As confidentially submitted to the Securities and Exchange Commission on March 20, 2014. This second draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

**Registration No. 333-**

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM S-1 REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

# **HISTOGENICS CORPORATION**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

3842 (Primary Standard Industrial Classification Code Number) 04-3522315 (I.R.S. Employer Identification Number)

Accelerated filer

Smaller reporting company

 $\left| X \right|$ 

830 Winter Street, 3rd Floor Waltham, Massachusetts 02451

(781) 547-7900

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Kevin McArdle Chief Financial Officer Histogenics Corporation

830 Winter Street, 3rd Floor

Waltham, Massachusetts 02451

(781) 547-7900

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Marc F. Dupré Michael A. Hedge **Richard C. Blake** Mark L. Johnson Keith J. Scherer **Damien A. Grierson Gunderson Dettmer Stough** K&L Gates LLP Villeneuve Franklin & Hachigian, LLP State Street Financial Center 850 Winter Street **One Lincoln Street** Waltham, Massachusetts 02451 Boston, Massachusetts 02111 Telephone: (781) 890-8800 Telephone: (617) 261-3100 Telecopy: (781) 622-1622 Telecopy: (617) 261-3175

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(2)</sup>
Common Stock, \$0.001 par value		
(1) Estimated pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price attributable to additional shares that the underwriters have the option to purchase to cover over- allotments, if any.		

<sup>(2)</sup> Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

#### **Explanatory Note**

This second draft registration statement is being submitted solely for the purposes of filing Exhibits 10.20, 10.26 and 10.27 and amending the disclosures in Item 16 of Part II of the draft registration statement. No changes or additions are being made hereby to the prospectus constituting Part I of the draft registration statement (not included herein) or to Items 13, 14, 15 or 17 of Part II of the draft registration statement.

## PART II INFORMATION NOT REQUIRED IN THE PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table presents the costs and expenses, other than underwriting discounts and commissions, payable in connection with the sale of common stock being registered. All amounts are estimates except the SEC registration fee, the FINRA filing fee and the exchange listing fee. Except as otherwise noted, all the expenses below will be paid by us.

SEC registration fee	*
FINRA filing fee	*
Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue sky fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous fees and expenses	*
Total	*

To be completed by amendment

#### Item 14. Indemnification of Directors and Officers.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or is or was serving at the request of a corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

In connection with the completion of this offering, the Registrant's amended and restated certificate of incorporation will contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of the Registrant's directors for monetary damages for breach of their fiduciary duties as directors. The Registrant's amended and restated bylaws to be in effect immediately prior to the completion of this offering provide that the Registrant must indemnify its directors and officers and may indemnify its employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

The Registrant has entered into indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its amended and restated bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The Registrant has purchased and intends to maintain insurance on behalf of any person who is or was a director or officer of the Registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The Underwriting Agreement, the form of which is attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters of the Registrant and its executive officers and directors, and by the Registrant of the



underwriters, for certain liabilities, including liabilities arising under the Securities Act and affords certain rights of contribution with respect thereto.

See also "Undertakings" set out in response to Item 17 herein.

#### Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding the shares of common stock and preferred stock and the warrant issued, and options granted, by us since February 14, 2011 that were not registered under the Securities Act of 1933.

- (1) Under the 2012 Equity Incentive Plan, we granted stock options to purchase shares of our common stock to certain of our employees, officers, consultants and advisors, as follows: (a) from August 15, 2012 to July 16, 2013, we granted stock options to purchase an aggregate of 5,391,806 shares of our common stock at an exercise price of \$0.07 per share; (b) on October 31, 2012, we issued 61,095 shares of restricted common stock at a price of \$0.001 per share; (c) on April 23, 2013, we issued 81,623 shares of restricted common stock at a price of \$0.001 per share; and (d) on December 11, 2013, we granted stock options to purchase an aggregate of 1,353,211 shares of our common stock at an exercise price of \$0.66 per share.
- (2) In 2012, we issued and sold an aggregate of 28,602,031 shares of Series A convertible preferred stock to investors for an aggregate purchase price of \$26.5 million, net of issuance costs.
- (3) In 2012, in connection with our Series A Financing, we issued warrants to investors and advisors exercisable for an aggregate of 2,266,841 shares of our common stock at a weighted average exercise price of \$0.0167 per share. These warrants are or will be exercisable upon the occurrence of certain defined events for an aggregate of up 2,266,841 shares of our common stock. These warrants terminate ten years after the date issued.
- (4) In December 2013, we issued and sold an aggregate of 10,323,988 shares of Series A-1 convertible preferred stock to investors for an aggregate purchase price of \$10.3 million.

The offers, sales, grants and issuances of the securities described in paragraph (1) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701. The recipients of such securities were our employees, officers, bona fide consultants and advisors and received the securities under our 2012 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offer, sale and issuance of the securities described in paragraphs (2), (3) and (4) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act in that the issuance of the securities to the accredited investors did not involve a public offering. The recipients of the securities in this transaction acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in this transaction. The recipients of the securities in this transaction were accredited investors under Rule 501 of Regulation D.

#### Item 16. Exhibits and Financial Statement Schedules.

<u>Exhibit</u>	Description
1.1*	Form of Underwriting Agreement
3.1‡	Fifth Amended and Restated Certificate of Incorporation, as amended (currently in effect)
3.2‡	Bylaws (currently in effect)
3.3*	Form of Sixth Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)

<u>Exhibit</u>	Description
3.4*	Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)
4.1*	Specimen stock certificate evidencing the shares of common stock
4.2‡	Second Amended and Restated Investors' Rights Agreement dated as of December 18, 2013
4.3‡	Second Amended and Restated Stockholders' Agreement dated as of December 18, 2013
5.1*	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
10.1‡	Form of Indemnity Agreement for directors and officers
10.2+‡	Employment Agreement, dated June 5, 2013, between the Registrant and Peter Greenleaf
10.3+‡	Offer letter, effective as of May 15, 2011, between the Registrant and Kevin McArdle
10.4+‡	Offer letter, dated September 23, 2013, between the Registrant and Nancy Lynch, M.D.
10.5+‡	Offer letter, effective as of August 5, 2013, between the Registrant and Stephen Kennedy
10.6+‡	2012 Equity Incentive Plan, as amended, and form of option agreement thereunder
10.7+*	2013 Equity Incentive Plan and form of option agreement thereunder
10.8+*	2013 Employee Stock Purchase Plan
10.9+*	Independent Director Compensation Policy
10.10†‡	License Agreement dated as of May 12, 2005 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.11†‡	Amendment to License Agreement dated as of August 31, 2007 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.12†‡	Second Amendment to License Agreement dated as of January 1, 2008 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
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10.15†‡	Fifth Amendment to License Agreement dated as of August 6, 2010 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.16†‡	Reinstatement Agreement and Sixth Amendment to License Agreement dated as of February 8, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.17†‡	Seventh Amendment to License Agreement dated as of March 31, 2011 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.18†‡	Eighth Amendment to License Agreement dated as of June 29, 2012 among the Registrant and Angiotech Pharmaceuticals (US), Inc. and Angiodevice International GmbH
10.19†‡	Paid-up License Agreement dated as of March 6, 2013 between the Registrant and Koken Co., Ltd.
10.20†	Agreement dated as of June 22, 2012 between the Registrant and Purpose Co., Ltd. f/k/a Takagi Sangyo Co. Ltd. and f/k/a Takagi Industrial Co Ltd.
10.21†‡	Exclusive Agreement dated as of April 15, 2001 between the Registrant and The Board of Trustees of The Leland Stanford Junior University

10.22<sup>+</sup> First Amendment to Exclusive Agreement dated as of October 26, 2005 between the Registrant and The Board of Trustees of The Leland Stanford Junior University

Exhibit	Description
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10.24†‡	Amendment No. 3 to the License Agreement Effective 4/15/2001 dated as of May 1, 2009 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.25†‡	Amendment No. 4 to the License Agreement Effective 4/15/2001 dated as of April 29, 2010 between the Registrant and The Board of Trustees of The Leland Stanford Junior University
10.26†	License Agreement dated as of January 6, 2008 between the Registrant (ProChon Biotech Ltd.) and Yeda Research and Development Company Limited
10.27†	Amendment to License Agreement dated as of March 23, 2010 between the Registrant (ProChon Biotech Ltd.) and Yeda Research and Development Company Limited
10.28‡	Lease Agreement dated of June 9, 2006 between the Registrant and Intercontinental Fund III 830 Winter Street LLC
10.29‡	First Amendment to Lease dated as of October 1, 2009 between the Registrant and Intercontinental Fund III 830 Winter Street LLC
21.1‡	List of Subsidiaries
23.1*	Consent of Grant Thornton LLP, independent registered public accounting firm
23.2*	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

\* To be filed by amendment.

+ Indicates management contract or compensatory plan.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. The omitted portions of this exhibit have been filed with the SEC.

‡ Previously submitted.

#### (b) Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes to provide the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

The undersigned registrant hereby undertakes that:

- 1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.
- 2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- 3. For the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was made in the registration statement or prospectus that was part of the registration statement or prospectus that was made in the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- 4. In a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (1) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (2) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (3) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (4) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

#### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on this day of , 2014.

#### HISTOGENICS CORPORATION

By:

President and Chief Executive Officer

#### SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints and Kevin McArdle, and each of them, as his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments) and any registration statement related thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
	Chief Executive Officer, President, and Director (Principal Executive Officer)	
Kevin McArdle	Chief Financial Officer (Principal Financial and Accounting Officer)	
Garheng Kong, M.D., Ph.D.	Chairman of the Board	
Joshua Baltzell	Director	
John H. Johnson	Director	
Michael Lewis	Director	
Kevin Rakin	Director	
	II-6	

## EXHIBIT INDEX

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+

Indicates management contract or compensatory plan. Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment. The omitted portions of this exhibit have † been filed with the SEC.

‡ Previously submitted.

