As filed with the Securities and Exchange Commission on July 17, 2014.

Registration No. 333-196983

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 2
to
FORM S-1
REGISTRATION STATEMENT
under
THE SECURITIES ACT OF 1933

ZOSANO PHARMA CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware	2834	45-4488360
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code No.)	(I.R.S. Employer Identification No.)

34790 Ardentech Court
Fremont, California 94555
(510) 745-1200
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Vikram Lamba
President and Chief Executive Officer
34790 Ardentech Court
Fremont, California 94555
(510) 745-1200
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Robert W. Sweet, Jr., Esq.
Jeffrey L. Quillen, Esq.
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Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02110
(617) 832-1000

John D. Hogoboom, Esq.
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1251 Avenue of the Americas
New York, New York 10020
(212) 262-6700

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

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 (the "Securities Act") please check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, 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(d) 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. ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

EXPLANATORY NOTE

This Amendment No. 2 to Registration Statement on Form S-1 is being filed solely for the purpose of amending Item 16 of "Part II—Information Not Required in Prospectus" and the related Exhibit Index, and refiling an amended version of Exhibit 10.4.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with this offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the FINRA filing fee.

	Amount
Securities and Exchange Commission registration fee	$ 11,376
FINRA filing fee	13,748
NASDAQ Global Market listing fee	125,000
Accountants' fees and expenses	80,000
Legal fees and expenses	1,000,000
Transfer agent's fees and expenses	10,000
Blue Sky fees and expenses	12,500
Printing and engraving expenses	250,000
Miscellaneous	97,376
Total Expenses	$1,600,000

Item 14. Indemnification of Directors and Officers.

Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Upon the closing of this offering, our certificate of incorporation will provide that none of our directors shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Upon the closing of this offering, our amended and restated bylaws will provide that we will indemnify each person who was or is a party or threatened to be made a party to or is involved in any threatened, pending or completed action, suit or proceeding by reason of the fact that he or she is or was a director or officer of Zosano Pharma Corporation, or is or was serving at our request as a director or officer of another corporation, partnership, joint venture, trust or other enterprise to the fullest extent permitted by the Delaware General Corporation Law. Upon the closing of this offering, our amended and restated bylaws will provide that expenses must be advanced to these indemnitees under certain circumstances.

The indemnification provisions contained in our amended and restated bylaws that will be effective as of the closing of this offering are not exclusive. In addition, we have entered into indemnification agreements with each of our directors. Each indemnification agreement provides that we will indemnify the director to the fullest extent permitted by law for claims arising in his capacity as a director, provided that he acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe that his conduct was unlawful. In the event that we do not assume the defense of a claim against a director, we are required to advance his expenses in connection with his defense, provided that he undertakes to repay all amounts advanced if it is ultimately determined that he is not entitled to be indemnified by us.

In addition, we maintain standard policies of insurance under which coverage is provided to our directors and officers against losses arising from claims made by reason of breach of duty or other wrongful act, and to us with respect to payments which may be made by us to such directors and officers pursuant to the above indemnification provisions or otherwise as a matter of law. In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended, against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Stock Options

At various times since June 2012, we have granted options to purchase an aggregate of 662,162 shares of common stock to our employees, directors, and consultants pursuant to our 2012 Stock Incentive Plan, at exercise prices ranging from $1.28 to $4.52 per share. None of these options have been exercised to date. The issuance of these options was exempt from registration pursuant to Rule 701 of the Securities Act of 1933, as securities issued pursuant to a compensatory benefit plan.

The following table provides information regarding the number of options issued pursuant to our 2012 Stock Incentive Plan in each calendar year during this period.

Year	Options Issued (#)	Weighted average exercise price of issued options ($)	Total shares of stock issued upon exercise of outstanding options (#)	Weighted average exercise price of exercised options ($)
2012	327,435	$ 1.41	—	$ —
2013	203,943	$ 1.40	—	$ —
2014	130,784	$ 1.28	—	$ —

Common Stock

On January 26, 2012, we sold an aggregate of 937,500 shares of common stock to our Chief Executive Officer, Vikram Lamba, and our Chief Scientific Officer, Peter Daddona. On December 11, 2012, we issued an aggregate of 12,500 additional shares of common stock to Mr. Lamba and Dr. Daddona pursuant to our 2012 Stock Incentive Plan. The issuance of these shares was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering, and pursuant to Rule 701 of the Securities Act of 1933, as securities issued pursuant to a compensatory benefit plan.

In April 2012, in a transaction to recapitalize our business, structured as a reverse triangular merger, a wholly-owned subsidiary of Zosano Pharma Corporation (then named ZP Holdings, Inc.) was merged with and into ZP Opco, Inc. (then named Zosano Pharma, Inc.), whereby ZP Opco was the surviving entity and became a wholly-owned subsidiary of Zosano Pharma Corporation. As part of this reorganization, we issued 2,812,498 shares of our common stock to the stockholders and optionholders of ZP Opco in exchange for the cancellation of all outstanding common and preferred stock of ZP Opco and all outstanding stock options. Also, in connection with this reorganization, all outstanding debt and related accrued interest of ZP Opco held by investors was cancelled, and all outstanding warrants to purchase capital stock were terminated. The issuance of these shares was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.

In April 2012, in connection with the restructuring of our lease with an affiliate of BioMed Realty Holdings, Inc., or BMR, for our facilities located in Fremont, California, we issued an aggregate of 1,344,314 shares of our common stock to BMR and another affiliate of BMR. The issuance of these shares was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering. In June 2014, in consideration of BMR agreeing to subordinate its secured promissory note and related security interest to our term loan facility with Hercules and its related security interest, we issued an aggregate of 31,250 shares of our common stock to BMR. The issuance of these shares was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.

BMR Promissory Note

In April 2012, in consideration of the amendment of our lease agreement with BMR's affiliate, we issued a new four year non-callable secured promissory note to BMR with an original principal amount of $8.6 million bearing interest at the rate of 8% per annum, compounded annually. All principal and interest will become due and payable under the note in April 2016. The note is secured by substantially all of our assets, including intellectual property. In addition to the note, we issued shares of our common stock to BMR and another affiliate of BMR in connection with the restructuring, described above under the heading "*Common Stock*". The issuance of the secured promissory note to BMR was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.

Convertible Promissory Notes

In September 2013, we issued and sold convertible promissory notes in the aggregate original principal amount of approximately $3.0 million to certain of our existing stockholders. In February 2014, we issued and sold additional convertible promissory notes in the aggregate original principal amount of $2.5 million to certain of our existing stockholders. Pursuant to their terms, all of these notes will automatically convert upon the closing of this offering into shares of our common stock, at a conversion price equal to 85% of the price per share at which our common stock is sold in this offering. The issuance of these bridge notes was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.

Item 16. Exhibits and Financial Statement Schedules.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the 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 Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- For purposes of determining any liability under the Securities Act of 1933, 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.
- For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Fremont, State of California, on the 17th day of July, 2014.

ZOSANO PHARMA CORPORATION

By: /s/ Vikram Lamba
Vikram Lamba
President and Chief Executive Officer

In accordance with the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Vikram Lamba **Vikram Lamba**	Chief Executive Officer, President and Director (Principal Executive Officer)	July 17, 2014
/s/ Winnie W. Tso **Winnie W. Tso**	Chief Financial Officer and Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	July 17, 2014
* **Peter Daddona**	Director	July 17, 2014
* **Bruce Steel**	Director	July 17, 2014
* **M. James Barrett**	Director	July 17, 2014
* **Kleanthis G. Xanthopoulos**	Director	July 17, 2014
* **Troy Wilson**	Director	July 17, 2014

* The undersigned, by signing his name hereto, does sign and execute this registration statement as attorney-in-fact pursuant to the powers of attorney executed by the above-named directors of the registrant, which powers of attorney were included in the signature page to the Registration Statement of Zosano Pharma Corporation on Form S-1 (File No. 333-196983) filed with the Securities and Exchange Commission on June 24, 2014.

/s/ Vikram Lamba
Vikram Lamba, attorney-in fact

EXHIBIT INDEX

Exhibit number	Description
1.1*	Underwriting Agreement
3.1†	Certificate of Incorporation of Zosano Pharma Corporation
3.2†	Certificate of Amendment to Certificate of Incorporation of Zosano Pharma Corporation, effective April 18, 2012
3.3†	Certificate of Amendment to Certificate of Incorporation of Zosano Pharma Corporation, effective June 23, 2014
3.4†	Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation, to be effective upon the closing of this offering
3.5†	Bylaws of Zosano Pharma Corporation
3.6†	Amended and Restated Bylaws of Zosano Pharma Corporation, to be effective upon the closing of this offering
3.7†	Certificate of Amendment to Certificate of Incorporation of Zosano Pharma Corporation, effective July 11, 2014
4.1*	Specimen certificate evidencing shares of common stock
4.2†	Note Purchase Agreement, dated as of September 9, 2013, among ZP Holdings, Inc., BMV Direct SO LP, BMV Direct SOTRS LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P. and ProQuest Management LLC
4.3†	Form of Subordinated Convertible Promissory Note dated September 9, 2013
4.4†	Note Purchase Agreement, dated as of February 26, 2014, among ZP Holdings, Inc., BMV Direct SO LP, BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership
4.5†	Form of Subordinated Convertible Promissory Note dated February 26, 2014
4.6†	Stock Repurchase Option Agreement, dated May 15, 2012, between ZP Holdings, Inc. and Peter Daddona
4.7†	Stock Repurchase Option Agreement, dated May 15, 2012, between ZP Holdings, Inc. and Vikram Lamba
4.8†	First Amendment, dated as of June 3, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated September 9, 2013
4.9†	First Amendment, dated as of June 3, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated February 26, 2014
5.1†	Opinion of Foley Hoag LLP
10.1**†	Collaboration, Development and License Agreement, dated January 31, 2014, between Zosano Pharma, Inc. and Novo Nordisk A/S
10.2†	Notice of Termination, dated January 27, 2014, of the Amended and Restated License Agreement dated as of April 1, 2012 among Zosano Pharma, Inc. and Asahi Kasei Pharma Corporation
10.3†	Letter Amendment to Intellectual Property License Agreement, dated February 22, 2011 between ALZA Corporation and Zosano Pharma, Inc.
10.4**	Intellectual Property License Agreement, dated as of October 5, 2006, between ALZA Corporation and The Macroflux Corporation
10.5†	Secured Promissory Note, dated April 26, 2012, between ZP Holdings, Inc. and BioMed Realty Holdings, Inc.

Exhibit number	Description
10.6†	Security Agreement, dated as of April 26, 2012, between ZP Holdings, Inc. and BioMed Realty Holdings, Inc.
10.7†	Intellectual Property Security Agreement, dated as of April 26, 2012, between ZP Holdings, Inc. and BioMed Realty Holdings, Inc.
10.8†	Guaranty, made as of April 1, 2012, by ZP Holdings, Inc. in favor of BMR-34790 Ardentech Court LP
10.9†	Lease Agreement, dated May 1, 2007, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP
10.10†	First Amendment to Lease, dated June 20, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP
10.11†	Second Amendment to Lease, dated October 16, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP
10.12†	Third Amendment to Lease, dated April 29, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP
10.13†	Fourth Amendment to Lease, dated July 31, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP
10.14†	Fifth Amendment to Lease, dated April 1, 2012, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP
10.15†	Form of Indemnification Agreement for Directors associated with an Investment Fund
10.16†	Form of Indemnification Agreement for Directors not associated with an Investment Fund
10.17±†	Employment Letter Agreement, dated April 30, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and W. Tso
10.18±†	Amendment to Amended and Restated Employment Letter Agreement, dated January 31, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Nandan Oza
10.19±†	Amended and Restated Employment Letter Agreement, dated July 22, 2013, among Zosano Pharma, Inc., ZP Holdings, Inc. and Nandan Oza
10.20†	Loan and Security Agreement, dated as of June 3, 2014, between Zosano Pharma, Inc. and Hercules Technology Growth Capital, Inc.
10.21†	Joinder Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.
10.22†	ZP Holdings, Inc. Pledge Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.
10.23±†	Amendment No. 2 to Employment Letter Agreement, dated January 16, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona
10.24±†	Amendment to Employment Letter Agreement, dated January 6, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona
10.25±†	Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona
10.26±†	Amendment to Employment Letter Agreement, dated December 17, 2013, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba

Exhibit number	Description
10.27±†	Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba
10.28†	Letter Amendment to Independent Director Agreement, dated July 15, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos
10.29†	Independent Director Agreement, dated as of March 28, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos
10.30±†	ZP Holdings, Inc. 2012 Stock Incentive Plan
10.31±†	Form of Incentive Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan
10.32±†	Form of Non-Statutory Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan
10.33±†	ZP Holdings, Inc. 2014 Equity and Incentive Plan
10.34†	Warrant Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.
10.35†	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BioMed Realty Holdings, Inc., Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.
10.36†	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P., ProQuest Management LLC, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.
10.37†	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.
10.38†	First Amendment to Secured Promissory Note, dated as of June 3, 2014, among BMV Direct SOTRS LP, ZP Holdings, Inc. and Zosano Pharma, Inc.
10.39†	Independent Director Agreement, dated as June 23, 2014, between Zosano Pharma Corporation and Troy Wilson
21.1†	Subsidiaries of Registrant
23.1†	Consent of Marcum LLP
23.2†	Consent of Foley Hoag LLP (included in Exhibit 5.1)
24.1†	Power of Attorney (included on signature page)

* To be filed by amendment
** Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission
† Previously filed
± Management contract or compensatory plan or arrangement

Exhibit 10.4

INTELLECTUAL PROPERTY LICENSE AGREEMENT

BETWEEN

ALZA CORPORATION

AND

THE MACROFLUX CORPORATION

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

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INTELLECTUAL PROPERTY LICENSE AGREEMENT

This Intellectual Property License Agreement (the "Agreement") is made and effective as of October 5, 2006 (the "Effective Date"), by and between ALZA Corporation, a Delaware corporation ("ALZA") and The Macroflux Corporation, a Delaware corporation ("TMC"). ALZA and TMC may be referred to individually herein as a "Party" or together as the "Parties".

RECITALS

1. ALZA is the owner of certain inventions and know-how regarding transdermal drug delivery systems and technologies.

2. TMC desires to acquire, certain know-how and patent licenses under ALZA's technology from ALZA on the terms set forth herein.

3. In consideration of (i) the issuance of shares of TMC Series A Convertible Participating Preferred Stock pursuant to the Asset Transfer and Series A Convertible Participating Preferred Stock Purchase Agreement made on or about the Effective Date, by and between TMC and ALZA (the **"Series A Agreement")** and (ii) the obligations of TMC hereunder, ALZA is willing to grant certain intellectual property licenses to TMC, subject to the terms and conditions of this Agreement.

4. The Parties hereto intend that the exchange of Licenses for TMC Series A Convertible Participating Preferred Stock **("Series A Preferred")** and Product Payments pursuant to the terms of this Agreement together with the transactions effected pursuant to the terms of the Series A Agreement and with all purchases of Series B Convertible Participating Preferred Stock **("Series B Preferred")** under the Series B Convertible Participating Preferred Stock Purchase Agreement made on or about the Effective Date, by and among TMC and certain investors (the **"Series B Agreement")** will be treated as a contribution of property (or cash in the case of the Series B Preferred) to TMC in exchange for shares (and boot in the case of

Product Payments) pursuant to Section 351 of the Internal Revenue Code of 1986, as amended (the **"Code")** for federal income tax purposes.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE 1 — DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, will have the meaning set forth below or, if not listed below, the meaning designated where first used in this Agreement.

1.1 **"Active Clinical Development"** of a Product means that at any given time TMC is diligently engaging in one or more of the following development activities for such Product in the Field: (a) awaiting protocol approval from an applicable institutional review board, FDA or other Regulatory Authority; (b) patient recruitment, patient treatment, data analysis, or report writing for any clinical trial; (c) regulatory file(s) being drafted or pending; and (d) manufacturing scale-up and validation.

1.2 **"Active Early Development"** of a Product means that at any given time TMC is diligently engaging in one or more of the following development activities for such Product in the Field: (a) formulation development; (b) preclinical studies to evaluate delivery or the feasibility of a prototype Product; (c) preclinical studies to evaluate pharmacokinetics, pharmacodynamics, and/or safety of a prototype Product; and (d) analytical development.

1.3 **"Affiliate"** means, with respect to any Party, any corporation or other business entity, which directly or indirectly controls, is controlled by, or is under common control with such Party. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any Party, will mean the possession of at least 50% of the voting stock or other ownership interest of the other corporation or entity, or the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint at

least 50% of the members of the governing body of the corporation or other entity through the ownership of the outstanding voting securities or by contract or otherwise.

1.4 **"Agreement"** means this Intellectual Property License Agreement, including its Attachments, as the same may be amended from time to time.

1.5 **"ALZA Inventions"** means any inventions arising out of work conducted by or on behalf of ALZA prior to the Effective Date that both (i) relate primarily to Microprojection Systems (including the use or manufacture thereof) and (ii) that are described in Attachment 1.5.

1.6 **"ALZA Know-How"** means all currently available and reasonably relevant tangible and written know-how, data, and reports owned or Controlled by ALZA as of the Effective Date that (i) relate to Microprojection Systems and Products or the business operations and plans of the Macroflux Internal Venture unit of ALZA, or (ii) that is otherwise necessary or useful for the development, manufacture, promotion or use of a Microprojection System or a Product, in each case to the extent such know-how, data, and reports are listed on Attachment 1.6 or on the Post-Closing List (as defined in Section 3.4), together with tangible and written know-how, data and reports generated after the Effective Date pursuant to the Transitional Services Agreement; provided, however, that ALZA Know-How will not include any written documentation, data or reports, or any portion thereof, relating solely to any compound proprietary to or Controlled by ALZA or any of its Affiliates (including but not limited to nesiritide) or consisting of Improperly Transferred Documents.

1.7 **"[**] Agreement"** means [**]

1.8 **"Commercialize" or "Commercialization"** means the ongoing process and activities (including pre-launch activities) generally engaged in by a pharmaceutical company to sell and market a pharmaceutical product. When used as a verb, "Commercialize" means to engage in Commercialization.

1.9 **"Confidential Information"** means, in the case of ALZA, ALZA Know-How, and other business and technical information regarding ALZA and its Affiliates, including information relating to technologies, compounds and products (other than Products), whether in development or Commercialized, or the use, manufacturing or Commercialization for any of the foregoing, or related clinical or regulatory affairs, and ALZA's processes and procedures, and financial and other business information regarding ALZA and its Affiliates, in each case to the extent such information has been disclosed to TMC by or on behalf of ALZA prior to or during

the Term for the purposes described in this Agreement or the purposes of ALZA and its Affiliates providing facilities or services to TMC ("**ALZA Confidential Information**"), and in the case of TMC, business and technical information regarding TMC and its Affiliates, limited to (i) information included in TMC's annual development activity reports, (ii) agreements between TMC and Sublicensees, (iii) financial information regarding Net Sales of Products and payments due to TMC regarding Third Party Products, and (iv) data and information developed by or on behalf of TMC after the Effective Date regarding the PTH Product or any other Product, in each case to the extent such information has been disclosed to ALZA by or on behalf of TMC during the Term for the purposes described in this Agreement ("**TMC Confidential Information**"), and in each case, which information is owned or Controlled by a Party hereto or any of its Affiliates or generated pursuant to this Agreement; provided, however, that Confidential Information will not include information which:

(a) is or becomes part of the public domain through no breach of this Agreement (or any other agreement between TMC and ALZA or its Affiliates) by the recipient or any of its Affiliates and through no breach of any agreement between individual TMC employees and ALZA or its Affiliates which breach occurs any time after August 1, 2006 (provided that it is understood that TMC will in no event be liable to ALZA with respect to any breach of a prior agreement between individual TMC employees and ALZA or its Affiliates);

(b) is known by the recipient or any of its Affiliates (without an obligation to keep such information confidential) prior to the disclosure thereof by the disclosing Party as demonstrated by the recipient's written records;

(c) becomes available to the receiving Party or its Affiliates on a nonconfidential basis, whether directly or indirectly, from a Third Party who has the right to make such disclosure;

(d) is independently developed by employees of the recipient who did not have knowledge of or access to any of the Confidential Information of the disclosing Party (as Confidential Information is defined without reference to this subsection (d)).

