UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1 REGISTRATION STATEMENT

Under The Securities Act of 1933

Xeris Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

2834 (Primary Standard Industrial Classification Code Number) 20-3352427 (I.R.S. Employer Identification Number)

Xeris Pharmaceuticals, Inc. 180 N. LaSalle Street, Suite 1800 Chicago, IL 60601 1-844-445-5704

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

Paul Edick President and Chief Executive Officer Xeris Pharmaceuticals, Inc. 180 N. LaSalle Street, Suite 1800 Chicago, IL 60601 1-844-445-5704

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

Copies of all communications, including communications sent to agent for service, should be sent to:

Joseph C. Theis, Jr., Esq. Mitchell S. Bloom, Esq. Goodwin Procter LLP 100 Northern Avenue Boston, Massachusetts 02210 (617) 570-1000 Brian Johnson, Esq.
Lisa Firenze, Esq.
Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, New York 10007
(212) 230-8800

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, as amended, 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 register auditional securities for all offering pursuant to Rule 402(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. \Box

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. \Box

5	nether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated fi v. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting ange Act.	1 0		ıy"
Large Accelerated Filer		Accelerated Fi	ler	
Non-Accelerated Filer	☑ (Do not check if a smaller reporting company)	Smaller Report	ing Company	
		Emerging Grov	wth Company	X
	ng standards provided pursuant to Section 13(a) of the Exchange Act. □ ———————————————————————————————————			
Common Stock, par value	Title of each Class of Securities to be Registered \$0.0001 per share	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
(2) Includes the offering The registrant hereby an shall file a further amend	the purpose of calculating the registration fee pursuant to Rule 457(o) under the Secur price of shares that the underwriters may purchase pursuant to an option to purchase an ends this registration statement on such date or dates as may be necessary to deladiment that specifically states that this registration statement shall thereafter becomes tites Act of 1933, as amended, or until this registration statement shall become effectives.	additional shares. ay its effective date un me effective in accorda	til the registrant unce with	

acting pursuant to said Section 8(a), may determine.

Explanatory Note

Xeris Pharmaceuticals, Inc. has prepared this Amendment No. 2 to the Draft Registration Statement on Form S-1 that was confidentially submitted to the Securities and Exchange Commission on March 21, 2018 (the "Registration Statement") solely for the purposes of filing Exhibit 10.14 to the Registration Statement and making corresponding updates to Item 16 and the Exhibit Index. This Amendment No. 2 does not modify any provision of the Prospectus that forms Part I of the Registration Statement and accordingly such Prospectus has not been included herein.

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses, other than underwriting discounts and commissions, to be paid by us in connection with the sale of the shares of common stock being registered hereby.



^{*} To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws to be in effect upon the closing of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- · any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director or executive officer in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Capital Stock

In December 2015, with subsequent closings in December 2016, May 2017, December 2017 and February 2018, we sold an aggregate of 13,542,592 shares of our Series C preferred stock at a purchase price of \$6.2705 per share.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and Exercises of Stock Options

Between March 1, 2015 and March 1, 2018, we have granted stock options to purchase an aggregate of 4,019,951 shares of our common stock, with exercise prices ranging from \$0.87 to \$3.33 per share, to employees, directors and consultants pursuant to the 2011 Stock Option Plan, or the 2011 Plan. Since December 31, 2017, and through the date of filing, shares of common stock have been issued upon the exercise of stock options pursuant to the 2011 Plan.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

(c) Issuances of Warrants

On March 1, 2015, the Company issued warrants to purchase 35,500 shares of Series B preferred stock at an exercise price of \$3.319 per share. On February 28, 2018, the Company issued warrants to purchase 95,686 shares of its Series C preferred stock at an exercise price of \$6.2705 per share.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

EXHIBIT NUMBER	EXHIBIT TABLE
1.1*	Form of Underwriting Agreement
3.1**	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
3.2*	Amendment to Amended and Restated Certificate of Incorporation of the Registrant
3.3*	Form of Amended and Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4**	Amended and Restated By-laws of the Registrant , as currently in effect
3.5*	Form of Amended and Restated By-laws (to be effective upon the closing of this offering)
4.1**	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 31, 2015
4.2*	Form of Specimen Common Stock Certificate
5.1*	Opinion of Goodwin Procter LLP
10.1*#	2011 Stock Option and Incentive Plan and forms of award agreements thereunder
10.2*#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder
10.3*#	Senior Executive Cash Incentive Bonus Plan
10.4*#	Form of Director Indemnification Agreement
10.5*#	Form of Officer Indemnification Agreement
10.6**	Lease Agreement, dated as of September 29, 2017, by and between Are-SD Region No. 30, LLC and the Registrant
10.7*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Paul Edick (to be entered into in connection with this offering)
10.8*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and John Shannon (to be entered into in connection with this offering)
10.9*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Steven Prestrelski (to be entered into in connection with this offering)
10.10*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Ken Johnson (to be entered into in connection with this offering)
10.11**+	API Supply Agreement, dated as of January 1, 2018, by and between the Registrant and Bachem Americas, Inc.
10.12**+	Quality Assurance Agreement, dated as of November 20, 2015, by and between Bachem AG and the Registrant, as amended by (i) Amendment 1 to the Quality Assurance Agreement, dated as of October 31, 2016, by and between Bachem AG and the Registrant and (ii) Amendment 2 to the Quality Assurance Agreement, dated as of January 26, 2017, by and between Bachem AG and the Registrant.
10.13**+	Master Service Agreement, dated as of November 1, 2016, by and between Pyramid Laboratories and the Registrant
10.14+	Joint Development Agreement, dated as of January 29, 2016, by and between the Registrant and Scandinavian Health Limited
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EXHIBIT NUMBER	EXHIBIT TABLE
10.15**	Loan and Security Agreement, dated as of February 28, 2018, by and between Oxford Finance, LLC, Silicon Valley Bank and the Registrant
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

- * To be filed by amendment.
- ** Previously filed.
- + Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.
- # Indicates a management contract or any compensatory plan, contract or arrangement

(b) Financial Statements Schedules:

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the consolidated financial statements or the notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to 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.

Insofar as indemnification for liabilities arising under the Securities Act 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act 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 and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act 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, 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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, Xeris Pharmaceuticals, Inc. has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chicago, State of Illinois, on the day of , 2018.

Xeris	Pharmaceuticals	. Inc.

By: Paul Edick

President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul Edick and Barry Deutsch, and each of them, either of whom may act without the joinder of the other, as his true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done or 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 indicated on the day of , 2018.

SIGNATURE	TITLE				
	President and Chief Executive Officer				
Paul Edick	(Principal Executive Officer)				
	Chief Financial Officer (Principal Financial Officer				
Barry Deutsch	and Principal Accounting Officer)				
	Director				
John Schmid					
	Director				
BJ Bormann					
	Director				
Jeffrey Sherman					
	Director				
Jonathan Rigby					
	Director				
Marla Persky					
	<u>Director</u>				
Dawn Halkuff					

JOINT DEVELOPMENT AGREEMENT

BETWEEN

XERIS PHARMACEUTICALS, INC.

AND

SCANDINAVIAN HEALTH LIMITED

DATED: JANUARY 29, 2016

JOINT DEVELOPMENT AGREEMENT

THIS JOINT DEVELOPMENT AGREEMENT (the "Agreement") is entered into as of January 29, 2016 (the "Effective Date") and is made by and between Xeris Pharmaceuticals, Inc., a Delaware corporation, with its principal office at 3208 Red River Street, Suite 300, Austin, TX 78705, USA ("XPI") and Scandinavian Health Limited, a company existing under the laws of Hong Kong, having its principal office at Room 810, Argyle Centre, Phase 1, 688 Nathan Road, Kowloon, Hong Kong ("SHL"). XPI and SHL are each referred to as a "Party", and collectively as the "Parties".

