Representations, Warranties and Covenants of Cardiokine. Cardiokine hereby represents, warrants, and covenants to Wyeth as follows:  
(i) as of the signing of this Agreement, Cardiokine has properly determined that the fair market value of the transactions contemplated by this Agreement is less than [####]and no filing under the Xxxx-Xxxxx-Xxxxxx Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder is required in connection with the transactions contemplated hereby; and  
(ii) it is not entering into this Agreement and taking the license granted herein for the purpose of transferring rights under the Licensed Patents or Licensed Know-How to any Third Party for payments, royalties or other compensation.  
9.4 Additional Representations, Warranties and Covenants of Wyeth. Wyeth hereby represents, warrants and covenants to Cardiokine as follows:  
(a) all Licensed Patents as of tire Effective Date are listed on Exhibit A attached hereto;  
(b) as of the Effective Date, there are no claims, judgments or settlements against or owed by Wyeth relating to the Licensed Patents or Licensed Know-How;  
(c) as of the Effective Date, neither Wyeth or its Affiliates has any vasopressin, antagonist within the Field at IND track or in clinical trials or later stage of development or commercialization;  
(d) neither Wyeth nor its Affiliates have, prior to the Effective Date, entered into, and Wyeth shall not, and shall ensure that its Affiliates shall not, following the Effective Date, enter into any agreement to, or grant any license, right or privilege which agreement, license, right or privilege limits or conflicts in any way with Cardiokine’s rights hereunder or otherwise with the terms or conditions of this Agreement;  
(e) except as set forth on Exhibit A, Wyeth is the sole and exclusive owner of all right, title and interest in and to the Wyeth Intellectual Property, free and clear of any liens or other encumbrances;  
(f) to Wyeth’s current knowledge, without any duty of investigation, Wyeth has not done anything to invalidate or render unenforceable any of the Licensed Patents;  
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(g) to Wyeth’s current knowledge, without any duty of investigation, the making, using, distribution, sale, offering for sale, import or export of the Licensed Compound in the Territory will not infringe, misappropriate or otherwise conflict with any intellectual property rights of any other Person; and  
(h) no claims of infringement, misappropriation or other conflict with any intellectual property rights or other rights of any Third Party have been made or threatened with respect to the Licensed Compound or any Wyeth Intellectual Property, and Wyeth is not aware of any infringement or misappropriation of any of the Wyeth Intellectual Property by any Third Party.  
9.5 Representation by Legal Counsel. Each Party represents to the other that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting of this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.  
10. GOVERNMENT APPROVALS.  
10.1 Government Approvals. Wyeth and Cardiokine will cooperate and use respectively all reasonable efforts to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated hereby.  
11. TERM AND TERMINATION.  
11.1 Term. The term of this Agreement will commence on the Effective Date and expire, unless this Agreement is terminated earlier in accordance with this Section 12, on a country-by-country and Licensed Product-by-Licensed Product basis, upon the later of (i) the expiration of the last to expire Licensed Patent conferring exclusivity to the Licensed Product or (ii) the ten (10) year anniversary of the First Commercial Sale of each Licensed Product in the particular country. Upon the expiration of this Agreement with respect to a particular Licensed Product in a particular country, Cardiokine shall be deemed to have an irrevocable, nonexclusive, fully paid-up, perpetual and royalty-free, folly transferable license under the Wyeth Intellectual Property to Manufacture and Commercialize such Licensed Product in such country, which license shall include the right to grant sublicenses.  
11.2 Termination for Material Breach.  
This Agreement may be terminated effective on a country-by-country and Licensed Product-by-Licensed Product basis on written notice by Wyeth at any time during the term of this Agreement for material breach of a material term or condition of this Agreement by Cardiokine, its Affiliates or sublicensees if, after the Parties have completed the dispute resolution process set forth in Section 13.1 hereof in a good faith effort to resolve any dispute relating to such alleged material breach, such alleged material breach remains uncured for [####]in the case of nonpayment of any undisputed amount due, and [####]for all other material breaches, each measured from (i) the date written notice of such material breach is given to Cardiokine or (ii) in the case of a dispute relating  
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to such alleged material breach, the date of completion of the dispute resolution process set forth in Section 13.1 hereof; provided, however, that if such alleged material breach is not reasonably susceptible of cure within such [####] period and Cardiokine uses reasonable and diligent good faith efforts to cure such alleged material breach, such [####] period shall be extended to [####].  
11.3 Termination by Cardiokine at Will. Cardiokine, in its sole discretion, may terminate this Agreement:  
11.3.1 by giving written notice to Wyeth subsequent to Cardiokine’s completion of a Phase II or Phase III clinical study in humans, which study is designed with efficacy endpoints and with sufficient statistical power such that it is intended to be a clinical study for demonstration of efficacy as part of a Regulatory Approval Application but prior to the filing of any Regulatory Approval Application, such termination to be effective [####] after the date of such notice; or  
11.3.2 after completion of the first pivotal clinical trial and prior to NDA filing by giving Wyeth written notice, which termination shall become effective [####] after the date of such notice; and thereafter upon [####] written notice to Wyeth,  
11.4 Consequences of Wyeth Termination for Material Breach by Cardiokine. In the event this Agreement is terminated by Wyeth pursuant to Section 11.2, all of the following shall occur:  
(a) all licenses granted by Wyeth to Cardiokine herein will terminate and all rights granted herein to Cardiokine will revert to Wyeth;  
(b) Cardiokine will deliver to Wyeth copies of all documents, data, computer-based data, and other materials constituting, including, summarizing or otherwise disclosing Licensed Know-How;  
(c) Cardiokine will cease use of Licensed Know-How and cease manufacture and sale of Licensed Compound and Licensed Products; provided, however, that Cardiokine shall have the right to sell off any existing inventory of Licensed Compounds and Licensed Products for not more than [####]after the effective date of termination;  
(d) an officer of Cardiokine will certify in writing to Wyeth that Cardiokine has complied with Sections 11.4(b) and 11.4(c);  
(e) Cardiokine will submit a report in accordance with Section 5.3.1 within [####]after the date of termination;  
(f) Cardiokine will permit an audit in accordance with Section 5.4.2 within [####]after the date of termination; and  
(g) Cardiokine will pay to Wyeth all amounts accruing pursuant to the terms of this Agreement prior to the date of termination.  
11.5 Special Termination Provisions. In the event this Agreement is terminated by Cardiokine pursuant to Section 11.3 or by Wyeth pursuant to Section 11.2 for an uncured material breach by Cardiokine in addition to all of the provisions of Section 114, upon written request from Wyeth within [####]after the date of termination, Cardiokine will  
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(a) grant to Wyeth an irrevocable, royalty-free, nonexclusive, worldwide license under all patents and trademarks owned by Cardiokine that were used by Cardiokine in the Manufacture, use or sale of Licensed Compounds or Licensed Products (“Cardiokine IP”) to use such Cardiokine IP solely to Manufacture, use, and sell Licensed Compounds and Licensed Products and for no other purpose whatsoever;  
(b) provide to Wyeth, at Wyeth’s expense, all available Cardiokine Know-How used by Cardiokine in the Manufacture, use or sale of Licensed Compounds or Licensed Products and grant to Wyeth an irrevocable, royalty-free, nonexclusive, worldwide license to use such Cardiokine Know-How solely to Manufacture, use and sell Licensed Compounds and Licensed Products and for no other purpose whatsoever;  
(c) transfer and grant to Wyeth commercial rights in all available data and documentation relating to any Regulatory Filing for and all issued Regulatory Approvals for Licensed Products provided that Wyeth will pay all out-of-pocket costs incurred by Cardiokine for such transfers;  
(d) sublicense or assign to Wyeth, as applicable and allowable, all agreements with any Third Party that relate to development, manufacture or sale of Licensed Products (provided that Cardiokine has the right to sublicense or assign any such agreements to Wyeth hereunder without any financial obligation to, or conflict with the rights of, any other Person and provided further that any such transfer shall be subject to the terms and conditions of any such agreements); and  
(e) for [####]after the date of termination, subject to Wyeth reimbursing Cardiokine for all of its out-of-pocket expenses in connection therewith, make available to Wyeth assistance that is reasonably necessary to effect an orderly transfer to Wyeth of the .materials set forth in subsections (b) - (d) above.  
11.6 Bankruptcy. Each Party may, in addition to any other remedies available to it by law or in equity, exercise the rights set forth below by written notice to the other Party (the “Insolvent Party”), in the event the Insolvent Party shall have become insolvent or bankrupt, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the Insolvent Party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the Insolvent Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect, or there shall have been issued a warrant of attachment, execution, distraint or similar process against any substantial part of the property of the Insolvent Party, and any such event shall have continued for [####]undismissed, unbonded and undischarged. All rights and licenses granted under or pursuant to this Agreement by Wyeth are, and shall otherwise be deemed to be, for purposes of Section 365 (n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code.  