#### AGREEMENT

Agreement made and entered into as of the 22nd day of June, 2012, by and between Purpose Co., Ltd., f/k/a Takagi Sangyo Co. Ltd., and also f/k/a Takagi Industrial Co., Ltd., a Japanese corporation ("Takagi"), and Histogenics Corporation, a Delaware corporation ("Histogenics") (the "Agreement"). The parties agree as follows:

1. Introduction. Takagi and Histogenics are parties to the following agreements and no others (the "Existing Agreements"):

Subscription and Business Agreement dated July 6, 2000

Amendment to Subscription and Business Agreement dated September 23, 2005

Supplemental Agreement dated May 11, 2006.

The purpose of this Agreement is to amend, restate and otherwise terminate the Existing Agreements and replace them with this Agreement. The parties further acknowledge that Histogenics is party to a term sheet dated February 24, 2012 with \*\*\*\* (the "\*\*\*\* Term Sheet"), a copy of which is attached hereto as Exhibit A. This Agreement is being entered into in contemplation of the Initial Closing under the \*\*\*\* Term Sheet (the "Effective Date"), and this Agreement shall be in full force and effect as of the Effective Date.

2. <u>Termination of Existing Agreements</u>. Upon the Effective Date, the Existing Agreements shall be of no further force and effect and this Agreement and any other agreements attached as or contemplated by Exhibits to this Agreement shall represent the entire understanding of the parties.

3. License of Technology.

(a) <u>License to Histogenics</u>. Takagi hereby grants to Histogenics outside of Japan the perpetual (with respect to patent rights, for the full term of each patent licensed hereunder), paid-up, worldwide, sublicensable, exclusive right under all patent rights ("Takagi Patents") and technology (including, but not limited to, all know-how, trade secrets, copyrightable works, design and technical information and all improvements, modifications, updates or derivatives thereof) (the "Takagi Technology") relating to Takagi's exogenous tissue processor as used for producing the Histogenics Product Line (as such term is defined in Section 3(b) below), whether owned by Takagi or based upon

\*\*\*\*CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

rights held by Takagi, and whether now owned or held by Takagi or at any time following the date of this Agreement , in the Field of Use (as defined below) to (i) use, make, have made, sell, offer for sale, and import products or services that would, but for the license granted under the Takagi Patents, infringe a valid claim of any Takagi Patent, and (ii) use, reproduce, modify and create derivative works of the Takagi Technology for the design, development, manufacture, testing, support and commercialization of any product or service that incorporates or builds upon the Takagi Technology. The Takagi Patents hereby include, without limitation, the patent rights owned by Takagi that are listed on Exhibit B-1 to this Agreement. The "Field of Use" consists of any applications of the Takagi Technology and Histogenics Technology (as defined below) in connection with articular cartilage, ligaments, tendons and meniscus. Takagi retains its rights to the Takagi Technology and Takagi Patents for any applications outside the Field of Use. Takagi shall also have the right to sell its TEPs (as such term is defined below) in Section 4 to research institutes for general but noncommercial use anywhere in the world. Takagi Patents.

(b) License to Takagi. Histogenics hereby grants to Takagi the perpetual (with respect to patent rights, for the full term of each patent licensed hereunder), paid-up, subslicensable, exclusive right solely in Japan under all patent rights ("Histogenics Patents") and technology (including, but not limited to, all know-how, trade secrets, copyrightable works, design and technical information and all improvements, modifications, updates or derivatives thereof) (the "Histogenics Technology") relating to Histogenics' biotechnology and biomaterials, whether owned by Histogenics or based upon rights held by Histogenics, and whether now owned or held by Histogenics or at any time following the date of this Agreement in the Field of Use to (i) use, make, have made, sell, offer for sale, and import products and services that would, but for the license granted under the Histogenics Patents, infringe a valid claim of any Histogenics Patent, and (ii) use, reproduce, modify and create derivative works of the Histogenics Technology for the design, development, manufacture, testing, support and commercialization of any product or service that incorporates or builds upon the Histogenics Technology. The Histogenics Patents

hereby include, without limitation, the patent rights owned by Histogenics that are listed on Exhibit B-2 to this Agreement. Histogenics retains its rights to the Histogenics Technology and Histogenics Patents for any applications outside the Field of Use and for inside the Field of Use anywhere in the world other than Japan. Histogenics acknowledges that the license granted hereby gives Takagi the right, but not the obligation, to use the Histogenics Technology or practice the Histogenics Patents in Japan. Notwithstanding anything to the contrary contained in the foregoing, the license rights granted to Takagi under this Section 3(b) are limited to the following Histogenics' products: Neocart\*\*\*\* (both individually and collectively, the "Histogenics Product Line"). Histogenics represents to Takagi that as of the date of this Agreement the Histogenics Product Line represents all of the products it has currently under development.

4. <u>Sale of Machines</u>. Takagi shall continue to manufacture and sell single unit exogenous tissue processor machines (so-called "TEPs") to Histogenics to the extent desired by Histogenics. Prior to the commercialization of Histogenics' first product ("Neocart"), Takagi shall sell TEPs to Histogenics at \*\*\*\*. Thereafter, Takagi shall sell TEPs to Histogenics at \*\*\*\*. Within 60 days of the execution of this Agreement, the parties shall enter into a service agreement, the form of which shall be attached to this Agreement as Exhibit C, which service agreement shall cover the maintenance and servicing of both the existing TEPs owned by Histogenics and any additional TEPs that Histogenics may purchase from Takagi in the future. The parties agree that the service agreement shall be "industry standard" as to its form and terms.

5. <u>Reimbursement of Development Costs</u>. The parties acknowledge that Takagi has incurred 19,572,000 YEN in costs prior to the date of this Agreement in developing a multi-unit TEP on Histogenics behalf. On the Effective Date Histogenics shall pay that amount to Takagi. Takagi acknowledges that Histogenics intends to continue the development of a multi-unit TEP with an alternative supplier and that Histogenics shall not be liable for any future costs incurred by Takagi in developing a multi-unit TEP absent a separate written agreement between the parties for that purpose.

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6. <u>Territories</u>. The parties acknowledge that pursuant to the Existing Agreements various portions of the world were not allocated between the parties as exclusive Territories for exploiting the Takagi Technology and Histogenics' Technology. The parties hereby acknowledge and agree that Histogenics shall have worldwide rights to its products and technology and, within the Field of Use, the Takagi Technology with the sole exception that Takagi shall retain the exclusive rights to commercialize, manufacture, and sell the Histogenics Product Line in the Field of Use in Japan. Histogenics shall cooperate with Takagi, and provide such Histogenics Technology, data and technical information, support, and assistance to Takagi, at Takagi's sole cost and expense, in order to commercialize all or any portion of the Histogenics Product Line in the Field of Use and to obtain the requisite governmental approvals to manufacture and sell the Histogenics shall supply Takagi with its clinical requirements of collagen scaffolds and CT3 at \*\*\*\*. Upon commercialization of the Histogenics Product Line in Japan, Histogenics shall supply Takagi with such components at \*\*\*\*. Takagi shall be responsible for \*\*\*\*. Prior to commercialization of any of the products included in the Histogenics Product Line in Japan, the parties shall enter into an agreement that will address supply of components, sales and royally reporting and payments due to third parties, audit rights of sales records, and other commercially reasonable requirements. To the extent that Takagi is assisted in the commercialization, manufacture, sale or governmental approval process of the Histogenics Product Line or other Histogenics products in the Field of Use by third parties, Takagi agrees that it shall cause such parties to enter into appropriate nondisclosure and confidentiality agreements in such form as Histogenics shall reasonably require.

7. <u>Brigham and Women's License</u>. Reference is made to the existing license between Takagi and the Brigham and Women's Hospital, Inc. dated August 1, 2001 as amended by agreements dated December 30, 2005 and May 4, 2010 (the "B&W License"). Pursuant to the Existing Agreements,

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Histogenics has undertaken to pay any royalties due under the B&W License to the extent that such royalties are measured by Histogenics' revenue. Histogenics has also agreed to pay any minimum royalties or milestone payments required by Sections 4.4 and 4.5 of the B&W License. Histogenics shall continue to honor these obligations until such time as Histogenics is no longer using the technology licensed by the B&W License. Upon written notice from Histogenics of its intent to cease using the technology licensed by the B&W License, Takagi shall reassume all responsibility under the B&W License or, at Takagi's option, allow the B&W License to lapse. Histogenics shall defend, indemnify and hold Takagi harmless from any claim by or liability to \*\*\*\*.

8. <u>Consideration</u>. At such time as when Histogenics enters into a transaction that would constitute an "Event of Liquidation" as defined in the \*\*\*\* Term Sheet (a "Liquidity Event"), then, upon the closing of such Liquidity Event, Takagi shall be paid from the proceeds, as, if; when and "in-kind" received by Histogenics or its stockholders, the Consideration (as such term defined below). The term "Consideration" shall mean 7.8125% of the net proceeds of any Liquidity Event. In the event that Histogenics requires financing exceeding the \$\*\*\*\* contemplated by the \*\*\*\* Term Sheet prior to a Liquidity Event, and one or more the investors (including their successors and assigns) participating in the financing contemplated by the \*\*\*\* Term Sheet (the "\*\*\*\* Investors") also participate in such additional financing, then the Consideration will be subject to dilution pursuant to the following formula:

$$\frac{\$^{****}}{(\$^{****}+\$x)} x 7.8125\% = \text{New Consideration Percentage}$$

where \$x is the additional amount of equity investment beyond the \$\*\*\*\* contemplated by the \*\*\*\* Term Sheet. The Consideration shall be paid from the net proceeds to be received by the Histogenics' stockholders after the payment of; (a) transaction costs to unaffiliated third parties, (b) repayment of debt incurred after the Effective Date, if any, and (c) the payment of all rights and

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preferences due to the \*\*\*\* Investors. To the extent that the stockholders of Histogenics receive payment of the purchase price from a Liquidity Event over time, such as an escrow, installment sale or earnout, then the Consideration shall be paid as funds (whether in cash or in-kind) are actually received by the stockholders of Histogenics. At the Effective Date, the stockholders (which term in this Agreement includes the \*\*\*\* Investors) shall enter into a Stockholders Agreement whereby they agree on behalf of themselves and their successors and assigns to irrevocably authorize Histogenics to pay the Consideration upon the occurrence of a Liquidity Event from the proceeds thereof directly to Takagi in accordance with the terms hereof.