1.10 **"Control" or "Controlled"** means possession of the ability to grant a license or sublicense of Patents, know-how or other intangible rights as provided for herein without violating the terms of any contract or other arrangements with any Third Party.

1.11 **"Derivative Information"** means information, data or know-how (unless and until such information, data or know-how is part of the public domain) that (a) is generated while performing work on a product in the Field covered by a Valid Patent Claim of the Licensed Patents or (b) arises out of the use of or reference to ALZA Know-How or ALZA Confidential Information.

1.12 **"Development Agreements"** means the agreements described on Attachment 1.11.

1.13 **"Dollars"** means the legal currency of the United States.

1.14 **"Effective Date"** means the date of this Agreement as set forth in the first paragraph above.

1.15 **"FDA"** means the United States Food and Drug Administration or any successor agency to its responsibilities for pharmaceutical products such as Products.

1.16 **"Field"** means (a) passive, diffusion-mediated delivery of one or more therapeutic or prophylactic agents into or through the skin from a Microprojection System, which Microprojection System is coated with such therapeutic or prophylactic agents; or (b) diffusion-mediated delivery of one or more therapeutic or prophylactic agents into or through the skin by way of pathways formed by a Microprojection System. For clarity, the Field does not include any other applications of Microprojection Systems, such as (i) delivery of therapeutic or prophylactic agents into or through the skin utilizing a Microprojection System in combination with any delivery system that utilizes a driving source (including, but not limited to, delivery systems that utilize one or more driving sources such as electrical potential gradients, sound waves, heating systems, laser energy, hydraulic systems or radio waves), other than as provided by the microprojections, the therapeutic or prophylactic agent itself or chemical permeation enhancers, or (ii) the use of a Microprojection System for sampling or sensing.

1.17 **"Financial Records"** will have the meaning ascribed thereto in Section 5.6.

1.18 **"Financing Transaction"** means a private equity financing transaction to fund TMC raising a minimum of $75 million in cash from Third Parties reasonably acceptable to ALZA.

1.19 **"First Sale"** means with respect to each Product, the first sale in an arms length transaction and shipment of such Product to a Third Party by or on behalf of TMC or its

Sublicensee in a country in the Territory following receipt of applicable Regulatory Approval for such Product in such country.

1.20 **"Future ALZA Inventions"** means any inventions conceived or reduced to practice and arising out of work conducted by or on behalf of ALZA or any of its licensees after the Effective Date and for so long as TMC holds a license to the ALZA Know-How under Section 2.1.2 that relate primarily to Microprojection Systems (including the use or manufacture thereof); provided, however, that Future ALZA Inventions will not include (i) inventions arising out of work conducted independently by ALZA's licensees outside of any agreement with ALZA by employees of such licensees without access to, use of or reference to any ALZA Know-How, ALZA confidential information (including ALZA Confidential Information) or other Future ALZA Inventions, TMC Inventions or confidential information of TMC, (ii) inventions developed by ALZA's licensees to the extent made by employees of such licensee without access to, use of or reference to any ALZA Know-How, ALZA confidential information (including ALZA Confidential Information) or other Future ALZA Inventions, TMC Inventions or confidential information of TMC, (iii) inventions that ALZA demonstrates by clear and convincing evidence were independently developed solely by ALZA employees without access to or knowledge of any ALZA Know-How, TMC Confidential Information or TMC Inventions and (iv) any invention developed by a Third Party whom ALZA had engaged to develop an ALZA product utilizing such Third Party's proprietary Microprojection System under an agreement with ALZA, provided that ALZA has not obtained from such Third Party the right to grant TMC a license to such invention (although ALZA will be under no obligation to do so) and provided further that ALZA fulfilled its obligations under Article 12 prior to having entered into such agreement with such Third Party.

1.21 **"Future ALZA Patents"** means Patents based on Future ALZA Inventions.

1.22 **"License"** means the licenses granted in Sections 2.1.1, 2.1.2 and 2.1.4.

1.23 **"Licensed Patent(s)"** means the patents and patent applications that are identified in Attachment 1.23, as well as all Patents derived therefrom. Licensed Patents are divided into two categories, Category A and Category B, as described in Attachment 1.23. Additionally, Licensed Patents will include all Patents based on ALZA Inventions, which Patents will be deemed to be included in Category B.

1.24 **"NDA"** means, for a particular Product, its United States New Drug Application, filed with the FDA, as such application may be amended or supplemented from time to time.

1.25 **"Microprojection System"** means a microprojection array having a plurality of microprojections which pierce at least through the outmost layer (i.e., the stratum corneum layer) of the skin.

1.26 **"Natrecor® (nesiritide)"** means any product incorporating nesiritide.

1.27 **"Net Sales"** means [**]

1.28 **"Nesiritide Product"** means a Product incorporating nesiritide or any analog or derivative thereof.

1.29 **"Patent(s)"** means all multinational, foreign and domestic patents and patent applications, including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, as well as any patents throughout the world issuing with respect to any such patent applications, continuations, continuations-in-part, divisions, provisionals or substitute applications, and any reissues, reexaminations, renewals and extensions (including any supplemental patent certificates) of any of the foregoing and any confirmation patent or registration patent or patent addition based on any such patent.

1.30 **"Product"** means a product in the Field (i) the manufacture, sale or use of which would but for the license granted herein, infringe a Valid Patent Claim of the Licensed Patents or (ii) that is developed, in whole or in part, by TMC employees or Third Party employees with access to or knowledge of any ALZA Know-How, ALZA Confidential Information, TMC Inventions, TMC Confidential Information, (as defined without reference to whether such TMC Confidential Information is disclosed to ALZA) or Derivative Information; provided, however, that in the case of subsection (ii), Product will not include (x) a product that TMC demonstrates by clear and convincing evidence was independently developed by TMC employees or Third Party employees without access to or knowledge of any ALZA Know-How, ALZA Confidential Information, TMC Inventions, TMC Confidential Information (as defined without reference to whether such TMC Confidential Information is disclosed to ALZA), or Derivative Information, and (y) a product that TMC acquires from a Third Party provided that such Third Party developed such product without access to or knowledge of any ALZA Know-How, ALZA Confidential Information, TMC Inventions, TMC Confidential Information (as defined without

reference to whether such TMC Confidential Information is disclosed to ALZA) or Derivative Information.

1.31 **"Product Payments"** will have the meaning ascribed thereto in Section 5.2.

1.32 **"PTH"** means a peptide commonly known as parathyroid hormone or any analog or derivative thereof (including PTH (1-34) OH).

1.33 **"PTH Product"** means a Product incorporating PTH.

1.34 **"Quarter"** or "**Quarterly**" means each three month period ending March 31, June 30, September 30 or December 31 of each year during the term of this Agreement.

1.35 **"Regulatory Approval"** means in any country, written notice of required marketing approval (including pricing approval, if required) by the Regulatory Authority having jurisdiction in such country, which approval is required before a product may be commercially sold in such country for the marketing, sale and/or use of a product on a commercial basis in the applicable country.

1.36 **"Regulatory Authority"** means the national (e.g., the FDA) or supra-national (e.g., the European Commission, the Council of the European Union, or the EMEA) agency, if any, with which a pharmaceutical or biological product must be registered or by which a pharmaceutical or biological product must be approved prior to its manufacture, use or sale in a country.

1.37 **"Regulatory Documents"** means that certain IND No. 70,973 submitted to the FDA together with the associated Form FDA 1571 (IND Serial No. 0007) as well as all written communications between ALZA and the FDA and ALZA's internal contact reports, in each case, relating to IND No. 70,973.

1.38 [**]

1.39 **"Sublicensee"** means, with respect to a particular Product, a Third Party to whom TMC has granted a license or sublicense under the License to make, have made, use, import, sell, offer for sale or have sold any and sell such Product.

1.40 **"Term"** will have the meaning ascribed thereto in Section 15.1.

1.41 **"Territory"** means the entire world.

1.42 **"Third Party"** means an individual, corporation or other entity other than a Party or any of its Affiliates.

1.43 **"Third Party Product"** means any Product being developed by TMC for a Sublicensee that (a) incorporates the Sublicensee's proprietary compound(s), or (b) is a vaccine. A compound is considered proprietary to a Sublicensee if there is no generic equivalent of the compound commercially available to the public or if the unauthorized manufacture, use or sale of the compound by a person or entity other than such Sublicensee would infringe one or more Patents owned or licensed by such Sublicensee.

1.44 **"TMC Inventions"** means any inventions conceived or reduced to practice and arising out of work conducted by or on behalf of TMC or any of its Affiliates or Sublicensees after the Effective Date and for so long as TMC holds a license to the ALZA Know-How under Section 2.1.2 that relate primarily to Microprojection Systems (including the use or manufacture thereof); provided, however, that TMC Inventions will not include (i) inventions arising out of work conducted independently by TMC's Sublicensees or other Third Parties outside of any agreement with TMC or its Affiliates by employees of such Sublicensee or other Third Party without access to, use of or reference to any ALZA Know-How, ALZA confidential information (including ALZA Confidential Information), Future ALZA Inventions or other TMC Inventions, TMC Confidential Information (as defined without reference to whether such TMC Confidential Information is disclosed to ALZA), or Derivative Information, (ii) inventions developed by TMC's (or its Affiliates') Sublicensees to the extent made by employees of such Sublicensee without access to, use of or reference to any ALZA Know-How, ALZA confidential information (including ALZA Confidential Information), Future ALZA Inventions or other TMC Inventions or TMC Confidential Information (as defined without reference to whether such TMC Confidential Information is disclosed to ALZA), or Derivative Information, and (iii) inventions that TMC demonstrates by clear and convincing evidence were independently developed solely by TMC employees without access to or knowledge of any ALZA Know-How, ALZA Confidential Information, TMC Confidential Information (as defined without reference to whether such TMC Confidential Information is disclosed to ALZA) or TMC Inventions (as defined without reference to this subsection (iii)) or Derivative Information.

1.45 **"TMC Patents"** means Patents based on TMC Inventions.

1.46 **"Trademark"** means the trademark applications and registrations for the mark "MACROFLUX" as described in Attachment 1.46, including the goodwill associated therewith.

1.47 **"Transitional Services Agreement"** means the transitional services agreement entered into between the Parties effective on the Effective Date.

1.48 **"Valid Patent Claim"** means a claim of an issued patent in a country of the Territory or a claim of a pending application filed in good faith for a patent in a country of the Territory, provided that such claim has not expired, or been determined to be invalid or unenforceable by a final unappealable decision of a court or other appropriate body of competent jurisdiction, and which has not been admitted to be invalid by the patent owner through public disclaimer or dedication to the public.

ARTICLE 2 — GRANT OF LICENSE RIGHTS.

2.1 **License to TMC**. Subject to the terms and conditions of this Agreement and contingent on and subject to TMC's closing of the Financing Transaction, ALZA hereby grants to TMC:

(a) an exclusive license (even as to ALZA) under the Licensed Patents to make, have made, import, use, sell, offer for sale and have sold Products in the Field in the Territory, subject to rights already granted to [**] under the Development Agreement between ALZA and [**]; and

(b) a non-exclusive royalty-free license under the Future ALZA Patents to make, have made, import, use, sell, offer for sale and have sold Products in the Field in the Territory.

(c) Notwithstanding the foregoing license grant(s), ALZA reserves the right to use all Licensed Patents and Future ALZA Patents to the extent necessary to fulfill its obligations under this Agreement and the Transitional Services Agreement.

2.1.2 Subject to the terms and conditions of this Agreement and contingent on and subject to TMC's closing of the Financing Transaction, ALZA hereby grants to TMC an exclusive license to the ALZA Know-How to make, have made, import, use, sell, offer for sale and have sold Products in the Field in the Territory, subject to rights already granted to [**] under the [**] Agreement.

2.1.3 To the extent the Licensed Patents, Future ALZA Patents or ALZA Know-How cover technologies or products outside the Field, or are otherwise useful outside the Field,

ALZA grants no rights to TMC, and ALZA specifically retains any and all such rights, in each case to the extent outside the Field.

2.1.4 To the extent any Patents issue from the patent applications listed in Attachment 2.1.4 and such Patents have a Valid Patent Claim covering a Product or the use of a Product, ALZA hereby grants to TMC a non-exclusive royalty-free license under such Patents, to make, have made, use, import, sell, offer for sale and have sold Products in the Territory in the Field; provided, however, that any such Patents will not become Licensed Patents.

2.1.5 TMC will have the right to grant and authorize sublicenses to Third Parties and TMC Affiliates with respect to its rights under the License in accordance with the terms and conditions of this Agreement. Any sublicense granted to a Third Party will be on a Product-by-Product basis, or on a specific multi-Product basis (e.g., based on specified sets or classes of compounds or multiple vaccines), provided that TMC does not sublicense all (or substantially all) of TMC's rights under this Agreement to any single Sublicensee (alone or together with such Sublicensee's Affiliates). TMC will provide ALZA with notice of the identity of each Sublicensee and will ensure (i) that each such agreement with its Sublicensee will be subject and subordinate to, and consistent with, the terms and conditions of this Agreement and (ii) that the rights of ALZA under this Agreement are not prejudiced or in any way reduced or limited by such sublicensing arrangement; and (iii) that any Sublicensee will not further sublicense except on terms consistent with this Section 2.1.5. TMC will provide ALZA with a copy of each such sublicense agreement within thirty (30) days after the execution thereof. Such copy may be redacted to exclude any information not necessary for assessing TMC's compliance with its obligations to ALZA under this Agreement.

2.1.6 TMC may carry out its obligations under this Agreement in whole or in part through its Affiliates, Sublicensees, consultants and contractors, provided that TMC will remain responsible to ALZA for the performance of each such obligation that it so delegates.

2.1.7 TMC will not permit any Sublicensees, Affiliates or delegated parties to use ALZA Confidential Information without provisions safeguarding confidentiality which are at least equivalent to those provided in this Agreement and TMC ensures the compliance by each of its Sublicensees, Affiliates and delegated parties with all such applicable provisions safeguarding confidentiality in accordance with the terms and conditions of this Agreement.

2.2 **License to ALZA**. Subject to the terms and conditions of this Agreement, TMC hereby grants to ALZA an irrevocable, perpetual, royalty-free, worldwide, nonexclusive license, with the right to sublicense, under the TMC Patents to make, have made, use, import, sell, offer for sale and have sold products outside the Field. If the License is terminated on or prior to the third anniversary of the Effective Date and TMC has made all payments due under the [**] Agreement which accrued on or before the effective date of such termination and TMC is not then in material default under the [**] Agreement or which default is cured by TMC within the time frame set forth in the [**] Agreement, TMC hereby grants and ALZA will automatically receive an irrevocable, perpetual, worldwide, nonexclusive license, with the right to sublicense, under TMC Patents, to make, have made, use, import, sell, offer for sale and have sold products in the Field to the extent the License is so terminated, and on a product-by-product basis, and country-by-country basis, ALZA will pay TMC a royalty equal to [**] of ALZA's (or its Affiliates or sublicensee's) Net Sales (as such term is defined in this Agreement but with the terms TMC and ALZA being reversed for purposes of this Section 2.2) of each product covered by such TMC Patents so long as there is a Valid Patent Claim of a TMC Patent covering such product in such country and the Parties will negotiate in good faith an agreement regarding the timing and mode of such payments, the requirement for ALZA to maintain financial records related to such payments and the right of TMC to audit such financial records, on terms similar to those imposed on TMC herein. If the License is terminated on or prior to the third anniversary of the Effective Date and TMC has not made all payments due under the [**] Agreement and which default is not cured within the time frame set forth in the [**] Agreement or is in material default under the [**] Agreement and which default is not cured within the time frame set forth in the [**] Agreement or if the License is terminated at any time after the third anniversary of the Effective Date, TMC hereby grants and ALZA will automatically receive an irrevocable, perpetual, royalty-free, worldwide, nonexclusive license, with the right to sublicense, under the TMC Patents to make, have made, use, import, sell, offer for sale and have sold products in the Field. If the License is terminated at any time, and at ALZA's request, the Parties will negotiate in good faith, on commercially reasonable terms, for ALZA to obtain an exclusive, royalty-bearing license under the TMC Patents to make, have made, use, import, sell, offer for sale and have sold products in the Field.

ARTICLE 3 — DEVELOPMENT AND COMMERCIALIZATION.

3.1 **Development Responsibility and Costs.** TMC will have the sole responsibility and right to develop Products and will bear the cost of conducting development of Products (it being understood that TMC may satisfy such responsibilities and exercise such rights itself or through its Affiliates and Sublicensees); provided, however, ALZA will provide certain support services to TMC for a limited transition period pursuant to the Transitional Services Agreement.

3.2 **Regulatory Responsibilities and Costs.** TMC will have the sole responsibility for, and will bear the cost of preparing, all regulatory filings and related submissions with respect to Products (it being understood that TMC may satisfy such responsibilities itself or through its Affiliates and Sublicensees). Promptly after the Effective Date, the Parties will work together to transfer and assign to TMC the Regulatory Documents.

3.3 **Existing Agreements**.

3.3.1 The Parties acknowledge that prior to the Effective Date, ALZA made available to TMC all current agreements between ALZA and Third Parties relating to Microprojection Systems requested by TMC. For the agreements listed on Attachment 3.3.1 attached hereto, ALZA agrees that promptly after the Effective Date, it will assign such agreements to TMC, when possible, and, if required, will request the consent of the relevant Third Party to such assignment. TMC will assume all ongoing responsibilities and obligations under such agreements as of the Effective Date.