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(a) Wyeth. In the event Wyeth shall be an Insolvent Party, Cardiokine may:  
(i) terminate this Agreement; or  
(ii) keep this Agreement in full force and effect and retain all licenses granted by Wyeth to Cardiokine herein, subject to the payment to Wyeth of all payments set forth above.  
(b) Cardiokine. In the event Cardiokine shall be an Insolvent Party, Wyeth may, to the extent permitted by applicable law, terminate this Agreement and all licenses granted to Cardiokine by Wyeth herein will revert to Wyeth and Cardiokine will comply with the provisions of Section 11.5.  
11.7 Survival of Certain Obligations. Expiration or termination of the Agreement shall not relieve the Parties of any obligation accruing before such expiration or termination (including, without limitation, payment obligations so accruing under Sections 5.1 and 5.2), and the provisions of Sections 4.5, 7.2, 9.1, 11.4, 11.5 and 11.6 and Articles 1, 5, 8, 12 and 13 shall survive the expiration or termination of the Agreement for any reason. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination, including, without limitation, the obligations to pay royalties for Products sold before such termination.  
12. INDEMNIFICATION.  
12.1 Indemnification by Cardiokine. Cardiokine will indemnify, defend and hold harmless Wyeth, its Affiliates, and each of their respective employees, officers, directors and agents (each of the foregoing, a “Wyeth Indemnified Party”) from and against any and all liability, loss, damage, expense (including reasonable attorneys’ fees and expenses) and cost (collectively, a “Liability”) that the Wyeth Indemnified Party may incur or be required to pay resulting from or arising out of and one or more of the following:  
(i) any Third Party claims of any nature arising out of the Research, Development, Manufacture or Commercialization of Licensed Compound(s) and Licensed Product(s) by or on behalf or under the authority of any Cardiokine Indemnified Party (as defined in Section 12.2) or any sublicensee or subcontractor of any Cardiokine Indemnified Party, including, without limitation, in connection with the conduct of any clinical trials or obtaining or maintenance of Regulatory Approvals; and  
(ii) the material breach by Cardiokine of any of its representations or warranties set forth in this Agreement.  
12.2 Indemnification by Wyeth. Wyeth will indemnify, defend and hold harmless Cardiokine and its Affiliates and any of their sublicensees, and each of their respective employees, officers, directors and agents (each of the foregoing, a “Cardiokine Indemnified Party”) from and against any and all Liabilities that the Cardiokine Indemnified Party may incur or be required to pay resulting from or arising out of one or more of the following: (i) any Third Party claims of any nature arising out of the Research, Development, Manufacture or Commercialization of  
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Licensed Compound(s) and Licensed Product(s) by or on behalf or under the authority of any Wyeth Indemnified Party or any sublicensee or subcontractor of any Wyeth Indemnified Party, including, without limitation, in connection with the conduct of any clinical trials or obtaining or maintenance of Regulatory Approvals in the event Wyeth receives the license rights specified in Section 11.5 or otherwise; and (ii) the material breach by Wyeth of any of its representation or warranties set forth in this Agreement.  
12.3 Procedure. Each Party will notify the other in the event it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) shall be instituted involving any Person in respect of which indemnity may be sought pursuant to this Article 12, such Person (the “Indemnified Party”) shall promptly notify the Party with the responsibility to indemnify such Person (the “Indemnifying Party”) in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any claims that are the subject matter of such proceeding. The Indemnifying Party, upon request of the Indemnified Party, shall retain counsel reasonably satisfactory to the Indemnified Party to represent the Indemnified Party and shall pay the reasonable fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party unless (a) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (b) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses shall be reimbursed as they are incurred. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent (which consent shall not be unreasonably withheld or delayed), but if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to indemnify the Indemnified Party from and against any loss or liability by reason of such settlement or judgment.  
12.4 Insurance. Cardiokine agrees to obtain and maintain, during the term of this Agreement, commercial general liability insurance, including product liability insurance, with reputable and financially secure insurance carriers, in each case with limits of not less than [####]per occurrence and [####]annually in the aggregate. Each such policy shall name Wyeth as an additional insured. Within [####]after the Effective Date and thereafter within [####]after Wyeth’s request, Cardiokine shall provide Wyeth with a standard XXXXX certification demonstrating compliance with this Section 12.4.  
13. MISCELLANEOUS.  
13.1 Disputes. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement. In the event of the occurrence of such a dispute and if the Parties are unable to resolve informally a dispute between them arising from performance of or otherwise relating to this Agreement, either Party may, by written notice to the other Party (which notice shall specify, without limitation, the particulars of the dispute and the relevant provisions of this Agreement relating to such dispute), have such dispute referred to their respective officers (designated below) or their successors for attempted resolution by good faith negotiations. Said designated officers are as follows:  
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For Wyeth: Executive Vice President, Wyeth  
For Cardiokine: President, Cardiokine, Inc.  
Any such dispute shall be submitted to the above-designated executive officers no later [####]following such request by either Wyeth or Cardiokine. In the event the designated executive officers are not able to resolve any such dispute within [####]after submission of the dispute to such executive officers, Wyeth or Cardiokine, as the case may be, may pursue any legal or equitable remedies available to it by filing a claim in the state or federal courts of the state of Delaware and each Party hereby consents to the jurisdiction of such court. Notwithstanding the foregoing, nothing in this Section 13.1 shall prohibit a Party from seeking temporary or injunctive relief from a state or federal court in Delaware pending the resolution of a dispute in accordance with the provisions of this Section 13.1. All negotiations pursuant to this Section 13.1 shall be treated as compromise and settlement negotiations. Nothing said or disclosed, nor any document produced, in the course of such negotiations which is not otherwise independently discoverable shall be offered or received as evidence or used for impeachment or for any other purpose in any current or future arbitration or litigation.  
13.2 Assignment. Neither this Agreement nor any interest hereunder shall be assignable by Cardiokine without the prior written consent of Wyeth. The preceding sentence notwithstanding, Cardiokine may assign this Agreement and the licenses granted herein to an Affiliate and to any Person in conjunction with any acquisition of Cardiokine, including in connection with the sale, transfer, or merger of all or substantially all of the assets or business of Cardiokine. 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 shall be deemed to include the names of such Party’s successors and permitted assigns to the extent necessary to carry out the interest of this Agreement. Any assignment not in accordance with this Section 13.2 shall be void.  
13.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to cany out the purposes and intent of the Agreement.  
13.4 Force Majeure. Neither Party shall be liable to the other for delay or failure in the performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence. It shall notify the other Party promptly should such circumstances arise, giving an indication of the likely extent and duration thereof and shall use all Commercially Reasonable Efforts to resume performance of its obligations as soon as practicable. Force Majeure shall not excuse obligations to pay amounts due.  
13.5 Correspondence and Notices.  
13.5.1 Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered personally, mailed by reputable overnight courier or certified mail (return receipt requested) or sent by facsimile (confirmed thereafter by certified mail which includes a copy of the report generated by the sending facsimile machine that shows the date and time of transmission and that all pages of the notice were successfully transmitted) to tire Parties at the following addresses or at such other addresses as shall be specified by the Parties by like notice:  
 -23-  
 (i)  
If to Cardiokine:  
Cardiokine, Inc.  
0000 Xxxxxx Xxxxxx, 0xx Xxxxx  
Xxxxxxxxxxxx, XX 00000  
Attention: Chief Executive Officer  
Fax Number: [####]  
with a copy to:  
[####]  
Xxxxxxxx Ingersoll  
000 Xxxx X Xxxxxx, Xxxxx 0000  
Xxx Xxxxx, XX 00000  
 (ii)  
If to Wyeth: Wyeth  
Five Giralda Farms  
Madison, New Jersey 07940  
Attention: Senior Vice President  
 and General Counsel  
Fax Number: [####]  
with a copy to:  
Wyeth Pharmaceuticals  
000 Xxxxxx Xxxx  
Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000  
Attention: Senior Vice President,  
 Global Business Development  
Fax Number: [####]  
Notice so given (in the case of notice so given by mail) shall be deemed to be given and received on the third calendar day after mailing or the next business day if sent by a reputable overnight courier and in the case of notice so given by facsimile or personal delivery on the date of actual transmission or personal delivery, as the case may be.  
13.6 Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.  