If, in lieu of a Liquidity Event, Histogenics shall undertake an initial public offering of its common stock (an "IPO") then immediately prior to the IPO Histogenics and/or its stockholders shall pay the Consideration in shares of its common stock valued at the IPO price, as determined by the Histogenics IPO pricing committee (the "Shares"). For purposes of determining the aggregate number of Shares to be issued to Takagi in such case, Histogenics shall take its pre-IPO value as determined by the Histogenics IPO pricing committee, subtract from that amount the transaction costs of the IPO, the amount of post-Effective Date indebtedness, if any, of Histogenics at the time and the amount of all rights and preferences of the \*\*\*\* Investors, and then multiply the result by the Consideration percentage. \*\*\*\*

Subject to execution of any applicable confidentiality or nondisclosure agreement, Takagi shall have the right to receive and review copies of the closing documentation and agreements relating to any Liquidity Event.

9. <u>Cooperation with \*\*\*\* Closing</u>. Takagi agrees to cooperate with Histogenics to assist it in closing the transactions contemplated by the \*\*\*\* Term Sheet including without limitation executing such documents, votes, and certificates as Histogenics or the investors in the

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transactions contemplated thereby may reasonably request; provided, however, that none of such documents, votes or certificates shall be inconsistent with the provisions of this Agreement.

10. <u>Indemnification</u>. Each party shall indemnify, defend and hold each other and their respective directors, officers, employees and agents, and their respective heirs, successors and assigns (the "Indemnitees") harmless from and against any liability, damage, loss or expense (including reasonable attorney's fees) incurred by or imposed upon the Indemnitees or any one of them in connection with any third-party claims, suits, actions, demands or judgments arising out of \*\*\*\*.

11. <u>Confidentiality</u>. Except as specified in Section 6, above, each party shall keep confidential any non-public information disclosed by or on behalf of, and belonging to, the other party in connection with this Agreement, whether marked as proprietary or confidential, or which, by the circumstances of the disclosure, would reasonably be understood as the proprietary information of such other party, including, but not limited to all know-how, trade secrets and proprietary technical information. The receiving party shall not disclose the other party's confidential information to any third party and shall protect such information with the same degree of care as it uses to protect its own confidential information of similar importance, but in no case using less than a reasonable degree of care, and may only disclose the confidential information to its affiliates, employees, agents or independent contractors on a need-to-know basis and who are bound by written confidentiality obligations consistent with the receiving party's obligations hereunder. The receiving party shall only use the other party's confidential information to perform its obligations or exercise its rights under this Agreement. If the receiving party receives a request pursuant to a court order, governmental body request or other legal process to disclose the other party's confidential information, the receiving party will promptly notify the other party and provide reasonable assistance to limit the scope of the required disclosure or seek a protective order. The receiving party shall not be subject to confidentiality obligations for confidential information that (a) at the time of receipt was already known to it without confidentiality obligation; (b) becomes publicly known through no wrongful act of the receiving party; (c) was received from a third party without

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confidentiality restrictions; (d) is independently developed by the receiving party without use of the confidential information of the other party; or (e) is approved for release by prior written authorization by the other party or its authorized agent.

12. <u>Patent Prosecution</u>. Each party will have the sole right to make all decisions regarding the filing, prosecution and maintenance of its respective patents. Without limiting the foregoing, if a party does not make any filing or payment related to the prosecution or maintenance of any patent or patent application which it owns and is licensed under this Agreement (the Takagi Patents or Histogenics Patents, as applicable) or intends not to make such payment or filing or to abandon or allow any right to any such patent or patent application to lapse, it will promptly inform the other party, and such other Party will have the right, exercisable in its sole discretion and expense, to file or continue the prosecution or maintenance of such patent or patent application in its own name.

13. <u>Patent Enforcement</u>. Each party shall promptly notify the other party of any suspected infringement by a third party of which it is aware concerning the Takagi Patents or Histogenics Patents. \*\*\*\* will have the first right, but not the obligation to initiate and prosecute legal proceedings with respect to any patent \*\*\*\* under this Agreement (\*\*\*\*, as applicable), at its own expense, and to control the defense of any such action. If \*\*\*\* does not intend to pursue any legal proceeding, \*\*\*\* will promptly inform \*\*\*\*, and \*\*\*\* will have the right, but not the obligation, to initiate an action at its own cost and expense only to the extent the potential infringement pertains to \*\*\*\*'s products or services covered by a patent \*\*\*\*. \*\*\*\* will reasonably cooperate with \*\*\*\* in any such effort, including being joined as a party to such action if necessary, at the expense of \*\*\*\*.

14. <u>Miscellaneous</u>. The interpretation and application of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts, which shall also serve as the exclusive venue for the resolution of any disputes. The failure of any party to enforce at any time any provision of this Agreement or any right with respect thereto, or to exercise any election as herein provided, shall in no

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way be considered to be a waiver of such provision, right or election, or in any way affect the validity of this Agreement. The exercise by any party of any right or election under the terms of this Agreement shall not preclude or prejudice any party from exercising the same or any other right it may have under this Agreement. Neither this Agreement nor the rights or obligations under it may be assigned by either party to a third party without the prior written consent of the other party, except that either party may assign this Agreement, or the rights or obligations under it, in connection with any merger, consolidation, sale of all or substantially all of its assets, equity or the business to which this Agreement relates, or similar business combination.

15. <u>Notices</u>. Written notices under this Agreement shall be addressed as follows:

If to Takagi:	Purpose Co., Ltd. Medical Technology and Business Development Department 201 Nishi-Kashiwabara Shinden Fuji-shi Shizuoka 417-8505 Japan Attn: ****
With a copy to:	****
If to Histogenics:	Histogenics Corporation 830 Winter Street 3rd Floor Waltham, MA 02451 Attn: Patrick O'Donnell, President and CEO
With a copy to:	Brown Rudnick LLP One Financial Center Boston, MA 02111 Attn: ****

or to such other address as either party may request in writing. Notices sent by mail, facsimile, overnight delivery or email shall be effective if actually received.

16. <u>Entire Agreement</u>. This Agreement and the Exhibits hereto constitute the entire agreement and understanding between the parties and neither party shall be obligated by any condition or

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representation other than those expressly stated herein or as may be subsequently agreed by the parties hereto in writing.

17. <u>Counterparts</u>. This Agreement may be executed in one or more counterpart signature pages, and executed signature pages may be delivered via facsimile or via email with PDF scan attachment, each of which shall be deemed an original but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as an instrument under seal by their duly authorized representatives.

#### PURPOSE CO., LTD., F/K/A TAKAGI SANGYO CO., LTD. AND F/K/A TAKAGI INDUSTRIAL CO., LTD.

#### HISTOGENICS CORPORATION

By:	****	By:	/s/ Patrick O'Donnell
Name:	****	Name:	Patrick O'Donnell
Title:	****	Title:	President & CEO
Date:	June 25, 2012	Date:	June 25, 2012

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## EXHIBIT A

## \*\*\*\* TERM SHEET

#### CONFIDENTIAL TERM SHEET FOR PROPOSED INVESTMENT IN HISTOGENICS CORPORATION

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#### [Signature Page Follows]

## Accepted by Histogenics Corporation:

# Accepted by \*\*\*\*:

/s/ Patrick O'Donnell	2-28-12	/s/ ****	2/14/12	
Signature	Date	Signature	Date	
Patrick O'Donnell		****		
Printed Name		Printed Name		
President & CEO				
Position		Position		

\*\*\*\*Certain information has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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## EXHIBIT B-1

TAKAGI PATENTS

## EXHIBIT B-1

#### TAKAGI PATENTS\*

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## EXHIBIT B-2

## HISTOGENICS PATENTS

### EXHIBIT B-2

### HISTOGENICS PATENT

\*\*\*\*

# EXHIBIT C

SERVICE AND MAINTENANCE AGREEMENT

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\*\*\*\*

\*\*\*\*

#### \*\*\*\*

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives:

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\_\_\_\_\_

PURPOSE CO., LTD.

By:

Name:

Title:

Authorized Representative for **Customer** 

HISTOGENICS CORPORATION

By:

Name:

\_

Title:

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## EXHIBIT A

### Equipment List

	***	****	****
1	****	****	****
2	****	****	****
3	****	****	****
4	****	****	****
5	****	****	****
6	****	****	****
7	****	****	****
8			
9			

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#### LICENCE AGREEMENT

#### Between

#### YEDA RESEARCH AND DEVELOPMENT COMPANY LIMITED

a company duly registered under the laws of Israel of P 0 Box 95, Rehovot 76100, Israel

(hereinafter, "Yeda")

and

#### PROCHON BIOTECH LTD.

a company duly registered under the laws of Israel, having its principal place of business at 7 Golda Meir Street, Science Park, Nes Ziona, Israel

(hereinafter, "the Company")

### PREAMBLE:

WHEREAS: (A) in the course of research conducted at the Weizmann Institute of Science ("the Institute"), under the supervision of \*\*\*\* of the Institute and \*\*\*\* ("\*\*\*\*"), formerly a scientist at the Institute (and currently an employee of the Company), \*\*\*\* together with \*\*\*\* and other scientists of the Institute, all of the aforementioned persons, collectively "the Inventors", arrived at an invention entitled "\*\*\*" ("the Inventor"), all as more fully described in \*\*\*\* and in the patent applications listed in <u>Appendix A</u>) hereto ("the Existing Patent Applications") and created and/or generated the plasmid p80 BS and methods of use thereof ("the Know How"); and

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- (B) by operation of Israeli law and/or under the terms of employment of the Inventors (excluding \*\*\*\*) at the Institute and pursuant to an agreement between the Institute, Yeda and the Inventors (excluding \*\*\*\*), all the right, title and interest in and to the Licensed Information (as hereinafter defined) and the Existing Patent Applications otherwise vesting in the Inventors (excluding \*\*\*\*) or in the Institute, vests and shall vest in Yeda; and \*\*\*\* assigned all his rights in and to the Licensed Information and the Existing Patent Applications to the Company pursuant to a deed of assignment dated June 5, 2006 accordingly, the Licensed Information and the Existing Patent Applications are owned jointly by Yeda and the Company; and
- (C) subject to and in accordance with the terms of this Agreement, the Company wishes to receive, and Yeda is willing to grant to the Company, a worldwide, royalty-bearing exclusive licence in respect of Yeda's rights in and to the Licensed Information and under the Joint Patents (as hereinafter defined), for the development, manufacture, production, marketing and sale of Licensed Products (as hereinafter defined), all subject to and in accordance with the terms and conditions of this Agreement below,