3.3.2 [**]

3.4 **ALZA Know-How**. The Parties acknowledge that prior to the Effective Date, except as otherwise noted in Attachment 1.6, ALZA made available to TMC the ALZA Know-How listed on Attachment 1.6 as well as (i) the contents of the office files of TMC employees (collectively, "Employee Office Files"), (ii) a copy of the contents of TMC employee's folders on a shared hard drive designated for the Macroflux Internal Venture unit of ALZA (including a copy of each employee's archived e-mail) (collectively, "H-Drive Files"), and (iii) a copy of the contents of the Macroflux Technology Development Folder (collectively, "Tech Dev Files") (the Employee Office Files, H-Drive Files and Tech Dev Files, collectively the "Transferred Information"). The parties acknowledge that ALZA has retained an electronic copy of the H-Drive Files and Tech Dev Files and TMC will provide ALZA with a written inventory of the

Employee Office Files prior to the Effective Date. Promptly after the Effective Date, TMC will use commercially reasonable efforts to review the Transferred Information to confirm that it does not contain ALZA documents or files that (A) do not relate to either the Microprojection Systems and Products or the business operations and plans of the Macroflux Internal Venture unit of ALZA, (B) are not otherwise necessary or useful for the development, manufacture, promotion or use of a Microprojection System or a Product, (C) relate solely to any compound proprietary to or Controlled by ALZA or any of its Affiliates (including but not limited to nesiritide), (D) include confidential information of a Third Party, (E) relate solely to technologies of ALZA or its Affiliates other than Microprojection Systems, or (F) include confidential information of ALZA or its Affiliates that applies generally to ALZA's or its Affiliate's businesses and not specifically to the Macroflux Internal Venture unit of ALZA or any Transferred Employee (as defined in the Series A Agreement) (including but not limited to worldwide policies, human resources forms and job descriptions, and financial policies) (any such documents or files, "Improperly Transferred Documents"). If any document or file in the Transferred Information contains both ALZA Know-How and any of the types of information described in clauses (A) through (F) of the preceding sentence, the parties will work together to separate such information or redact the improper portion of the information document or file to the extent practicable so that the document or file no longer contains the types of information described in clauses (A) through (F). In the event TMC discovers that it possesses any Improperly Transferred Documents, either during its review of the Transferred Information described above or at any point in the future, TMC shall promptly notify ALZA, provide a general description of such confidential or proprietary information, and either promptly return to ALZA or destroy, at ALZA's option, all tangible materials that disclose or embody such confidential or proprietary information. Within seven (7) days of the Effective Date, TMC shall provide ALZA with (i) a list of any Improperly Transferred Documents identified by TMC in its review of the Transferred Information, and (ii) an index of all other written know-how, data, and reports remaining in the Transferred Information after the removal of such Improperly Transferred Documents (such index, the "Post-Closing List"). The parties acknowledge that other than the ALZA Know-How identified in Attachment 1.6 as remaining to be transferred (which know-how, data, and reports shall be transferred to TMC by the applicable transfer date specified for such item in Attachment 1.6), ALZA has no obligations to provide any additional

Know-How generated prior to the Effective Date to allow TMC to practice under the License. Notwithstanding the foregoing, or anything in Section 18.2 to the contrary, for a period of six (6) months following the Effective Date, in the event that TMC identifies a particular item of ALZA Know-How that was not made available to TMC, and TMC would be materially impeded in the development of the Microprojection System or the development or Commercialization of Products by not having such item, ALZA will use commercially reasonable efforts to make such ALZA Know-How available to TMC in a timely manner. At the termination of the Transitional Services Agreement, ALZA will make available to TMC all ALZA Know-How generated in the performance of the transitional services. Any duplication of the ALZA Know-How for TMC will be at TMC's sole cost and expense. If TMC identifies additional Improperly Transferred Documents or additional ALZA Know-How identified by TMC for a period of six (6) months following the Effective Date after the generation of the Post-Closing List, in either case, pursuant to this Section 3.4, TMC will amend the Post-Closing List to exclude or include such information and will provide such revised list to ALZA. Following the termination of the Transitional Services Agreement, TMC will amend the Post-Closing List to include ALZA Know-How generated in the performance of the transitional services, and will provide such revised list to ALZA. The parties will each maintain a copy of the most recent Post-Closing List. Notwithstanding anything in this Section 3.4 to the contrary, ALZA will not be required to transfer or make available any ALZA Know-How that would require ALZA to breach any obligation it may have to a Third Party or violate any law, statute, ordinance or regulation. For the avoidance of doubt, the transfer of any tangible manifestations of ALZA Know-How pursuant to this Section 3.4 will not alter the ownership or other rights of ALZA or its Affiliates with respect to such ALZA Know-How. In the event of a dispute between the Parties regarding the procedures in this Section 3.4, the Parties will use the dispute resolution procedures described in Section 17.1, provided that the first sixty (60) day period described therein will be reduced to ten (10) business days and the second sixty (60) day period will be reduced to thirty (30) days for such dispute.

3.5 **Future Vendor Agreements**. Neither TMC nor ALZA will enter into any agreement with any Third Party vendor that prohibits such Third Party from providing services to the other Party or its Affiliates related to Microprojection Systems or the components,

manufacture, assembly or packaging thereof, for use in the Field, in the case of TMC, or for use outside the Field, in the case of ALZA.

3.6 **TMC Diligence**.

3.6.1 General Diligence Obligations. During the Term, TMC will use diligent efforts to continue development of Microprojection Systems in the Field and to develop and obtain Regulatory Approval for Products within the Territory in a manner consistent with the efforts United States-based, mid-sized, specialty pharmaceutical companies devote to products having similar market potential at a similar stage of development or life of such product based on conditions then prevailing with respect to the applicable product and the relevant market.

3.6.2 Specific Diligence Obligations. In addition to TMC's general development diligence requirements set forth above, and in no way limiting them, at all times during the period of time beginning with the Effective Date and ending on the date of the First Sale of the second Product to be Commercialized, TMC will have at least two Products in a combination of Active Early Development and/or Active Clinical Development (it being understood that this obligation will be satisfied if TMC has (i) two or more Products in Active Early Development, (ii) two or more Products in Active Clinical Development, or (iii) one Product in Active Early Development and one Product in Active Clinical Development); provided, however, TMC will not be deemed to be in breach of this specific diligence obligation if TMC encounters an adverse technical, clinical or other condition/event regarding a particular Product (and not a condition/event that applies generally to TMC) which, in TMC's reasonable judgment, requires the termination or suspension of development work on such particular Product, so long as TMC is engaged in Active Early Development on at least one additional Product within 6 months following the date TMC terminates or suspends such development program.

3.6.3 Consequences of Default. If TMC does not fulfill its general diligence obligations set forth in Section 3.6.1 above, ALZA will be entitled, but not obligated, to terminate the License and this Agreement, subject to the terms of Section 15.4 below. If TMC does not fulfill its specific diligence obligations set forth in Section 3.6.2 above, ALZA will be entitled, but not obligated, to terminate the License and this Agreement immediately upon written notice to TMC.

3.7 **Annual Development Activity Report**. Within ninety (90) days after the Effective Date, TMC will submit to ALZA a written development plan containing at least

development timelines and milestones for the PTH Product and for at least one other Product. Thereafter, on or before February 28th of each calendar year, TMC will submit to ALZA a written, non-confidential annual report summarizing in reasonable detail the development work conducted by TMC during the prior calendar year and TMC's development plans for the then-current year. TMC will blind the identity of the active pharmaceutical ingredients in any Product that it is developing (or considering developing) that is not subject to the Exclusivity provisions of Article 14 below and which has not been previously publicly disclosed when describing such Product in such annual reports and will limit the information disclosed in such annual reports to non-confidential information regarding the Products being developed provided that the information contained in such reports is sufficiently detailed to allow ALZA to evaluate TMC's compliance with the provisions of this Agreement. To the extent that TMC has entered into any agreements with Third Parties for the development or Commercialization of Third Party Products, TMC will include in the development report the status of such programs including the work conducted on such programs and any milestones achieved in the previous year. To the extent necessary for assessing TMC's compliance with its obligations to ALZA under this Agreement, ALZA may request additional confidential information related to TMC's development activities after receipt of such report, and, subject to the consent of any applicable Third Party, TMC will provide such requested information subject to the terms of this Agreement, including, but not limited to, Article 6. TMC will provide such reports unless and until an authorized corporate officer of ALZA requests TMC to terminate such reports in whole or in part and thereafter will provide such reports only to the extent requested.

3.8 **Commercial Responsibilities**. TMC agrees to use commercially reasonable efforts to Commercialize Products, which efforts are consistent with the efforts and resources that TMC or a United States-based, mid-sized, specialty pharmaceutical company devotes to products of similar market potential and in similar product lifecycle positions based on conditions then prevailing with respect to the applicable product and the relevant markets. If TMC does not fulfill its commercial diligence obligations set forth in this Article 3, ALZA will be entitled, but not obligated, to terminate the License and this Agreement, subject to the terms of Section 15.4 below.

ARTICLE 4 — TRADEMARK RIGHTS TO TMC.

4.1 **Trademark Assignment**. ALZA will assign (and, if necessary, cause its Affiliates to assign) to TMC the Trademarks, including the goodwill associated therewith. In connection with and in furtherance of the transfer of the Trademarks, the Parties (and, if necessary, ALZA's Affiliates) will execute the trademark assignments in the forms attached hereto as Attachment 4.1, or such equivalent form as may be required in any non-U.S. jurisdiction. As of the Effective Date, the costs of prosecution, issuance and maintenance of applications and registrations of the Trademarks incurred after the Effective Date will be paid by TMC.

4.2 **Limited Continued Obligations**. For a period of up to one year following the Effective Date, ALZA will provide (and, if necessary, cause its Affiliates to provide) the necessary information and original registration certificates, and will execute all reasonable documents necessary to permit TMC, at TMC's expense, to effect and perfect the transfer of the registrations of the Trademarks. Notwithstanding Section 18.2 below, after such one year period, ALZA (and its Affiliates) will have no further obligations in respect thereof.

4.3 **Trademark Maintenance**. If TMC elects to abandon its use of the Trademarks then it will give at least 60 days advance notice to ALZA. In such case, ALZA (or its designated Affiliate) may elect in its own discretion to continue the prosecution, issuance and maintenance of any such Trademarks and require TMC to assign such Trademarks to ALZA (or its designated Affiliate) and any associated goodwill, without compensation to TMC.

4.4 **Trademark Enforcement**. For as long as TMC owns the Trademark in a country, TMC will have the right, but not the obligation, to defend or enforce the Trademark in such country.

4.5 **Effect of Termination**. In the event of termination under Sections 15.2, 15.3, 15.4 or 15.6: TMC will assign the Trademarks and any associated goodwill to ALZA (or its designated Affiliate), without compensation to TMC, and will execute a trademark assignment in the form attached hereto as Attachment 4.5; provided, however, that if the Agreement is terminated (i) by ALZA due to TMC's failure to meet its specific diligence obligations described in Section 3.5, and the License to TMC is converted to a Product specific license in accordance with Section 15.7.3, or (ii) by either Party for any reason and one or more Sublicensees are

entitled to have their sublicenses survive such termination in accordance with 15.7.3, then ALZA will grant to TMC, and its Sublicensees and Affiliates, as applicable, the royalty-free right to use the Trademarks in association with the Product developed and commercialized under the Product specific license, or with respect to the Products being developed under such surviving sublicense, as applicable, in the Territory in the Field under terms of a Trademark License Agreement that will be negotiated by the Parties and that will contain appropriate quality control provisions.

ARTICLE 5 — FINANCIAL PROVISIONS

5.1 **Purchase Price.** In exchange for the Licenses granted hereunder and such other consideration as set forth in the Series A Agreement, TMC will issue to ALZA shares of TMC Series A Preferred, as specified in the Series A Agreement.

5.2 **Product Payments.** In addition to the purchase price described in Section 5.1, TMC will pay to ALZA product payments for each Product ("Product Payments") as described in this Article 5. Product Payments, when made, will be non-refundable, non-recoupable and non-creditable.

5.2.1 For each Product other than a Third Party Product, TMC will pay to ALZA Product Payments as follows:

(a) With respect to each of the [**] such Product for which a First Sale occurs, TMC will pay to ALZA:

(i) [**] of Net Sales of such Products by TMC and its Affiliates; and

(ii) the greater of: [**] of Net Sales of such Products by Sublicensees, or [**] of all royalties received by TMC or its Affiliates from Sublicensees based on commercial sales of such Products.

(b) With respect to the [**] and each subsequent Product for which a First Sale occurs, TMC will pay to ALZA:

(i) [**] of Net Sales of such Products by TMC and its Affiliates; and

(ii) the greater of: [**] of Net Sales of such Products by Sublicensees, or [**] of all royalties received by TMC or its Affiliates from Sublicensees based on their commercial sales of such Products.

5.2.2 For each Third Party Product, TMC will pay to ALZA Product Payments as follows:

(a) [**] of Nonroyalty Revenue received by TMC or its Affiliates from a Sublicensee prior to the receipt of Regulatory Approval of such Third Party Product; and

(b) [**] of Nonroyalty Revenue received by TMC or its Affiliates from a Sublicensee with respect to, and following the receipt of, Regulatory Approval of such Third Party Product; and

(c) [**] of all royalties received by TMC or its Affiliates from Sublicensees based on sales of such Third Party Product.

(d) For purposes of this Section 5.2.2, "Nonroyalty Revenue" will mean all upfront payments, milestone payments and all other consideration (other than royalties) received by TMC or its Affiliates from Sublicensees with respect to such Third Party Product. In case of non-financial consideration of value, Nonroyalty Revenue will be calculated on a fair market value of the consideration received. Notwithstanding the foregoing, the following payments (if any) received by TMC or its Affiliates from such Sublicensees will be specifically excluded from Nonroyalty Revenue:

(i) an equity investment by such Sublicensee (but solely to the extent that such investment is at a price equal to or less than the fair market value of TMC's stock sold in such investment),

(ii) a nonforgivable loan (but solely to the extent that such loan is subject to commercially reasonable terms with respect to repayment (including conversion to equity at the fair market value of TMC's stock)),

(iii) reimbursement of TMC's actual research and development costs directly related to the Third Party Product that is the subject of a sublicense granted by TMC and only to the extent incurred by TMC after the effective date of such sublicense,

(iv) reimbursement of TMC's actual patent prosecution or maintenance expenses directly related to the Third Party Product that is the subject of a sublicense granted by TMC and only to the extent incurred by TMC after the Effective Date of this Agreement, and

(v) payments directly attributable to TMC's supplying such Third Party Product (or components of such Third Party Product) (at no more than 100% of TMC's actual manufacturing cost) to such Sublicensee.

(e) Notwithstanding the foregoing, for each Third Party Product, if the compound in such Third Party Product or the vaccine comprising such Third Party Product becomes owned or Controlled by TMC or TMC becomes owned or Controlled by such Sublicensee, then as of such date the relevant Product will no longer be a Third Party Product, and, going forward, TMC will pay Product Payments to ALZA as described in Section 5.2.1. Any Product Payments regarding such Third Party Product already due to ALZA pursuant to Section 5.2.2 will not be affected.

5.3 **Single Royalty, Product Payment Term.**

5.3.1 Single Product Payment. In no event will more than a single Product Payment be due under this Article 5 with respect to the sale of any Product unit, unless TMC or its Affiliates receives, more than a single payment with respect to the sale of any Third Party Product unit.

5.3.2 Non-Third Party Product Payment Term.

(a) For each Product (excluding Third Party Products), the Product Payments will be payable on a Product-by-Product and country-by-country basis until five (5) years after the expiration date of the last Valid Patent Claim of any Licensed Patent anywhere in the Territory; provided, however, that beginning on the date in a country that the Product is no longer covered by a Valid Patent Claim of any Licensed Patent, the otherwise applicable Product Payment rate described in Section 5.2.1 for such Product in such country will be reduced by [**] going forward. For clarity, if there is no issued Licensed Patents in a country, the Product Payment rate described in Section 5.2.1 for such Product in such country will be [**] of the rate described in Section 5.2.1 until five (5) years after the expiration date of the last Valid Patent Claim of any Licensed Patent anywhere in the Territory.

(b) Notwithstanding Section 5.3.2(a) above, in cases where TMC enters into a sublicense agreement with a Sublicensee for the Sublicensee to Commercialize a Product other than a Third Party Product, the foregoing Product Payments for each such Product sold by or on behalf of such Sublicensee will be payable on a Product-by-Product basis until, on a country-by-country basis, the later of (i) the expiration date of the last Valid Patent Claim of any Licensed Patent covering such Product in such country, (ii) ten (10) years following the First Sale of such Product in such country, or (iii) the last date on which the Sublicensee is required to make payments to TMC based on commercial sales of such Product in such country, provided that (A) beginning on the date in a country that the Product is no longer covered by a Valid Patent Claim of any Licensed Patent in a country or (B) where there

are no issued Licensed Patents in a country, the otherwise applicable Product Payment rate described in Section 5.2.1 for such Product in such country will be reduced by [**] going forward; and provided further, however, that in no event shall any Product Payments be payable under this Section 5.3.2(b) after the date that is five (5) years after the expiration date of the last Valid Patent Claim of any Licensed Patent anywhere in the Territory. If a Sublicensee has a non-exclusive right to Commercialize a Product in a country, or an exclusive right to Commercialize a Product only in certain countries, the Product Payments to ALZA will be calculated separately for TMC pursuant to Section 5.2.1(a)(i) or 5.2.1(b)(i) and each such Sublicensee pursuant to Section 5.2.1(a)(ii) or 5.2.1(b)(ii).

5.3.3 Third Party Product Payment Term. For each Third Party Product, the Product Payments will be payable for as long as TMC receives payments from such Sublicensee; provided, however, that in no event shall any Product Payments be payable under this Section 5.3.3 after the date that is five (5) years after the expiration date of the last Valid Patent Claim of any Licensed Patent anywhere in the Territory.

5.4 **Timing and Mode of Payment**. All payments to ALZA hereunder will be in Dollars and will be made by wire transfer in the requisite amount to the account designated by ALZA. Product Payments pursuant to Sections 5.2.1(a)(i) and 5.2.1(b)(i) will be made within forty-five (45) days after the close of each Quarter. Product Payments pursuant to Sections 5.2.1(a)(ii), 5.2.1(b)(ii) and Section 5.2.2 will be made within thirty (30) days after the date the payments on which they are based are due to TMC.

5.5 **Product Payment Reports**.

5.5.1 During the Term, TMC will notify ALZA each time it enters into an agreement with a Sublicensee regarding the development or Commercialization of a Third Party Product pursuant to which TMC will receive Nonroyalty Revenue and/or royalties based on sales of such Third Party Product and will provide to ALZA a copy of such agreement within 30 days after the execution thereof. Such copy may be redacted to exclude any information that is not necessary for assessing TMC's compliance with its obligations to ALZA under this Agreement. Thereafter, TMC will furnish to ALZA a written report regarding Product Payments due to ALZA pursuant to Section 5.2.2 within 30 days after the date the payment on which such Product Payment is based is due to TMC showing: (a) the amount due to TMC from such Third Party; (b) a description of the milestone or event on which such payment is based; (c) the Product Payments, payable in Dollars, in respect of such payment; and (d) the exchange rates

used, if any, in converting into Dollars from the currencies in which the payments were made to TMC.

5.5.2 During the Term and commencing with the First Sale of each Product, TMC will furnish or cause to be furnished to ALZA on a Quarterly basis, a written report or reports covering each Quarter (each such Quarter being sometimes referred to herein as a "reporting period") showing: (a) gross invoiced sales and total deductions used to calculate Net Sales of each Product sold by TMC and its Sublicensees during the reporting period on a country-by-country basis; (b) the Product Payments, payable in Dollars, which will have accrued hereunder in respect of such Net Sales; (c) the exchange rates used, if any, in converting into Dollars, from the currencies in which sales of Product were made; (d) dispositions of such Product other than pursuant to sale for cash; and (e) any withholding taxes required to be paid from such Product Payments. In addition, with each such report on a Quarterly basis, TMC will furnish to ALZA a statement of the total amount due from TMC to [**] pursuant to the [**] Agreement and evidence to ALZA's reasonable satisfaction that such payment was made to [**].