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13.7 Waiver. The failure of a Party at any time to require or enforce the strict performance by the other Party of any term or condition of this Agreement shall not constitute a surrender or waiver of that particular breach or default, or of any subsequent breach or default by such other Party with respect to any term or condition of this Agreement, or the waiver by a Party of a breach or default committed by the other Party with respect to any term or condition of this Agreement, and shall not to any extent prejudice or adversely effect such first Party’s rights, interest or remedies available or provided to it by law or otherwise which it may exercise or invoke with respect to that particular breach or default or any subsequent breach or default. Without limitation to the foregoing, no provision of this Agreement may be waived except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.  
13.8 Severability. If any provisions of this Agreement shall be held to be illegal, invalid or unenforceable under any applicable law, then such contravention or invalidity shall not invalidate the entire Agreement. Such provision shall be deemed to be modified to the extent necessary to render it legal, valid and enforceable, and if no such modification shall render it legal, valid and enforceable, then this Agreement shall be construed as if not containing the provision held to be invalid, and the rights and obligations of the Parties shall be construed and enforced accordingly; provided, that in the case of any such deemed modification or construction, the Parties shall endeavor to retain to the maximum extent practicable the Parties’ intent upon entering into this Agreement.  
13.9 Descriptive Headings and Section References. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. References to “Articles”, “Sections” and “Clauses” shall be deemed to be references to articles, sections and clauses of this Agreement. In this Agreement, the singular shall include the plural and vice versa and the words “including” and “include” shall be deemed to be followed by the phrase “without limitation.”  
13.10 Governing Law. This Agreement shall be governed, interpreted, construed and enforced in accordance with the internal laws of the State of Delaware, without giving effect to the principles of conflicts of law thereunder.  
13.11 Entire Agreement. With the exception of the Non-Disclosure Agreement between the Parties effective as of April 10, 2003 (the “NDA”), this Agreement (including all Exhibits) constitutes the entire agreement, and supersedes all prior and contemporaneous agreements and undertakings, both written and oral, between the Parties with respect to the subject matter hereof and is not intended to confer upon any other Person any rights or remedies hereunder. The NDA, however, shall govern only disclosures made prior to the Effective Date, and this Agreement shall govern disclosures made on and after the Effective Date.  
13.12 Independent Contractors. Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.  
 -25-  
13.13 Counterparts. This Agreement may be executed in two (2) counterparts, each of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.  
IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.  
 WYETH, acting through its WYETH  
PHARMACEUTICALS DIVISION  
 CARDIOKINE INC.  
By: /s/ Xxxx Xxx By: /s/Xxxxx Xxxxxx   
Name: Xxxx X. Xxx Name: Xxxxx Xxxxxx  
Title: Sr. Vice President, Business Development Title: CEO  
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EXHIBIT A  
[####]  
 A-1  
EXHIBIT B  
[####]  
 B-1  
[####]  
 B-2  
[####]  
 B-3  
[####]  
 B-4  
[####]  
 B-5  
AMENDMENT TO THE LICENSE AGREEMENT  
THIS AMENDMENT (this “Amendment”) is entered into this 3rd day of May, 2004 (the “Amendment Date”), by and between Wyeth, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals Division (“Wyeth”), and Cardiokine, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 0000 Xxxxxx Xxxxxx, 0xx Xxxxx, Xxxxxxxxxxxx, XX 00000 (“Cardiokine”). Wyeth and Cardiokine may each be referred to herein individually, as a “Party” and collectively, as the “Parties”.  
WHEREAS, the Parties entered into that certain License Agreement dated March 15,2004 (the “License Agreement”), and  
WHEREAS, the Parties now wish to amend the License Agreement, as set forth in this Amendment.  
NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:  
1. Amendment.  
1.1 The Parties hereby agree to amend the License Agreement to add the following new Section 4.6:  
4.6. Transfer of IND to Cardiokine. Wyeth shall assign to Cardiokine [####] (hereinafter, the IND ), (b) provide Cardiokine with a complete copy of the IND, and (c) submit a letter to the FDA stating that the IND has been assigned to Cardiokine. Cardiokine shall submit a letter to FDA, together with a revised first page of the IND (a completed Form 1571), accepting the ownership of the IND and identifying the effective date of the transfer of the IND. The disclaimer of warranties in Section 9.1 of this Agreement shall apply to the IND and all studies, data and information in the IND.  
1.2 The Parties hereby agree to further amend the License Agreement to delete the current Section 6.1 of the License Agreement in its entirety and replace it with the following new Section 6.1:  
6.1 Right of First Negotiation.  
In the event Cardiokine at any time seeks or determines to enter into a marketing partnership, co-promotion or other equivalent or similar arrangement (a “Marketing Partnership”) for a Licensed Product within the Territory, Cardiokine shall provide Wyeth with written notice thereof (the “Initial Notice”) and comply with this Section 6.1 prior to negotiating with any Third Party for such Marketing Partnership. Cardiokine shall also provide ‘to Wyeth, together with such written notice, an electronic copy of the NDA submitted to the FDA for such Licensed Product (if one  
has been submitted at the time of such Initial Notice) as well as the market studies and reports and other similar or related information and data in respect of such Licensed Product in Cardiokine’s or its Affiliates’ possession or control in order for Wyeth to determine its interest in entering into a Marketing Partnership with Cardiokine. All such information provided to Wyeth hereunder shall be deemed to be Confidential Information of Cardiokine. Wyeth shall have [####]from the date of its receipt of the Initial Notice to give Cardiokine written notice that it is exercising ‘ its right to negotiate with Cardiokine regarding a Marketing Partnership (such notice being an “Exercise Notice”). If Wyeth gives Cardiokine an Exercise Notice within the foregoing [####]period, then during the period beginning on the date of the Exercise Notice and ending on the date that is [####]after the date of the Exercise Notice, the Parties shall promptly and diligently negotiate, on an exclusive basis and in good faith, to enter into a Marketing Partnership for such Licensed Product on commercially reasonable terms If (i) Wyeth fails to give an Exercise Notice within the foregoing [####]period or (ii) if the Parties are unable, within the foregoing [####], to enter into a term sheet or letter of intent setting forth the principal terms of the Marketing Partnership to be entered into, or (iii) if the Parties are unable to enter into a definitive agreement setting forth all the terms and conditions of the Marketing Partnership within [####]after entering into said term sheet or letter of intent, then Cardiokine shall be free to negotiate and enter into an agreement for a Marketing Partnership for such Licensed Product (the “Marketing Partnership Agreement”) with any Third Party; provided that the terms of the Marketing Partnership Agreement with the Third Party, taken as a whole, may not be less favorable to Cardiokine than those last offered to Wyeth or proposed by Wyeth; and provided, further, that the Marketing Partnership Agreement must comply with the terms and conditions of this Agreement. If the terms of the Marketing Partnership Agreement with the Third Party, taken as a whole, are less favorable to Cardiokine than those last offered to Wyeth or proposed by Wyeth, then Cardiokine may offer such terms (the “Alternative Offer”) to Wyeth, and if Wyeth does not, within [####]of its receipt of the Alternative Offer, notify Cardiokine of its acceptance thereof and willingness to enter into further negotiations (the “Second Exercise Notice”) to enter into a Marketing Partnership Agreement, then Cardiokine shall be free to enter into such Marketing Partnership Agreement with such Third Party. In the event that Wyeth gives Cardiokine the Second Exercise Notice, the parties shall negotiate in good faith for a period not to exceed [####], unless otherwise mutually agreed, and if a definitive Marketing Partnership Agreement shall not be concluded, then Cardiokine shall be entitled to enter into such Agreement with the Third Party. The provisions applicable to Cardiokine under this Article 6 shall also apply to any Affiliate of Cardiokine to which Cardiokine has granted or otherwise extended its rights hereunder.  
2. Continuing Effect. This Amendment shall be effective for all purposes as of the Amendment Date. Except as otherwise expressly modified by this Amendment, the License Agreement shall remain in full force and effect in accordance with its terms.  
3. Defined Terms. All terms used, but not defined, in this Amendment shall have the respective meanings as set forth in the License Agreement.  
4. Counterparts. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.  
IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amendment to be effective as of the Amendment Date.  
 WYETH, acting through its WYETH  
PHARMACEUTICALS DIVISION  
By: /s/ Xxxx X. Xxx  
Name: Xxxx X. Xxx  
Title: Sr. Vice President, Business Development  
CARDIOKINE, INC.  
By: Xxxxx Xxxxxx  
Name: Xxxxx Xxxxxx  
Title: CEO  
SECOND AMENDMENT TO LICENSE AGREEMENT  
THIS SECOND AMENDMENT TO LICENSE AGREEMENT (“Amendment”), effective as of October 14, 2004 (the “Amendment Effective Date”), is entered into between WYETH, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals division (“Wyeth”) and CARDIOKINE, INC., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 0000 Xxxxxx Xxxxxx, 0xx Xxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000 (“Cardiokine”).  