#### NOW THEREFORE IT IS AGREED BETWEEN THE PARTIES HERETO AS FOLLOWS:

#### 1. PREAMBLE, APPENDICES AND INTERPRETATION

- 1.1 The Preamble and Appendices hereto form an integral part of this Agreement.
- 1.2 In this Agreement the terms below shall bear the meanings assigned to them below, unless the context shall indicate a contrary intention:
- 1.2.1 **"Affiliated Entity"** shall mean, with respect to any party hereto, any company, corporation, other entity or person (hereinafter, collectively, "**entity**"), which directly or indirectly, is controlled by, or controls, or is under common control with, such party. For the purposes of this definition, "**control**" shall mean the ability, directly or indirectly, to direct the activities of the relevant entity (save for an ability flowing solely from the fulfilment of the office of director or another office) and shall include, without limitation, the holding, directly or indirectly, of more than 50% (fifty percent) of the issued share capital or of the voting

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- 2 -

	power of the relevant entity or the holding, directly or indirectly, of a right to appoint more than 50% (fifty percent) of the directors of such entity or of a right to appoint the chief executive officer of such entity;
1.2.2 "Combination Product"	- shall mean a product which comprises (a) a Product or part thereof; and (b) at least one other active ingredient, material or a medical device, which, if administered independently of the Product, would have a clinical effect
1.2.3 "Exchange Rate"	- shall mean, with respect to any amount to be calculated, or which is paid or received in a currency other than US Dollars, the average of the selling and buying exchange rates of such currency (in respect of cheques and remittances) and the US Dollar prevailing at **** at the end of business on the date of calculation, payment or receipt, as the case may be;
1.2.4 "First Commercial Sale"	- shall mean, with respect to any Licensed Product in any country, the first commercial sale of such Licensed Product in such country after U.S. Food and Drug Administration ("FDA") New Drug Approval, European Medicines Agency ("EMEA") or national medicinal agency marketing approval or equivalent approval or any other necessary regulatory approval in such country has been obtained for such Licensed Product;
1.2.5 <b>"Joint Patents</b> "	- shall mean: (i) the Existing Patent Applications and all patents which may be granted thereon; and (ii) patent applications corresponding to the Existing Patent Applications and all patents or certificates of invention which may be granted thereon; as well as all continuations, continuations-in-part, patents of addition, divisions, renewals, reissues and extensions (including any patent term extension) of any of the aforegoing patents, but excluding: (a) patents that have been invalidated or cancelled pursuant to the final (i.e. unappealed or unappealable) judgment of a competent court; and (b) patent applications that have been withdrawn or have expired, in each case such exclusion to be effective only from the date of such invalidation, cancellation, withdrawal or expiry, as the case may

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be.

1.2.6 "Licence"

1.2.7 "Licensed Information"

1.2.8 "Licensed Products"

1.2.9 "Net Sales"

For the purposes of this Agreement, the term "**Joint Patent**" shall also mean Supplementary Protection Certificate (within the meaning of such term under Council Regulation (EU) No. 1768/92) or any other similar statutory protection;

- shall mean an exclusive worldwide license in respect of Yeda's rights in and to the Licensed Information and the Joint Patents, for the development (by the Company or by a Subcontractor on the Company's behalf), manufacture (by the Company or by a Subcontractor on the Company's behalf), production, use, marketing, distribution, offering for sale, export and import and sale of the Licensed Products, subject to the provisions of clause 4.1 below and the other terms and conditions of this Agreement;

- shall mean: (i) the Invention; and (ii) the Know How;
- shall mean: (i) the Products; and (ii) the Combination Products;

- shall mean the total amount invoiced by the Company and the total amount invoiced by the Company's Affiliated Entities in connection with the sale of Licensed Products (for the removal of doubt, whether such sales are made before or after the First Commercial Sale of any Licensed Product in any country); provided that, with respect to sales which are not at arms-length and/or are not in the ordinary course of business and/or are not according to then current market conditions for such a sale, the term "**Net Sales**" shall mean the total amount that would have been due in an arms-length sale made in the ordinary course of business and according to the then current market conditions for such sale or, in the absence of such current market conditions, according to market conditions for sale of products similar to the Licensed Products, in all cases after deduction of:

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(i) sales taxes, excise or similar taxes (including value added taxes) to the extent applicable to such sale and included in the invoice in respect of such sale;

(ii) freight and insurance charges to the extent such items are separately itemized on invoices;

(iii) credits or allowances, if any, actually granted on account of price adjustments, recalls, rejections or returns of Licensed Products previously sold;

and provided further that, with respect to sales by the Company to any Affiliated Entity of the Company, the term "**Net Sales**" shall mean the higher of: (a) "Net Sales", as defined above, with respect to sales which are not at arms-length and/or in the ordinary course of business and/or according to current market conditions; and (b) the total amount invoiced by such Affiliated Entity on resale to an independent third party purchaser after the deductions specified in subparagraphs (i) through (iii) above, to the extent applicable. For the removal of doubt if any Licensed Product is sold by the Company to an Affiliated Entity of the Company and is subsequently resold by such Affiliated Entity, the Company shall pay Yeda royalties on the Net Sales value as determined as aforesaid (and not on both the sale and resale of such Product). For the further removal of doubt, the disposition of any Licensed Product, without charge, for demonstration and/or testing purposes shall not be considered to be a sale for the purposes of this clause 1.2.9 and clause 4.1.2 below;

- shall mean any products, the development or production of which is based on, or involves, the use of the Licensed Information, or part thereof, or which are produced or manufactured using a process, method or system covered by a claim under any Joint Patent;

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1.2.10 "Products"

1.2.11 "Subcontracting Agreement" and "Subcontractor"	- shall mean a <i>bona fide</i> subcontracting agreement pursuant to which a contractor is engaged on a pure work order basis for the sole purpose of manufacturing or developing any of the Licensed Products (or part thereof) on the Company's behalf, for monetary consideration only; and the term <b>"Subcontractor"</b> shall be construed accordingly;
1.2.12 "Sublicence" and "Sublicensee"	"Sublicence" shall mean any right granted, licence given, or agreement entered into, by the Company to or with any other person or entity, permitting any use of the Licensed Information and/or the Joint Patents (or any part thereof) for the development and/or manufacture and/or production and/or marketing and/or distribution and/or sale of Licensed Products (whether or not such grant of rights, license given or agreement entered into is described as a sublicense or as an agreement with respect to the development and/or manufacture and/or production and/or distribution and/or marketing and/or sale of Licensed Products or otherwise), provided, however, that a Subcontracting Agreement shall not be deemed to be a "Sublicence"; and the term "Sublicensee" shall be construed accordingly;
1.2.13 "Sublicensing Receipts"	- shall mean consideration, whether monetary or otherwise, received (for the removal of doubt, whether received before or after the First Commercial Sale in any country) by the Company for or from the grant of Sublicences and/or pursuant thereto, or in connection with the grant of an option for a Sublicence, including ****

\*\*\*\*Certain information has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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\*\*\*\*, provided that:

\*\*\*\*,

\*\*\*\*; and

\*\*\*\*,

it being agreed, for the removal of doubt, that any amounts received by the Company as aforesaid, but not expended and/or incurred as set out above, shall be deemed to be Sublicensing Receipts;

- shall bear the definitions assigned to them respectively in the heading or the preamble hereto, as the case may be.

1.2.14 the terms: "Yeda", "the Company", "the Institute", "\*\*\*\*", "the Inventors", "the Invention", "Know-How" and "the Existing Patent Applications",

1.3 In this Agreement:

- 1.3.1 words importing the singular shall include the plural and *vice-versa* and words importing any gender shall include all other genders and references to persons shall include partnerships, corporations and unincorporated associations;
- 1.3.2 any reference in this Agreement to the term "patent" shall also include any re-issues, divisions, continuations or extensions thereof (including measures having equivalent effect);

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- 1.3.3 any reference in this Agreement to the term "patent applications" shall include any provisional patent applications, applications for continuations, continuations-in-part, divisions, patents of addition or renewals, as well as any other applications or filings for similar statutory protection;
- 1.3.4 any reference in this Agreement to the term "sale" shall include the sale, lease, rental or other disposal of any Licensed Product; and
- 1.3.5 **"including**" and **"includes**" means including, without limiting the generality of any description preceding such terms.

#### 2. LICENCE

- 2.1 Yeda hereby grants the Licence to the Company, and the Company hereby accepts the Licence from Yeda, during the period, for the consideration and subject to the terms and conditions set out in this Agreement.
- 2.2 For the removal of doubt, nothing contained in this Agreement shall prevent Yeda or the Institute from using the Licensed Information for academic research or other scholarly purposes.
- 2.3 The Licence shall remain in force in each country in the world with respect to each Licensed Product (if not previously terminated in accordance with the provisions of this Agreement) until the later of:
- 2.3.1 the date of expiry in such country of the last of any Joint Patent (including, for the removal of doubt, any patent application, as referred to in the definition of "Joint Patents" in clause 1.2.5 above) in such country covering such Licensed Product to expire; and
- 2.3.2 the date of expiry of a period of 10 (ten) years commencing on the date of First Commercial Sale of the first Licensed Product in such country, or in relation to any country in which there have not been any sales of any Licensed Products the expiry of a period of 10 (ten) years from the date of the last First Commercial Sale of such Licensed Product worldwide.

For the purposes of clause 2.3.1. above, a Licensed Product shall be deemed to be covered by a Joint Patent in any country even after the Joint Patent in such country covering such Licensed Product has expired, in the event that, and for so long as, such Licensed Product is protected and/or covered by "Orphan Drug" status (within the meaning-of such term under the US Orphan Drug Act), paediatric use approval and/or by any type of data exclusivity or data protection or by any other regulations and/or provisions granting similar statutory or regulatory protection of such Licensed Product in such country.