WITNESSETH:

WHEREAS, SHL possesses technology, intellectual property and/or know-how in the development, design, manufacture and/or supply of auto-injectors for drug delivery and is prepared to conduct certain customization, development, design and manufacturing work in accordance with this Agreement;

WHEREAS, XPI has developed a glucagon product and desires to have SHL develop and initially manufacture an auto-injection delivery device to deliver the glucagon it contains;

WHEREAS, the Parties desire to enter into this Agreement to establish a framework for undertaking the development of the auto-injection delivery device.

NOW, **THEREFORE**, for and in consideration of the premises and the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto do hereby agree as follows:

ARTICLE I DEFINITIONS

The following capitalized terms shall have the respective meanings set forth below:

Section 1.1 "Acceptance Criteria" means the mutually agreed activities described in each phase of the schedule set forth in each SOW.

Section 1.2 "Action" means any claim, action, cause of action, chose in action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, examination, audit, investigation, hearing, charge, complaint, demand, notice or proceeding to, from, by or before any governmental authority or arbitrator(s).

Section 1.3 "Affiliate" means, with respect to any Person, any other Person that, directly or indirectly, through one or more intermediaries controls, is controlled by, or is under common control with, such Person. For purposes of this definition, "control" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities or general partnership or managing member interests, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control any other Person in which it owns, directly or indirectly, a majority of the ownership interests.

- Section 1.4 "**Agreement**" has the meaning ascribed to it in the Preamble.
- Section 1.5 "cGMP" means current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, ICH Q7, and ICH Q10 as amended from time to time.
- Section 1.6 "Claim" or "Claims" means any claim, liability, demand, subpoena, inquiry, investigation, cost, expense, damage, deficiency, loss or obligation, of any kind or nature (including the reasonable attorneys' fees and other costs and expenses of defense) by a Third Party.
- Section 1.7 "Commercially Reasonable Efforts" means the efforts and resources that a Party would use in conducting its activities or obligations under this Agreement, based upon the standard of reasonableness of what would normally be exerted or employed by pharmaceutical companies of reasonably similar size and resources as such Party under like circumstances as the Parties to this Agreement find themselves, conducted in good faith and in accordance with commonly accepted commercial practice, and as judged by the standards of the applicable business community in which the Parties hereto operate within.
 - Section 1.8 "Completion" or "Completed" means that each phase of any SOW has been completed such that XPI is able to commercialize a Product.
 - Section 1.9 "Compound" means XPI's non-aqueous glucagon drug product.
 - Section 1.10 "Components" means the individual parts of the Device to be developed and manufactured by SHL under this Agreement.
- Section 1.11 "**Confidential Information**" as used herein, means (i) any non-public information or materials discovered, received, or otherwise acquired by one Party and disclosed to the other Party or its Affiliates in connection with this Agreement; (ii) the terms of this Agreement and any attached SOW; (iii) the Results; and (iv) IPR arising in connection with the performance of the Parties or of Persons acting on behalf of a Party under this Agreement. Notwithstanding the foregoing, Confidential Information will not include:
- (a) information that either Party can establish was generally available to the public or otherwise part of the public domain at the time of its development or disclosure; or
- (b) information that either Party can establish became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, other than through any act or omission of such Party or any of its Affiliates.
- (c) information, other than information exclusively relating to (1) the XPI Materials, XPIs glucagon (or any formulations, trademarks, trade names or trade dress of any glucagon injection device), Device or Product, (2) any Results and (3) any materials, products and deliverables developed for XPI under this Agreement, that either Party can establish was already known by such Party (other than under an obligation or reasonable expectation of confidentiality) at the time of disclosure or development;

The occurrence of (a), (b) or (c) above shall not be deemed to grant to either Party any license or other right, express or implied, to any portion of the information or other proprietary rights of the other Party relating thereto. Any compilation of otherwise public information in a form not publicly known shall be considered Confidential Information.

- Section 1.12 "Control" or "Controlled" means, with respect to any IPR, possession by a Party (including its Affiliates) of the right (whether by ownership, license or otherwise) to grant to another Party a license or a sublicense under such IPR without violating the terms of any agreement or other arrangement with any Third Party.
- Section 1.13 "**Device**" means the SHL developed and manufactured auto-injector delivery device, which has been customized according to XPIs specifications to be suitable for housing the Intermediate Product. The Device, which has been pre-configured for the injection of the Compound, is more particularly described on Schedule 1.24. The Device does not include the Intermediate Product.
 - Section 1.14 "Effective Date" has the meaning ascribed to it in the Preamble.
 - Section 1.15 "FDA" means the United States Food and Drug Administration, and any successor agency having substantially the same functions.
 - Section 1.16 "FDCA" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 et seq., as amended from time to time.
- Section 1.17 "**Intermediate Product**" shall mean the syringe, an embodiment of which is more particularly described on <u>Schedule 1.24</u>, which contains the Compound.
- Section 1.18 "**IPR**" means all intellectual property and industrial property rights, including Patent Rights, Know-How, rights in registered and unregistered trademarks (including domain names and vanity phone numbers), rights in registered and unregistered designs, trade or business names, database rights and copyright (including moral rights), performer protection rights or other industrial, intellectual or commercial rights (including rights in any invention, discovery or process), and applications for registration of any of the foregoing (specifically published patent applications), and the right to apply therefore, in each case in any part of the world, as well as all applications, registrations, renewals, extensions, continuations, continuations-in-part, divisions or reissues of any of the foregoing.
- Section 1.19 "**Know-How**" means any confidential or proprietary, unpatented or unpatentable technology or other intellectual property, compound, cell line or other biological material, probe, sequence, technical information, method or other confidential information or material, in all cases to the extent, but only to the extent, not in the public domain.

Section 1.20 "**Legal Requirements**" means any United States federal, state or local or foreign law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any Governmental Order, or any license, franchise, permit or similar right granted under any of

the foregoing, or any similar provision having the force or effect of law, including without limitation, the FDCA and all other applicable laws, regulations, rules and guidelines, relating to the packaging of the Product and storage of the Product, including, but not limited to, cGMP and those related to the environment, food or drugs and occupational health and safety, including all enforced or promulgated by the FDA and any relevant Regulatory Authority.

- Section 1.21 "Party" and "Parties" have the meanings ascribed to them in the Preamble.
- Section 1.22 "**Patent Rights**" means (a) all patents, patent applications and similar government-issued rights (e.g., utility models) protecting inventions in any country or jurisdiction however denominated, (b) all priority applications, international applications, divisionals, continuations, substitutions, continuations-in-part of and any applications claiming priority to any of the foregoing and (c) all patents and similar government-issued rights (e.g., utility models) protecting inventions issuing on any of the foregoing applications, together with all registrations, reissues, renewals, re-examinations, confirmations, supplementary protection certificates, pediatric extensions and extensions of any of (a), (b) or (c).
- Section 1.23 "**Person**" means any individual or corporation, association, partnership, limited liability company, joint venture, joint stock or other company, business trust, trust, organization, university, college, governmental authority or other entity of any kind.
- Section 1.24 "**Product**" means the final assembled combination of the Intermediate Product and Device for the injection of the Compound, an embodiment of which is more particularly described on <u>Schedule 1.24</u>.
- Section 1.25 "**Regulatory Authority(ies)**" means any federal, state, or local governmental regulatory authority in any of the territories listed on <u>Schedule 1.25</u> involved in regulating any aspect of the development, market approval, sale, distribution or use of the Product. Schedule 1.25 may be amended from time to time by mutual written agreement of the Parties.
- Section 1.26 "Results" means all information, concepts, ideas, inventions, improvements, designs, products, deliverables and Know-How (whether patentable or not or copyrightable or not) which may be conceived, invented, reduced into practice or fixed in a tangible medium during the performance under each SOW or which arise out of or result from the work conducted hereunder.
 - Section 1.27 "Services" means all activities that SHL will provide to XPI under each SOW.
 - Section 1.28 "SHL" has the meaning ascribed to it in the Preamble.

Section 1.29 "SHL IPR" means (i) subject to Section 10.2(e), any IPR conceived, created, developed, or reduced to practice in connection with the performance of this Agreement by SHL or its Affiliates, or by Persons acting on behalf of SHL or its Affiliates, including prior to engaging in or independent of the Services, and including IPR that relates to the pharmaceutical delivery system for drug delivery developed by SHL prior to the Effective Date; (ii) any IPR as set forth in Section 10.2(d), including any IPR that relates to devices that are not for the injection of the Compound created under this Agreement; and (iii) the SHL Results.