RECITALS  
A. The parties have entered into a license Agreement effective as of March 15, 2004, with respect to a vasopressin antagonist compound known as lixivaptan (the “Agreement”). All terms used, but not defined, in this Amendment shall have the respective meanings set forth in the Agreement.  
B. The parties have entered into a first Amendment to the License Agreement effective as of May 3, 2004.  
C. The parties now desire to further amend the Agreement in certain respects on the terms and conditions set forth below  
NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the parties hereby amend the Agreement and otherwise agree as follows:  
1. AMENDMENTS.  
1.1 Section 5.1 is amended and restated as follows:  
5.1 Payments. Subject to the terms and conditions, and during the term of this Agreement, Cardiokine shall make the following payments to Wyeth:  
Within [####]after the Effective Date (the “Signing [####] Fee”)  
And within [####]after the first occurrence of each of the following events with respect to the Licensed Product(s) to achieve such milestone:  
 [####] $[####]  
[####] $[####]  
[####] $[####]  
[####] $[####]  
[####] $[####]  
[####]Total of Signing Fee and Milestone Payments $[####]  
Each of the foregoing payments shall be non-refundable and not creditable against any other payments required by this Agreement. Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Cardiokine to Wyeth under this Agreement or for other Licensed Products.  
2. MISCELLANEOUS.  
2.1 This Amendment shall be effective for all purposes as of the Amendment Effective Date. Except as otherwise expressly modified by this Amendment, the Agreement shall remain in full force and effect in accordance with its terms.  
2.2 This Amendment may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.  
IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Amendment effective as of the Amendment Effective Date.  
 WYETH, acting through CARDIOKINE, INC.  
its WYETH PHARMACEUTICALS DIVISION   
By: /s/ Xxxx X. Xxx   
Name: Xxxx X. Xxx   
/s/ Xxxxx Xxxxx  
 Xxxxx Xxxxx  
Title: Sr. VP, Business Dev. Pharma Chief Executive Officer  
THIRD AMENDMENT TO LICENSE AGREEMENT  
THIS THIRD AMENDMENT TO LICENSE AGREEMENT (“Amendment”), effective as of June 21, 2007 (the “Amendment Effective Date”), is entered into between WYETH, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals division (“Wyeth”) and CARDIOKINE, INC., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 00 Xxxxx 00xx Xxxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000 (“Cardiokine”).  
RECITALS  
 A.  
The parties have entered into a License Agreement effective as of March 15, 2004, with respect to a vasopressin compound known as lixivaptan (the “License Agreement”). All capitalized terms used, but not defined, in this Amendment shall have the respective meanings set forth in the License Agreement.  
 B.  
The parties have entered into a first amendment to the License Agreement effective as of May 3, 2004, and second amendment to the License Agreement effective as of October 14, 2004.  
 C.  
The parties now desire to further amend the License Agreement in certain respects on the terms and conditions set forth below.  
 1.  
Amendments.  
The following sentence is added to Section 2.1 of the License Agreement:  
Wyeth hereby grants to Cardiokine a paid-up, royalty-free nonexclusive license, including the right to grant sub-licenses, under [####] solely to Research, Develop, Manufacture and Commercialize Licensed Compounds and Licensed Products in the Field in the Territory.  
 2.  
Miscellaneous.  
 2.1  
This Amendment shall be effective for all purposes as of the Amendment Effective Date. Except as otherwise expressly modified by this Amendment, the License Agreement shall remain in full force and effect in accordance with its terms.  
 2.2  
This Amendment may be executed in counterparts, each of which shall be deemed an original and together shall be deemed to be one and the same document.  
IN WITNESS WHEREOF, the undersigned duly authorized representatives of the parties have executed and delivered this Amendment.  
 WYETH, acting through its CARDIOKINE, INC.  
Wyeth Pharmaceuticals division   
By: /s/ X.X. Xxxxx By: /s/ D. Brand  
Name: Xxxxxx X. Xxxxx Name: D. Brand  
Title: Senior Vice President Title: CEO  
FOURTH AMENDMENT TO LICENSE AGREEMENT  
THIS FOURTH AMENDMENT TO LICENSE AGREEMENT (“Amendment”), effective as of the date of signature of the last Party to sign this Amendment (the “Amendment Effective Date”), is entered into between WYETH, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals division (“Wyeth”) and CARDIOKINE BIOPHARMA, LLC, a limited liability company organized and existing under the laws of the State of Delaware and having a principal place of business at 00 Xxxxx 00xx Xxxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000 (“Cardiokine”).  
RECITALS  
 X.  
Xxxxx and Cardiokine, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 00 Xxxxx 00xx Xxxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000 (“Parent”), entered into a License Agreement effective as of March 15, 2004, with respect to a vasopressin compound known as lixivaptan (the “License Agreement”). All capitalized terms used, but not defined, in this Amendment shall have the respective meanings set forth in the License Agreement.  
 X.  
Xxxxx and Parent entered into a first amendment to the License Agreement effective as of May 3, 2004, a second amendment to the License Agreement effective as of October 14, 2004 and a third amendment to the License Agreement effective as of June 21, 2007.  
 C.  
Cardiokine is wholly-owned by Parent.  
 D.  
Effective on August 1 2007, and pursuant to Parent’s right under Section 13.2 of the License Agreement to assign the License Agreement to an Affiliate, Parent assigned to Cardiokine all its rights under, and Cardiokine assumed all of Parent’s obligations under, the License Agreement.  
 E.  
The parties now desire to further amend the License Agreement in certain respects on the terms and conditions set forth below.  
 1.  
Amendments.  
 1.1  
The following new Sections 5.5 and 5.6 are added to the License Agreement.  
 5.5  
Buy-Out Payments. Cardiokine shall make the following non- refundable payments to Wyeth to buy-out the Milestone Payments and Royalties:  
Within [####]after the Amendment Effective Date (the “Initial Buy-Out Payment”): [####]  
Within [####]after the first occurrence of each of the following events with respect to the first Licensed Product to achieve such milestone (the “Contingent Buy-Out Payments”):  
[####]: [####]  
[####]: [####]  
 5.6  
Effect of Buy-Out Payments. In the event Cardiokine pays the Initial Buy-Out Payment and both Contingent Buy-Out Payments to Wyeth, (a) the license to Cardiokine granted in Section 2.1 shall be fully paid-up with respect to all Licensed Patents and Licensed- Know-How; (b) Sections 3.1 (excluding the last sentence thereof), 3.2, 5.2, 5.3.1 and 11.6(b) shall be deemed to have been deleted from the Agreement; (c) Wyeth’s right to terminate this Agreement shall be limited solely to instances in which Cardiokine engages in Research, Development, Manufacture and/or Commercialization of Licensed Compounds and/or Licensed Products outside of the Field, and (d) in all other cases of a breach of this Agreement by Cardiokine, Wyeth’s remedy shall be limited to damages and equitable relief.  
 1.2  
Sections 5.1 (excluding the Signing [####] Fee, that has been paid), 5.4 and 6.1 of the License Agreement are hereby deleted.  
 1.3  
The reference to Section 2.2 in Section 2.2 is hereby amended to be a reference to Section 2.1  
 2.  
Miscellaneous.  
 2.1  
This Amendment shall be effective for all purposes as of the Amendment Effective Date. Except as otherwise expressly modified by this Amendment, the License Agreement shall remain in full force and effect in accordance with its terms.  
 2.2  
This Amendment may be executed in counterparts, each of which shall be deemed an original and together shall be deemed to be one and the same document.  
 -2-  
IN WITNESS WHEREOF, the undersigned duly authorized representatives of the parties have executed and delivered this Fourth Amendment To License Agreement.  
 WYETH, acting through its CARDIOKINE BIOPHARMA, LLC  
Wyeth Pharmaceuticals division   
By: /s/ X.X. Xxxxx By: /s/ Xxxxxx Xxxxxx  
Name: Xxxxxx X. Xxxxx Name: Xxxxxx Xxxxxx M.D., F.A.H.A.  