5.6 **Financial Records**. TMC will keep accurate records for three (3) years from the end of each reporting period, including, without limitation, gross invoiced sales, Net Sales, and Product Payments, in accordance with United States generally accepted accounting principles, in sufficient detail to enable the amounts due hereunder to be determined and verified by ALZA ("Financial Records").

5.7 **Currency Exchange**. In the case of sales of any Product outside the United States or payments received from Third Parties outside of the United States, for the purpose of calculating Net Sales and making Product Payments where the consideration is based in a currency other than Dollars, conversion from such foreign currency to Dollars will be at the average rate of exchange published in the New York edition of The Wall Street Journal (or, if The Wall Street Journal is not then published, such other financial periodical of general circulation in the United States) with respect to the currency of the country of origin of such Net Sales or other payments for the Quarter for which such Product Payments are being paid.

5.8 **Audit**. Financial Records under this Agreement will be available during reasonable business hours for a period of three (3) years from the end of the reporting period to which they relate for audit purposes. Upon the written request of ALZA but not more often than once each year, at ALZA's expense, TMC will permit an independent public accounting firm of

national prominence selected by ALZA and reasonably acceptable to TMC to have access during normal business hours to those records of TMC as may be reasonably necessary for the sole purpose of verifying the accuracy of the Net Sales report and Product Payment calculation conducted by TMC pursuant to this Agreement. The aforementioned independent public accountant will execute an appropriate and customary confidentiality agreement with TMC and its Sublicensees, as applicable.

5.8.1 TMC will include in each sublicense entered into by it pursuant to this Agreement; a provision requiring, among others, the Sublicensee or commercialization partner to keep and maintain adequate Financial Records pursuant to such sublicense agreement and will use commercially reasonable efforts to cause such Sublicensee to grant access to such Financial Records by the aforementioned independent public accountant for the reasons specified in this Agreement, provided that in the event that TMC is unable to obtain the consent of a Sublicensee to such an audit by ALZA's auditors, TMC will obtain for itself such right and, at the request of ALZA, TMC will exercise such audit right with respect to Sublicensees and provide the results of such audit for inspection by ALZA pursuant to this Section 5.8.1. It is understood and agreed that this Section 5.8.1 shall not apply to Non-Stocking Distributors unless such Non-Stocking Distributor is maintaining Financial Records on behalf of TMC.

5.8.2 In order to initiate an audit for a particular calendar year, ALZA will provide written notice to TMC. ALZA will provide TMC with notice of one or more proposed dates of the audit not less than forty-five (45) days prior to the first proposed date and TMC will reasonably accommodate the scheduling of such audit.

5.8.3 The report prepared by such independent public accounting firm, a copy of which will be sent or otherwise provided to TMC by such independent public accountant at the same time as it is sent or otherwise provided to ALZA, will contain the conclusions of such independent public accountant regarding the audit and will specify that the amounts paid to ALZA pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment.

5.8.4 If such independent public accounting firm's report establishes any underpayment, TMC will remit to ALZA within 30 days after TMC's receipt of such report, (i) the amount of such underpayment and (ii) if such underpayment exceeds [**] of the total amount owed for the calendar year then being audited, the reasonable and necessary fees and expenses of

such independent public accountant performing the audit, subject to reasonable substantiation thereof. If such independent public accounting firm's report establishes any overpayment, TMC will receive a credit equal to such overpayment against the Product Payment otherwise payable to ALZA.

5.9 **Interest Due.** In the case of any delay in payment by TMC to ALZA of any amounts due, interest on the overdue payment will accrue at an annual interest rate, compounded monthly, equal to the prime rate as reported in The Wall Street Journal, as determined for each month on the last business day of that month, plus [**], assessed from the day payment was initially due. The foregoing interest will be due from TMC without any special notice.

5.10 **Tax Withholding.** Any income or other taxes which TMC is required by law to pay or withhold on behalf of ALZA with respect to Product Payments, and any interest thereon, payable to ALZA under this Agreement will be deducted from the amount of such Product Payments and interest due and paid or withheld, as appropriate, by TMC on behalf of ALZA. Any such tax required to be paid or withheld will be an expense of, and be borne solely by, ALZA. TMC will furnish ALZA with reasonable evidence of such withholding payment in electronic or written form as soon as practicable after such payment is made. The Parties hereto will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable law in connection with the making of any required withholding payment, or any claim to a refund of any such payment.

ARTICLE 6 — CONFIDENTIAL INFORMATION.

6.1 **Confidentiality Obligations.** Each Party agrees that, for the Term of this Agreement and for ten (10) years thereafter, it will keep confidential and will not publish or otherwise disclose and will not use for any purpose (except as expressly permitted hereunder) Confidential Information of the other Party; provided, however, that TMC can use ALZA Know-How to the extent reasonably necessary to develop, manufacture or use Microprojection Systems in the Field and to develop and commercialize Products and TMC can disclose ALZA Know-How only to the extent relating primarily to Microprojection Systems (including the manufacture or use thereof) in the Field and to Products. For clarity, TMC may not disclose any specific information relating to any agents or compounds proprietary to or Controlled by ALZA or its

Affiliates (including the identity or structure of such agents or compounds), in each case to the extent such information would not fall within any of exceptions (a)-(d) of Section 1.9.

6.2 **Written Assurances and Permitted Uses of Confidential Information**.

6.2.1 Each Party will inform its employees and consultants who perform work under this Agreement of the obligations of confidentiality specified in Section 6.1, and all such persons will be bound by obligations of confidentiality substantially similar to those set forth herein.

6.2.2 Each Party may disclose Confidential Information of the other Party to the extent necessary to comply with applicable governmental regulations and/or submitting information to tax or other governmental authorities, or to the extent the receiving Party is compelled to disclose such information by a court or other tribunal of competent jurisdiction, provided, however, that in such case the receiving Party will give prompt notice to the other Party so that the other Party may seek a protective order or other remedy from said court or tribunal. In any event, the receiving Party will disclose only that portion of the Confidential Information that, in the opinion of its legal counsel, is legally required to be disclosed and will exercise reasonable efforts to ensure that any such information so disclosed will be accorded confidential treatment by said court or tribunal.

6.2.3 To the extent it is reasonably necessary or appropriate to fulfill its obligations and exercise its rights under this Agreement, either Party may use the Confidential Information of the other Party and may disclose such Confidential Information to its Affiliates, officers, employees, consultants, outside contractors, agents, clinical investigators, Sublicensees, potential Sublicensees, financial investors, attorneys and others that have a need to know the Confidential Information in order for the receiving Party to exercise its rights and perform its obligations under this Agreement, on condition that those individuals and entities to whom the receiving Party discloses such Confidential Information agree to keep the Confidential Information confidential for the same time periods and to the same extent as such Party is required to keep the Confidential Information confidential under this Agreement, and to any regulatory authorities to the extent reasonably necessary to obtain Regulatory Approval.

6.2.4 The terms and conditions of this Agreement will be treated by each Party as Confidential Information of the other Party and may be disclosed solely as permitted under this Article 6. For clarity, either Party will have the right to disclose this Agreement to the extent

required by applicable law or regulation, including filing this Agreement with the United States Securities and Exchange Commission. If a Party discloses this Agreement because it is required by law, it will give the other Party at least [**] advance notice, where possible, of the scope of the Agreement to be disclosed with any proposed redactions so that the other Party will have an opportunity to comment. To the extent the receiving Party reasonably requests the redaction of any information in the Agreement, the disclosing Party will delete such information unless, in the opinion of the disclosing Party's legal counsel, such information is legally required to be fully disclosed.

6.3 **Public Announcements**. An initial press release will be agreed upon by the Parties promptly after the Effective Date. Otherwise, neither Party will originate any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to the terms of this Agreement, performance under it or any of its terms, to any amendment hereto or performances hereunder without the prior written consent of the other Party, save only such announcements that are required by law to be made or that are otherwise agreed to by the Parties. Such announcements will be brief and factual. If a Party decides to make an announcement required by law, it will give the other Party at least [**] advance notice, where possible, of the text of the announcement so that the other Party will have an opportunity to comment upon the announcement. To the extent that the receiving Party reasonably requests the deletion of any information in the materials, the disclosing Party will delete such information unless, in the opinion of the disclosing Party's legal counsel, such Confidential Information is legally required to be fully disclosed. For purposes of clarity, disclosures which have already been approved and made public will be exempted from the foregoing restrictions.

6.4 **Publications**. Each Party recognizes that the publication of papers regarding the results of non-clinical scientific studies or clinical trials related to the Products in the Field, including oral presentations and abstracts, may be beneficial to both Parties provided such publications are subject to reasonable controls to protect ALZA Confidential Information. Accordingly, TMC will deliver to ALZA a complete copy of any proposed publication by TMC that relates to or discloses ALZA Confidential Information at least [**] prior to submitting such proposed publication. ALZA will review any such proposed publication and give its comments to TMC within [**] of the delivery of such proposed publication to ALZA. With respect to oral

presentation materials, ALZA will make reasonable efforts to expedite review of such materials, and will return such items as soon as practicable to TMC with appropriate comments, if any, but in no event later than [**] from the date of delivery to ALZA. TMC will comply with ALZA's request to delete references to ALZA's Confidential Information in any such proposed publication. Notwithstanding anything to the contrary herein, TMC may publish information about clinical trials performed or to be performed on the Products in the Field, without the need to obtain ALZA's prior written approval (provided, however, that TMC will use diligent efforts to inform ALZA and to allow ALZA to comment on the disclosure), to the extent that such disclosure is required, in TMC's reasonable opinion, to comply with applicable laws and regulations.

ARTICLE 7 — PATENTS AND INTELLECTUAL PROPERTY.

7.1 **Ownership; Inventions.** ALZA will own and retain and will continue to own and retain, all rights, title and interest to (i) any inventions conceived and reduced to practice by employees of ALZA, or by or on behalf of ALZA by Third Parties, prior to the Effective Date, including the Licensed Patents, and (ii) all ALZA Inventions, even if conceived by or on behalf of ALZA, prior to the Effective Date and reduced to practice by TMC after the Effective Date. Any invention conceived and reduced to practice and arising out of work conducted by or on behalf of a Party after the Effective Date that relates primarily to Microprojection Systems (including the use or manufacture thereof), including, but not limited to, Future ALZA Inventions and TMC Inventions, will (i) be owned by that Party and that Party will retain all rights, title and interest to the invention subject to the terms of this Agreement, including the right to file patent applications based on the invention and to prosecute; issue and maintain Patents that issue based on such Party's invention, or (ii) if owned by a Third Party, will be licensed to the applicable Party under terms permitting such Party to fulfill its obligations to the other Party under Sections 2.1.1(b) or 2.2, as applicable. For purposes of clarity, inventorship for patentable inventions will be determined in accordance with United States patent laws for determining inventorship. In the event of a dispute regarding inventorship, if the Parties are unable to resolve such inventorship dispute, the Parties will establish a procedure to resolve such dispute, which may include engaging a Third Party patent attorney jointly selected by the Parties to resolve such dispute.

7.2 **Disclosure of Patentable Inventions**. ALZA will promptly notify TMC in writing of any Future ALZA Patents. TMC will promptly notify ALZA in writing of any TMC Patents.

7.3 **Prosecution of Licensed Patents**.

7.3.1 ALZA Prosecution and Enforcement of Future ALZA Patents. ALZA will own and retain all rights, title and interest to Future ALZA Patents, subject to this Agreement. ALZA will be responsible for, and will bear the expenses for all filing, prosecution, issuance and maintenance of Future ALZA Patents. ALZA retains all rights to defend and enforce Future ALZA Patents at ALZA's sole cost and expense.

7.3.2 TMC Prosecution of Licensed Patents.

(a) As of the Effective Date, TMC will be responsible for and will bear the expenses for all filing, prosecution, issuance and maintenance of all Licensed Patents.

(b) TMC will use good faith efforts to file patent applications to protect and cover the ALZA Inventions. TMC will file the patent applications based on such ALZA Inventions, and any additional Patents claiming priority to Licensed Patents that are filed by TMC, in ALZA's name. Such patent applications will be assigned to ALZA or an Affiliate of ALZA, will be approved in writing by ALZA prior to filing, and will be included in the Licensed Patents licensed hereunder, and TMC will bear all costs of preparation, filing, prosecution, issuance and maintenance thereof. TMC will use reasonable efforts to file initially all such patent applications in the United States and as a Patent Cooperation Treaty application with the Worldwide Intellectual Property Organization ("WIPO") designating all countries, filing at the very least in the United States, France, Japan, United Kingdom, Germany, Italy and Spain. TMC agrees to use reasonable efforts to ensure that any such Patents filed outside of the United States prior to a United States filing will be in a form sufficient to establish the date of original filing as a priority date for the purposes of a subsequent United States filing. All such Patent filings will be made in accordance with local foreign filing license requirements. In furtherance of and not in limitation of the foregoing, TMC will provide ALZA with a draft copy of each United States, foreign and WIPO patent application to be filed by it relating to the ALZA Inventions or claiming priority to the Licensed Patents in order, and sufficiently in advance, to obtain comments from ALZA's patent counsel, as well as a list of countries in which such applications will be filed at least [**] in advance of TMC's estimated filing date. TMC will provide to ALZA

as filed copies of all such United States and WIPO patent applications promptly after the filing of such applications.

(c) TMC will use good faith efforts to prosecute to allowance the Licensed Patents and to seek the broadest claims within and outside the Field for all inventions described in the Licensed Patents and defend against oppositions filed against the grant of the Licensed Patents, and upon and after the grant of any letters patent based on any such ALZA Inventions or Licensed Patents in any country where it files patent applications, maintain such letters patent in force by duly filing all necessary papers and paying any fees required for such purpose by the patent laws of the particular country in which such letters patent was granted. TMC will consult with ALZA on all such Licensed Patents, in a timely manner so that ALZA's comments can be duly considered and incorporated by TMC, and will disclose to ALZA the complete text of all such Licensed Patents and provide ALZA with copies of all material correspondence with the applicable patent office and any agent working on TMC's behalf that relate to such Licensed Patents. TMC will provide to ALZA a copy of each U.S. Patent and Trademark Office "Office Action," or its foreign equivalent, sufficiently in advance of the response due date, to obtain substantive comment of ALZA's patent counsel. TMC will consider in good faith ALZA's suggestions and recommendations regarding any such ALZA Inventions and Licensed Patents (such suggestions and recommendations not to be unreasonably delayed) before any action is taken, and in any event will obtain ALZA's prior approval for any filings, actions and decisions regarding such Licensed Patents listed in Category B (such approval not to be unreasonably withheld or delayed).

(d) (i) If, on a country by country basis in the Territory, TMC decides at any time to discontinue the prosecution or maintenance of any of the Licensed Patents, or has decided not to pursue the filing of any foreign counterpart of an existing Licensed Patent in a country where the Licensed Patents are not already filed in as of the Effective Date of this Agreement, in each case, TMC will promptly notify ALZA in writing and will take no action to file a replacement patent application thereof. Such notification will be given at least [**] prior to the date on which such patent application(s) or patent(s) will become abandoned. ALZA will then have the option to assume full responsibility, at its discretion and sole cost, for the filing, prosecution and maintenance of the affected patent applications(s) or patent(s) in such country or countries. TMC will provide such reasonable assistance as is reasonably necessary to allow

ALZA to assume the filing, prosecution and maintenance of such affected patent application(s) or patent(s), including executing any documents to reflect ALZA's interests therein. In the event TMC elects not to proceed with the filing, prosecution or maintenance of any such patent application or patent, then such affected patent application(s) or patent(s) and inventions embodied in such patent application(s) or patent(s) will be deemed to no longer be included as Licensed Patents with respect to those jurisdictions in which TMC has elected not to proceed with the filing, prosecution or maintenance of such patent application(s) or patent(s).

(ii) TMC will use good faith efforts to file patent applications based on ALZA Inventions in accordance with Section 7.3.2(b). In the event TMC elects not to proceed with the filing of any patent application for:

(A) any commercially significant patentable invention in the Field contained in any ALZA Invention(s), ALZA will have the right to file and prosecute patent application(s) or patent(s) in respect of such ALZA Invention(s), to the extent set forth in subsection (iv) below, and such patent application(s) or patent(s) will be deemed to no longer be included as Licensed Patents with respect to those jurisdictions in which ALZA has elected to proceed with the filing, prosecution or maintenance of such patent application(s) or patent(s).

(B) any patentable invention outside the Field contained in any ALZA Invention(s), ALZA will have the right to file and prosecute patent application(s) or patent(s) in respect of such ALZA Invention(s), and such patent application(s) or patent(s), to the extent not claiming inventions within the Field, will be deemed to no longer be included as Licensed Patents with respect to those jurisdictions in which ALZA has elected to proceed with the filing, prosecution or maintenance of such patent application(s) or patent(s).

(iii) Further, TMC will notify ALZA in writing prior to the issuance of any patent from the Licensed Patents and afford ALZA the opportunity to seek protection by filing patent applications for:

(A) any commercially significant patentable inventions in the Field that are embodied in the patent application from which the issued patent matures and for which TMC does not intend to seek protection, and any such ALZA-filed patent application will not be considered Licensed Patents to the extent set forth in subsection (iv) below with respect to those jurisdictions in which the ALZA-filed patent applications are filed.

(B) any patentable inventions outside the Field that are embodied in the patent application from which the issued patent matures and for which TMC does not intend to seek protection, and any such ALZA-filed patent application, to the extent not claiming inventions within the Field, will not be considered Licensed Patents with respect to those jurisdictions in which the ALZA-filed patent applications are filed.

(iv) In the event that (A) ALZA believes that TMC has failed to file a patent application claiming any commercially significant ALZA Invention(s), or (B) ALZA believes there are additional commercially significant patentable inventions embodied in any patent application from which a patent is expected to issue and for which TMC has elected not to file a subsequent patent application claiming priority to said patent application, then ALZA will so inform TMC, specifying with reasonable particularity the commercially significant invention that it believes TMC has failed to file on. In the event that TMC agrees with ALZA's assessment, TMC will proceed with the filing of a patent application claiming such invention and any resulting patent applications, and any patents issuing therefrom shall be included in the Licensed Patents. In the event that TMC disagrees with ALZA's assessment and elects not to file a patent application with respect to such invention in a particular jurisdiction, then ALZA will have the right to file for patent protection with respect to such inventions in such jurisdiction, and any patent claims that issue in such jurisdiction for such invention shall not be included within the Licensed Patents.

(e) In the event that a declaratory judgment action alleging invalidity of any of the Licensed Patents is brought against either Party, ALZA will have the right, but not the obligation, to assume the sole defense of the action at its own expense.

7.3.3 TMC Prosecution of TMC Patents. TMC will own and retain all rights, title and interest to TMC Patents, subject to the terms of this Agreement. TMC will be responsible for, and will bear the expenses for all filing, prosecution, issuance and maintenance of TMC Patents. TMC retains all rights to defend and enforce TMC Patents at TMC's sole cost and expense.

7.4 **Infringement Claims by Third Parties**.

7.4.1 Notice. If the manufacture, use or sale of any Product results in a claim or a threatened claim by a Third Party against a Party hereto for patent infringement or for inducing or contributing to patent infringement ("Infringement Claim"), the Party first having notice of an

Infringement Claim will promptly notify the other in writing. The notice will set forth the facts of the Infringement Claim in reasonable detail.