- Section 1.30 "SHL Project Manager" has the meaning ascribed to it in Section 2.4.
- Section 1.31 "SHL Results" has the meaning ascribed to it in Section 8.3.
- Section 1.32 "**SOW**" means any mutually agreed written statement of work plan setting forth the research and development activities to be conducted by the Parties under this Agreement for the design and development of the Product attached to and made a part of this Agreement, which may be mutually amended from time to time. The first SOW between the Parties is attached as <u>Schedule 1.32</u>. Each SOW negotiated and mutually agreed upon by both Parties in writing, shall substantially follow the form outlined in the first SOW and shall be attached and incorporated into this Agreement thereafter as agreed upon by both Parties. The Parties may mutually agree in writing to amend the SOW from time-to-time.
 - Section 1.33 "**Term**" has the meaning ascribed to it in <u>Section 2.6</u>.
 - Section 1.34 "Third Party" means any individual or entity that is not a Party to this Agreement.
- Section 1.35 "Unique Design" means the industrial design of the Product, including but not limited to color permutations, specifically created by SHL for XPI.
 - Section 1.36 "XPI" has the meaning ascribed to it in the Preamble.
- Section 1.37 "**XPI IPR**" means (i) subject to <u>Section 10.2(d</u>), any IPR conceived, created, developed, or reduced to practice in connection with the performance of this Agreement by XPI or its Affiliates, or by Persons acting on behalf of XPI or its Affiliates, including prior to engaging in or independent of this Agreement, and including XPI's proprietary XeriSolTM technology and XPIs glucagon (or any formulations, trademarks, trade names or trade dress of any glucagon injection device); (ii) any IPR as set forth in Section 10.2(e); and (iii) the XPI Results.
- Section 1.38 "XPI Materials" means all documents, information, compounds, materials and other substances supplied by XPI or its Affiliates to SHL for the purposes of SHL providing the Services for XPI under this Agreement, including the Compound and Intermediate Product.
 - Section 1.39 "XPI Project Manager" has the meaning ascribed to it in Section 2.7.
 - Section 1.40 "XPI Results" has the meaning ascribed to it in Section 8.3.

ARTICLE II GENERAL; CONDUCT OF RESEARCH

Section 2.1 <u>Joint Development</u>. Subject to the terms and conditions of this Agreement, the Parties agree to work together to complete each SOW, including the first SOW.

Section 2.2 Services. SHL shall use Commercially Reasonable Efforts to complete each SOW in accordance with the provisions of this Agreement.

Section 2.3 <u>Scope</u>. Each SOW shall establish: (a) the scope of the research activities which will be performed; (b) the research objectives, work plan activities and estimated schedules; (c) the estimated deliverables and documentation to be produced by SHL, (d) the Acceptance Criteria for each deliverable, warranty periods, schedule of performance, (e) the fixed-price budget, including cost and schedule of payments by XPI and, if applicable, a statement by SHL of then current rates, and (f) the respective obligations of the Parties with regard to the SOW. The SOW may be modified only by the written mutual agreement of the Parties.

Section 2.4 <u>SHL Project Manager</u>. SHL will appoint a qualified member of its staff to act as the Project Manager (the "**SHL Project Manager**"), whose duties shall be to act as liaison between XPI and SHL with respect to this Agreement and each SOW.

Section 2.5 SHL Staff. SHL will provide adequate staff to complete each SOW, preferably, within the estimated timeframe set forth therein.

Section 2.6 <u>Term</u>. Unless earlier terminated under Article 11 herein, the term of this Agreement and each SOW shall expire on the later of (i) Completion, or longer, if requested by XPI and agreed to by SHL, or (ii) when the Parties enter into a commercial supply agreement for the Product (the "**Term**").

Section 2.7 XPI Project Manager. XPI shall designate a Project Manager for each SOW (the "XPI Project Manager") who shall act as a liaison between XPI and SHL with respect to this Agreement and the SOW.

Section 2.8 Conduct of Research.

- (a) Standards. SHL shall perform the work set out in each SOW by using its Commercially Reasonable Efforts to allocate sufficient time, effort, equipment and facilities to the SOW and to use personnel with sufficient skills and experience as are required to accomplish the SOW in accordance with the terms of this Agreement. SHL shall exercise Commercially Reasonable Efforts to conduct the SOW in compliance with applicable Legal Requirements, and XPI shall not direct or require SHL to conduct the SOW out of compliance with any applicable Legal Requirements.
- (b) Subcontracting. SHL shall be entitled to utilize the services of Third Parties to perform its activities under the SOW as specifically set forth in the SOW or upon XPI's prior written consent, which consent shall not be unreasonably withheld, provided SHL will remain responsible and obligated for such activities performed by any such Third Party, and SHL will ensure that such Third Party has entered into agreements that contain provisions that comply with SHL's obligations under this Agreement. Notwithstanding any such consent, each Party shall remain at all times liable for its respective responsibilities under the SOW.

- Section 2.9 <u>Research Program</u>. SHL shall use Commercially Reasonable Efforts to initiate each SOW as soon as reasonably practicable after the later of the Effective Date and the mutual agreement of the SOW.
- Section 2.10 <u>Dispute Resolution</u>. If the Parties cannot reach agreement within [***] on whether any SOW has been Completed, the Parties will submit the dispute for settlement as specified in Section 14.5(a) of the Agreement. If they cannot reach agreement as per Section 14.5(a) of the Agreement:
- (a) If such dispute relates to scientific or technical disputes, each Party will select one (1) expert in the field [***] days, which experts shall be independent (i.e., no employee, consultants, contract employee or other persons receiving grant or compensation from such Party or Affiliate) of the Party selecting them. The two (2) experts shall select a third expert, which shall be independent (i.e., no employee, consultants, contract employee or other persons receiving grant or compensation from any Party or Affiliate) of the Parties or Affiliates, within [***] days. The Parties will submit the results and their position to the three (3) experts within [***] days. Said experts shall then determine within [***] days if the results indicate that the SOW successfully met all Acceptance Criteria. If the three (3) experts determine that all Acceptance Criteria have not been Completed, then SHL shall, in accordance with the SOW, further develop and test the deliverable and SHL shall be responsible for the full cost of the independent experts and all incidental costs arising from the dispute, including any costs and expenses incurred by XPI. If all Acceptance Criteria has been determined as Completed by the three (3) experts, then XPI shall be responsible for the full cost of the independent experts and all incidental costs arising from the dispute, including any costs and expenses incurred by SHL: and
 - (b) All other disputes shall proceed in accordance with Section 14.5 of this Agreement.
 - (c) All of the time periods specified in this Section 2.10 may be extended by the mutual agreement of the Parties.

Section 2.11 Records and Reports.

- (a) <u>Records</u>. SHL and XPI shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and Legal Requirements, which shall fully and properly reflect all work done and results achieved in the performance of the SOW.
 - (b) [***
 - (c) Meetings. If either Party shall reasonably request, the Parties shall hold status meetings to review the status of SHL and/or XPI performance.
- (d) <u>Final Report</u>. Within one month of Completion of each SOW, SHL shall submit a report to XPI, giving details of the SOW that has been completed. Such report will include transfer of Results, including information and deliverables in tangible and electronic formats as applicable.

ARTICLE III ACCEPTANCE

Section 3.1 SHL shall perform the Services and provide the Results in compliance with this Agreement and each SOW, and shall complete all required Acceptance Criteria. In the event any Acceptance Criteria are not met by SHL within a reasonable amount of time as mutually agreed to by the Parties, XPI shall provide any applicable notice of breach to SHL and provide SHL with a [***] period after such notice to cure such breach. Upon failing to cure a material breach, XPI may terminate this Agreement pursuant to Section 11.3 and shall be entitled to either internally or with any Third Party complete such Services or provide such Results in a manner acceptable to XPI.