Title: Senior Vice President, Title: President and CEO  
 Global Licensing   
Date: February 4, 2008 Date: February 6, 0000  
 -0-  
XXXXX XXXXXXXXX TO LICENSE AGREEMENT  
THIS FIFTH AMENDMENT TO LICENSE AGREEMENT (“Fifth Amendment”), executed as of the date of signature of the last Party to sign this Amendment (the “ Fifth Amendment Signing Date”), is entered into between WYETH LLC (formerly known as “Wyeth”), a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals division (“Wyeth”), and CARDIOKINE BIOPHARMA, LLC, a limited liability company organized and existing under the laws of the State of Delaware and having a principal place of business at 00 Xxxxx 00xx Xxxxxx, Xxxxxxxxxxxx, Xxxxxxxxxxxx 00000 (assignee of Cardiokine, Inc., a corporation organized and existing under the laws of the State of Delaware) (“Cardiokine”).  
RECITALS  
WHEREAS, Wyeth and Cardiokine entered into a License Agreement effective as of March 15, 2004, with respect to a vasopressin compound known as lixivaptan (as amended, the “License Agreement”);  
WHEREAS, Wyeth and Cardiokine entered into a first amendment to the License Agreement effective as of May 3, 2004, a second amendment to the License Agreement effective as of October 14, 2004, a third amendment to the License Agreement effective as of June 21, 2007, and a fourth amendment to the License Agreement effective as of February 6, 2008 (the “Fourth Amendment”);  
WHEREAS, Pursuant to a Patent Assignment executed on April 21, 2011 (the “Patent Assignment Date”) by Wyeth Holdings Corporation, Cardiokine acquired all right, title and interest in and to the Assigned Patents (as defined in the Patent Assignment) (the “Assigned Patents”);  
WHEREAS, Cardiokine, Inc. (the “ Company”), the parent of Cardiokine, is negotiating an agreement with Cornerstone Therapeutics Inc. (“Cornerstone”) pursuant to which Cornerstone would acquire, by way of a merger, all of the outstanding shares of the Company, such that the Company would become a wholly owned subsidiary of Cornerstone and Cardiokine would become an indirect subsidiary of Cornerstone (the “Cornerstone Acquisition Agreement”); and  
WHEREAS, in furtherance of and in connection with Cornerstone’s acquisition of Cardiokine pursuant to the Cornerstone Acquisition Agreement, the Parties now desire to further amend the License Agreement in certain respects.  
NOW THEREFORE, in consideration of the foregoing and of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:  
 1.  
Defined Terms. Except as otherwise set forth herein, all capitalized terms used, but not defined, in this Fifth Amendment shall have the respective meanings set forth in the License Agreement; provided, however, that, except as otherwise set forth therein, all capitalized terms used in Schedule A attached hereto shall have the respective meanings set forth in Schedule A.  
 1  
2.  
Effect of Fifth Amendment. The Parties agree that this Fifth Amendment shall become effective immediately prior to the [Effective Time] of the Cornerstone Acquisition Agreement (the “Fifth Amendment Effective Date”) and that should the Cornerstone Acquisition Agreement not be entered into or, if entered into, the Closing (as defined in the Cornerstone Acquisition Agreement) does not occur, this Fifth Amendment shall not become effective and shall be void ab initio.  
 3.  
Buy-Out Payments. As of the Fifth Amendment Effective Date, Sections 5.5 and 5.6 of the License Agreement are hereby deleted and replaced with the following:  
 “5.5  
Buy-Out Payments. Cardiokine or its Affiliate shall make the following nonrefundable payments to Wyeth to buy-out the Milestone Payments and royalties:  
 (a)  
Within [####]after the Amendment Effective Date (as defined in the Fourth Amendment) an initial payment (the “Initial Buy-Out Payment”) in the amount of [####].  
 (b)  
On the Closing Date (as defined in Schedule A), [####] (the “Acquisition Buy-Out Payment”).  
 (c)  
The Contingent Consideration (as defined in Schedule A); provided, however, that the portions of the Net Sales Payments and Ex-US Net Sales Payments (each as defined in Schedule A) which are paid to Wyeth pursuant to this Section 5.5(b) shall be fully credited toward the payments due pursuant to Section 5.2 of the Agreement.  
 (d)  
The maximum amount of the sum of the Acquisition Buy-Out Payment and Contingent Consideration payable by or on behalf of Cardiokine to Wyeth hereunder shall not exceed [####]. In the event that payment of any particular Contingent Payment (as defined in Schedule A) would result in the sum of the Acquisition Buy-Out Payment and all Contingent Payments to exceed [####], the amount of such Contingent Payment shall be reduced by the amount by which the sum of such payment, the Acquisition Buy-Out Payment and all previous Contingent Payments exceeds [####] and thereafter no further Contingent Payments shall be due under this Agreement.”  
 “5.6  
Effect of Buy-Out Payments. In the event Cardiokine or its Affiliates pay to Wyeth both (a) the Initial Buy-Out Payment and (b) the Acquisition Buy-Out Payment and Contingent Consideration, which Acquisition Buy-Out Payment and Contingent Consideration, in the aggregate, total [####], (i) the license to Cardiokine granted in Section 2.1 shall thereafter be fully paid-up with respect to all Licensed Patents and Licensed Know-How, (ii)  
 2  
 Sections 3.1 (excluding the last sentence thereof), 3.2, 5.2, 5.3.1, 5.3.2, 5.5 and 11.6(b) shall thereafter be deemed to have been deleted from the Agreement; (iii) Wyeth’s right to terminate this Agreement shall be limited solely to instances in which Cardiokine or any Affiliate of Cardiokine engages in Research, Development, Manufacture and/or Commercialization of Licensed Compounds and/or Licensed Products outside of the Field, and (iv) in all other cases of a breach of this Agreement by Cardiokine, Wyeth’s remedy shall be limited to damages and equitable relief.”  
 4.  
Wyeth Performance Obligations. Cardiokine acknowledges and agrees that Wyeth has met all of its performance obligations under the License Agreement and has no further performance obligations under the License Agreement as amended hereby.  
 5.  
Ratification. The License Agreement is hereby ratified as amended by this Fifth Amendment and shall remain in full force and effect in accordance with its terms as modified hereby. For the sake of clarity, the Parties acknowledge that the Initial Buy-Out Payment had been paid by Cardiokine to Wyeth prior to the Fifth Amendment Execution Date.  
 6.  
Counterparts. This Fifth Amendment may be executed in counterparts, each of which shall be deemed an original and together shall be deemed to be one and the same document.  
[Remainder of Page Intentionally Left Blank]  
 3  
IN WITNESS WHEREOF, the undersigned duly authorized representatives of the parties have executed and delivered this Fifth Amendment To License Agreement.  
 WYETH LLC, acting through its Wyeth  
Pharmaceuticals division  
 CARDIOKINE BIOPHARMA, LLC  
By: /s/ X.X. Xxxxx By: /s/ Xxx Xxxxxxx   
Name: Xxxxxx X. Xxxxx Name: Xxx Xxxxxxx  
Title: Senior Vice President Title: Vice President,All. MGMT and Corp. Dev.  
Date: December 27, 2011 Date: 12.27.2011  
 4  
SCHEDULE A  
Contingent Consideration  
(a) “Contingent Consideration” means each of the following payments (each, a “Contingent Payment”):  
(i) The following payments based on Approvals (collectively, the “Approval Contingent Payments”):  
(A) [####] within ten (10) Business Days after any Selling Person receives Approval A (the “Minimum Approval Payment”); and  
(B) [####] within ten (10) Business Days after any Selling Person receives Approval B, minus the amount (if any) previously paid to Wyeth pursuant to Section (a)(i)(A) of this Schedule A;  
(ii) Subject to Section (b) of this Schedule A, the applicable Earnout Percentage of the Net Sales Payments, payable within forty-five (45) calendar days after the end of each calendar quarter during the Earnout Period in the United States, where “Net Sales Payments” means Net Sales of Lixivaptan Products sold in the United States by a Selling Person during such calendar quarter, and “Earnout Percentage” means:  
(A) if a Selling Person has received Approval B at any time prior to the relevant calendar quarter; or  
(B) [####] if no Selling Person has received Approval B prior to the relevant calendar quarter;  
(iii) The following payments:  
(A) the First Sales Milestone Payment, payable within forty-five (45) calendar days after the calendar quarter in which the First Sales Milestone is achieved;  
(B) the Second Sales Milestone Payment, payable within forty-five (45) calendar days after the calendar quarter in which the Second Sales Milestone is achieved;  
(C) the Third Sales Milestone Payment, payable within forty-five (45) calendar days after the calendar quarter in which the Third Sales Milestone is achieved; and  
(D) the Fourth Sales Milestone Payment, payable within forty-five (45) calendar days after the calendar quarter in which the Fourth Sales Milestone is achieved, but only if a Selling Person has received Approval B at any time prior to the calendar quarter in which the Fourth Sales Milestone is achieved; and  
(iv) [####] of any Ex-US Payments, payable within ten (10) Business Days after the Buyer or any of its Affiliates (including the Surviving Corporation) actually receives such Ex-US Payment; provided, however, that  
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(A) with respect to any Ex-US Payments consisting of royalties paid to Buyer or its Affiliates by the relevant Selling Person measured as a percentage of sales of a Lixivaptan Product in a country outside the United States (“Ex-US Net Sales Payments”), such Ex-US Net Sales Payments shall equal [####] of such Ex-US Net Sales Payments or:  
(1) [####] of the applicable sales metric (including any reductions or adjustments therein) used in the calculation of royalties in connection therewith if a Selling Person has received Approval B at any time prior to the applicable calendar quarter; or  
(2) [####] of the applicable sales metric (including any reductions or adjustments therein) used in the calculation of royalties in connection therewith if no Selling Person has received Approval B at any time prior to the applicable calendar quarter;  
(B) with respect to Ex-US Net Sales Payments, the sales metric (including any reductions or adjustments therein) used in the calculation of royalties payable by Buyer hereunder shall be the same as the sales metric (including any reductions or adjustments therein) used in the calculation of royalties payable to Buyer or its Affiliates by the relevant Selling Person; and  
(C) such payments (excluding any portion of Ex-US Net Sales Payments paid by Buyer hereunder) will not exceed [####]; and  
(v) [####] of any US Payments, payable within ten (10) Business Days after the Buyer or any of its Affiliates (including the Surviving Corporation) actually receives such US Payment.  