7.4.2 Defense. TMC will have the right but not the obligation to defend any suit resulting from an Infringement Claim at its expense. Upon TMC's request and in connection with TMC's defense of any such Infringement Claim, ALZA will provide reasonable assistance to TMC at TMC's cost for such defense. TMC will keep ALZA reasonably informed on a Quarterly basis, in person or by telephone, prior to and during the pendency of any such suit.

7.4.3 Settlement. In the event that the manufacture, use or sale of a Product in a country would infringe a Third Party Patent and a license to such Third Party Patent is available, and TMC in its sole discretion seeks such a license, the Parties agree that TMC will be responsible for all costs associated with acquiring such Third Party license.

7.5 **Infringement Claims Against Third Parties**.

7.5.1 Cooperation. ALZA and TMC each agree to take reasonable actions to protect Licensed Patents from infringement in the Field. If one Party brings any such action or proceeding, the other Party may be joined as a Party plaintiff if necessary for the action or proceeding to proceed and, in case of joining, the other Party agrees to give the first Party reasonable assistance (and to execute all necessary and appropriate documents) and authority to file and to prosecute such suit. In the case of any such joinder, the other Party will be reimbursed for any costs associated with its participation. The Parties will keep each other informed of the status of their respective activities regarding any litigation or settlement thereof concerning Products in the Field.

7.5.2 Notice. If any Licensed Patent is infringed in the Field by a Third Party in any country in connection with the manufacture, use and/or sale of a Product in such country, the Party to this Agreement first having knowledge of such infringement, or knowledge of a reasonable probability of such infringement, will promptly notify the other in writing. The notice will set forth the known facts of such infringement in reasonable detail.

7.5.3 Institution of Proceedings.

(a) ALZA has the first right, but not the obligation, to bring and control an action to enforce Licensed Patents, whether the infringement has occurred in the Field or not; provided, however, that TMC will be entitled to join and participate in any such action to the extent the alleged infringement is in the Field, provided that ALZA will maintain control of

and direction of such action. If ALZA does not bring an action against the alleged infringer within 60 days after written notice from TMC, TMC may bring and control such an action with respect to infringement in the Field; provided, however, that ALZA will be entitled to join and participate in any such action. If TMC enforces Licensed Patents, TMC will not enter into any settlement that diminishes the rights or interests of ALZA outside of the Field or has an adverse effect on any Licensed Patent without ALZA's written consent. ALZA and TMC will each be represented by their own counsel at their own expense. The expense of the Parties in bringing suit will first be reimbursed out of any moneys recovered, with the Party bringing the suit being reimbursed first. The balance of any recovery for infringement in the Field will be distributed: (a) to TMC in an amount equal to its lost profits or a reasonable royalty on the sales of the infringer (whichever measure of damages were applied) with respect to the portion (percentage) of the total recovery that is reasonably related to infringement in the Field; provided, however, that TMC will pay to ALZA in an amount equal to the royalties and other fees due ALZA based on such sales (if a sales of the infringer measure of damages is applied) or a reasonable approximation of the royalties and other fees that TMC would have owed to ALZA on sales of products that TMC lost to the infringer (if a lost profits measure of damages is applied) based upon the recovery distributed to TMC; and then (b) [**] to ALZA with respect to the portion (percentage) of the total recovery that was reasonably related to infringement outside the Field. The balance, if any, remaining after TMC has been compensated for lost profits or lost sales within the Field and ALZA has been compensated for lost royalties in respect of infringement within the Field and ALZA has recovered all direct damages in respect of infringement outside the Field will be divided as follows: [**] to ALZA and [**] to TMC with respect to the portion (percentage) of the total recovery that is reasonably related to infringement in the Field and [**] to ALZA with respect to the portion (percentage) of the total recovery that is reasonably related to infringement outside the Field.

(b) ALZA will have the right, but not the obligation, to bring and control an action to enforce Licensed Patents outside the Field for ALZA's sole recovery; provided, however, that to the extent the alleged infringement is due to a Third Party product comprising a Microprojection System utilizing one or more driving sources (including, but not limited to, delivery systems that utilize one or more driving sources such as electrical potential gradients, sound waves, heating systems, laser energy, hydraulic systems, radio waves) for

delivery of a compound for which ALZA then has exclusivity obligations to TMC pursuant to Section 14.2, and at such time TMC is actively working on a Product for delivery of such compound utilizing a Microprojection System, TMC will have the right to request that ALZA initiate an enforcement action against the alleged infringer to halt such infringement. TMC will be entitled to join and participate in any such action against such alleged infringer provided that ALZA maintains control of and direction of such action. If ALZA does not bring an action against the alleged infringer within 60 days after a request by TMC to do so, TMC may bring and control such an action with respect to such infringement. ALZA will be entitled to join and participate in any such action against the alleged infringer. TMC will not enter into any settlement that diminishes the rights or interests of ALZA outside of the Field or has an adverse effect on any Licensed Patent without ALZA's written consent. ALZA and TMC will each be represented by their own counsel at their own expense. The expense of the Parties in bringing suit against the alleged infringer will first be reimbursed out of any moneys recovered, with the Party bringing the suit being reimbursed first. The balance of any recovery will be distributed: (a) to TMC in an amount equal to its lost profits or a reasonable royalty on the sales of the infringer (whichever measure of damages is applied) with respect to the portion (percentage) of the total recovery that were reasonably related to the infringement; provided, however, that TMC would pay to ALZA an amount equal to the royalties and other fees due ALZA based on such sales (if a sales of the infringer measure of damages is applied) or a reasonable approximation of the royalties and other fees that TMC would have owed to ALZA on sales of products that TMC lost to the infringer (if a lost profits measure of damages is applied) based upon the recovery distributed to TMC; and then (b) [**] to ALZA with respect to the portion (percentage) of the total recovery that is reasonably related to the damages suffered by ALZA (i.e., lost sales of ALZA products outside the Field). Any amount remaining from the recovery would be divided as follows: [**] to ALZA and [**] to TMC.

(c) Notwithstanding anything in this Section 7.5.3 to the contrary, neither ALZA (or any of its licensees, Affiliates, or assignees) nor TMC (or any of its Sublicensees, Affiliates, or assignees) will bring an action or join in any action to enforce certain Licensed Patents against [**] to the extent ALZA is so contractually obligated; provided, however, that ALZA will use commercially reasonable efforts in its negotiations with [**] in connection with the agreement contemplated in Section 3.3.2 above to identify which Licensed

Patents are subject to the obligations described in Section 4.6 of the [**] Agreement and ALZA will keep TMC reasonably informed (as reasonably requested by TMC) regarding the progress and substance of such negotiations with regard to such issue, and ALZA will consider in good faith TMC's comments regarding the terms proposed for such issue but ALZA will not be obligated to incorporate TMC's comments. If ALZA reaches agreement with [**], ALZA will promptly notify TMC of the identity of the Licensed Patents that are subject to Section 4.6 of the [**] Agreement, if any.

7.6 **Regulatory Listings and Notices Relating to the Act** . TMC will have the right to include the Licensed Patents in any list that TMC provides in any regulatory filing worldwide relating directly to a Product, such as an NDA or 505(b)(2) filing in the United States, or their foreign equivalent, after receiving ALZA's prior written approval. TMC will immediately, and in no event later than five (5) business days, give written notice to ALZA of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" (hereinafter the "Act"), including, but not necessarily limited to, notices pursuant to §§101 and 103 of the Act from persons who have filed an abbreviated NDA ("ANDA") or a "paper" NDA, based on an NDA filed by TMC relating to a Product, claiming that a Licensed Patent is invalid or unenforceable or that infringement will not arise from the manufacture, use or sale of any Product by a Third Party. ALZA will have the first right, but not the obligation, to bring and control an action to enforce the Licensed Patent; provided, however, that TMC will be entitled to join and participate in any such action to the extent any alleged infringement were in the Field so long as ALZA maintains control of and direction of such action. ALZA and TMC will each be represented by their own counsel at their own expense. If ALZA does not bring an action against the alleged infringer within forty (40) days after written notice to TMC of the certification, then TMC will have the right to bring and control such an action with respect to infringement in the Field in accordance with Section 7.5.3(a)(1) above.

7.7 **Patent Term Extensions** . After filing an application for Regulatory Approval for a Product, TMC will provide to ALZA a written list specifying all Licensed Patents that it is in good faith considering to be the subject of a patent extension with respect to such Product. After receiving Regulatory Approval for the Product, TMC will identify one Licensed Patent in the country in the Territory where the Product was approved and will have the right to request that ALZA file, at TMC's expense, an application and take all reasonable actions necessary to obtain

a patent extension pursuant to 35 USC 156, or like foreign statutes such as for a Supplementary Certificate of Protection of the Member States of the European Union, for such Licensed Patent and ALZA agrees to respond to such request within ten (10) business days. If ALZA fails to respond to such request (or notifies TMC that it is declining to pursue such patent extension) within such ten (10) business day period, or if having notified TMC that it intends to pursue such patent extension, fails to promptly take such action, then TMC will have the right on behalf of ALZA to file such application and take all such actions necessary to obtain such patent extension. For purposes of clarity, TMC and ALZA agree that if such Licensed Patent selected by TMC for patent extension could be the subject of a patent extension with respect to a Product for which ALZA or any of its Affiliates has received Regulatory Approval then ALZA will have the sole right to determine whether such Licensed Patent will be used to obtain a patent extension for such ALZA Product or for TMC's Product. TMC and ALZA agree to cooperate with one another in obtaining such extension and use reasonable efforts to take all such actions necessary to obtain such patent extension at TMC's cost.

7.8 **Marking .** TMC, and its Sublicensees and Affiliates, will mark all Products made under this Agreement with a notice in accordance with 35 USC 287 and similar marking provisions in countries other than the United States in the Territory.

7.9 **Entitlement Action**.

[**]

ARTICLE 8 — INDEMNIFICATION.

8.1 **Indemnification**.

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8.1.1 Indemnification by TMC. TMC will indemnify, defend and hold ALZA and its Affiliates and any of their agents, employees and directors (the "ALZA Indemnitees") harmless from and against any and all liability, damage, claim, loss, cost or expense, including reasonable attorneys' fees ("Losses") arising out of claims by Third Parties: (i) relating to the design, development, manufacture, use, handling, storage, sale or other disposition of any Microprojection System or any Product in the Field if such claims arise from the use or application of Microprojection Systems or Products by or on behalf of TMC, its Affiliates or Sublicensees after the Effective Date; (ii) arising from TMC's breach of the Agreement; (iii) arising from activities occurring on or after the Effective Date with respect to agreements entered

into by ALZA and Third Parties (and transferred to TMC pursuant to this Agreement) regarding the development of any Microprojection System or Product; or (iv) arising from TMC's negligence or willful misconduct, except, in each case, to the extent such Losses arise from claims by Third Parties covered by ALZA's indemnification obligations specified in Section 8.1.2.

8.1.2 Indemnification by ALZA. ALZA will indemnify, defend and hold TMC and its Affiliates and any of their agents, employees and directors ("TMC Indemnitees") harmless from and against any and all Losses arising out of claims by Third Parties: (i) based on activities occurring prior to the Effective Date with respect to ALZA's development of Microprojection Systems or Products in the Field (other than claims relating to (x) product liability or patent infringement in the Field or (y) other matters relating to the design or development of Microprojection Systems or Products if in the case of either clause (x) or (y) such claims arise from the use or application of Microprojection Systems or Products after the Effective Date ("Excluded Claims")), (ii) arising from ALZA's breach of this Agreement; or (iii) arising from ALZA's gross negligence or willful misconduct (other than Excluded Claims); except, in each case, to the extent such Losses arise from claims by Third Parties covered by TMC's indemnification obligations specified in Section 8.1.1.

8.1.3 Indemnification Procedure.

(a) Whenever any Loss is asserted against or incurred by a TMC Indemnitee or ALZA Indemnitee (the "Indemnified Party"), the Indemnified Party will give written notice thereof (a "Claim") to ALZA or TMC, respectively (the "Indemnifying Party"). The Indemnified Party will furnish to the Indemnifying Party in reasonable detail such information as the Indemnified Party may have with respect to the Claim. The failure to give such notice will not relieve the Indemnifying Party of its indemnification obligations under this Agreement, unless the failure to give such notice is materially prejudicial to an Indemnifying Party's ability to defend such action.

(b) Within [**] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, and at its expense, undertake the defense of Claims with attorneys of its own choosing. In the event the Indemnifying Party does not assume control of such defense, the Indemnified Party may undertake the defense of the Claim.

(c) The Party not controlling such defense may participate therein at its own expense; provided that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party will be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith; provided further, however, that in no event will the Indemnifying Party be responsible for the fees and expenses of more than one counsel in any one jurisdiction for all Indemnified Parties.

(d) The Party controlling such defense will keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and will consider recommendations made by the other Party with respect thereto.

(e) The Indemnified Party will not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which will not be unreasonably withheld. The Indemnifying Party will not consent to entry of any judgment or enter into any settlement that admits fault on the party of the Indemnified Party, except with the consent of the Indemnified Party, which such consent will not be unreasonably withheld or delayed. In the event the Indemnified Party refuses to consent to the entry of a judgment or a settlement for which the Indemnifying Party is solely and entirely responsible and has indicated its sole and entire responsibility in writing to the Indemnified Party, following such refusal, the liability of the Indemnifying Party to the Indemnified Party will be fixed at the amount of any money damages provided in the proposed judgment or settlement.

8.2 **Insurance Proceeds**. Any indemnification hereunder will be made net of any insurance proceeds recovered by the Indemnified Party; provided, however, that if, following the payment to the Indemnified Party of any amount under this Article 8, such Indemnified Party recovers any insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party will promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such indemnification payment) to the Indemnifying Party.

8.3 **Insurance**. TMC will use all commercially reasonable efforts to maintain insurance, including product liability insurance, with respect to its activities hereunder. Such

insurance will be in such amounts and subject to such deductibles as the Parties may agree, based upon standards prevailing in the industry at the time.

8.4 **Future Litigation Regarding Development Agreements.** In the event that any litigation arises with respect to any of the Development Agreements, at ALZA's request, TMC will cause former ALZA employees or consultants that are then employed by or consulting for TMC or its Affiliates to provide reasonable assistance to ALZA in connection with such litigation, including giving testimony. ALZA will not be required to compensate TMC or such former employees or consultants for their time and expense in providing such assistance; provided, however, that ALZA will reimburse such employees or consultants for travel costs incurred in connection with the provision of such assistance at ALZA's request in accordance with the then-current Johnson & Johnson travel reimbursement policy. ALZA will cover its own expenses regarding such litigation including meetings with and preparation of such TMC employees prior to such employees providing testimony. To the extent such employees want or require their own legal assistance, it will be at their sole cost and expense.

ARTICLE 9 — RIGHT OF FIRST NEGOTIATION FOR PTH PRODUCT

9.1 **ALZA Rights Regarding PTH Product.** On the terms set forth in this Article 9, ALZA (or its designated Affiliate) will have a right of first negotiation to an agreement whereby ALZA (or its designated Affiliate) would obtain from TMC, for mutually agreed consideration, an exclusive, worldwide license, with the right to sublicense, to make, have made, use, import, sell, offer for sale and have sold any PTH Product developed by or on behalf of TMC. TMC will not enter into, or enter into discussions or negotiations regarding, an agreement with a Third Party to make, have made, use, import, sell, offer for sale or have sold any PTH Product unless and until TMC has provided notice to ALZA pursuant to Section 9.2 and complied with the other procedures set forth in Sections 9.2 – 9.7.

9.2 **TMC Notice Regarding PTH Product.** At any time after the earlier of (i) TMC's receipt of the FDA minutes from its End of Phase I Meeting with the FDA regarding the PTH Product or (ii) equivalent written communication from the FDA responding to questions submitted in the TMC End of Phase I Meeting request regarding the PTH Product or (iii) the expiration of thirty (30) days following the submission by TMC to the FDA of a protocol for the Phase II study of the PTH Product without a written response from the FDA (in the event that the

FDA does not hold an End of Phase I Meeting and does not respond to questions submitted by TMC in its request for an End of Phase I Meeting); provided that in no event shall the time determined under Section 9.2(i)-(iv) be earlier than January 1, 2007, if TMC decides to seek a partner for further development or Commercialization of the PTH Product, TMC will provide notice in writing to ALZA of such intention. Together with such notice, TMC will deliver to ALZA all final study reports of all preclinical and clinical studies regarding the PTH Product conducted prior to such date, and (ii) such other data or information, if any, which is then Controlled by TMC or its Affiliates and which is, in TMC's reasonable estimation, reasonably necessary to permit ALZA (or its Affiliates) to evaluate whether to enter into an agreement regarding the development or Commercialization of the PTH Product (the "PTH Product Notice Package").

9.3 **Decision Regarding PTH Product.** Within 10 calendar days of its receipt of the PTH Product Notice Package, ALZA will inform TMC if it believes any additional information is required to reasonably evaluate the PTH Product opportunity. If ALZA believes additional information is required, it will provide TMC with a detailed list of such additional item(s) of information it is requesting, and in the event that TMC agrees that such additional item(s) of information are reasonably required to evaluate the PTH Product opportunity (such agreement not to be unreasonably withheld or delayed) and such additional items of information are reasonably accessible to TMC, TMC will promptly endeavor to provide such information to ALZA. Within 30 calendar days after ALZA's receipt of the PTH Product Notice Package, or in the event TMC agrees to provide ALZA additional information, within 20 days of TMC's delivery of such additional information to ALZA, ALZA will provide TMC with notice either that (i) ALZA would not like to negotiate an agreement regarding the PTH Product or (ii) ALZA would like to negotiate an agreement regarding the PTH Product. If ALZA fails to deliver any notice within such 30-day period, ALZA will be deemed to have provided notice that it would not like to negotiate an agreement regarding the PTH Product. Notwithstanding anything in Article 9 to the contrary, TMC may not provide any information regarding the PTH Product that was available at the time TMC provided the PTH Product Notice to ALZA (or became available during the period TMC was negotiating with ALZA pursuant to Section 9.5) and that was not included in the PTH Product Notice Package or provided to ALZA pursuant to Section 9.3 to any

Third Party for the purpose of discussing an agreement with such Third Party for the continued development or Commercialization of the PTH Product.

9.4 **No Negotiation of PTH Product.** If ALZA notifies TMC that it would not like to negotiate with TMC for an agreement regarding the PTH Product (or is deemed to have done so), ALZA will have no further rights to the PTH Product and TMC will have no further obligations to ALZA with respect to such PTH Product, in each case, except as provided in Section 9.7.

9.5 **Good Faith Negotiation Regarding PTH Product.** If ALZA notifies TMC that ALZA or any of its Affiliates would like to negotiate with TMC, the Parties will negotiate exclusively with each other in good faith for a period of [**] following such notice for a letter of intent covering an arrangement pursuant to which ALZA or its Affiliate will obtain worldwide rights for further development, licensing and marketing of the PTH Product. The arrangement will include the transfer to ALZA or its Affiliate ownership of any and all data, results, regulatory filings or Regulatory Approvals relating to the PTH Product obtained or Controlled by TMC. The [**] negotiation period may be extended by mutual agreement of the Parties. During any period of time in which the Parties are negotiating in good faith, TMC will provide ALZA with any additional material data and information developed by or on behalf of TMC during such time pertaining to the PTH Product.