ARTICLE IV COMPENSATION

Section 4.1 <u>Payments</u>. XPI shall timely pay SHL in accordance with the schedule of payments specified in each SOW, as invoiced by SHL. Payment terms shall be net [***] upon issuance by SHL. In case of late payment, interest shall accrue on the amount due commencing on the due date and interest shall accrue at [***], and shall be calculated on ACT/360 basis.

Section 4.2 <u>Taxes</u>. All prices payable to SHL do not include tax. All taxes, including but not limited to withholding taxes, sales and services tax and value added tax, applicable to amounts payable to SHL under this Agreement shall be[***].

ARTICLE V ACCOUNTING

Section 5.1 <u>Commercially Reasonable Efforts</u>. SHL agrees to use Commercially Reasonable Efforts to perform all work and all obligations under this Agreement within the estimated time period and budget set forth in each SOW. [***].

Section 5.2 <u>Maintenance of Records</u>. SHL and any approved subcontractors shall maintain complete and accurate written records with respect to the operations pursuant to this Agreement in a form in accordance with general accepted accounting principles to enable an independent CPA auditor identified by XPI and reasonably acceptable to SHL to obtain an accounting to substantiate SHL charges and expenses hereunder. SHL shall retain all such records for a period of at least [***] after termination of this Agreement.

ARTICLE VI CONFIDENTIALITY

Section 6.1 Confidentiality.

(a) <u>Non-Disclosure and Non-Use</u>. Each Party acknowledges that the other Party has a proprietary interest in maintaining the confidentiality of the Confidential Information and undertakes that, both during and after the termination of this Agreement, except as directed in writing by the Party owning the Confidential Information, each Party will take all reasonable

precautions and use reasonable efforts that are no less than what such Party uses to protect its own confidential information to maintain the confidentiality of all Confidential Information that such Party (the "Recipient") obtains from the other Party (the "Disclosing Party"), and not (i) disclose the Confidential Information to any Third Parties, or use the Confidential Information except for the purpose of this Agreement as may be deemed necessary, (ii) permit any Person to examine or make copies of any reports or any documents prepared by either Party or that come into such Party's possession or control, except for those of its personnel necessary to perform the Services under this Agreement and any SOW, or (iii) use any Confidential Information except as necessary to perform its obligation hereunder.

- (b) <u>Authorized Disclosure and Use</u>. Notwithstanding the foregoing provisions of Subsection (a), either Party may disclose Confidential Information belonging to a Party upon the Disclosing Party's prior written consent, or to the extent such disclosure is reasonably necessary to:
 - (i) prosecute or defend an Action between the Parties;
 - (ii) comply with applicable Legal Requirements and stock exchange rules (including the rules and regulations of the Securities and Exchange Commission);
 - (iii) make filings and submissions to, or correspond or communicate with, any governmental authority; or
 - (iv) disclose to Third Parties in connection with due diligence or similar investigations by or on behalf of a Third Party in connection with a potential license to, distribution agreement with or collaboration with such Third Party (including entry into any such agreement), or a potential merger or acquisition by such Third Party, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that such disclosure is limited to the terms of this Agreement and any attached SOW, and any such Third Party agrees, at a minimum, to use the same degree of care it uses to protect its own confidential information and expressly agrees to be bound by similar terms of confidentiality at least as stringent as those set forth in this Article 6. Each Party shall remain ultimately responsible for the preservation of confidentiality of any information it releases to said Third Parties and will be the responsible party in the event of a breach of the confidentiality.

In the event either Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to clauses (i), (ii) or (iii) of this Section 6.1(b), such Party will (unless prohibited by applicable Legal Requirements) give reasonable advance notice of such disclosure to the other Party, consult with the other Party with regard to the disclosure of Confidential Information and take all reasonable measures to ensure confidential treatment of such Confidential Information. Either Party will promptly notify the other Party upon becoming aware of any misappropriation or unauthorized disclosure or use of such Party's Confidential Information.

Section 6.2 <u>Employment and Contractor Agreements</u>. Both Parties represent that each of its members, staff, employees, students, consultants or outside contractors assigned to work on each SOW will have entered into a contract with such Party which provides for:

(i) compliance with this Agreement; (ii) maintaining the confidentiality of the Confidential Information; and (iii) a present and future assignment to such Party of all inventions, discoveries, patents, copyrights or other developments which fall within the terms of this Agreement. If, during the term of this Agreement, an SHL member, staff, employee, student, consultant or outside contractor as a result of his or her work makes an invention, discovery, patent, copyright or other development that is XPI IPR, SHL shall, to the extent possible, promptly make the fact of such invention, discovery, patent, copyright or other development known to XPI. At XPIs request, SHL shall use its Commercially Reasonable Efforts to cause such person to execute all papers necessary or incidental to convey to XPI complete title to all such inventions, discoveries and other developments and, if desired by XPI, to assist in the timely preparation and filing of proper copyright registrations and applications for patent in the United States and foreign countries. All copyright registrations and applications for patent shall be prepared, filed and prosecuted at the expense of the Party owning such IPR under this Agreement. In the event of a dispute over the ownership of any invention, discovery, patent, copyright or other development which fall within the terms of this Agreement, the Parties will follow the Dispute Resolution procedure in Section 14.5 of this Agreement.

Section 6.3 <u>Injunctive Relief</u>. Both Parties acknowledge that the other Party could be irreparably harmed by any breach of this <u>Article 6</u>, and agree, on its own behalf and on behalf of its Affiliates, that the limitations set forth in <u>Sections 6.1(a)</u> (Non-Disclosure and Non-Use) and <u>6.2</u> (Employment and Contractor Agreements) are reasonable and properly required for the adequate protection of each Party. Thus the Parties agree, that notwithstanding the provisions of <u>Section 14.5</u>, each Party may apply to any court having jurisdiction pursuant to <u>Section 14.4</u> to enforce a breach of <u>Sections 6.1(a)</u> or <u>6.2</u> of this Agreement.

Section 6.4 <u>Indemnification</u>. Notwithstanding anything to the contrary in this Agreement, each Party hereby undertakes to fully indemnify the other Party against any Claims suffered or incurred by such Party as a result of the unauthorized use or disclosure of any part of the Confidential Information by the other Party, its Affiliates and any of their respective members, staff, employees, students, consultants or outside contractors.

ARTICLE VII REPRESENTATIONS, WARRANTEES AND COVENANTS

Section 7.1 SHL Representations. SHL hereby represents and warrants to XPI, as of the Effective Date, as follows:

(a) <u>Organization</u>. SHL and any of its Affiliates that will be a Party to this Agreement is (a) duly organized, validly existing and to the extent such concept is applicable in a jurisdiction, is in good standing under the laws of the jurisdiction of its organization and (b) is duly qualified to do business and to the extent such concept is applicable in a jurisdiction, in good standing in each jurisdiction where the nature of the activities conducted by it or the character of the property owned by it make such qualification necessary.