2.4 A Sublicence under the Licence may be granted by the Company provided that: (i) the Sublicence is made by written agreement, the provisions of which are consistent with the terms and conditions of this Agreement; (ii) a final draft of

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the proposed Sublicence agreement is submitted to Yeda at least 10 (ten) days prior to the signature thereof and a copy of the signed Sublicence agreement and of all amendments thereto are submitted to Yeda promptly upon signature thereof; and provided further that the following conditions are fulfilled:

- 2.4.1 \*\*\*\*;
- 2.4.2 the proposed Sublicence is to be granted in a *bona fide* arms-length commercial transaction;
- 2.4.3 the proposed Sublicence contains, inter alia, the following terms and conditions:
- 2.4.3.1 \*\*\*\*;
- 2.4.3.2 that the Sublicence shall not be assignable, otherwise transferable or further sublicenseable;
- 2.4.3.3 that Yeda shall have the right, upon reasonable notice to the Sublicensee and at reasonable times, to send representatives in order to examine those books of accounts, records and other documentation of the Sublicensee as may be necessary in order to determine the correctness or completeness of any payment made under this Agreement, all without derogating from clause 4.5 below; and
- 2.4.4 any act or omission by the Sublicensee which would have constituted a breach of this Agreement by the Company had it been the act or omission of the Company, shall constitute a breach of the Sublicence agreement with the Company entitling the Company to terminate the Sublicence\*\*\*\*.
- 2.5 Nothing contained in this Agreement shall be deemed to be a representation or warranty, express or implied, by either party that the Existing Patent Applications or any of them, the Licensed Information or any portion thereof will be granted or that patents obtained on any of the said patent applications are or will be valid or will afford proper protection or that the Licensed Information or will be commercially exploitable or of any other value or that the exploitation of the Joint Patents or the Licensed Information will not infringe the rights of any third party.

#### 3. <u>TITLE</u>

Subject only to the Licence, all right, title and interest in and to the Licensed Information and the Joint Patents and all right, title and interest in and to \*\*\*\*

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\*\*\*\*, vest and shall vest in Yeda and the Company jointly.

#### 4. CONSIDERATION FOR GRANT OF LICENCE

- 4.1 In consideration for the grant of the Licence, the Company shall pay Yeda:
- 4.1.1 a non-refundable licence fee of US \$2,000 (Two Thousand United States Dollars) per year (or part thereof) (excluding Value Added Tax) ("**the** Annual Licence Fee") to be paid in advance at the beginning of each 1 (one) year period, commencing on the date being the earlier of: (i) 1 January 2009; and (ii) the date of First Commercial Sale of any Licensed Product ("**the Determining Date**"), during a period of 10 (ten) years after the Determining Date or until the expiry of the last of any Joint Patents (whichever is sooner). For the removal of doubt, the first Annual Licence Fee shall be paid on the Determining Date and thereafter on each anniversary of the Determining Date during the period referred to above. The amount of the Annual Licence Fee paid by the Company as aforesaid will be credited against royalties payable by the Company pursuant to clause 4.1.2 below during the 1 (one) year period in respect of which the Company shall have paid such Annual Licence Fee.
- 4.1.2
- 4.1.2.1 a royalty of \*\*\*\* of Net Sales of Products by the Company and by its Affiliated Entities; and
- 4.1.2.2 a royalty of \*\*\*\* of Net Sales of Combination Products by the Company and by its Affiliated Entities; and
- 4.1.2.3 \*\*\*\* of all Sublicensing Receipts.

For the removal of doubt, the Company undertakes that all sales (within the meaning of such term in clause 1.3.4 above) of Licensed Products by the Company and each Sublicensee shall be \*\*\*\*.

4.2 In calculating Net Sales and Sublicensing Receipts, all amounts shall be expressed in US Dollars and any amount received or invoiced in a currency other than US Dollars shall be translated into US Dollars, for the purposes of calculation, in accordance with the Exchange Rate between the US Dollar and such currency on the date of such receipt or invoice, as the case may be. For the removal of doubt, in calculating amounts received by the Company, whether by way of Net Sales or Sublicensing Receipts, any amount deducted or withheld in connection with any such payment on account of taxes on net income (including income taxes, capital gains tax, taxes on profits or taxes of a similar nature) payable by the Company in any jurisdiction, shall be deemed,

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notwithstanding such deduction or withholding, to have been received by the Company.

- 4.3
- 4.3.1 Amounts payable to Yeda in terms of this clause 4 shall be paid to Yeda in US Dollars: (i) with respect to Net Sales made and Sublicensing Receipts received during the period from the date of signature of this Agreement until the end of the first calendar year in which the aggregate amount of Net Sales made and Sublicensing Receipts received reaches US \$50,000 (fifty thousand United States Dollars) ("**the Initial Period**") —no later than \*\*\*\* after the end of each calendar year during the Initial Period; (ii) with respect to Net Sales made and Sublicensing Receipts received after the Initial Period—on a quarterly basis and no later than \*\*\*\* after the end of each calendar quarter, commencing on the first day after the expiry of the Initial Period.
- 4.3.2 The Company shall submit to Yeda: (i) no later than \*\*\*\* after the end of each calendar year during the Initial Period and no later than \*\*\*\* after the end of each calendar quarter after the Initial Period, a written report setting out amounts owing to Yeda in respect of such previous period to which such report refers, in a customary form, certified as being correct by the chief financial officer of the Company, and with full details of:
- 4.3.2.1 (i) the sales of Products made by the Company, including a breakdown of Net Sales according to country, identity of seller, currency of sales, dates of invoices, number and type of Products sold;
  - the sales of Combination Products made by the Company, including a breakdown of Net Sales according to country, identity of seller, currency of sales, dates of invoices, number and type of Combination Products sold;
  - (iii) the royalties received by the Company from Sublicensees based on sales by Sublicensees, including a breakdown of such royalties according to Products and Combination Products, identity of Sublicensees, country, currency and amounts of sales in respect of which such royalties were received, the currency of the royalty payments and date of receipt thereof;
  - (iv) the Sublicensing Receipts, including a breakdown of Sublicensing Receipts according to identity of Sublicensees, countries, the currency of the payment and date of receipt thereof;
  - (v) deductions applicable, as provided in the definition of "Net Sales"; and

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4.3.2.2 any other matter necessary to enable the determination of the amounts of royalties payable hereunder.

- 4.4 The Company shall keep and shall contractually obligate Sublicensees to keep complete, accurate and correct books of account and records consistent with sound business and accounting principles and practices and in such form and in such details as to enable the determination of the amounts due to Yeda in terms hereof. The Company shall retain and shall contractually obligate Sublicensees to retain the aforegoing books of account relating to a given calendar quarter for \*\*\*\* after the conclusion of that calendar quarter.
- 4.5 At Yeda's expense, Yeda shall be entitled to appoint representatives to inspect during normal business hours and to make copies of the Company's and Sublicensees' books of accounts, records and other documentation (including technical data and lab books) to the extent relevant or necessary for the ascertainment or verification of the amounts due to Yeda under this clause 4, provided however that Yeda shall coordinate such inspection with the Company or Sublicensee (as the case may be) in advance. In the event that any inspection as aforesaid reveals any underpayment by the Company to Yeda in respect of any year of the Agreement in an amount exceeding \*\*\*\* of the amount actually paid by the Company to Yeda in respect of such year then the Company shall (in addition to paying Yeda the shortfall together with interest thereon in accordance with clause 10.3 below), bear the costs of such inspection. The provisions of this clause 4 shall survive the termination of this Agreement for whatsoever reason. The parties agree that the inspection of technical data and lab books as aforesaid may only be conducted for the purposes of determining whether the product developed, manufactured, sold, marketed, distributed and/or used by the Company and/or Sublicensee is a Product or a Combination Product. If such inspection is carried out by an independent third party appointed by Yeda, such third party shall be bound by an obligation of confidentiality.

#### 5. JOINT PATENTS; PATENT INFRINGEMENTS

5.1

- 5.1.1 Subject to clauses 5.3 and 5.4 below, \*\*\*\* shall prosecute the Existing Patent Applications using the outside patent counsel retained by \*\*\*\* for such purpose prior to the execution of this Agreement, unless otherwise agreed by the parties in writing, and shall maintain at the applicable patent office(s) any patents issuing from the Existing Patent Applications. The Company and Yeda shall consult with one another and cooperate fully with regard to the prosecution of the Existing Patent Applications and in maintenance of such patents.
- 5.1.2 The parties shall consult with one another regarding the filing of patent applications corresponding to the Existing Patent Applications and other

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patent applications included in the definition of "Joint Patents", including the jurisdictions in which such applications should be filed, the timing of the filing of such applications and the contents thereof. Following such consultations, and subject to clauses 5.3 and 5.4 below, \*\*\*\* shall retain outside patent counsel to prepare, file and prosecute patent applications as aforesaid in such jurisdiction or jurisdictions as shall be determined by the parties in consultation as aforesaid. Subject to clauses 5.3 and 5.4 below, \*\*\*\* shall also maintain at the applicable patent office any patents granted as a result of any of the above patent applications. The parties agree that their joint policy will be to seek comprehensive patent protection for the Licensed Information as commercially feasible. The Company and Yeda shall cooperate fully in the preparation, filing, prosecution and maintenance of such patent applications and patents.