9.6 **No Agreement Regarding PTH Product.** If the Parties are unable to reach an agreement upon the terms of such letter of intent within such [**] period despite good faith negotiations during the [**] period or, if after reaching agreement upon a letter of intent the Parties are unable to enter into a definitive agreement regarding the PTH Product despite an additional [**] period of good faith negotiations (and any agreed extension thereof), TMC will have the right (i) to develop and market the PTH Product through its own in-house marketing and sales organization (or that of its Affiliates) on a worldwide basis, or (ii) to pursue an agreement with a Third Party for the continued development or Commercialization of the PTH Product so long as such Third Party agreement is not on terms which, when taken as a whole, are materially less favorable for TMC than the last proposal TMC made to ALZA (or its Affiliate) during the negotiation period (or any agreed extension thereof).

9.7 **Additional Rights Regarding PTH Product.** In the event that TMC decides not to seek a partner for further development or Commercialization of the PTH Product prior to the unblinding of data for the first Phase II clinical trial of the PTH Product, or in the event that

ALZA (or its Affiliate) and TMC do not enter into an agreement regarding the PTH Product following ALZA's receipt of the PTH Product Notice Package and TMC does not enter into an agreement with a Third Party for the continued development or Commercialization of the PTH Product prior to the unblinding of data for the first Phase II clinical trial of the PTH Product, then following completion of the first study report for the first Phase II clinical trial of the PTH Product that includes statistical analysis showing the positive statistical significance of the PTH Product against the primary endpoint established in the protocol for such trial, TMC will be obligated to provide to ALZA a PTH Product Notice Package, including all additional data developed regarding the PTH Product up to such date, and the provisions of this Article 9 will again apply to the PTH Product; provided that (i) if the final study report for such Phase II clinical trial is not materially different in its conclusions or the data presented from the initial draft report provided to ALZA, the 30-day time period specified in Section 9.3(i)-(ii) for ALZA to provide notice to TMC will be reduced to 15 days and will not commence with the receipt of such PTH Product Notice Package but will instead commence upon receipt by ALZA of the final study report for such Phase II clinical trial, or (ii) if the final study report for such Phase II clinical trial is materially different in its conclusions or the data presented from the initial draft report provided to ALZA, the 30-day time period specified in Section 9.3(i)-(ii) for ALZA to provide notice to TMC will remain 30 days and will not commence with the receipt of such PTH Product Notice Package but will instead commence upon receipt by ALZA of the final study report for such Phase II clinical trial. Similarly, in the event that TMC decides not to seek a partner for further development or Commercialization of the PTH Product prior to the unblinding of data for the first Phase III clinical trial of the PTH Product, or in the event that ALZA (or its Affiliate) and TMC do not enter into an agreement regarding the PTH Product following ALZA's receipt of the PTH Product Notice Package and TMC does not enter into an agreement with a Third Party for the continued development or Commercialization of the PTH Product prior to the unblinding of data for the first Phase III clinical trial of the PTH Product, then following completion of the first study report for the first pivotal Phase III clinical trial of the PTH Product that includes statistical analysis showing the positive statistical significance of the PTH Product against the primary endpoint established in the protocol for such trial, TMC will be obligated to provide to ALZA a PTH Product Notice Package, including all additional data developed regarding the PTH Product up to such date, and the provisions of this Article 9 will again apply

to the PTH Product; provided that (i) if the final study report for such Phase III clinical trial is not materially different in its conclusions or the data presented from the initial draft report provided to ALZA, the 30-day time period specified in Section 9.3(i)-(ii) for ALZA to provide notice to TMC will be reduced to 15 days and will not commence with the receipt of such PTH Product Notice Package but will instead commence upon receipt by ALZA of the final study report for such Phase III clinical trial, or (ii) if the final study report for such Phase III clinical trial is materially different in its conclusions or the data presented from the initial draft report provided to ALZA, the 30-day time period specified in Section 9.3(i)-(ii) for ALZA to provide notice to TMC will remain 30 days and will not commence with the receipt of such PTH Product Notice Package but will instead commence upon receipt by ALZA of the final study report for such Phase III clinical trial.

9.8 **No Implied Rights.** For purposes of clarity, it is acknowledged and agreed that TMC need only provide one such initial notice and PTH Product Notice Package under Section 9.2, and that TMC is not obligated to provide any further notice if TMC subsequently engages in discussions with more than one Third Party with respect to the PTH Product prior to the unblinding of data for the first Phase II clinical trial of the PTH Product. Similarly, it is acknowledged and agreed that in the event TMC is required to offer the PTH Product to ALZA pursuant to Section 9.7 above, TMC need only provide one such notice and PTH Product Notice Package at the end of the first Phase II clinical trial with respect thereto, if applicable, and one such notice and PTH Product Notice Package at the end of the first Phase III clinical trial with respect thereto, each as required under Section 9.7, and that TMC is not obligated to provide any further notice if TMC subsequently engages in discussions with more than one Third Party with respect to the PTH Product.

ARTICLE 10 — OPTION FOR NESIRITIDE PRODUCT.

10.1 **Option for Nesiritide Product.** On the terms set forth in this Article 10, TMC hereby grants to ALZA and its Affiliates an exclusive, irrevocable option for a period commencing on the Effective Date and ending on a date that is the third anniversary of the Effective Date (the "Option Period"), to enter into good faith negotiations with TMC for a separate development and commercialization agreement with TMC, upon the terms and conditions set forth in Attachment 10.1, and such additional reasonable terms and conditions as

the Parties agree, covering the development, manufacture and commercialization of a Nesiritide Product.

10.2 **Exercise Of Option.** ALZA (or its Affiliates) may exercise its option by providing TMC with written notice within the Option Period of its desire to exercise such option. If ALZA (or its Affiliates) exercises its option within the Option Period described in Section 10.1, the Parties will commence good faith negotiations for a development and commercialization agreement upon the terms and conditions set forth in Attachment 10.1, and such additional reasonable terms and conditions as the Parties mutually agree, covering the development, manufacture and commercialization of a Nesiritide Product.

ARTICLE 11 — TMC'S RIGHT OF FIRST NEGOTIATION FOR EXPANDED LICENSE.

11.1 **ALZA Notice Regarding Expanded License.** Prior to entering into negotiations with or offering to any Third Party a license outside the Field under the Licensed Patents for delivery of therapeutic or prophylactic agents into or through the skin utilizing Microprojection Systems in combination with delivery systems that utilize a driving source (and such license were not related to a specific product or products or a specific energy based delivery system), ALZA will deliver notice to TMC of ALZA's intent to offer such license together with a description of the rights it is proposing to license in sufficient detail, in ALZA's reasonable estimation, to permit TMC to evaluate its interest in such opportunity.

11.2 **Decision Regarding Expanded License Negotiations.** Within 30 calendar days of TMC's receipt of such notice and description of rights, TMC will provide ALZA with notice either that (i) TMC would not like to negotiate such license or (ii) TMC would like to negotiate for the rights to such license. If TMC fails to deliver any notice within such 30-day period, TMC will be deemed to have provided notice that it would not like to negotiate such license.

11.3 **No Negotiation Regarding Expanded License.** If TMC notifies ALZA that it would not like to negotiate with ALZA for an agreement regarding such license (or is deemed to have done so), TMC will have no further rights to such license and ALZA will have no further obligations to TMC with respect to such license.

11.4 **Good Faith Negotiation Regarding Expanded License.** If TMC notifies ALZA within the 30 calendar day period that it would like to negotiate with ALZA for such license, the Parties will negotiate exclusively with each other in good faith for a period of [**] following

such notice for a letter of intent covering an arrangement pursuant to which TMC will obtain such license. The [**] negotiation period may be extended by mutual agreement of the Parties.

11.5 **No Agreement Regarding Expanded License.** If the Parties are unable to reach an agreement upon the terms of such letter of intent within such [**] period despite good faith negotiations during the [**] period or if after reaching agreement upon a letter of intent the Parties are unable to enter into a definitive license agreement despite an additional [**] period of good faith negotiations (or any agreed extension thereof), ALZA will have the right to pursue an agreement with a Third Party for such license so long as for a period of [**] following the termination of the negotiations between ALZA and TMC, such Third Party license is not on terms which, when taken as a whole, are materially less favorable for ALZA than the last proposal ALZA had made to TMC during the negotiation period (or any agreed extension thereof).

ARTICLE 12 — TMC'S RIGHT OF FIRST NEGOTIATION ON PRODUCTS UTILIZING MICROPROJECTION SYSTEMS OUTSIDE THE FIELD.

12.1 **ALZA Notice Regarding Collaboration.** Prior to entering into a collaboration with a Third Party to develop an ALZA product utilizing a Microprojection System in combination with any delivery system that utilizes an energy-based driving source, ALZA will deliver notice to TMC of its intent to enter into such collaboration together with a description of the proposed collaboration in sufficient detail, in ALZA's reasonable estimation, to permit TMC to evaluate its interest in such opportunity. Notwithstanding the foregoing, if after consulting with TMC regarding the proposed collaboration, ALZA reasonably determines that TMC's Microprojection Systems are not at such time suitable for ALZA's intended application, ALZA will so inform TMC and will meet with TMC to discuss the basis of its decision. Thereafter, TMC will have no further rights regarding such collaboration and ALZA will have no further obligations to TMC with respect to such collaboration.

12.2 **Decision Regarding Collaboration Negotiations.** Within 30 calendar days of TMC's receipt of such notice and written description of proposed collaboration, and if ALZA has not informed TMC that TMC's Microprojection Systems are not suitable for ALZA's intended application, TMC will provide ALZA with notice either that (i) TMC would not like to negotiate with ALZA for an agreement regarding such collaboration or (ii) TMC would like to negotiate with ALZA for an agreement regarding such collaboration. If TMC fails to deliver any notice

within such 30-day period, TMC will be deemed to have provided notice that it would not like to negotiate for an agreement regarding such collaboration.

12.3 **No Negotiation Regarding Collaboration.** If TMC notifies ALZA that it would not like to negotiate with ALZA for an agreement regarding such collaboration (or is deemed to have done so), TMC will have no further rights regarding such collaboration and ALZA will have no further obligations to TMC with respect to such collaboration.

12.4 **Good Faith Negotiations Regarding Collaboration.** If TMC notifies ALZA within the 30 calendar day period that it would like to negotiate with ALZA for an agreement regarding such collaboration, the Parties will negotiate exclusively with each other in good faith for a period of [**] following such notice for a letter of intent covering such collaboration. The [**] negotiation period may be extended by mutual agreement of the Parties.

12.5 **No Agreement Regarding Collaboration.** If the Parties are unable to reach an agreement upon the terms of such letter of intent within such [**] period despite good faith negotiations during the [**] period or if after reaching agreement upon a letter of intent the Parties are unable to enter into a definitive collaboration agreement despite an additional [**] period of good faith negotiations (or any agreed extension thereof), ALZA will have the right to pursue an agreement with a Third Party for such collaboration so long as for a period of [**] following the termination of the negotiations between ALZA and TMC, such Third Party license is not on terms which, when taken as a whole, are materially less favorable for ALZA than the last proposal ALZA had made to TMC during the negotiation period (or any agreed extension thereof).

ARTICLE 13 — TMC'S RIGHT TO MEET.

13.1 **TMC Proposal.** Beginning on a date that is 18 months after the Effective Date, TMC may notify ALZA on a nonconfidential basis that TMC would like to initiate good faith negotiations with ALZA to obtain a nonexclusive license of the Licensed Patents for the delivery of a specific therapeutic or prophylactic agent into or through the skin utilizing a Microprojection System in combination with a delivery system that utilizes a driving source other than iontophoresis. ALZA and TMC will meet at ALZA's facilities at a mutually agreeable time and date that is within 45 days of ALZA's receipt of such notice. At the meeting, TMC may present its proposal for such arrangement to ALZA on a nonconfidential basis. ALZA will not have any

additional obligations of any kind regarding such proposal or such product, including but not limited to, any obligation to negotiate in good faith or to respond in any way to such proposal or to agree to any form of additional license.

ARTICLE 14 — EXCLUSIVITY.

14.1 **TMC Exclusivity.** Notwithstanding anything in this Agreement to the contrary, beginning on the Effective Date and continuing until a date that is the later of (i) December 31, 2014, or (ii) the end of the period that ALZA, its Affiliates or sublicensees, have a Valid Patent Claim covering Natrecor® (nesiritide) or regulatory exclusivity (including any data package or marketing exclusivity) from any Regulatory Authority regarding Natrecor® (nesiritide) (collectively, the "Exclusivity Period"), or (iii) the date on which Natrecor® (nesiritide) is no longer being sold by ALZA or any ALZA Affiliate, TMC will not conduct (itself or with an Affiliate or a Third Party) any material development or Commercialization activities with respect to any Product (other than the Nesiritide Product with ALZA or its Affiliate as described in Section 10.2) incorporating nesiritide or any analog or derivative thereof.

In addition, beginning on the Effective Date and continuing until a date that is the later of (i) December 31, 2014, or (ii) the end of the Exclusivity Period anywhere in the Territory, TMC will not conduct (itself or with an Affiliate or a Third Party) any material development or Commercialization activities with respect to any Product (other than the Nesiritide Product with ALZA or its Affiliate as described in Section 10.2) incorporating any natriuretic peptide, stresscopin, urocortin, or any analog or derivative of a natriuretic peptide, stresscopin or urocortin in the Field.

14.2 **ALZA Exclusivity.**

14.2.1 Notwithstanding anything in this Agreement to the contrary, during such time as TMC is actively working on a PTH Product, ALZA will not conduct any material development or Commercialization activities with respect to any product for delivery of PTH into or through the skin via a Microprojection System in combination with a driving source (including, but not limited to, delivery systems that utilize one or more driving sources such as electrical potential gradients, sound waves, heating systems, laser energy, hydraulic systems or

radio waves), unless ALZA and TMC have entered into a separate agreement regarding such product.

14.2.2 Notwithstanding anything in this Agreement to the contrary, during the time beginning on the Effective Date and ending on the six month anniversary of the Effective Date (or such earlier date that TMC notifies ALZA of its selection of no more than two compounds as described below), ALZA will not conduct (itself or with an Affiliate or Third Party) any material development or Commercialization activities with respect to any product for delivery of human growth hormone (hGH), alpha-interferon (alpha-IFN), beta-interferon (beta-IFN), granulocyte colony stimulating factor (G-CSF), or desmopressin or any analog of any of the foregoing into or through the skin via a Microprojection System in combination with a driving source (including but not limited to, delivery systems that utilize one or more driving sources such as electrical potential gradients, sound waves, heating systems, laser energy, hydraulic systems or radio waves), unless ALZA and TMC have entered into a separate agreement regarding such product. On or prior to the six month anniversary of the Effective Date, TMC will notify ALZA that it has selected up to two compounds from the compounds listed above for which ALZA's exclusivity obligations to TMC as described above will continue thereafter for a period of two years from the Effective Date provided that such obligations will only remain in effect with respect to each compound selected by TMC pursuant to this Section 14.2.2 during the period when TMC is actively working on a Product for delivery of such compound. ALZA will have no continuing exclusivity obligations to TMC for the compounds not so selected.

14.2.3 TMC will inform ALZA of the status of its development projects pursuant to the annual development reports described in Section 3.6. If TMC terminates the active development of the PTH Product, it will so notify ALZA within 30 days of the termination of such program. If TMC begins active work on a Product for delivery of any of the compounds listed in Section 14.2.2 or terminates active work on a Product for delivery of any of the compounds listed in Section 14.2.2, it will so notify ALZA within 30 days of such initiation or termination of such work. If, at any time, TMC is not actively working on a Product for delivery of any of PTH, or one of the compounds listed in Section 14.2.2 (or TMC has not notified ALZA that it has commenced active work on such compound) and ALZA begins work on a product outside the Field for the delivery of such compound, ALZA will no longer have any obligation

under Section 14.2 regarding such compound, even if TMC later begins working on a Product for delivery of such compound in the Field.

ARTICLE 15 — TERM AND TERMINATION.

15.1 **Term.** This Agreement will commence on the Effective Date and will remain in effect until the expiration of TMC's obligation to make Product Payments for all Products, unless earlier terminated as provided in this Article 15 (the "Term"). TMC's license with respect to the ALZA Know-How will survive the expiration, (but not an earlier termination) of this Agreement.

15.2 **Termination of this Agreement by TMC for any Reason.** TMC may terminate this Agreement for any reason upon ninety (90) days advance written notice to ALZA.

15.3 **Termination by ALZA.** ALZA may terminate this Agreement if TMC or any of its Affiliates or Sublicensees initiates or voluntarily maintains, or participates in or, in the absence of a subpoena or other court order (a copy of which subpoena or court order will be promptly provided to ALZA if not prohibited under such subpoena or order), cooperates with any Third Party to initiate or maintain, any action or proceeding seeking a declaration or judgment of invalidity with respect to any of the Licensed Patents or to challenge the ownership or inventorship of any of the Licensed Patents. This clause is not intended to create any rights for TMC or any of its Affiliates or Sublicensees to participate in any actions not authorized by law.

15.4 **Termination By Either Party for Breach.** Either Party may terminate this Agreement in the event the other Party commits a material breach of any obligation of this Agreement. A material breach by TMC will include, but not be limited to, TMC's failure to satisfy any of its diligence obligations described in Sections 3.5 and 3.7.

15.5 **Effective Date of Termination.** For any breach other than a failure by TMC to pay when due any amount due hereunder, termination will become effective either (i) sixty (60) calendar days after the date of such notice unless TMC cures such material breach or withdraws or terminates such action or proceeding described in Section 15.3 during such sixty (60) day period (or, if such material breach, by its nature, is a curable breach that is not curable within such 60 day period, such longer period as would be reasonably necessary for a diligent party to cure such material breach), or (ii) immediately if such material breach, by its nature, is incurable or if TMC has failed to engage in Active Early Development on at least one additional Product

within 6 months following the date TMC terminates or suspends a development program, as described in Section 3.5.

For any breach consisting of a failure by TMC to pay when due any amount due hereunder, termination will become effective twenty (20) calendar days after the date of such notice unless ALZA receives all undisputed amounts due, together with all interest due and payable thereon, within such twenty (20) day period and, if any of the amount is in dispute, a notice specifying the disputed amount, together with a reasonably detailed explanation of the basis for such dispute.

15.6 **Termination for Bankruptcy.** This Agreement will terminate automatically without any notice to TMC in the event: (i) TMC is declared insolvent or bankrupt by a court of competent jurisdiction, (ii) a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against TMC and such petition is not dismissed within ninety (90) days after filing, or (iii) TMC makes or executes an assignment of substantially all of its assets for the benefit of creditors.

15.7 **Effect of Termination.**

15.7.1 Subject to Sections 15.7.2 and 15.7.3, in the event of termination under Section 15.2, Section 15.3, Section 15.4 or Section 15.6: all rights licensed herein will revert to ALZA and the license to ALZA in Section 2.2 will remain in full force and effect.

15.7.2 Notwithstanding Section 15.7.1, if the Agreement is terminated by ALZA due to TMC's failure to meet its specific diligence obligations described in Section 3.6.2 prior to the First Sale of the second Product to be Commercialized, the License and Agreement will be terminated with respect to all Products except (i) any Product that, on the effective date of termination, TMC is diligently Commercializing or that TMC is diligently developing and that has been introduced into a patient in a human clinical study and (ii) any Third Party Product in Active Early Development, Active Clinical Development or any later stage of development or Commercialization by TMC or its Sublicensee.