- (b) <u>Power and Authorization</u>. The execution, delivery and performance by SHL and its Affiliates of this Agreement to which SHL or such Affiliate is (or will be) a Party and the consummation of the contemplated transactions are within the power and authority of SHL and any such Affiliate and have been duly authorized by all necessary corporate action on the part of SHL and any such Affiliate. This Agreement to which SHL or any of its Affiliates is (or will be) a Party (a) has been duly executed and delivered by SHL or any such Affiliate and (b) assuming the due execution and delivery by XPI, is a legal, valid and binding obligation of SHL and any such Affiliate, enforceable against SHL and such Affiliates, as applicable, in accordance with its terms, except as that enforceability may be (i) limited by any applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors' rights generally and (ii) subject to general principles of equity (regardless of whether that enforceability is considered in a proceeding in equity or at law).
- (c) <u>Industry Standards</u>. SHL will perform the Services under this Agreement exercising Commercially Reasonable Efforts and in a professional manner consistent with industry standards.
- (d) <u>Title to Business Methods</u>. SHL owns the legal and marketable rights, title, and interest in and to the IPR necessary to employ the processes or methods of providing the Services under this Agreement.
- (e) <u>Conveyances</u>. SHL has not and will not make any assignments, grants, licenses, encumbrances, obligations or agreements covering or concerning the Device or Components which are inconsistent with this Agreement.
 - (f) <u>Title to SHL IP</u>. SHL Controls the legal and marketable rights, title, and interest in and to SHL IP.
 - (g) Legal Compliance. SHL shall not violate any Legal Requirements, nor to its knowledge cause XPI to violate any Legal Requirements.
- (h) <u>Conflicts</u>. SHL is not under any obligation to any Person, contractual or otherwise, that conflicts in any material respect with the terms of this Agreement.
- (i) <u>Government Compliance</u>. SHL has not, and will not at any time during the Term, knowingly use in any capacity the services of any individual, corporation, partnership, institution or association which is debarred by the FDA. In the event it becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, institution or association providing services to it, which directly or indirectly relate to its activities under this Agreement, it will notify XPI immediately.
- (j) <u>Survival</u>. SHL's representations and warranties contained in <u>Section 7.1</u> of this Agreement shall survive during the Term or until the expiration of the applicable statute of limitations, if earlier.
 - Section 7.2 XPI Representations. XPI hereby represents and warrants to SHL, as of the Effective Date, as follows:
- (a) <u>Organization</u>. XPI and any of its Affiliates that will be a Party to this Agreement is (a) duly organized, validly existing and to the extent such concept is applicable in a jurisdiction, is in good standing under the laws of the jurisdiction of its organization and (b) is duly qualified to do business and to the extent such concept is applicable in a jurisdiction, in good standing in each jurisdiction where the nature of the activities conducted by it or the character of the property owned by it make such qualification necessary.

- (b) <u>Power and Authorization</u>. The execution, delivery and performance by XPI and its Affiliates of this Agreement to which XPI or such Affiliate is (or will be) a Party and the consummation of the contemplated transactions are within the power and authority of XPI and any such Affiliate and have been duly authorized by all necessary limited liability company action on the part of XPI and any such Affiliate. This Agreement to which XPI or any of its Affiliates is (or will be) a Party (a) has been duly executed and delivered by XPI or any such Affiliate and (b) assuming die due execution and delivery by SHL, is a legal, valid and binding obligation of XPI and any such Affiliate, enforceable against XPI and such Affiliates, as applicable, in accordance with its terms, except as that enforceability may be (i) limited by any applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors' rights generally and (ii) subject to general principles of equity (regardless of whether that enforceability is considered in a proceeding in equity or at law).
 - (c) Title to XPI IP. XPI Controls the legal and marketable rights, title, and interest in and to XPI EP.
 - (d) Legal Compliance. XPI shall not violate any Legal Requirements, nor to its knowledge cause SHL to violate any Legal Requirements.
- (e) <u>Conflicts</u>. XPI is not under any obligation to any Person, contractual or otherwise, that conflicts in any material respect with the terms of this Agreement.
- (f) <u>Government Compliance</u>. XPI has not, and will not at any time during the Term, knowingly use in any capacity the services of any individual, corporation, partnership, institution or association which is debarred by the FDA. In the event it becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, institution or association providing services to it, which directly or indirectly relate to its activities under this Agreement, it will notify SHL immediately.
- (g) <u>Survival</u>. XPIs representations and warranties contained in Section 7.2 of this Agreement shall survive during the Term or until the expiration of the applicable statute of limitations, if earlier.

Section 7.3 <u>DISCLAIMER</u>. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, WHETHER EXPRESS, STATUTORY OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW; PROVIDED THAT THIS SECTION 7.3 SHALL NOT LIMIT THE REPRESENTATIONS AND WARRANTIES MADE BY THE PARTIES IN ANY OTHER AGREEMENT BETWEEN THE PARTIES.

ARTICLE VIII TRANSFER OF TANGIBLE TECHNICAL INFORMATION

Section 8.1 <u>Access</u>. Subject to XPIs compliance with this Agreement, SHL shall, in a timely fashion, reasonably provide XPI full access to the Results for each SOW.

Section 8.2 <u>Delivery</u>. At the reasonable request of XPI and subject to XPIs compliance with the payment terms and other obligations of this Agreement, and the SOW, SHL shall deliver to XPI copies of all laboratory note books and all other technical and research tangible items including documents, electronically stored data and formulas associated with and prepared during the SOW.

Section 8.3 <u>Ownership</u>. The Parties agree that any Results, including any papers, documents, drawings, samples, equipment, computer software or other tangible items, developed by SHL by performing the Services, which are (i) solely related to the Device or the Components are the sole and exclusive property of SHL ("SHL Results"), and (ii) related to the Intermediate Product or the Compound, including test results specific to the Intermediate Product assembled in the Device from the design assessment, verification and validation activities, are the sole and exclusive property of XPI ("XPI Results"). Copies of such SHL Results and XPI Results shall be delivered to XPI on Completion of the SOW or upon termination of this Agreement (if earlier), provided that SHL Results shall be treated at all times by XPI as SHL's Confidential Information.

ARTICLE IX PUBLICATION AND USE OF RESULTS

Section 9.1 SHL shall not disclose, publish or use any XPI Results or any other Confidential Information of XPI or XPI IPR other than as permitted in this Agreement. XPI shall not disclose, publish or use any SHL Results or any other Confidential Information of SHL or SHL IPR other than as permitted in this Agreement, except with the prior written consent of SHL. Notwithstanding the foregoing, XPI may disclose or use any SHL Results, SHL Confidential Information, or SHL IPR to the extent necessary to seek and support regulatory review and approval of the Product by Regulatory Authorities, provided that XPI shall reasonably consult with SHL regarding the scope of such disclosures and uses.

Section 9.2 XPI shall have the right to publish and use any XPI Results or XPI IPR, including in filing patent applications, in filing for regulatory approvals, in filing copyright registrations and for any other commercial purposes. To the extent XPI seeks the written consent of SHL to publish any SHL Results, SHL Confidential Information, or SHL IPR, XPI shall provide drafts of such publications at least [***] in advance of submission for publication to allow SHL to review the proposed publication for the purpose of determining whether and the extent to which SHL will provide such consent. In the event SHL does not respond within such [***] period, SHL shall be deemed to have provided its written consent to XPI for such publication.

ARTICLE X INTELLECTUAL PROPERTY

Section 10.1 Notification. SHL will promptly notify XPI of any IPR conceived or made during the term of this Agreement under any SOW.

Section 10.2 Ownership.

- (a) Any IPR that was existing prior to the Effective Date shall be Controlled by the Party who Controlled the IPR on the Effective Date.
- (b) Any IPR developed or acquired by a Party outside of this Agreement after the Effective Date, shall be Controlled by such Party.
- (c) [***].
- (d) [***].
- (e) [***].

Section 10.3 <u>Infringement</u>. Both Parties own without limitation the right to defend, sue and collect damages for past, present and future infringement or misappropriation of IPR owned by such Party as specified in Section 10.2.

Section 10.4 Grant of Rights.

- (a) SHL hereby grants to XPI [***], non-exclusive license to use any IPR Controlled by SHL solely to the extent required by XPI (i) to define XPI's requirements for the Intermediate Product, Device and Product to be developed by SHL and (ii) any other uses necessary to comply with its obligations under this Agreement so as to benefit from the provision of Services by SHL to XPI.
 - (b) SHL hereby grants to XPI a [***], non-exclusive license [***].
- (c) XPI hereby grants to SHL until termination or expiry of this Agreement a royalty-free, non-exclusive, non-transferable license to use the XPI Materials solely to the extent required by SHL to provide the Services.
- (d) Nothing in this Section 10.4 shall be construed or deemed to have granted or to grant to a Party, either expressed or implied, any rights in the IPR or Confidential Information owned or Controlled by the other Party other than those set forth above in Subsections (a)-(c), nor does it grant the right or license to use, sell or convey any of the other Party's information, rights, licenses, and/or IPR, unless reduced to a written agreement entered into between the Parties.