- 5.1.3 Without derogating from the aforegoing, \*\*\*\* shall, at its expense, take all necessary steps, to the extent appropriate and commercially feasible, in order to obtain, or, at \*\*\*\*'s election, assist \*\*\*\* to obtain, the extension of each patent referred to in this clause 5.1 above, or in the case of a patent in any member state of the European Union, a Supplementary Protection Certificate as referred to in clause 1.2.5 above (including, the preparation and filing of applications for such extensions and Supplementary Protection Certificates), within the period prescribed therefore under applicable law and, if applicable, take all necessary steps in order to obtain "Orphan Drug" status (within the meaning of such term under the US Orphan Drug Act or under Council Regulation (EU) No. 141/2000, as the case may be), or paediatric use approval, within the period prescribed therefore under applicable law. \*\*\*\* shall notify \*\*\*\* promptly in writing and shall provide a copy to \*\*\*\* of each marketing authorization granted in respect of each Licensed Product in each country and, if applicable, of "Orphan Drug" or paediatric use approval granted in respect of a Licensed Product and shall keep \*\*\*\* informed and shall provide copies to \*\*\*\* of all documents regarding all applications, activities and/or proceedings regarding such extensions and/or any Supplementary Protection Certificates and/or "Orphan Drug" or paediatric use approval, as aforesaid.
- 5.2 All applications to be filed in accordance with the provisions of clauses 5.1.2 and 5.1.3 above, shall be filed in the name of \*\*\*\* or, should the law of the relevant jurisdiction so require, in the name of the relevant inventors and then assigned to \*\*\*\*.
- 5.3 In the event that, following such consultations between the parties regarding the filing, prosecuting and/or maintenance (as applicable) of patent applications and/or patents pursuant to clauses 5.1.1 and 5.1.2 above, \*\*\*\* shall not wish to file and/or continue to prosecute a patent application and/or maintain a patent in any country (including any of the Existing Patent Applications) as aforesaid, then \*\*\*\*, in its discretion, may elect to file and/or

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continue to prosecute such patent application and/or maintain such patent in such country at its own cost and expense. \*\*\*\* shall notify \*\*\*\* in writing of \*\*\*\*'s election to file and/or continue to prosecute such application and/or maintain such patent in such country as aforesaid, at \*\*\*\*'s expense (such notice, "the \*\*\*\* **Notice**"), and, in the event that \*\*\*\* shall not, within 30 (thirty) days of receipt of the \*\*\*\* Notice: (i) reimburse \*\*\*\* for all out-of-pocket costs and fees incurred by \*\*\*\* until the date of the \*\*\*\* Notice (the \*\*\*\* Notice to be supported by receipts or other appropriate documents evidencing such costs and fees) in connection with the said patent application (in the preparation and/or filing and/or prosecution and/or maintenance of such application) and/or such patent such costs and fees to be expressed in the currency in which paid by \*\*\*\* and to be reimbursed or paid (as the case may be) by \*\*\*\* to \*\*\*\* in US Dollars in accordance with the Exchange Rate of such currency on the date of reimbursement or payment; and (ii) undertake in writing to \*\*\*\* to bear all additional and future expenses relating to such patent application and/or patent, then \*\*\*\* shall be entitled, at any time after the expiry of the said 30 (thirty) day period after such notice, to terminate the Licence granted to \*\*\*\* under this Agreement in respect of such patent application and/or patent in such country, and to take whatever action it deems fit (in its sole discretion) with respect to such patent application and/or patent.

5.4

- 5.4.1 \*\*\*\* has borne (up to the date of signature of this Agreement), and shall continue to bear and pay all costs and fees incurred in the preparation, filing, prosecution and the like of the Existing Patent Applications and of all patent applications filed in accordance with the provisions of clauses 5.1.2 and 5.1.3 above (including patent applications corresponding to the Existing Patent Applications), and the maintenance at the appropriate patent office and the like of all patents issuing from the Existing Patent Applications and all patent applications referred to above, and all costs and fees incurred in undertaking any activities referred to in clause 5.1.3 above.
- 5.4.2 Unless otherwise instructed by \*\*\*\* in writing, \*\*\*\* shall pay directly to \*\*\*\*'s relevant outside patent counsel amounts payable by \*\*\*\* pursuant to this clause 5.4 above or clause 5.3 above.

5.5

5.5.1 (i) Should \*\*\*\* determine that a third party is infringing one or more of the Joint Patents, then \*\*\*\* shall notify \*\*\*\* promptly in writing, giving full particulars thereof and \*\*\*\* shall be entitled to sue for such infringement.

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(ii) \*\*\*\* shall cooperate with \*\*\*\* in prosecuting such litigation.

The provisions of paragraph (ii) above shall be subject to the following:

- (a) any expenses or costs or other liabilities incurred in connection with such litigation (including attorneys' fees, costs and other sums awarded to the counterparty in such action) shall be borne by \*\*\*\*, which shall indemnify \*\*\*\* against any out-of-pocket expenses or other liabilities, the above without derogating from the provisions of clause 9 below;
- (b) in the event that \*\*\*\* shall be named as a party in any such litigation then \*\*\*\* shall be entitled to select its own legal counsel in such litigation, at \*\*\*\*'s expense, provided that if there is a conflict of interests between \*\*\*\* and \*\*\*\*, the fees and costs of legal counsel selected by \*\*\*\* as aforesaid shall be borne by \*\*\*\*, and, if \*\*\*\* elects not to select its own counsel, and no conflict of interests exists the selection of the legal counsel representing \*\*\*\* and \*\*\*\* in such litigation shall be subject to the prior written approval of \*\*\*\*, which approval shall not be withheld unreasonably and \*\*\*\*'s response to such request for approval shall not be delayed unreasonably; and
- (c) no settlement, consent order, consent judgment or other voluntary final disposition of such action whereby a Joint Patent may be invalidated or which requires any act or omission by the Institute, \*\*\*\* or any of the Inventors may be entered into without the prior written consent of \*\*\*\* (such consent not to be unreasonably withheld and \*\*\*\*'s response to such request for approval shall not be delayed unreasonably).
- 5.5.2 (i) Should \*\*\*\* discover any allegation by a third party that, or be sued on the grounds that, the manufacture, use or sale of a Licensed Product by it or by a Sublicensee under any of the Joint Patents or using the Licensed Information or any portion thereof infringes upon the patent rights of a third party, then \*\*\*\* shall notify \*\*\*\* promptly in writing, giving full particulars thereof, and \*\*\*\* shall be entitled to defend such action.

(ii) \*\*\*\* may elect, at its own initiative, to join as a party to such action, at its own expense.

(iii) All expenses, costs and/or other liabilities incurred in connection with such litigation (including attorneys' fees, costs and other sums awarded to the counterparty in such action) shall be borne by \*\*\*\*.

(iv) The provisions of clause 5.5.1 (c) above shall apply, *mutatis mutandis*.

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- 5.5.3 Any recovery in any litigation relating to an infringement as aforesaid in clauses 5.5.1 and 5.5.2 above shall first be applied to cover costs and thereafter divided \*\*\*\* to \*\*\*\* and \*\*\*\* to \*\*\*\*.
- 5.5.4 For the removal of doubt, **\*\*\*\*** shall not itself be obliged to take any action to sue for any infringement or to defend any action as referred to in this clause 5.5 above.
- 5.6 If \*\*\*\* fails to take action to abate any alleged infringement of a Joint Patent, or to defend any action as aforesaid, within \*\*\*\* of a request by \*\*\*\* to do so (or within a shorter period, if required to preserve the legal rights of \*\*\*\* under applicable law), then \*\*\*\* shall have the right (but not the obligation) to take such action at its expense and \*\*\*\* shall cooperate in such action at \*\*\*\*'s expense and, if required under applicable law or contract, consent to be named as a party to any such action. \*\*\*\* shall have full control of such action and shall have full authority to settle such action on such terms as \*\*\*\* shall determine. Any recovery in any such litigation shall first be applied to cover costs (of both parties) and thereafter be for the account of \*\*\*\* only:
- 5.7 \*\*\*\* shall promptly keep \*\*\*\* informed and provide copies to \*\*\*\* of all documents regarding all such actions or proceedings instituted by or against \*\*\*\* as contemplated under any of the provisions of clause 5.5 above.

### 6. DEVELOPMENT AND COMMERCIALIZATION

- 6.1 \*\*\*\*.
- 6.2 The Company shall provide Yeda on December 31 of each calendar year during the term of the Licence with written progress reports ("**Progress Reports**") which shall include information of a general nature relating to the manner and extent of the exploitation by the Company of the Licence, including with respect to any applications filed with any regulatory authority regarding any Licensed Products and any significant development activities.
- 6.3 For the removal of doubt, nothing contained in this Agreement shall be construed as a warranty by the Company that any development program carried by it will actually achieve its aims and the Company makes no

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warranties whatsoever as to any results to be achieved in consequence of the carrying out of any development.

6.4 The Company shall mark, and cause all its Sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number or numbers, of each Joint Patent applicable to such Licensed Product.

#### 7. CONFIDENTIALITY

- 7.1 The Company shall maintain in confidence all information relating to this Agreement and the terms hereof (hereinafter, "**the Confidential Information**"), except and to the extent that the Company can prove that any such information becomes part of the public domain thereafter (other than through a violation by the Company of this obligation of confidentiality). Notwithstanding the foregoing, the Company may disclose to its personnel and to other third parties (including Sublicensees) the Confidential Information to the extent necessary for the exercise by it of its rights hereunder or in the fulfilment of its obligations hereunder, provided that the Company shall bind such personnel and other third parties with a similar undertaking of confidentiality in writing.
- 7.2 In addition to and without derogating from the aforegoing, the Company undertakes not to make mention of the names of Yeda, the Inventors (excluding \*\*\*\*), the Institute or any scientists or other employees of the Institute or any employee of Yeda in any manner or for any purpose whatsoever in relation to this Agreement, its subject-matter and any matter arising from this Agreement or otherwise, unless the prior written approval of Yeda thereto has been obtained.
- 7.3 Notwithstanding the provisions of clauses 7.1 and 7.2 above, the Company shall not be prevented from mentioning the name of Yeda, the Inventors, the Institute and/or any scientists or other employees of the Institute or any employee of Yeda or from disclosing any information if, and to the extent that: (i) such mention or disclosure is to competent authorities for the purposes of obtaining approval or permission for the exercise of the Licence, or (ii) in the fulfilment of any legal duty owed to any competent authority (including a duty to make regulatory filings) (Yeda hereby acknowledging that it is aware that such competent authority may not be bound by any confidentiality obligations and may disclose or be required to disclose such information to a third party, whether by order of court or by law or otherwise), or (iii) same is necessary for the purpose of stating, in any private placement memorandum or a public offering registration statement, conduct of due diligence in connection therewith, or the such like, that the Company is a licensee of Yeda under this Agreement provided that any other mention or disclosure of information (i.e. other than that the Company is a licensee of Yeda as aforesaid) in a private placement memorandum or a public registration statement shall be subject to Yeda's consent, which consent shall not be withheld unreasonably .