For the avoidance of doubt, any Sales Milestone may be satisfied in the same calendar quarter as any other Sales Milestone, and Sales Milestones are measured on a rolling four (4) consecutive calendar quarter basis.  
(b) Generic Competition. Upon the first commercial sale by any Person (other than Buyer, any of Buyer’s Affiliates or any other Selling Person) of a product which received Regulatory Approval from the FDA of an abbreviated new drug application using a Lixivaptan Product as its reference product, the rate payable pursuant to Section (a)(ii)(A) or Section (a)(ii)(B) of this Schedule A, as applicable, shall be reduced by fifty percent (50%).  
(c) [Reserved]  
(d) Reporting.  
(i) For each calendar quarter in which a Contingent Payment comes due or with respect to which a Contingent Payment is calculated, the Buyer shall furnish Wyeth with a quarterly report of each Contingent Payment due during such quarter or calculated with respect to such quarter, and all relevant information required to calculate such Contingent Payment, within thirty (30) days after the end of each calendar quarter; and (2) for each other calendar quarter, the Buyer shall famish the Indemnification Representative with a written notice that no Contingent Payment is due. Each report pursuant to clause (1) shall include (A) Net Sales, on a country-by-country basis, during such calendar quarter, (B) Annual Net Sales during each consecutive four  
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calendar quarter period ending during such calendar quarter, (C) the “gross to net” adjustments with respect to the calculation of Net Sales for such calendar quarter, on a country-by-country basis, (D) if any deduction is made to Net Sales during such calendar quarter pursuant to clause (B) of the definition of Net Sales, an explanation of how the share of the excise tax deducted pursuant to such clause (B) was allocated to Lixivaptan Product sales, and (E) the amount of each Approval Contingent Payment, Ex-US Payment and US Payment and the calculation thereof.  
(e) [Reserved]  
(f) Definitions. For the purposes of this Agreement the following terms shall have the following meanings:  
(i) “Affiliate” shall mean any person who is an “affiliate” of that party within the meaning of Rule 405 promulgated under the Securities Act of 1933, as amended (the “Securities Act”).  
(ii) “Annual Net Sales” shall mean the Net Sales of Lixivaptan Products during any consecutive four calendar quarter period ending prior to the expiration of the Last Measured Earnout Period.  
(iii) “Approval” shall mean any of the following indications for which the FDA grants Marketing Approval for a Lixivaptan Product:  
(A) euvolemic hyponatremia (“Approval A”), or  
(B) euvolemic hyponatremia and hypervolemic hyponatremia, regardless of whether therapy is initiated inside or outside of a hospital (“Approval B”);  
where, “euvolemic hyponatremia” means hyponatremia associated with the Syndrome of Inappropriate Anti-Diuretic Hormone secretion (SIADH), and “hypervolemic hyponatremia” means hyponatremia associated with Congestive Heart Failure (CHF), and Approval B shall be deemed received whether or not other forms of hypervolemic hyponatremia (including hypervolemic hyponatremia associated with liver cirrhosis or hypervolemic hyponatremia in patients with acutely decompensated heart failure) are contraindicated or the subject of a warning in the label.  
(iv) “Business Day” shall be any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York, New York are permitted or required by law, executive order or governmental decree to remain closed.  
(v) “Buyer” shall mean Cornerstone Therapeutics Inc., a Delaware corporation.  
(vi) “Closing Date” means a date to be specified by the Buyer and the Company, which shall be no later than the second Business Day after satisfaction or waiver of the conditions set forth in Article VII of the Cornerstone Acquisition Agreement (other than delivery of items to be delivered at the Closing and other than satisfaction of those conditions that by their nature are to be satisfied at the Closing, it being understood that the occurrence of the Closing shall remain subject to the delivery of such items and the satisfaction or waiver of such conditions at the Closing).  
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(vii) “Company” means Cardiokine, Inc.  
(viii) “Company Intellectual Property” shall mean the Intellectual Property owned by the Company, together with the Intellectual Property owned by any Subsidiary of the Company.  
(ix) “Cornerstone Acquisition Agreement” has the meaning set forth in the body of the Fifth Amendment.  
(x) “Earnout Period” shall mean, on a country-by-country basis, the period commencing on the Closing Date and expiring upon the later of: (A) expiration of the last Valid Claim of any Lixivaptan Patent Right in such country, or (B) the expiration of the market exclusivity period(s) granted by a Regulatory Authority for Lixivaptan Product in such country during which such Regulatory Authority will not grant Regulatory Approval of a product (1) containing lixivaptan or the active moiety thereof, (2) using a Lixivaptan Product as its reference product, or (3) relying in any other manner on the regulatory data or filings for a Lixivaptan Product.  
(xi) “Effective Time” means the effectiveness of the Merger upon the filing of the Certificate of Merger with the Secretary of State of the State of Delaware or at such later time as is established by the Buyer and the Company and set forth in the Certificate of Merger.  
(xii) “Europe” shall mean (A) the European Union, as constituted as of the relevant time, or (B) if the European Union is disbanded, the countries on the continent of Europe.  
(xiii) “Ex-US Payments” shall mean any amounts (including Ex-US Net Sales Payments) actually received by the Buyer or any of its Affiliates (including the Surviving Corporation), calculated net of Taxes incurred by the Buyer or any of its Affiliates (including the Surviving Corporation) in connection with the receipt of such amounts (which Taxes shall be deemed to be incurred at a combined rate of 42% (the “Assumed Tax Rate”)) and without duplication, after the Effective Time from a Selling Person or its Affiliate (other than the Buyer or its Affiliates) in consideration: (A) for granting a Selling Person a license, sublicense or other similar rights with respect to a Lixivaptan Product (including a license or sublicense of any Lixivaptan Patent Rights) outside the United States at any time prior to the end of the applicable Earnout Period, (B) for selling, assigning or transferring to a Selling Person any Company Intellectual Property or Third Party Intellectual Property owned by or licensed to the Company or any of its Subsidiaries as of immediately prior to the Effective Time (including any Lixivaptan Patent Right), outside the United States at any time prior to the end of the applicable Earnout Period, or (C) for consummating an Ex-US Lixivaptan Product Line Sale at any time prior to the end of the applicable Earnout Period; provided, that, with respect any sale of active ingredient in bulk, such amounts shall only include the net profit realized by Buyer and its Affiliates with respect to such sale and the Buyer and the Indemnification Representative shall negotiate in good faith upon such a sale to agree upon the calculation thereof. For the avoidance of doubt, Ex-US Payments exclude the portion of any payments made to Buyer or its Affiliates by a Selling Person in respect of the Buyer’s obligations to make a Sales Milestone Payment pursuant to this Agreement which portion is required to be paid by Buyer hereunder.  
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(xiv) “Ex-US Lixivaptan Product Line Sale” shall mean a sale, transfer or assignment to any third party who is not an Affiliate of the Buyer of any material rights relating to any Lixivaptan Product outside the United States (including any applicable Lixivaptan Patent Rights, Regulatory Approvals or active ingredient in bulk), other than, for the avoidance of doubt, sales of a Lixivaptan Product subject to royalties paid to Buyer or its Affiliates by the relevant Selling Person measured as a percentage of sales.  
(xv) “FDA means the United States Food and Drug Administration.  