Section 10.5 <u>Labeling</u>. XPI shall provide SHL with artwork, copy or other materials developed or produced in support of final Product labels, printed packaging materials and Product inserts/leaflets in order for SHL to undertake any commercial readiness or regulatory activities as reasonably requested by XPI to the extent necessary to prevent SHL delaying regulatory approvals. SHL will not make any change to the artwork, copy or other materials provided by XPI or submitted to any Regulatory Authority by XPI without the prior written approval of XPI. XPI shall have the right to specify any commercially reasonable package sizes and types.

Section 10.6 Patent Prosecution.

- (a) <u>IPR Prosecution, Maintenance and Enforcement</u>. XPI shall have sole authority to prosecute, maintain and enforce XPI IPR. SHL shall have sole authority to prosecute, maintain and enforce SHL IPR. The Party having the right to prosecute, maintain and enforce certain IPR shall be responsible for all costs and expenses incurred during such prosecution, maintenance and enforcement and shall have the right to designate patent or other legal counsel of its choice to assist it in carrying out its duties and obligations under this <u>Article 10</u>.
- (b) <u>Cooperation</u>. Each Party agrees to execute any documents required to effect the title to the IPR developed hereunder owned by the other Party and, subject to cost reimbursement, to provide reasonable assistance in the filing and prosecution of any such applications

ARTICLE XI TERMINATION

Section 11.1 Termination Without Cause.

- (a) The Parties may terminate this Agreement by mutual written consent at any time, and such consent shall state any monetary payments to be paid or reimbursed as mutually agreed by the Parties.
- (b) XPI may terminate this Agreement without cause upon [***] prior written notice. In the event of such termination, XPI shall pay to SHL upon demand for all costs and expenses already incurred or uncancellable commitments made by SHL for materials and labor as of the termination date, including, without limitation, design, processing, handling, fabrication, packing, shipping, travel, supplier termination, and restocking charges, plus reasonable amounts for overhead. SHL shall not be entitled to anticipated profit or anticipated overhead charges. Furthermore, and independently of any other amount SHL shall be entitled to pursuant to this Section, XPI acknowledges, agrees, and understands that [***].
 - (c) SHL may terminate this Agreement pursuant to Section 14.2.

Section 11.2 <u>Return of Confidential Materials</u>. Subject to <u>Section 11.6</u>, upon the expiration or termination of this Agreement, each Party shall at the other Party's reasonable request, as promptly as is reasonably practicable and in any event within [***] days, return to the other Party the other Party's Confidential Information, as well as all copies and any other tangible and electronic embodiments thereof in that Party's possession, custody or control; provided, however, that each Party may retain a copy of such information for archive purposes and to ensure compliance with the terms of this Agreement. The Parties shall, upon request, provide to the other Party a written confirmation that all the foregoing information or materials have been either returned to the Party to whom they belong or have been lost or destroyed such that no copy, electronic or otherwise, exists in the confirming Party's possession, custody or control, other than the copy permitted for archive and compliance purposes as noted above. Except to the extent XPI has been granted rights under <u>Section 10.4(b)</u>, any licenses to IPR shall be deemed cancelled and revoked without need of any further writing between the Parties.

Section 11.3 <u>Termination With Cause.</u> In addition to any other specified right to terminate this Agreement, each Party shall have the right to terminate this Agreement in the event the other Party:

- (a) fails to make any payment required pursuant to this Agreement within [***] after notification that such payment is overdue;
- (b) becomes insolvent;
- (c) institutes any proceeding under any bankruptcy, insolvency or moratorium law;
- (d) assigns substantially all of its assets for the benefit of creditors;
- (e) places its assets in the hands of a trustee or a receiver unless the receivership or trust is dissolved within [***] thereafter; or
- (f) materially breaches any other material term of this Agreement.

Section 11.4 <u>Time is of the Essence</u>. Both Parties acknowledge that time is of the essence in performing its respective duties and obligations under the terms of this Agreement. Both Parties are obligated to adhere to the agreed upon timelines for performance as set forth in any SOW.

Section 11.5 Exercise. A Party desiring to exercise its right of termination pursuant to Section 11.3 shall do so by giving the other Party, or its trustees or receivers or assigns, [***] prior written notice of exercise of the election to terminate. Upon the expiration of such period, this Agreement shall automatically terminate unless the other Party has previously cured the breach or condition permitting termination under the preceding paragraph, in which case this Agreement shall not terminate, provided that if there is a dispute as to whether a material breach has been cured or is incurable, such matter shall be first referred for Dispute Resolution pursuant to Section 14.5 and termination shall be stayed pending resolution of such proceedings. Such notice and termination shall not prejudice a Party's right to any payments due hereunder and shall not prejudice any cause of action or claim accrued or to accrue on account of any breach or default.

Section 11.6 Effect.

(a) If this Agreement is terminated by XPI under Section 11.3, SHL within [***] days shall return, or at XPIs direction destroy, all tangible IPR Controlled by XPI. Unless SHL is directed to destroy such IPR, SHL will thereupon deliver to XPI a copy of any information related to IPR Controlled by XPI (including without limitation plans, drawings, papers, notes, writings and other document samples, organisms, biological materials and models) and XPI Results specifically in its possession or control. Further, SHL shall not use or publish any portion of XPIs Confidential Information. XPI, after tendering payment, shall also have the right to take possession of the Devices and/or Product (in whatever state of design or manufacture it is at such time) and of all materials and Components related to the Devices and/or Product, immediately after payment from XPI to SHL for all work performed by SHL prior to such termination, including costs and expenses already incurred and for commitments made by SHL prior to such termination. Upon such payment, XPI shall have the right to the Continued use of the Devices and/or Product, including the related materials and Components.

(b) If this Agreement is terminated by SHL under Section 11.1(c) or 11.3, SHL shall have the right to take possession of all materials and Components related to the Devices in whatever stage of design, manufacture, or installation it is at such time, except such materials, Components, Devices and/or Product which have already been delivered and paid in full by XPI and except any partially completed Devices and/or Product for which XPI pays in full within [***] days of the end of the cure period referenced above. SHL shall be under no obligation to finish the work, provide further support or information, or provide further Devices or Product. In the event of such termination, XPI shall pay SHL for all work performed prior to the termination, including costs and expenses already incurred and for commitments made by SHL prior to such termination plus reasonable expenses incurred after termination to recover the Devices, Product, and related materials and Components, plus reasonable amounts for overhead. [***]

Section 11.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction where a Party is situated (collectively, the "Bankruptcy Laws"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including, a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, and this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including, a Title 11 trustee), shall provide to the other Party copies of all information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. It is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 11.7 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy.

ARTICLE XII LIABILITY

Section 12.1 Indemnity. SHL agrees:

(a) to defend, at its own cost and expense, from and against any Claim against XPI and its Affiliates, and the directors, officers, stockholders and employees of such entities and the successors and assigns of any of the foregoing (the "XPI Indemnitees") for [***];

- (b) to indemnify and hold XPI Indemnitees harmless from and against any and all liabilities, losses, damages and expenses associated with any such Claim set forth in Section 12.1(a);
- (c) to indemnify and hold XPI Indemnitees harmless against any and all Claims for personal injury or property damage arising out of SHL' activities furnishing or performing of the Services or Product provided hereunder.

Section 12.2 Indemnity. XPI agrees:

- (a) [***]
- (b) to indemnify and hold SHL Indemnitees harmless from and against any and all liabilities, losses, damages and expenses associated with any such Claim set forth in Section 12.2(a); and
- (c) to indemnify and hold SHL Indemnitees harmless against any and all Claims in connection with or arising out of a recall, personal injury, products liability, or any instruction, requirement, or omission requested of XPI and followed by SHL related to the Product; provided, however, the indemnity in this Section 12.2(c) shall not apply to the extent SHL is obligated to indemnify XPI under Section 12.1 or to the extent that such Claim is due to a significant or material SHL design defect or SHL manufacturing defect (not caused by SHL adherence to XPIs specifications, instructions, or requirements), or the gross negligence, or willful misconduct of an SHL Indemnitee.