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- 7.4 The termination of this Agreement, for whatever reason, shall not release the Company from any of its obligations under this clause 7 and such obligations shall survive any termination as aforesaid, subject to clause 7.7 below.
- 7.5 Yeda shall maintain in confidence the reports received by Yeda from the Company pursuant to clauses 4.3.2 and 6.2 above and any information received by Yeda from the Company which has been designated by the Company in writing as confidential, except and to the extent that: (i) any such information or data is in the public domain at the date of the signing hereof or becomes part of the public domain thereafter (other than through a violation by Yeda of this obligation of confidentiality) or is released by the Company from this obligation of confidentiality by notice in writing; (ii) Yeda is required to disclose such information in order to fulfil its obligations under this Agreement (including in connection with \*\*\*\*); or (iii) Yeda is required to disclose such information in fulfilment of any legal duty owed to any competent authority (the Company hereby acknowledging that it is aware that such competent authority may not be bound by any confidentiality obligations and may disclose or be required to disclose such information (not being part of the Licensed Information) independently developed at the Institute without reference to the confidential information received from the Company.
- 7.6 For the removal of doubt, Yeda shall have the right to allow the scientists of the Institute to publish articles relating to the Licensed Information in scientific journals or posters or to give lectures or seminars to third parties relating to the Licensed Information, on the condition that, to the extent that the information to be published or disclosed is Licensed Information which is not in the public domain, a draft copy of the said contemplated publication or disclosure shall have been furnished to the Company at least \*\*\*\* before the making of any such publication or disclosure and the Company shall have failed to notify Yeda in writing, within \*\*\*\* from receipt of the said draft publication or disclosure, of its opposition to the making of the contemplated publication or disclosure. Should the Company notify Yeda in writing within \*\*\*\* from the receipt of the draft contemplated publication or disclosure that it opposes the making of such publication or disclosure because it includes material (which has been specified in said notice) in respect of which there are reasonable grounds (which have also been specified in said notice) requiring the postponement of such publication or disclosure so as not adversely to affect the Company's interests under the Licence because such information is patentable subject-matter for which patent protection pursuant to clause 5.1 above should be sought, then Yeda shall not permit such publication or disclosure unless and until there shall first have been filed an appropriate patent application in respect of the material to be published or disclosed as aforesaid. The Company acknowledges that it is aware of the importance to the

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researchers of publishing their work and, accordingly, the Company will use its best efforts not to oppose such publications.

7.7 Both parties' obligations under this clause 7 shall continue until the date of expiry of a period of \*\*\*\* after the termination or expiry of this Agreement.

#### 8. NO ASSIGNMENT

- 8.1 The Company shall not be entitled to assign or encumber all or any of its rights or obligations under this Agreement or arising therefrom, unless it shall have received the prior written consent of Yeda to such assignment or encumbrance, which consent, if given, \*\*\*\*. For the purposes of this clause 8, the merger of the Company with another entity (whether or not the Company is the surviving entity) and the sale of all or substantially all of the assets or business of the Company to others shall be deemed to be an assignment, subject to the provisions of clause 8.2 below.
- 8.2 Notwithstanding the aforegoing, the sale of all or substantially all of the assets or the business of the Company to others ("**the Acquisition**") will not require the written consent of Yeda as aforesaid if all of the following conditions are met: \*\*\*\*.

### 9. EXCLUSION OF LIABILITY AND INDEMNIFICATION

9.1 Yeda, the Inventors (excluding \*\*\*\*), the Institute and the directors, officers and employees of Yeda and/or of the Institute (hereinafter collectively "**the Indemnitees**") shall not be liable for any claims, demands, liabilities, costs, losses, damages or expenses (including legal costs and attorneys' fees) of whatever kind or nature (all of the aforegoing, collectively, "**Liabilities**") caused to or suffered by any person or entity (including the Company or any Sublicensee) that directly or indirectly arise out of or result from or are encountered \*\*\*\*

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#### \*\*\*\*.

9.2 In the event that any of the Indemnitees should incur or suffer any Liabilities that directly or indirectly arise out of or result from or are encountered in connection with this Agreement or the exercise of the Licence as aforesaid in clause 9.1 above, or shall be requested or obliged to pay to any person or entity any amount whatsoever as compensation for any Liabilities as aforesaid in clause 9.1 above, then the Company shall indemnify and hold harmless such Indemnitees from and against any and all such Liabilities. Without limiting the generality of the aforegoing, the Company's indemnification as aforesaid and the exclusion of liability in clause 9.1 above shall extend to \*\*\*\*.

Yeda shall, or shall procure that any of the Indemnitees shall notify the Company promptly in writing of any such claim; and Yeda may, at its sole option, allow the Company, at the Company's expense, to assume control over defending such claim, in which case it will provide the Company with reasonable assistance and any information reasonably required for defending such a claim, at the Company's expense; provided that if the Company shall assume control over the defence of such claim, no settlement, consent order, consent judgment or other voluntary final disposition of such action may be entered into without the prior written consent of Yeda which shall not be withheld unreasonably.

9.3 The Company shall at its own expense insure its liability pursuant to clause 9.2 above during the period beginning on the date of the signing of this Agreement and continuing during the entire period that the Licence is in force in any country, plus an additional period of \*\*\*\*. Such insurance shall be in reasonable amounts and on reasonable terms in the circumstances, having regard, in particular, to the nature of the Licensed Products, and shall be subscribed for from a reputable insurance company. The named insured under such insurances shall be \*\*\*\*. The policy or policies so issued shall include \*\*\*\* and shall further provide that the insurer will be obliged to notify each insured in writing at least \*\*\*\* in advance of the expiry or cancellation of the policy or policies. The Company hereby undertakes to comply punctually with

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all obligations imposed upon it under such policy or policies and in particular, without limiting the generality of the aforegoing, to pay in full and punctually all premiums and other payments for which it is liable pursuant to such policy or policies. The Company shall be obliged to submit to Yeda copies of the aforesaid insurance policy or policies within \*\*\*\* of the date of issue of each such policy.

9.4 The provisions of this clause 9 shall survive the termination of this Agreement for whatsoever reason.

#### 10. TERM AND TERMINATION

- 10.1 Unless otherwise agreed to in writing, or earlier terminated as provided in this clause 10, this Agreement shall continue in full force and effect for as long as the Licence is in force in any country with respect to any Licensed Product as aforesaid in clause 2.3 above.
- 10.2 Without derogating from the parties' rights hereunder or by law to any other or additional remedy or relief, it is agreed that either Yeda or the Company may terminate this Agreement and the Licence hereunder by serving a written notice to that effect on the other upon or after: (i) the commitment of a material breach hereof by the other party, which material breach cannot be cured or, if curable, which has not been cured by the party in breach within 30 (thirty) days (or, in the case of failure by the Company to pay any amount due from the Company to Yeda pursuant to or in connection with this Agreement on or before the due date of payment, 14 (fourteen) days) after receipt of a written notice from the other party in respect of such breach, or (ii) the granting of a winding-up order in respect of the other party, or upon an order being granted against the other party for the appointment of a receiver, or if such other party passes a resolution for its voluntary winding-up, or if a temporary or permanent liquidator or receiver is appointed in respect of such other party shall seek protection under any laws or regulations, the effect of which is to suspend or impair the rights of any or all of its creditors, or to impose a moratorium on such creditors, or if anything analogous to any of the aforegoing in this clause 10.2(ii) above under the laws of any jurisdiction occurs in respect of such other party; provided that in the case that any such order or act is initiated by any third party, the right of termination shall apply only if such order or act as aforesaid is not cancelled within 60 (sixty) days of the grant of such order or the performance of such act.
- 10.3 Any amount payable hereunder by one of the parties to the other, that has not been paid by its due date of payment, shall bear interest from its due date of payment until the date of actual payment, at the maximum rate of \*\*\*\* per month or *pro rata* for part thereof.

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- 10.4 Upon the termination of this Agreement for whatever reason, except by the passage of time, the Licence granted under this Agreement shall forthwith terminate and all rights granted to the Company under this Agreement with respect to Yeda's rights in the Licensed Information and the Joint Patents shall revert to Yeda.
- 10.5 The termination of this Agreement for any reason shall not relieve the Company or Yeda of any obligations which shall have accrued prior to such termination.
- 10.6 For the avoidance of doubt, it is hereby recorded and agreed that following the expiry of the Licence hereunder in any country with respect to any Licensed Product (hereinafter "**the said country**" and "**the said Licensed Product**"), by passage of time only pursuant to clause 2.3 above, the Company shall be entitled to continue to produce, manufacture, use, market, distribute and/or sell the said Licensed Product in the said country without having to pay royalties to Yeda in respect of such activities subsequent to such expiry date. This clause 10.7 shall survive termination of this Agreement pursuant to clause 10.1.

#### 11. NOTICES

Any notice or other communication required to be given by one party to the other under this Agreement shall be in writing and shall be deemed to have been served: (i) if personally delivered, when actually delivered; or (ii) if sent by facsimile, the next business day after receipt of confirmation of transmission; or (iii) 10 (ten) days after being mailed by certified or registered mail, postage prepaid (for the purposes of proving such service, it being sufficient to prove that such notice was properly addressed and posted) to the respective addresses of the parties set out below, or to such other address or addresses as any of the parties hereto may from time to time in writing designate to the other party hereto pursuant to this clause 11:

11.1	to Yeda at:	P.O. Box 95
		Rehovot 76100
		Attention: the CEO
		Facsimile: (08) 9470739
44.0		
11.2	to the Company at:	7 Golda Meir Street, Science Park,
11.2	to the Company at:	7 Golda Meir Street, Science Park, Nes Ziona
11.2	to the Company at:	

#### 12. VALUE ADDED TAX

The Company shall pay to Yeda all amounts of Value Added Tax imposed on Yeda in connection with the transactions under this Agreement.

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### 13. GOVERNING LAW AND JURISDICTION

This Agreement shall be governed in all respects by the laws of \*\*\*\* and the parties hereby submit to the exclusive jurisdiction of the competent \*\*\*\* courts, except that Yeda may bring suit against the Company in any other jurisdiction outside \*\*\*\* in which the Company has assets or a place of business.