(xvi) “First Sales Milestone Payment” shall mean a payment of [####] for the achievement of the First Sales Milestone prior to the expiration of the Last Measured Earnout Period, where “First Sales Milestone” means the first time that Annual Net Sales of Lixivaptan Products equal or exceed [####].  
(xvii) “Fourth Sales Milestone Payment” shall mean the payment of [####] for the achievement of the Fourth Sales Milestone prior to the expiration of the Last Measured Earnout Period, where “Fourth Sales Milestone” means the first time that Annual Net Sales of Lixivaptan Products equal or exceed [####].  
(xviii) “Governmental Entity” means any court, arbitrational tribunal, administrative agency or commission or other governmental or regulatory authority, agency or instrumentality.  
(xix) “Indemnification Representative” means the then- current “Indemnification Representative” pursuant to the Cornerstone Acquisition Agreement.  
(xx) “Intellectual Property” means (i) patents, trademarks, service marks, trade names, domain names, copyrights, designs and trade secrets, (ii) applications for and registrations of such patents, trademarks, service marks, trade names, domain names, copyrights and designs, (iii) proprietary or confidential processes, formulae, methods, schematics, technology, know-how and computer software programs and applications, (iv) other proprietary or confidential information, and (v) any and all intellectual property rights and similar proprietary rights in any jurisdiction, including all rights to xxx for past, present and future infringement or misappropriation of any of the items in clauses (i), (ii), (iii) and (iv).  
(xxi) “Last Measured Earnout Period” shall mean the longest of (a) the Earnout Period in the United States, (b) the Earnout Period in Europe, and (c) the Earnout Period in any country in which, at the end of the longer of the Earnout Period in the United States and the Earnout Period in Europe, any Lixivaptan Product is then being sold by a Selling Person.  
(xxii) “Lixivaptan” means Company’s lixivaptan product candidate.  
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(xxiii) “Lixivaptan Patent Right” shall mean the rights and interests in and to the patent or patent application owned by or licensed to Company or any of its Subsidiaries as of immediately prior to the Effective Time which claims the composition of matter, use or method of manufacture of any Lixivaptan Product, or any Counterpart thereof, regardless of whether such patent or patent application, as of the relevant time, is owned by or licensed to Buyer, any of its Affiliates (including the Surviving Corporation) or any Selling Person or Affiliate of a Selling Person. For purposes of this definition, “Counterpart” shall mean (A) all divisionals, continuations, continuations-in-part of any patent application; (B) any patents (including certificates of correction) issuing from a patent application; (C) any substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, re-examinations and renewals of any of the patents and patent applications described in clause (A) or (B); and (D) foreign counterparts of any of the foregoing.  
(xxiv) “Lixivaptan Product” shall mean Lixivaptan or any pharmaceutical product containing lixivaptan as an active pharmaceutical ingredient.  
(xxv) “Lixivaptan Product Line Buyer” shall mean any Person (other than Buyer and its Affiliates) with whom Buyer or any of its Affiliates (including the Surviving Corporation), directly or indirectly consummates a US Lixivaptan Product Line Sale or an Ex-US Lixivaptan Product Line Sale, as the case may be.  
(xxvi) “Marketing Approval” shall mean the approval by the FDA of a new drug application for a Lixivaptan Product.  
(xxvii) “Merger” means the acquisition of the Company shall be effected through a merger, pursuant to the Cornerstone Acquisition Agreement.  
(xxviii) “Net Sales” shall mean the gross amount invoiced for any sale of a Lixivaptan Product by a Selling Person to a non-Affiliate of the Selling Person or to an Affiliate of the Selling Person if such Affiliate is not itself a Selling Person, less the sum of the following deductions, in each case to the extent actually and reasonably allowed or incurred in connection with such sale of such Lixivaptan Product in accordance with GAAP:  
(A) reasonable and customary trade, cash and quantity discounts off the invoiced price;  
(B) all excise, sales and other consumption taxes and custom duties to the extent included in the invoice price; provided, however, that, with respect to excise tax payments pursuant to Section 9008 of the Patient Protection and Affordable Care Act of 2010, any such deduction shall be limited to the proportionate share of such excise tax equal to the proportionate share that the aggregate sales of such Lixivaptan Product by such Selling Person during the period to which such excise tax relates bears to the aggregate sales of all products by such Selling Person subject to such excise tax;  
(C) freight, insurance and other transportation charges to the extent included in the invoice price;  
(D) amounts repaid, credited or accrued, or allowances or adjustments made, by reason of returns, rejections, or recalls, or because of chargebacks, retroactive price reductions, or billing errors;  
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(E) reasonable and customary launch discounts, stocking fees and other discounts extended to wholesalers, distributors, chain drug stores and other third party organizations who distribute the Lixivaptan Product to pharmacies;  
(F) reasonable and customary rebates and chargebacks to pharmacy benefit managers, federal, state, or local governments (or their agencies or purchasers), and managed health organizations (including Medicaid rebates); and  
(G) any amounts actually written off or specifically identified as uncollectible in accordance with GAAP;  
solely to the extent the above deductions are taken in accordance with GAAP applicable to the particular Selling Person.  
Such amounts shall be determined from the books and records of the applicable Selling Person, maintained in accordance with U.S. Generally Accepted Accounting 11  
Principles or other similar generally accepted accounting principles used by such Selling Person, consistently applied (“GAAP”). Sales of a Lixivaptan Product between or among the Selling Persons and/or Affiliates of Selling Person for resale, or for use in the production or manufacture of Lixivaptan Product, shall not be included within Net Sales; provided, however, that any subsequent sale of a Lixivaptan Product by any Selling Person or its Affiliates to another person or entity that is not a Selling Person shall be included within Net Sales.  
Use of Lixivaptan Product for promotional, sampling or compassionate use purposes or for use in clinical trials (but excluding post-approval clinical trials for which compensation is received by the Selling Person) shall not be considered in determining Net Sales.  
In the case of any sale of a Lixivaptan Product for value other than in an arm’s length transaction exclusively for cash, such as barter or counter-trade, Net Sales shall be calculated based on the fair market value of the consideration received; provided that (i) sales to a third party distributor, wholesaler, group purchasing organization, pharmacy benefit manager or retail chain customer who is a non-Affiliate of a Selling Person and does not need a license or sublicense in order to resell such Lixivaptan Product shall be considered sales to a non-Affiliate of the Selling Person and not to a sublicensee, and (ii) Net Sales by a Selling Person to a consignee non-Affiliate of the Selling Person are not recognized as Net Sales by such Selling Person until the such consignee sells the Lixivaptan Product.  
With respect to sales of a Lixivaptan Product invoiced in U.S. dollars, Net Sales shall be expressed in U.S. dollars. With respect to sales not invoiced in U.S. dollars, Net Sales shall be converted to U.S. dollars using the applicable exchange rate as published by The Wall Street Journal, Eastern Edition on the last Business Day of the calendar quarter in which such sales are made.  
(xxix) “Person” shall mean an individual, corporation, partnership, limited liability company, joint venture, association, trust, unincorporated organization, or other entity.  
(xxx) “Pricing Approval” means the approval, agreement, determination or governmental decision establishing the price or level of reimbursement for the relevant pharmaceutical or biological product, if required in the relevant country or jurisdiction prior to sale of such product in such country or jurisdiction  
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(xxxi) “Regulatory Approval” shall mean, with respect to a pharmaceutical or biological product and a country or jurisdiction, any approval, registration, license or authorization that is required by the applicable governmental agency or authority to market and sell such pharmaceutical or biological product in such country or jurisdiction, including Pricing Approval.  
(xxxii) “Regulatory Authority” shall mean any governmental agency or authority responsible for granting Regulatory Approvals for pharmaceutical or biological products, as applicable, in a country or jurisdiction, including the FDA in the United States.  
(xxxiii) “Sales Milestone” shall mean any of the First Sales Milestone, Second Sales Milestone, Third Sales Milestone or Fourth Sales Milestone.  
(xxxiv) “Sales Milestone Payment” shall mean any of the First Sales Milestone Payment, Second Sales Milestone Payment, Third Sales Milestone Payment or Fourth Sales Milestone Payment.  
(xxxv) “Second Sales Milestone Payment” shall mean the payment of [####]for the achievement of the Second Sales Milestone prior to the expiration of the Last Measured Earnout Period, where “Second Sales Milestone” means the first time Annual Net Sales of Lixivaptan Products equal or exceed [####].  