Section 12.3 <u>LIMITATION ON DAMAGES</u>. EXCEPT AS MAY ARISE IN THE CASE OF FRAUD, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR LOSS OF PROFITS, OR ANY INDIRECT OR SPECIAL, CONSEQUENTIAL, PUNITIVE OR TNCDDENTAL DAMAGES, HOWEVER CAUSED, EVEN *IF* ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. IN NO EVENT WILL EITHER PARTY'S AGGREGATE LIABILITY UNDER THIS AGREEMENT EXCEED [***].

Section 12.4 Insurance.

- (a) During the Term of this Agreement and for a period of at least [***] following the expiration or earlier termination of the Term of this Agreement, SHL shall maintain, at its sole cost and expense, (i) general liability insurance, (ii) errors & omission insurance and (iii) product liability insurance, such insurances covering at least bodily injury, death and property damage limits, in such amounts and with such scope of coverage to insure its indemnification. Upon request, SHL shall provide XPI with certificates of insurance evidencing such coverage.
- (b) During the Term of this Agreement and for a period of at least [***] years following the expiration or earlier termination of the Term of this Agreement, XPI shall maintain, at its sole cost and expense, (i) general liability insurance, (ii) contractual liability insurance and (iii) product liability insurance, such insurances covering at least bodily injury, death and property damage limits, in such amounts and with such scope of coverage to insure its indemnification. Upon request, XPI shall provide SHL with certificates of insurance evidencing such coverage.

ARTICLE XIII NOTICES

Section 13.1 <u>Notices</u>. All notices, requests, demands, Claims and other communications required or permitted to be delivered, given or otherwise provided under this Agreement must be in writing and must be delivered, given or otherwise provided: by hand (in which case, it will be effective upon delivery); by Email (in which case, it will be effective upon receipt of confirmation of good transmission); or by overnight delivery by a nationally recognized courier service (in which case, it will be effective on the business day after being deposited with such courier service); in each case, to the address or email listed below:

For Administrative and legal notices:

If to SHL:

Scandinavian Health Limited Room 810, Argyle Centre 688 Nathan Road, Kowloon, Hong Kong Email: [***]

Email: [***]
Attn: [***]

With a copy to:

Scandinavian Health Limited General Counsel 136 Guosheng 2nd Street Taoyuan 33060, Taiwan Email: [***]

For scientific and technical notices:

If to SHL:

SHL Pharma, LL.C. 588 Jim Moran Boulevard Deerfield Beach, FL 33442 Email: [***]

Attn: [***]

If to XPI:

Xeris Pharmaceuticals, Inc., 3208 Red River St, Suite 300 Austin, TX 78705 Email: [***] Attn: [***]

With a copy to:

Baker Botts LLP 98 San Jacinto Blvd, Suite 1500 Austin, Texas 78701-4078 Email: [***] Attn: [***]

If to XPI:

Xeris Pharmaceuticals, Inc., 3208 Red River St, Suite 300 Austin, TX 78705 Email: [***] Attn: [***]

With a copy to:

Xeris Pharmaceuticals, Inc., 3208 Red River St, Suite 300 Austin, TX 78705 Email: [***] Attn: [***]

Either Party may give written notice of a change of address and, after notice of such change has been received, any notice or request shall thereafter be given to such Party at such changed address.

ARTICLE XIV MISCELLANEOUS

Section 14.1 <u>Use of Names</u>. Unless required by governmental authority or Legal Requirements, XPI and SHL agree that neither will use the other's name, trademark, service mark, trade names, trade dress, corporate names, logos, slogans, brand names and other source identifiers (and all translations, adaptations, derivations and combinations of the foregoing) and Internet domain names, together with all goodwill associated with each of the foregoing, either expressed or implied, in its publicity, advertising, promotional or product related literature, or in documents seeking investor financing (where such information is not disclosed on a confidential basis in accordance with Article 6) without the other's prior written consent, which consent will not be unreasonably withheld. [***].

Section 14.2 <u>Assignment</u>. Neither Party may, without the prior written consent of the other Party, delegate, transfer, convey, assign or pledge any of its rights or obligations under this Agreement to any other Person. Notwithstanding the previous sentence, each Party, upon providing the other Party written notice, may without the consent of the other Party (i) assign any or all of its rights and interests hereunder to one or more of its Affiliates and/or designate one or more of its Affiliates to perform its obligations hereunder, in each case, so long as the assigning Party is not relieved of any liability hereunder and so long as any such Affiliate remains such Party's Affiliate and (ii) assign this Agreement to any Person that succeeds, by way of sale, transfer, or divestiture, to all or substantially all of the business to which this Agreement pertains (a "Change of Control"); provided, however, that such Affiliate or Person obtaining such assignment provide the other Party with written acknowledgement of, and agreement to, the assigning Party's obligations under the Agreement that were assigned to it. In the event of a Change of Control of XPI to a Person whose primary business is the manufacture and supply of auto-injectors for drug delivery or a Person who manufactures auto-injectors in its normal course of business (each type of Person herein described is respectively a competitor of SHL), this Agreement may be terminated at the sole discretion of SHL, provided that SHL gives [***] written notice that it intends to terminate under this Subsection 14.2. [***]. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 14.2 shall be null and void.

Section 14.3 <u>Independent Contractors</u>. SHL and XPI are independent contractors. Neither Party nor its employees, agents or representatives are or shall be deemed for any purpose to be employees, agents or representatives of the other Party. Neither Party shall be responsible to the other Party or its employees, nor any governing body for any payroll related taxes related to any performance by the other Party or its employees, agents or representatives under this Agreement. Each Party agrees to indemnify the other Party with respect to Claims or proceedings relating to any such payroll related taxes. Nothing in this Agreement shall be construed to constitute XPI or SHL as a partner, joint venturer, agent or other representative of

the other. Each is an independent entity retaining complete control over and complete responsibility for its own operations and employees. Nothing in this Agreement shall be construed to grant either Party any right or authority to assume or create any obligation on behalf of or in the name of the other; or to accept summons or legal process for the other; or to bind the other in any manner whatsoever.

Section 14.4 <u>Governing Law</u>. The validity, interpretation and performance of the Contract shall be governed by and construed in accordance with the laws of the state of New York, USA. XPI and SHL hereby submit to the exclusive jurisdiction of the Courts situated in New York City, New York, USA for resolution of disputes arising with respect to this Agreement.

Section 14.5 Dispute Resolution and Related Matters.

- (a) The Parties shall attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiations between executives who have the authority to settle such dispute. Either Party may give the other Party written notice of any dispute hereunder not resolved in the normal course of business. Within [***] following delivery of such notice, executives of both Parties shall discuss such dispute by telephone or by meeting at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to exchange relevant information, and to attempt to resolve such dispute.
- (b) If the matter has not been resolved within [***] following the other Party's receipt of the disputing Party's notice, or if the Parties fail to discuss or meet within the [***] period, then within [***] thereafter, the dispute may be resolved by a court of competent jurisdiction as set forth above.
- (c) All applicable statutes of limitations and defenses based upon the passage of time shall be tolled while the negotiation and mediation procedures set forth above are pending. The Parties will take such action, if any, as may reasonably be required to effectuate such tolling.
- (d) Each Party shall pay its own costs and expenses incurred in attempting to resolve a dispute pursuant to the procedures set forth in this section and shall share equally the cost of the mediation.
- Section 14.6 <u>Compliance with Laws</u>. Notwithstanding anything contained in this Agreement to the contrary, the obligations of the Parties shall be subject to all laws, present and future, of any government having jurisdiction over the Parties and this transaction, and to orders, regulations, directions or requests of any such government.
- Section 14.7 <u>Fees and Costs</u>. Except for the provisions in Sections 14.5(e), (Dispute Resolution and Related Matters), and 14.15, (Costs), for any dispute arising out of this Agreement, the prevailing Party is entitled to recover its reasonable attorneys' fees and costs at all levels of the dispute, including litigation and all appellate levels against the other.

Section 14.8 <u>Severability</u>. The terms and conditions stated herein are declared to be severable. If any paragraph, provision, or clause in this Agreement shall be found or be held to be invalid or unenforceable in any jurisdiction in which this Agreement is being performed, the remainder of this Agreement shall be valid and enforceable and the Parties shall use good faith to negotiate a substitute, valid and enforceable provision which most nearly effects the Parties' intent in entering into this Agreement.