#### 14. MISCELLANEOUS

- 14.1 The headings in this Agreement are intended solely for convenience or reference and shall be given no effect in the interpretation of this Agreement.
- 14.2 This Agreement constitutes the entire agreement between the parties hereto in respect of the subject-matter hereof, and supersedes all prior agreements or understandings between the parties relating to the subject-matter hereof (including, the Memorandum of Understanding between Yeda and the Company dated October 9, 2005) and this Agreement may be amended only by a written document signed by both parties hereto. No party has, in entering into this Agreement, relied on any warranty, representation or undertaking, except as may be expressly set out herein.
- 14.3 This Agreement may be executed in any number of counterparts (including counterparts transmitted by fax), each of which shall be deemed to be an original, but all of which taken together shall be deemed to constitute one and the same instrument.
- 14.4 No waiver by any party hereto, whether express or implied, of its rights under any provision of this Agreement shall constitute a waiver of such party's rights under such provisions at any other time or a waiver of such party's rights under any other provision of this Agreement. No failure by any party hereto to take any action against any breach of this Agreement or default by another party hereto shall constitute a waiver of the former party's rights to enforce any provision of this Agreement or to take action against such breach or default or any subsequent breach or default by such other party.
- 14.5 If any provision of this Agreement is held to be unenforceable under applicable law, then such provision shall be modified as set out below and the balance of this Agreement shall be interpreted as if such provision were so modified and shall be enforceable in accordance with its terms. The parties shall negotiate in good faith in order to agree on the terms of an alternative provision which complies with applicable law and achieves, to the greatest extent possible, the same effect as would have been achieved by the invalid or unenforceable provision.
- 14.6 Nothing contained in this Agreement shall be construed to place the parties in a relationship of partners or parties to a joint venture or to constitute either party an agent, employee or a legal representative of the other party and neither

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party shall have power or authority to act on behalf of the other party or to bind the other party in any manner whatsoever.

- 14.7 All payments to be made to Yeda hereunder shall be made in US Dollars by banker's cheque or by bank transfer to Yeda's bank account, the details of which are as follows: \*\*\*\*.
- 14.8 All payments to be made to Yeda hereunder shall be made free and clear of, and without any deduction for or on account of, any set-off, counterclaim or tax, except any deductions that the Company is required to make from the payments to be made hereunder on account of income tax, tax on profit or any other taxes of a similar nature imposed on Yeda by law, ("withholding tax"), provided that: (i) the Company shall immediately notify Yeda of such requirement and the Company shall deduct the withholding tax from the payments referred to above, as prescribed by applicable law, unless Yeda provides the Company with evidence of an exemption from such tax, and (ii) shall provide Yeda with the necessary tax receipts in a timely manner.
- 14.9 Each party agrees to execute, acknowledge and deliver such further documents and instruments and do any other acts, from time to time, as may be reasonably necessary, to effectuate the purposes of this Agreement.
- 14.10 None of the provisions of this Agreement shall be for the benefit of, or enforceable by, any person who is not a party to this Agreement, save for clauses 7 and 9 above.

#### IN WITNESS WHEREOF the parties hereto have set their signatures as of this 6th day of January, 2008.

for	YEDA RESEARCH AND DEVELOPMENT COMPANY LIMITED	for <b>PROCH</b>	ION BIOTECH LTD.
Signature:	/s/ ****	Signature:	/s/ ****
Name:	***	Name:	***
Title:	***	Title:	***
Date:	Jan. 06, 2008	Date:	Dec. 19, 2007

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### APPENDIX A

### THE EXISTING PATIENT APPLICATIONS

## PATENT CARD

### <u>2000-097</u>

### Title: \*\*\*\*

Inventors: \*\*\*\*, \*\*\*\*, \*\*\*\*, \*\*\*\*

Country	Application	Publication	Grant	Status
****	****	****	****	****
****	****	****	****	****
****	****	****	****	****
****	****	****	****	****

#### AMENDMENT TO LICENCE AGREEMENT

Made and entered in to this 23rd day of March 2010

By and between

#### YEDA RESEARCH AND DEVELOPMENT COMPANY LIMITED

a company duly registered under the laws of Israel of P O Box 95, Rehovot 76100, Israel

(hereinafter, "Yeda")

and

#### PROCHON BIOTECH LIMITED

a company duly registered under the laws of Israel having its principal place of business at 7 Golda Meir Street, Science Park, Nes Ziona, Israel

(hereinafter, "the Company")

WHEREAS the parties have entered into a Licence Agreement dated 6 January 2008, ("the Licence Agreement"); and

WHEREAS in light of a collaboration agreement entered into between the Company and \*\*\*\* (as hereinafter defined) the parties have agreed to amend the Licence Agreement, as more particularly set out herein.

### NOW THEREFORE IT IS AGREED BETWEEN THE PARTIES HERETO AS FOLLOWS:

### 1. CAPITALISED TERMS, PREAMBLE AND HEADINGS

1.1 Capitalised terms in this Amendment ("**this Amendment**") which are defined in the Licence Agreement shall have the same meaning attributed to them therein, unless otherwise defined in this Amendment.

1.2 The preamble hereto shall form an integral part of this Amendment.

1.3 The headings in this Amendment are intended solely for convenience or reference and shall be given no effect in the interpretation of this Amendment.

\*\*\*\*CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

### 2. <u>AMENDMENT OF LICENCE AGREEMENT</u>

- 2.1 The Licence Agreement and this Amendment shall be read as one and shall represent the complete current understanding between the parties with respect to the subject matters hereof and thereof.
- 2.2 Subject only to the modifications contained herein, the provisions of the Licence Agreement shall remain unaltered and in full force and effect.
- 2.3 The following clause shall be added to the Licence Agreement as clause 1.2.1A:

**"'Collaboration Agreement"** – shall mean a collaboration agreement dated hereinafter defined);" 2005 entered into between the Company and \*\*\*\* (as

- 2.4 The following clause shall be added to the Licence Agreement as clause 1.2.7A: \*\*\*\*
- 2.5 The following clause shall be added to the Licence Agreement as clause 4A:

### "4A. COLLABORATION AGREEMENT

- 4A.1 The Company acknowledges that the rights granted by it to \*\*\*\* pursuant to the Collaboration Agreement in respect of what is defined thereunder as the "Second Product" (the Company hereby declaring that what is defined as the "First Product" thereunder has never been and never will be developed), include the grant of rights to use Yeda's rights in the Licensed Information and/or the Joint Patents, and that consequently, subject only to clause 4A.2 below:
  - (a) all products defined in the Collaboration Agreement as "Products" ("**Collaboration Agreement Products**") shall constitute Licensed Products under this Agreement;

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- (b) the Collaboration Agreement shall thus constitute a Sublicence and \*\*\*\* a Sublicensee;
- (c) royalties are due to Yeda in respect of Net Sales by the Company (or any Affiliated Entities thereof) of Collaboration Agreement Products;
- (d) all amounts received by the Company from \*\*\*\* in respect of Collaboration Agreement Products or additional Licensed Products (with the exception of amounts advanced to the Company by \*\*\*\* as participation in its process development costs, whether such participation is by way of shareholder loans or otherwise, as per the side letter between the Company and \*\*\*\* dated January 4, 2010 ("the Side Letter"), and subject to clause 4A.4 below) shall constitute Sublicensing Receipts; and
- (e) any additional products which may in future fall under the definition of "Covered Products", as contemplated, *inter alia*, pursuant to clause 5 of the Collaboration Agreement (for the avoidance of doubt, including any products constituting First Products as defined in the Collaboration Agreement), shall constitute Licensed Products under this Agreement, unless the Company can prove, with respect to any specific Covered Product, that same does not constitute a Licensed Product hereunder;
- (f) the Company's ability to permit any use of Yeda's rights in the Licensed Information and/or the Joint Patents under the Collaboration Agreement shall expire automatically upon the termination of the Licence for any reason other than by passage of time only pursuant to clause 2.3 hereof;
- 4A.2 The provisions of clause 4A.1 notwithstanding, the provisions of clauses 2.4 and 4.1 hereof shall not (subject to clause 4A.4 below) apply to the Collaboration Agreement or to Collaboration Agreement Products, but the provisions of this Agreement, including but not limited to clause 4A.3 below, shall otherwise apply thereto.
- 4A.3 The Company shall pay to Yeda:

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- (a) subject to clause 4A.4 below, an amount equal to \*\*\*\* of all amounts received by the Company from \*\*\*\* (with the exception of amounts advanced to the Company by \*\*\*\* as participation in its process development costs, whether such participation is by way of shareholder loans or otherwise, as per the Side Letter); and
- (b) a royalty of \*\*\*\* of Net Sales by the Company (or any Affiliated Entities thereof) of any Collaboration Agreement Products.

The Company undertakes that it will not agree to any reduction in the percentage amounts payable to it by **\*\*\*\*** pursuant to the Collaboration Agreement.

- 4A.4 In reliance on the Company's declaration hereby that all FGF variant provided to \*\*\*\* in connection with the Second Product pursuant to the Collaboration Agreement shall either (a) be sold by \*\*\*\* by way of incorporation in the Second Product (as defined in the Collaboration Agreement), or (b) shall be used for clinical trials purposes, \*\*\*\*
- 2.5 In clauses 4.3.1 and 4.5 there shall be added, after the words "this clause 4" the words "and clause 4A below"; for the avoidance of doubt, references in clause 4.3.2.1 to Products and Combination Products shall include (as appropriate) reference to Collaboration Agreement Products.

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2.6 In clause 4.3.2.1 there shall be added, as subclause (iv), the following: "details as to FGF variants supplied to \*\*\*\* by the Company and as to the Net Sales thereof of the Company to \*\*\*\* in cases where royalties are payable to Yeda on such Net Sales hereunder in accordance with clause 4A.4 above".

## 3. ENTIRE AGREEMENT

For the avoidance of doubt, this Amendment constitutes the entire agreement between the parties hereto in respect of the subject-matter hereof, and supersedes all prior agreements or understandings between the parties relating to the subject-matter hereof (including, any previous correspondence in this regard, between the parties, or on their behalf) and may be amended only by a written document signed by both parties hereto.

#### IN WITNESS WHEREOF the parties hereto have set their signatures:

for	YEDA RESEARCH AND DEVELOPMENT COMPANY LIMITED	for	PROCHON BIOTECH LIMITED
Signature:	/S/ **** /S/ ****	Signature:	/s/ Patrick O'Donnell
Name:	***	Name:	Patrick O'Donnell
Title:	***	Title:	CEO
Date:		Date:	4-7-10

\*\*\*\*CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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