15.7.3 Upon termination of this Agreement for any reason following the First Sale of the second Product, any sublicense granted by TMC to a Sublicensee will survive termination only if all of the following conditions are met: (a) the Sublicensee is not then in default under the terms of its sublicense agreement; (b) the Sublicensee has a sublicense which was not granted by TMC in violation of this Agreement; (c) the Sublicensee has, at the time this

Agreement is terminated, at least one Third Party Product or other Product in Active Early Development, Active Clinical Development, or Commercialization and (d) the Sublicensee agrees in writing that: (i) ALZA will be entitled to enforce all relevant provisions of such sublicense agreement directly against such Sublicensee; (ii) ALZA will not assume, and will not be responsible to such Sublicensee for, any representations, warranties, or obligations of TMC to such Sublicensee (including, but not limited to, any obligations to manufacture for, or provide technology transfer to, the Sublicensee), other than to permit such Sublicensee to make, have made, import, use, sell, offer for sale and have sold Products under the Licensed Patents and ALZA Know-How to the extent such rights are sublicensed to such Sublicensee under the applicable sublicense agreement; (iii) ALZA will be responsible for the direction of the filing, prosecution, issuance and maintenance of all Licensed Patents and ALZA Inventions and the extension and maintenance of any such Patents, and the handling of such matters will be in ALZA's reasonable discretion; (iv) the royalties and non-royalty payments to ALZA by such Sublicensee in respect of each applicable Product and Third Party Product will be the greater of (x) what ALZA would have received from TMC under this Agreement in respect of such Sublicensee's activities with respect to such applicable Product or Third Party Product or (y) what such Sublicensee would have owed to TMC under its sublicense agreement; (v) the Sublicensee will pay its portion of ALZA's patent filing, prosecution, issuance and maintenance expenses related to the Licensed Patents which would otherwise have been borne by TMC under Section 7.3.2(a) of this Agreement, which expenses will be apportioned pro rata among each surviving Sublicensee; (vi) the Sublicensee will be subject to the same diligence obligations as TMC under Sections 3.6.1 and 3.8 of this Agreement with respect to Sublicensee's Product(s); and (vii) the Sublicensee may not exercise its rights to make, have made, import, use, sell, offer for sale and have sold Products under the Licensed Patents and ALZA Know-How (to the extent such rights are sublicensed to such Sublicensee under the applicable sublicense agreement) for any Products that are not in Active Early Development, Active Clinical Development or Commercialization at the time this Agreement is terminated. ALZA may require any Sublicensee that is a party to a sublicense agreement that survives termination of this Agreement pursuant to this Section 15.7.3 to enter into a direct license with ALZA to replace such sublicense agreement on terms that are substantially identical to the terms set forth in such sublicense agreement with such changes as are necessary to implement the standards set forth in this Section 15.7.3(c)(i)-

(vii). If ALZA desires to enter into a direct license with a Sublicensee, ALZA will provide written notification to such Sublicensee and will, for a period of ninety (90) days after providing such notice, negotiate in good faith with such Sublicensee for a direct license under the Licensed Patents, Future ALZA Patents, and ALZA Know-How, in each case, to the extent such rights were sublicensed from TMC to such Sublicensee in the sublicensed field. It is understood and agreed that the sublicense agreements held by any such Sublicensee will survive commencing on termination of this Agreement and, should ALZA desire to enter into a direct license with such Sublicensee, end after the 90 day negotiation period described above.

15.7.4 Also in the event of termination under Section 15.2, Section 15.3, Section 15.4, or Section 15.6, for any Products (excluding Third Party Products and any Products sublicensed to Sublicensees whose sublicenses survive in accordance with Section 15.7.3) for which TMC's rights have terminated, TMC will, at ALZA's request, negotiate in good faith, on commercially reasonable terms, for ALZA to obtain (i) the right and license, with the right to sublicense, to use, cross-reference and access all regulatory submissions and Regulatory Approvals regarding such Products and all preclinical data, clinical data and regulatory information regarding such Products, and (ii) a worldwide, sublicensable exclusive license to TMC Patents and know-how, in each case, solely to the extent required by ALZA (or its designated Affiliate) to make, have made, use, sell, have sold, offer to sell and import such Products. TMC will execute and deliver further instruments and the Parties will take such other actions as may be reasonably required to carry out the intent and purposes of this Section 15.7.4, including assignment to ALZA (or its designated Affiliate).

15.8 **No Waiver.** The right of a Party to terminate this Agreement, as provided in this Article 15 will not be affected in any way by its waiver or failure to take action with respect to any prior default.

15.9 **Consequences of Termination.** Except as otherwise provided herein, upon expiration or termination of this Agreement, all remaining records and materials in its possession or control containing the other Party's Confidential Information and to which the former Party does not retain rights hereunder, will promptly be returned or destroyed, at the other Party's request. Notwithstanding the foregoing, (i) one copy of such records may be retained by legal counsel for the former Party solely for evidentiary purposes, (ii) TMC will have no obligation to return ALZA Confidential Information to the extent such information (x) is necessary to develop

and Commercialize a Product for which TMC has a Product-specific license under this Agreement, or (y) TMC has previously sublicensed the right to develop and Commercialize a Product to a Sublicensee and such sublicense survives the termination of this Agreement pursuant to Section 15.7.3.

15.10 **[**]**

15.11 **Survival of Obligations.** The termination or expiration of this Agreement will not relieve the Parties of any obligations accruing prior to such termination, and any such termination will be without prejudice to the rights of either Party against the other. The provisions of Sections 2.2, 4.5, 5.6, 5.7, 5.8, 5.9, 7.5.3(a)-(b) (with respect solely to the allocation of any recovery and not with respect to the institution of proceedings for infringement actions (i) filed prior to termination or expiration of this Agreement or (ii) pertaining to the acts of infringement occurring during the Term), 15.7, 15.9 – 15.12, 16.5.2, 16.6 and Articles 1, 6, 8, 17 and 18 will survive any termination of this Agreement.

15.12 **Termination Not Sole Remedy.** Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as expressly agreed to otherwise herein.

ARTICLE 16 — REPRESENTATIONS AND WARRANTIES.

16.1 **Authority.** Each Party represents and warrants that as of the Effective Date, it has the full right, power and authority to enter into this Agreement and that this Agreement has been duly executed by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable in accordance with its terms.

16.2 **No Conflicts.** Each Party represents and warrants that the execution, delivery and performance of this Agreement by such Party does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

16.3 **ALZA Representations.** TMC and ALZA acknowledge and agree that Pete Daddona, [**] (the "**Former ALZA Business Managers**") were employees of ALZA or ALZA Affiliates and were closely involved in the management and operations of the Macroflux® group at ALZA. Accordingly, ALZA will in no event be liable to TMC, TMC Indemnitees or any other

party for any breach of ALZA's representations and warranties contained in the Agreement to the extent that any such Former ALZA Business Managers had, or reasonably should have had as a result of their involvement with the Macroflux® business prior to the Effective Date, knowledge of any material fact or facts which reasonably gives rise to such breach or knowledge, as of the Effective Date, that ALZA was making a material misstatement, omission, misrepresentation, or inaccuracy herein, or was in breach of any of the representations or warranties contained in the Agreement. The Parties agree that in any dispute or legal proceeding, TMC will bear the burden of proof that no such Former ALZA Business Manager had knowledge (or should not reasonably have had such knowledge) of such breach or of the material facts giving rise to such breach. Subject to the foregoing, ALZA hereby represents and warrants to TMC, as of the Effective Date.

16.3.1 ALZA has the lawful right to grant the License.

16.3.2 Except as disclosed in Attachment 1.10, ALZA has not previously assigned, transferred, conveyed or otherwise encumbered its rights, title and interest in the Licensed Patents and Trademarks and there are currently no existing license agreements for the Licensed Patents and Trademarks that are in conflict with the Licenses.

16.3.3 To ALZA's actual knowledge as of the Effective Date (without any inference or duty of investigation), it owns and Controls all right, title and interest in and to the ALZA Know-How and the patents and patent applications listed on Attachment 1.22, subject to rights granted in the [**] Agreement.

16.3.4 Except for the matters disclosed in Attachment 16.3.4, ALZA has received no written notice of any claim by any Third Party that (a) such Third Party has any rights to the Licensed Patents in the Field that prevent ALZA from granting to TMC the License or (b) the Licensed Patents (to the extent representing issued Patents) are invalid or unenforceable.

16.3.5 To ALZA's actual knowledge as of the Effective Date (without any inference or duty of investigation), ALZA has not received any written notice or other written communication from any Third Party regarding any breach by ALZA of its obligations under any of the agreements listed on Attachment 3.3.1.

16.3.6 Except for the matters disclosed in Attachment 16.3.4, to ALZA's actual knowledge as of the Effective Date (without any inference or duty of investigation), there is no

litigation threatened, impending or existing against ALZA or to which ALZA is a party relating to the Licensed Patents or Trademarks.

16.3.7 ALZA has made available to TMC true and correct copies of the Product Development Agreements and the [**] Agreement.

16.3.8 To ALZA's actual knowledge as of the Effective Date (without any inference or duty of investigation) there have been no FDA inspections of clinical studies conducted by ALZA or manufacturing facilities for the manufacture of clinical supplies, in each case, regarding the PTH Product and ALZA's activities regarding the PTH Product have been and are being conducted in substantial compliance with all applicable laws and regulations.

16.3.9 To ALZA's actual knowledge as of the Effective Date (without any inference or duty of investigation), neither ALZA nor any of its officers, employees or agents has made an untrue statement of a material fact or fraudulent statement to the FDA or any other Regulatory Authority or failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority regarding the PTH Product.

16.3.10 To ALZA's actual knowledge, in the course of the clinical development of the PTH Product over the past [**], ALZA has not used any employee or consultant who (at the time such employee or consultant provided services to ALZA with respect to such products) was debarred by the FDA or the subject of pending disbarment proceedings by the FDA.

16.4 **No Implication By ALZA.** Except as expressly stated herein, nothing in the Agreement will be construed as:

16.4.1 A warranty or representation by ALZA as to the validity or patentability or scope of any of the Licensed Patents or the ALZA Know-How;

16.4.2 A warranty or representation by ALZA that anything that has been or will be made, used, sold, offered for sale, or imported under the License provided herein is or will be free from infringement of patents of Third Parties;

16.4.3 An obligation on the part of ALZA to bring or prosecute actions or suits against Third Parties for infringement of any of the Licensed Patents or for entitlement of any patents or applications that relate to the [**]; or

16.4.4 A grant by implication, estoppel, or otherwise, any licenses or rights under patents or other intellectual property of ALZA or an Affiliate of ALZA other than that expressly included in the License.

16.5 **TMC Representations.** During this Agreement, TMC will:

16.5.1 comply in all material respects with all applicable laws and regulations concerning the development, manufacture, use and sale of Microprojection Systems and Products;

16.5.2 comply with the terms and conditions of the [**] Agreement and will notify ALZA promptly of any claim or notice received by TMC asserting that TMC is in breach of the [**] Agreement; and

16.5.3 have adequate terms and conditions in its sublicense agreements to allow TMC to comply with all relevant terms and conditions of the Agreement.

16.6 **Disclaimer of Warranties.** ALZA MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE LICENSED PATENTS OR KNOW-HOW LICENSED HEREUNDER, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ANY INFORMATION PROVIDED BY ALZA TO TMC IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

ARTICLE 17 — DISPUTE RESOLUTION

17.1 **Dispute Resolution and Arbitration.** In the case of any disputes between the Parties arising from this Agreement, and in case this Agreement does not provide a solution for how to resolve such disputes, the Parties will discuss and negotiate in good faith a solution acceptable to both Parties and in the spirit of this Agreement. If, after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement within [**], then the President of ALZA and the Chief Executive Officer of TMC will discuss in good faith an appropriate resolution to the dispute. If these executives fail, after good faith discussions, to

reach an amicable agreement within [**], then either Party may upon written notice to the other submit the dispute to binding arbitration pursuant to Section 17.2.

17.2 **Arbitration.** Any claim, dispute or controversy arising out of or in connection with or relating to this Agreement (including, without limitation, disputes with respect to the rights and obligations of the Parties following termination) not settled by the procedures set forth in Section 17.1 above, or the breach or alleged breach of a material provision of this Agreement, will be adjudicated by arbitration in accordance with the Arbitration Proceedings as set forth in Attachment 17.2.

ARTICLE 18 — MISCELLANEOUS PROVISIONS.

18.1 **Entire Agreement.** This Agreement and each of the Attachments hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter.

18.2 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

18.3 **Binding Effect.** This Agreement and the rights granted herein will be binding upon, and will inure to the benefit of, ALZA, TMC and their respective lawful successors and permitted assigns.

18.4 **Assignment.** Neither Party will assign this Agreement without the prior written consent of the other Party (such consent not to be unreasonably withheld) except that a Party may assign this Agreement to an Affiliate or to a successor in connection with the merger, consolidation or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement. The sublicense of all (or substantially all) of TMC's rights under this Agreement will be deemed to be an assignment under this Section 18.4. Any permitted assignee will assume all obligations of its assignor under this Agreement. No assignment will have the effect of relieving any Party to this Agreement of any of its obligations hereunder. It is understood and agreed that any Third Party excluding any "person" or "group" (within the meaning of Section 13(d) or 14(d) of the Securities Exchange Act of 1934, as

amended) that is controlled directly or indirectly by ALZA or TMC or such Party's present officers or directors, (a) that directly or indirectly acquires all or substantially all of the stock or assets of ALZA or TMC or (b) into which ALZA or TMC is consolidated or merged, shall not be required to provide the other Party with rights under Section 2.1.1(b) or Section 2.2, as the case may be, in the event and to the extent that those provisions would require such acquiring Third Party to grant licenses to the other Party covering inventions conceived and reduced to practice by such Third Party prior to the date it acquires ALZA or TMC, without access to or knowledge of any ALZA Know-How, ALZA Confidential Information, TMC Confidential Information (as defined without reference to whether such TMC Confidential Information is disclosed to ALZA), TMC Inventions or Derivative Information (unless such access to or knowledge of was provided to such Third Party by the non-acquired Party). In each case, the burden of establishing such exception to the Section 2.1.1(b) or Section 2.2 license will fall upon the acquiring Third Party.

18.5 **No Implied Licenses.** No rights to any other patents, know-how or technical information, or other intellectual property rights, other than as explicitly identified herein, are granted or deemed granted by this. Agreement. No right, expressed or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of this Agreement.

18.6 **No Waiver.** No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

18.7 **Force Majeure.** The failure of a Party to perform any obligation under this Agreement by reason of force majeure, limited to acts of God, acts of governments, riots, wars, strikes, accidents or deficiencies in materials or transportation or other causes of a similar magnitude beyond its control, will not be deemed to be a breach of this Agreement, for so long as the affected Party is using diligent efforts to remedy the force majeure event and perform its obligations as soon as practicable. The Party which is affected by any force majeure will contact the other Party for discussion of possible emergency measures.

18.8 **Independent Contractors.** Both Parties are independent contractors and not agents or employees of the other Party under this Agreement. Nothing contained in this

Agreement is intended nor is to be construed so as to constitute ALZA or TMC as partners or joint venturers with respect to this Agreement. Neither Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.

18.9 **Notices and Deliveries .** Any notices, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given when it is received, whether delivered in person, transmitted by facsimile with contemporaneous confirmation, or delivery by registered letter (or its equivalent) or delivery by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party will have last given by notice to the other Parties.

If to TMC:

The Macroflux Corporation
2000 Charleston Road, M12-2A
Mountain View, CA 94043
Attention: Chief Executive Officer
Facsimile: [**]

With a copy to:

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: [**]
Facsimile: [**]

If to ALZA:

ALZA Corporation
1900 Charleston Road
Mountain View, CA 94043
Attention: Legal Department
Facsimile: [**]

with a copy to:

Office of General Counsel
Johnson & Johnson

One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Facsimile: [**]

18.10 **Headings.** The captions to the sections and articles in this Agreement are not a part of this Agreement, and are included merely for convenience of reference only and will not affect its meaning or interpretation.

18.11 **Severability.** In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and this Agreement will be construed as if such invalid or unenforceable provision had not been included herein.

18.12 **Applicable Law.** This Agreement will be governed by and interpreted in accordance with the laws of the State of Delaware without reference to its choice of laws or conflicts of laws provisions.

18.13 **Advice of Counsel.** TMC and ALZA have each consulted with counsel of their choice regarding this Agreement, and each acknowledges and agrees that this Agreement will not be deemed to have been drafted by one Party or another and will be construed accordingly.

18.14 **Counterparts.** This Agreement may be executed in two or more counterparts, or facsimile versions, each of which will be deemed to be an original, and all of which together will be deemed to be one and the same agreement.

18.15 **Waiver.** Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy will not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

18.16 **Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by TMC or ALZA are, and will otherwise be deemed to be, for purposes of Section 365(n) of Title II, U.S. Code (the "Bankruptcy Code"), licenses of right to "Intellectual Property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that the Parties as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections they would have in the case of a licensor bankruptcy under the Bankruptcy Code. Each Party agrees during the term of this Agreement to create or maintain current copies,

or if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such intellectual property licensed to the other Party.

18.17 **Compliance with Laws.** The Parties will comply with all applicable laws, rules, regulations and orders of the United States and applicable European countries and supra-governmental organizations and all jurisdictions and any agency or court thereof in connection with this Agreement and the transactions contemplated thereby.