(xxxvi) “Selling Person” shall mean the Buyer, each of its Affiliates (including the Surviving Corporation) and each (A) licensee, sublicensee, assignee or other grantee of rights from Buyer or any of its Affiliates or another Selling Person to develop, market or sell a Lixivaptan Product, (B) buyer, transferee or assignee of any Company Intellectual Property or Third Party Intellectual Property (for the sake of clarity to avoid double-counting, other than, in each case, rights granted with respect to any Lixivaptan Patent Right pursuant to clause (A)), from Buyer or its Affiliates (including the Surviving Corporation) or another Selling Person, (C) a Lixivaptan Product Line Buyer or (D any Affiliate of the foregoing.  
(xxxvii) “Subsidiary” means, with respect to any party, any corporation, partnership, trust, limited liability company or other non-corporate business enterprise in which such party (or another Subsidiary of such party) holds stock or other ownership interests representing (a) more than 50% of the voting power of all outstanding stock or ownership interests of such entity or (b) the right to receive more than 50% of the net assets of such entity available for distribution to the holders of outstanding stock or ownership interests upon a liquidation or dissolution of such entity.  
(xxxviii) “Surviving Corporation” means the Company following the merger pursuant to the Cornerstone Acquisition Agreement.  
(xxxix) “Taxes” means all taxes, charges, fees, levies or other similar assessments or liabilities in the nature of a tax, including income, gross receipts, ad valorem, premium, value-added, excise, real property, personal property, sales, use, services, transfer, withholding, employment, payroll and franchise taxes imposed by any Governmental Entity, and any interest, fines, penalties, assessments or additions to tax resulting from, attributable to or incurred in connection with any tax or any contest or dispute thereof  
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(xl) “Third Party Intellectual Property” means the Intellectual Property licensed or sublicensed to the Company or which the Company otherwise possesses legally enforceable rights to use, together with the Intellectual Property licensed or sublicensed to any Subsidiary of the Company or which any Subsidiary of the Company otherwise possesses legally enforceable rights to use.  
(xli) “Third Sales Milestone Payment” shall mean the payment of [####] for the achievement of the Third Sales Milestone prior to the expiration of the Last Measured Earnout Period, where “Third Sales Milestone” means the first time that Annual Net Sales of Lixivaptan Products equal or exceed [####].  
(xlii) “US” or “United States” means the United States of America, its territories and possessions.  
(xliii) “US Lixivaptan Product Line Sale” shall mean a sale, transfer or assignment to any third party who is not an Affiliate of the Buyer of any material rights relating to any Lixivaptan Product in the United States (including any applicable Lixivaptan Patent Rights or Regulatory Approvals), other than, for the avoidance of doubt, sales of a Lixivaptan Product subject to royalties paid to Buyer or its Affiliates by the relevant Selling Person measured as a percentage of sales.  
(xliv) “US Payments” shall mean any amounts actually received by the Buyer or any of its Affiliates (including the Surviving Corporation), calculated net of Taxes incurred by the Buyer or any of its Affiliates (including the Surviving Corporation) in connection with the receipt of such amounts (which Taxes shall be deemed to be incurred at the Assumed Tax Rate) and without duplication, after the Effective Time from a Selling Person or its Affiliate (other than the Buyer or any of its Affiliates) in consideration: (A) for granting a Selling Person a license, sublicense or similar rights with respect to a Lixivaptan Product (including a license or sublicense of any Lixivaptan Patent Rights) in the United States at any time prior to the end of the applicable Earnout Period, (B) for selling, assigning or transferring to a Selling Person any Company Intellectual Property or Third Party Intellectual Property owned by or licensed to the Company or any of its Subsidiaries as of immediately prior to the Effective Time (for the sake of clarity to avoid double-counting, other than, in each case, rights granted with respect to any Lixivaptan Patent Right pursuant to clause (A)) in the United States at any time prior to the end of the applicable Earnout Period, or (C) for consummating a US Lixivaptan Product Line Sale at any time prior to the end of the applicable Earnout Period. For the avoidance of doubt, US Payments exclude (i) the portion of any payments made to Buyer or its Affiliates by a Selling Person in respect of the Buyer’s obligation to make an Approval Contingent Payment or a Sales Milestone Payment pursuant to this Agreement which portion is required to be paid by Buyer hereunder, and (ii) Net Sales Payments.  
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(xlv) “Valid Claim” shall mean (A) a claim of an issued and unexpired patent which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other governmental agency or authority of competent jurisdiction and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue), or (B) a claim of a pending patent application, which claim has not been irretrievably revoked, cancelled, withdrawn or abandoned, or finally disallowed without the possibility of appeal or refiling of such application (or which is not appealed or refilled within the time allowed for appeal); provided, however, that unless and until a pending patent issues, “Valid Claim” will exclude any such pending claim in an application that has not been granted within five (5) years following the filing date for such application.  
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SIXTH AMENDMENT TO LICENSE AGREEMENT  
THIS SIXTH AMENDMENT TO LICENSE AGREEMENT (“Sixth Amendment”), executed as of the date of signature of the last Party to sign this Amendment (the “Effective Date”), is entered into between WYETH LLC (formerly known as “Wyeth”), a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at Five Xxxxxxx Xxxxx, Xxxxxxx, Xxx Xxxxxx 00000, acting through its Wyeth Pharmaceuticals division (“Wyeth”), and CARDIOKINE BIOPHARMA, LLC, a limited liability company organized and existing under the laws of the State of Delaware and having a principal place of business 0000 Xxxxxxxxx Xxxx, Xxxxxxx, Xxxxxxxxxxxx 00000 (assignee of Cardiokine, Inc., a corporation organized and existing under the laws of the State of Delaware) (“Cardiokine”).  
RECITALS  
WHEREAS, Wyeth and Cardiokine entered into a License Agreement effective as of March 15, 2004, with respect to a vasopressin compound known as lixivaptan (as amended, the “License Agreement”);  
WHEREAS, Wyeth and Cardiokine entered into a first amendment to the License Agreement effective as of May 3, 2004, a second amendment to the License Agreement effective as of October 14, 2004, a third amendment to the License Agreement effective as of June 21, 2007, a fourth amendment to the License Agreement effective as of February 6, 2008, and a fifth amendment to the License Agreement effective as of December 27, 2011;  
WHEREAS, Cardiokine, Inc., a Delaware corporation and parent of Cardiokine (the “Company”), was recently acquired by Palladio Acquisition Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Palladio Biosciences, Inc. (“Palladio”), pursuant to a Stock Purchase Agreement, dated as of July 26, 2016, by and among Chiesi USA, Inc., Palladio Biosciences, Inc. and Palladio (the “Cardiokine Acquisition”; and  
WHEREAS, in furtherance of and in connection with Cardiokine Acquisition, the Parties now desire to further amend the License Agreement in certain respects.  
NOW THEREFORE, in consideration of the foregoing and of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:  
 1.  
Defined Terms. Except as otherwise set forth herein, all capitalized terms used, but not defined, in this Sixth Amendment shall have the respective meanings set forth in the License Agreement.  
 2.  
Amendment to Cardiokine Notice Provision. Effective as of the Effective Date, the Parties hereby agree that Section 13.5.I(i) of the License Agreement shall be deleted in its entirety and replaced with the following:  
 (i)  
If to Cardiokine:  
Cardiokine, Inc.  
c/o Palladio Biosciences, Inc.  
0000 Xxxxxxxxx Xxxx Xxxxxxx, Xxxxxxxxxxxx 00000  
Attention: Xxxxxxx Xxxxxxxxxx, Chief Executive Officer  
with a copy to:  
Xxxxxx, Xxxxx & Bockius  
000 Xxxxxxxx Xxxxxx  
Xxxxxxxxx, Xxx Xxxxxx 00000  
Attn: [####]  
Fax Number: [####]  
 4.  
Ratification. The License Agreement is hereby ratified as amended by this Sixth Amendment, and, except as expressly amended by this Sixth Amendment, the provisions of the License Agreement shall remain in full force and effect in accordance with its terms.  
 5.  
Counterparts. This Sixth Amendment may be executed in counterparts, each of which shall be deemed an original and together shall be deemed to be one and the same document.  
[Remainder of Page Intentionally Left Blank]  
IN WITNESS WHEREOF, the undersigned duly authorized representatives of the parties have executed and delivered this Sixth Amendment To License Agreement.  
 WYETH, acting through its Wyeth CARDIOKINE BIOPHARMA,  
Pharmaceuticals division LLC  
By: /s/ X.X. Xxxxx By: /s/ Xxxxxxx Xxxxxxxxxx  
Name: Xxxxxx X. Xxxxx Name: Xxxxxxx Xxxxxxxxxx  
Title: Senior Vice President Title: Chief Executive Officer  
Date: December 1, 2016 Date: Nov. 29, 2016