Section 14.9 <u>Amendments and Waivers</u>. No amendment or waiver of any provision of this Agreement will be valid and binding unless it is in writing and signed, in the case of an amendment, by each Party hereto, or in the case of a waiver, by the Party against whom the waiver is to be effective. No waiver by any Party of any breach or violation or, default under or inaccuracy in any representation, warranty, agreement or covenant hereunder, whether intentional or not, will be deemed to extend to any prior or subsequent breach, violation, default of, or inaccuracy in, any such representation, warranty, agreement or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence. No delay or omission on the part of any Party in exercising any right, power or remedy under this Agreement will operate as a waiver thereof.

Section 14.10 Entire Agreement. This Agreement and any documents, instruments and certificates explicitly referred to herein, constitutes the entire agreement among the Parties hereto with respect to the subject matter hereof and supersedes any and all prior discussions, negotiations, proposals, undertakings, understandings and agreements, whether written or oral, with respect thereto.

Section 14.11 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute but one and the same instrument. This Agreement will become effective when duly executed by each Party hereto.

Section 14.12 <u>Headings</u>. The headings contained in this Agreement are for convenience purposes only and will not in any way affect the meaning or interpretation hereof.

Section 14.13 Third Party Beneficiaries. Except as specifically provided herein, all rights, benefits and remedies under this Agreement are solely intended for the benefit of XPI and SHL, and no Third Parties shall have any rights whatsoever to (i) enforce any obligation contained in this Agreement; (ii) seek a benefit or remedy for any breach of this Agreement; or (iii) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, set off or counterclaim to any action or claim brought or made by the Parties.

Section 14.14 <u>Cooperation</u>. SHL and XPI agree to execute any instruments reasonably believed by the other Party to be necessary to implement the provisions of this Agreement.

Section 14.15 Costs. Each Party shall bear its own costs and expenses incurred in connection with the negotiation and execution of this Agreement.

Section 14.16 Excusable Delays. Neither Party shall be liable for delays caused by bona fide labor disputes, war, civil or military disturbances, acts or lack of action of governments or governmental authorities, accidents, fires, explosions, epidemics, forces of nature, acts of God or other causes reasonably beyond its control, but each Party shall use all reasonable efforts to avoid such delays and to minimize the extent of any delays that do occur.

Section 14.17 <u>Contract Control</u>. In the event of a conflict between the terms of this Agreement and any SOW, the terms of this Agreement shall govern, unless the language of the SOW, agreed upon in writing by both Parties, expressly states that the SOW controls.

Section 14.18 <u>English Language</u>. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required and permitted to be given hereunder, and all written, electronic, oral or other communication between the Parties regarding this amendment or pursuant to this Amendment shall be in the English language unless otherwise agreed to.

Section 14.19 <u>Drafting</u>. This Agreement was negotiated at arm's length and entered into freely by the Parties and upon the advice of their respective counsel. All Parties hereto are to be deemed the drafters of this Agreement. No provision hereof shall be construed in favor of or against any Party hereto based upon principles of *contra proferentem* or any other presumption as to inequality or bargaining power or otherwise.

Section 14.20 <u>Certain Rules of Construction</u>. Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article, Exhibit or Schedule means a Section or Article of, or Schedule or Exhibit to this Agreement, unless another agreement is specified, (b) the word "or" is not exclusive and the word "including" will be construed as "including without limitation," (c) words in the singular or plural form include the plural and singular form, respectively, (d) references to a particular person include such person's successors and assigns to the extent not prohibited by this Agreement; (e) the words "shall" and "will" will have the same meaning, and (f) the terms "hereof," "herein," "hereby," and derivative or similar towards refer to this entire Agreement.

Section 14.21 <u>Survivability</u>. The provisions of Articles 1, 6, 8, 9, 10, 12, 13 and 14, and Sections 2.11,5.2,7.3,11.4 and 11.6 shall survive any expiration or termination of this Agreement. Any payments for Services provided or expenses incurred by SHL or others under this Agreement prior to such expiration or termination shall, unless disputed in good faith by XPI, remain due and payable to SHL thereafter according to the terms of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, effective as of the Effective Date, each of the Parties have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

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By: [***]
[***]

Date: 2016-02-25

XERIS PHARMACEUTICALS, INC.

By: /s/ Douglas Baum

Douglas Baum

President & Chief Executive Officer

Date: 2016-03-14

SCHEDULE 1.24

PRODUCT

The "Product" is the assembled, labelled, and packaged combination of an Intermediate Product and Device for the injection of the Compound.

The "Intermediate Product" is a syringe with a pre-staked needle, along with a plunger and a needle cover, that contains the Compound ([***] μ L or [***] μ L).

The "**Device**" is the SHL developed and manufactured auto-injector delivery device pre-configured for the injection of the Compound. The Device components will be customized by SHL as needed to satisfy the design input requirements. The Device will be manufactured by SHL in the component colors selected by XPI and agreed to by SHL.

The Product will consist of the following:

- ***
- [***]
- [***
- [***

SCHEDULE 1.25

REGULATORY AUTHORITIES

- [***]
- [***]
- [***]
- [***]

SCHEDULE 1.32

STATEMENT OF WORK

Scope:

SHL will develop an auto-injector based on its technology which will serve as the injector platform for XPIs [***] (glucagon injection) product. [***]

Deliverables:

The following deliverables shall be provided to XPI by SHL:

- [***]:
 a. [***]
 b. [***]
- 2. All documents listed as requiring XPI approval in the SHL Design and Development Plan [***] [***].

Activities and Schedule:

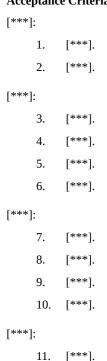
Stage	Description	Target Timing	Fees Due (USD), tea excluded
Stage 1	[***]	[***]	
	-[***]		
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2	[***]	[***]	
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3	[***]	[***]	
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	-[***] [***]		
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4	[***]	[***]	
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	-[***]		
	[***]		

Specifications:

The specifications for the Product will be developed jointly by XPI and SHL during the initial stages of the project. SHL shall manufacture the Devices in strict accordance with the Specifications, with ISO requirements, and with all applicable laws, rules and regulations, including the US Federal Food and Drug Administration's (or other appropriate regulatory authority's) current Good Manufacturing Practices for Medical Devices ("cGMPs"). The applicable standards/guidance/regulatory requirements are listed in the [***] Design Input Requirements, SHL document number [***].

SHL shall be responsible for obtaining any permits or licenses required by any regulatory authority for manufacturing the Components only. XPI shall be responsible for obtaining any permits or licenses required by any regulatory authority for manufacturing and selling the Product.

Acceptance Criteria:



[***].

[***].

12.

13.

Budget and Payment Schedule:

[***]

Facilities:

SHL shall provide or locate all scientific equipment, laboratory and service facilities, as required for prompt completion of the SOW and shall include its facilities in Deerfield Beach, Broward County, Florida, USA, Taoyuan, Taiwan, and/or any other facility as may be designated by SHL, from time to time, as approved by XPI for use in connection with completion of this SOW.

Design Changes:

XPI agrees to follow SHL's documented ISO procedures regarding the processing of design changes and shall ensure that all changes are properly approved by XPIs authorized personnel without unreasonable delay. [***]. The schedule for all materials or Components affected by any design study shall be extended by a period of time equal to the hold time, if any, associated with such study, whether or not XPI authorizes or approves the proposed change.

Device Master File:

SHL shall assist XPI in maintaining and submitting a Device Master File (MAF) to the FDA and other Regulatory Authorities that may be used to provide detailed information about facilities or articles used in the manufacturing, processing, packaging, and storing of the Devices. Contents may include proprietary information and can be referenced only with the specific permission of the Device Master File holder. Provided the submission is sufficient to satisfy all regulatory requirements, SHL shall have the right in consultation with XPI to determine which documents and/or information may be contained within the Device Master File.

SCHEDULE 14.1

PRESS RELEASE

The press release will be drafted post execution of this agreement with the written consent of both parties required prior to release to the public.