18.18 **Certain Tax Matters.** The Parties will, for all federal, state and local income tax purposes, treat the exchange of Licenses for Series A Preferred and Product Payments as part of the transaction under Section 351 of the Code described in Section 7.4 of the Series A Agreement and will not take any position or action contrary thereto or inconsistent therewith. For the avoidance of doubt, the parties agree to treat the Product Payments as boot pursuant to Section 351 of the Code.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

ALZA CORPORATION

By: /s/ Erik Wiberg
Name: Erik Wiberg
Title: VP Pharmaceuticals Group
Business Development

THE MACROFLUX CORPORATION

By: /s/ Peter Daddona
Name: Peter Daddona

Title: Chief Scientific Officer

Attachment 1.5 - Certain ALZA Inventions

[**]

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

Attachment 1.6 - ALZA Know-How

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

Attachment 1.6 - ALZA Know-How Index

Note: ALZA Know-How will also include data and documents that will be generated under the Transitional Services Agreement. These data and documents will be transferred at the end of the Transition Period. Requirements:

(1) Electronic copies of all documents

(2) Controlled copies must have a hardcopy that is updated per GPSG - Macroflux® Corporation Agreement

# denotes data and documents that will be transferred to TMC after the Effective Date

Document Type	Schedule
Regulatory Documents	IND No. 70,973, Form FDA 1571 (IND Serial No. 0007), as well as all written communications between ALZA and the FDA and ALZA's internal contact reports, in each case, relating to IND No. 70,973
Laboratory Notebooks	Schedule A
Employee Training Records	Schedule B
SOPs	Schedules C-1 and C-2
Forms	Schedule D
Technical reports	Schedule E
Toxicology Reports	Schedule F
Design History Files	Schedule G
Training Modules	Schedule H
ALZA Analytical Methods (AAM)	Schedule I
ALZA Quality Specification (AQS)	Schedule J
Clinical Production Record (CPR)	Schedule K
Packaging Material Specifications (PMS)	Schedule L
Clinical Files	Schedule M
Bioanalytical CRO documentation	Schedule N
Vendor Fifes	Schedule 0
Completed Batch Records	Schedule P
Equipment Files	
Equipment Manuals	
Drawing files (CAD)	

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Schedule A: Lab Notebooks
Note: transfer of Notebooks to be completed by October 31, 2006

[**]	8953#		6156	[**]	7220
[**]	7136#		6580	[**]	3890
	7188#		7144		7256
	7312#		7737		7219
	7405#	[**]	8805	[**]	8743
	7528#	[**]	8301	[**]	5097
	7679#		8409	[**]	8380
	7929#		8593	[**]	6586
[**]	8415#	[**]	7739		6675
	8414#		8060		6796
	8422#		8067		6960
	8484#		8066		7190
	8485#		8304		7290
[**]	6844#		8305		7374
	7344#		8335		7537
	8157#		8334		7650
[**]	7304#		8421		7667
	7425#		8423		7668
	7456#		8580		7922
	7457#		8647		8138
	7641#		8694		8507
	7822#	[**]	6055		8644
	8144#		6995		8645
	8269#		7488		8646
	8520#	[**]	8381	[**]	7182
	8702#		8549	[**]	8705
	8952#		8554		8591
[**]	7577#		8797	[**]	7533
	8052#	[**]	7261		7619
[**]	8248#		7262		8136
[**]	5128#		7263		8331
	5129#		8972	[**]	7646

5756#	[**]	8607	7647

[**]	7648#	[**]	6830		7876
	7649#	[**]	7901		7913
[**]	8980#		8234		8013
[**]	8456#		8827		8010
	8629#	[**]	6709	[**]	6435
	8786#		7410		6824
	8806#	[**]	7814		7993
	8961#		8065		8468
[**]	8729#		8495		8552
[**]	7771#		8870	[**]	8253
[**]	5585#	[**]	7639		7429
	7826#		7671		8137
	8007#		7704	[**]	7421
	8673#		7777		7422
[**]	8804#		7811		

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Schedule B; Employee Training Records

Employee Name	WWID
[**]	701089503
[**]	332708
[**]	128009636
[**]	181837
[**]	128009768
[**]	701090331
[**]	341136
[**]	180920
[**]	333305
[**]	191935
[**]	365850
Daddona, Pete	180405
[**]	340710
[**]	128009326
[**]	104759
[**]	128008889
[**]	366617
[**]	701084297
[**]	701093113
[**]	174510
[**]	701085092
[**]	701084298
[**]	701088378
[**]	128005057
[**]	197229
[**]	128011652
[**]	128005078
[**]	182026
[**]	181643
[**]	332715
[**]	701077855

[**]	194628
[**]	181971

[**]	701091650
[**]	180601
[**]	333306
[**]	180442
[**]	701086157
[**]	332717

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Schedule B: Employee Training Records

Employee Name	WWID
[**]	358707
[**]	195876
[**]	366468
[**]	332726
[**]	180233
[**]	701086391
[**]	104560
[**]	701085629
[**]	83251
[**]	357636
[**]	180060
[**]	161600
[**]	330872
[**]	191534
[**]	701087267
[**]	701091073
[**]	172542
[**]	336464
[**]	701084448
[**]	104528
[**]	337092
[**]	334826
[**]	338021
[**]	128005503
[**]	128005055
[**]	201135
[**]	198594
[**]	103974
[**]	701085359
[**]	701091773
[**]	180181

[**] 181545]

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Schedule C-1: Controlled SOPs

SOP Number	SOP Title
Manufacturing	
0-005	ALZA Corporate Document Control
0-006	Document Change Order Procedure
0-017	Guidelines For Cleaning Manufacturing Equipment and Cleaning Validation
0-018	Employee Training
0-103	First Article Inspection Procedure
0-301	Facility, Equipment, and System Qualification
0-302	Guidelines for Determining if a Computer System Requires Computer Validation
0-500	Quality Organization and Scope of Responsibilities
0-501	Line Sign-Off and Materials Verification
0-502	ALZA Quality Specifications
0-503	Dispositioning Materials
0-550	Clinical Packaging Sample Retains Handling
0-551	Periodic Review of Quality Standards
0-554	Process Change Request
0-704	Facility Equipment Logbook Procedures
22-000	[**]
22-001	[**]
22-002	Operating and Cleaning Procedures for the Allegra 6 Beckman Centrifuge
22-003	Operating and Cleaning the Glas-Col Rotator
22-004	[**]
22-005	Operating and Cleaning of Mettler Toledo Balances
22-006	Cleaning, Sanitization, and Operation Procedure for Unidirectional Air Flow Hoods
22-007	Operating and Cleaning Procedure for the Van der Sthal Heat Sealer
22-009	[**]
22-010	REVCO Refrigerator Model REL 404
22-011	REVCO Freezer Model ULT350-3-A31
22-012	[**]

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Schedule C-1: Controlled SOPS

SOP Number	SOP Title
22-013	[**]
22-014	Operating and Cleaning Procedures for the Bransonic Sonicators (Model 5510-MT and 8510-MT)
22-015	Gowning Requirements and Personnel Practices in the Macroflux® Pilot Plant
22-016	Personnel, Equipment, and Material Flow for the Macroflux® Pilot Plant
22-017	Sanitization and Use of the M-12 Macroflux® Pilot Plant Pass Through
22-018	Cleaning and Sanitization of the Macroflux® Pilot Plant
22-021	Operation of the Vortex Genie 2 Mixer
22-022	Operating and Cleaning Procedure for the Despatch SDC2-30 Oven
22-026	Setup, Operation, and Cleaning Procedures for Macroflux® Dew Point Control System (DPCS)
22-027	Setup, Operation, and Cleaning of the Macroflux® Tangential Flow Filtration System
22-028	Setup, Operation, and Cleaning of the Fuji Heat Sealer (MS-350NP)
22-029	Operation and Cleaning of the Macroflux® Applicator Test Stand
22-030	Operation and Cleaning for the Macroflux® Leica L2 Microscope
22-031	Operation of MANOSTAT Peristaltic Pump for Macroflux® Manufacturing
22-032	Operating and Cleaning Procedure for Macroflux® Labconco Freeze Drying Equipment
22-033	Operation and Cleaning of Hudson Clicker Press
22-034	Operation and Cleaning of Chaffee Rotor Sealer
22-035	Operation and Cleaning Procedure for the Blue M Mechanical Convection Oven
22-037	Vacuum Chamber for Pouch Seal Integrity
22-041	Operating and Cleaning Procedures for the Multivac C-400 Heat Sealer
22-043	Calibration and Operation of 10 Scientific Instrument (Model miniLab 1Q125) pH Meter
22-044	Personnel Flow within the Macroflux® Pilot Plant
22-045	Setup, Cleaning and Operation of the Macroflux® Resistance Cutter
22-046	Operating and Cleaning Procedures for the Macroflux® Subassembly & Outer Ring Tube Loader

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Schedule C-1: Controlled SOPs

SOP Number	SOP Title
22-050	Procedure For Sanitization of Carts in Macroflux® Pilot Plant
5-005	QED Line Audits
5-039	Retain Sample File In Mountain View
7-001	Guidelines for the Preparation, Review and Approval of Master Clinical Production and Control Records
7-002	Audit of Clinical Production Records for Disposition
7-003	Guidelines For The Preparation Of A Clinical Batch Record For Clinical Production
7-004	Guidelines for the Preparation and Approval of Phase I Clinical Supplies used in IND or Ex-US, IND Exempt, or Non-Drug , Demonstrator Placebo Studies
7-009	Accountability of Materials in Clinical Production
7-013	Guidelines For Two Or More Operations In A Manufacturing Area At The Same Time
7-019	Handling and Flow of Material In Clinical Production
7-034	Mountain View Research Inventory Control Shipping Procedure
7-048	Material Dispensing from Mountain View Research Inventory
7-049	Approval, Preparation and Use of Clinical and Non-Clinical Labels
7-053	Solvent Handling And Dispensing
7-056	In-Process Inspections for Pouching/Labeling Operations in Clinical Production
7-057	Cleaning Supply Solvents
7-061	Controlled Substances Accountability
7-064	Review and Release Procedures for Incoming Materials Used in Clinical Manufacture
7-086	Clinical Packaging Record Review and Release Checklist
7-095	Guidelines for Completing Clinical Production Paperwork
7-096	Guidelines For The Preparation Of Aseptic Process Simulation Test Protocol
7-097	Evaluation of Drug Actives for Dispensing in M5 Warehouse
7-099	M5 Weighing and Dispensing Isolator Operating and Cleaning Procedure
7-100	Lot Characterization For Clinical Products

SOP Number	SOP Title
Formulation & Analytical	
0-005	ALZA Corporate Document Control
0-006	Document Change Order Procedure
0-018	Employee Training
0-047	GMP Training Program
0-053	Guidance for Using Plateau Training Management System
0-109	Departure Notice Procedure
10-212	Good Laboratory Practices Audit Program
10-213	GLP Internal Facility and Process-based Inspections
130-0000	Calibration, Test Equipment and Work Orders
14-005	Bioanalytical Method Validation
14-006	Method Validation Requirements for Transferring LC/MS/MS Assays
14-008	Bioanalytical Sample Analysis
150-0010	HPLC Systems
150-1007	Waters 2690/2695 HPLC and GPC Separations Module
150-1011	ALZA Metrology HPLC Systems
150-1115	HPLC Column Heaters
150-1117	Preventive Maintenance, Performance Verification, and Performance Qualification SOP for HPLC System Vacuum Degasser
150-1122	Beckman Coulter Capillary Electrophoresis
150-1202	Preventive Maintenance, Performance Verification, and Performance Qualification SOPs for HP 1100 HPLC Autosampler G1313A
150-1402	Preventive Maintenance, Performance Verification, and Performance Qualification SOPs for the HP1100 HPLC Column Heater G1316A
150-1601	Preventive Maintenance, Performance Verification, and Performance Qualification SOPs for the HP/Agilent 1100 Vacuum Degasser G1322A, G1379A
151-1010	Thermo-Nicolet FT-IR
151-2003	Agilent 8452A and 8453 Diode Array UV-VIS Spectrophotometers
151-2010	Molecular Devices SPECTRAmax Plus Microplate Spectrophotometers
151-3202	Waters Micromass Mass Spectrometer System

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Schedule C-1: Controlled SOPs

SOP Number	SOP Title
152-0011	Calibration of Scales and Balances
154-0022	Simple Measurement Instruments
154-0050	Liquid Volume Dispensers
154-0080	Procedure for pH and Conductivity Meters
154-0091	Haake RheoStress RS100 Rheometer
154-0098	Simple Laboratory Equipment
154-0101	Thermometers
154-0102	Reference Standard Laboratory Desiccators
154-0105	WESCOR 5520 Vapor Pressure Osmometer
155-1103	Brookfield Viscometers
155-3101	Differential Scanning Calorimeter 2920 and Thermogravimetric Analyzer 2950
156-0025	General Purpose Water, Steam, and Oil Temperature Baths
156-0031	Refrigerators and Freezers
156-0051	Ovens
156-0062	Dessicators
156-0067	Temperature and Humidity Environmental Test Chambers
158-0010	Purified Water Systems in the Laboratory
158-1002	Millipore Academic and Synthesis Purified Water Systems
159-0020	Preventive Maintenance, Performance Verification, Calibration and Performance Qualification of Centrifuges
159-0032	Qualification of Shakers
159-1008	Analytical Laboratory Glassware Washers/Dryers
16-0013	Differential Scanning Calorimeter 2920 and Thermogravimetric Analyzer 2950
16-0023	Amersham Biosciences Personal Densitometer SI Laser Densitometer
16-0024	Amersham Personal Densitometer SI System Software
16-01105	HP 1100 Binary Pump
16-01202	HP 1100 Autosampler
16-01306	HP 1100 Diode Array Detector
16-01402	HP 1100 Thermostatted Column Compartment

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Schedule C-1: Controlled SOPs

SOP Number	SOP Title
16-01601	HP 1100 Vacuum Degasser
16-12011	Operation of Agilent 8453 UV-visible Spectrophotometer
16-40080	Radiometer/Copenhagen PHM220 Lab pH Meter
16-48001	Operation Manual for Benchtop pH/ISE Meters Model 420A
2-016	Hazardous Waste Disposal
9-003	cGMP Operations in Analytical Laboratories
9-004	Content of Analytical Data Set
9-012	Procedures For Sample Documentation Log-in, and Handling
9-016	Validation of Analytical Methods For Drug Analysis From Swabs of Cleaned Equipment
9-028	Worksheet Tracking Forms
9-030	Format of Laboratory Instrument Specific Operation Manual
9-038	ALZA Analytical Laboratory Training/Retraining Procedures
9-040	Archive and Restoration of Electronic Test Data In Analytical Sciences
9-041	Laboratory Procedures for Handling Controlled Substances
9-042	Procedures for the Issuance and Use of Instrument Usage Logbooks
9-043	Laboratory Reagent Preparation and Maintenance
9-047	Procedure for Certification, Handling, and Distribution of Analytical Reference Standards
9-048	Qualification for Laboratory Analytical Instrument/Equipment Hardware
9-049	Handling Hazardous Chemicals and Solvents in Analytical Testing Laboratories
9-050	Qualification of IR Reference Spectra
9-051	Determination of Stability of Solutions
9-402	Laboratory Data Documentation, Review, and Approval Procedures in Analytical Sciences
9-406	NDA-Level Method Validation Protocols for Chromatographic and UV-Spectroscopic Quantitative Analytical Methods for Small Molecules
9-407	Analytical Method Documentation System
9-408	Analytical Method Transfer
9-409	Validation of Quantitative Analytical Methods

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Schedule C-1: Controlled SOPs

SOP Number	SOP Title
9-410	Preparation, Labeling and Expiration Dating for Laboratory Solutions, Samples and Standards
9-412	Procedure for Calculating, Recording and Reporting Impurities and Degradation Products
9-413	Handling "Lost" Samples
9-417	Validation of Qualitative Analytical Methods
9-418	Validation of Instrumental Measurement Analytical Methods
9-419	IND-Phase 11 *and* Phase III Clinical Studies Method Validation Protocols for Chromatographic and UV-Spectroscopic Quantitative Analytical Methods for Small Molecules
9-423	Access Control for Computerized Systems in Analytical Sciences
9-424	Audit Trail Requirements for Computerized Laboratory Instruments in Analytical Sciences
9-425	Changing Date and Time Stamps for Computerized Systems in Analytical Sciences
9-426	Definition of Electronic Records for Computerized Systems in Analytical Sciences
9-427	Resetting Forgotten Passwords for Computerized Systems in Analytical Sciences
9-429	Data Record and Signature Linking for Hybrid Systems in Analytical Sciences
9-430	Use of Electronic Signatures in Analytical Sciences
9-431	Daily Calibration Procedure for pH meters
9-432	Daily Temperature Check for Refrigerators/Freezers
9-433	Analytical Sciences Area Policy
9-439	Validation of Qualitative Near Infrared Spectroscopy Methods
9-440	NIR Test Procedure
9-441	Investigations for Laboratory Testing in Analytical Sciences
9-442	Procedural Deviation Investigation for Analytical Sciences
9-443	Computer System Validation of Analytical Laboratory Instruments
9-445	Analytical Sciences LIMS Policy
9-446	Day Of Use Balance Verification in Analytical Sciences

SOP Number	SOP Title
9-449	Analytical Sciences Empower CDS - System Security
9-450	Analytical Sciences Empower CDS - System Administration
9-451	Analytical Sciences Empower CDS - General Use
9-452	Analytical Sciences Empower CDS - Empower Change Requests
9-453	Analytical Sciences Empower Chromatography Data System Development and Validation of Custom Fields
9-454	Administration of the ExRx Origin for Analytical Sciences Investigations
9-455	HIAC Royco Particle Counter with PharmSpec Software
9-466	Analytical Sciences Document Control Process
9-468	ALZA R&D LabWare LIMS System Security
9-469	ALZA R&D LIMS Configuration Control within a Validated Database
Design Control	
0-15001	Design and Development Planning (D&DP)
0-15002	Design Input (User/Stakeholder Needs)
0-15003	Product Design Risk Management
0-15004	Design Output
0-15005	Design Review
0-15006	Design Verification
0-15007	Design Validation
0-15008	Design Change
0-15009	Design History File
0-15010	Manufacturing Risk Assessment
0-15011	Manufacturing Launch Strategy
0-15013	Design Transfer
0-15014	Design Master Record (DMR)

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Schedule C-2: Additional SOPs

SOP Number	SOP Title
Scientific Writing	
0-054	Procedure for Completing and Amending Clinical Study Reports
0-055	Procedure for Completing and Updating Investigator's Brochures
Clinical Operations	
11-002	Central Files
11-003	Training Program
11-100	Preparation and Approval of Protocols and Protocol Amendments
11-101	Informed Consent
11-106	Monitoring Clinical Trials
11-107	Planning, Documenting and Conducting a Pre-study Visit
11-108	Preparing for Study Initiation
11-109	Planning, Documenting and Conducting a Initiation Visit
11-110	Planning, Documenting and Conducting a In Progress Visit
11-111	Planning, Documenting and Conducting a Termination Visit
11-114	Accountability and Reconciliation of Investigational Drug Supplies
11-115	Contract Manufacture and Packaging of Clinical Supplies
11-117	Procurement of Clinical Packaging Components
11-210	Shipment of Clinical Materials from 3rd Party Contractor to an Investigational Site
11-211	Retrieval of Investigational Drug Product from Clinical Sites
11-212	Reassignment of Marketed Product for Clinical Use
11-213	Reporting Serious Adverse Events Originating from Pharmaceutical Clinical Trials
11-214	Procedures for Handling Complaints for Clinical Trial Material at Clinical Study Sites
11-216	[**]
11-217	Guidelines for the Development, Review and Approval of Clinical Development Plans
11-218	Mapping Adverse Events
Statistics and Data Management	
23-001	Volume Structure of Clinical Studies and Access Rights
23-002	Creation of Study Case Report Forms within DataFax for Clinical Pharmacology Studies

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Schedule C-2: Additional SOPs

SOP Number	SOP Title
23-004	Study Edit Checks: Document, Programs and Processing
23-005	Validation of DataFax Records
23-006	Query Process for DataFax Database Data
23-007	DataFax Router Management
23-008	Quality Assurance Procedure Performed on Clinical Databases
23-009	DataFax Training
23-010	Access Restrictions to DataFax Databases
23-011	Electronic Transfer of Data
23-012	Employee Training for Computerized Systems Within the Clinical Division
23-017	Physical Security for Clinical Computer System Servers
23-027	Study Randomizations
23-030	Guidelines for SAS Coding Conventions
23-031	Guideline for SAS Log Review
23-032	Guideline for Volume Structure and Access Rights
23-037	Study Data Access Restriction and Finalization
23-039	Use of Statistics and Data management Study Process Checklist
23-040	Guidelines for Quality Assurance Sampling and Auditing
23-041	Guidelines for Quality Assurance Error Number Calculation
23-042	Guidelines for Randomization Programs
23-042	Guidelines for Making CRF Changes
23-044	Guidelines for Emergency Shutdown Procedure for the DataFax Server
23-048	Guideline for Exporting Electronic Data From DataFax
23-050	Guideline for SAS Names
23-052	Guideline for SAS Volume Directories
23-053	Guideline for the Production of Quality Assurance of Case Report Form Tabulations
23-056	Security Access and Control of dsNavigator
539-000	DataFax User Study Access Form
539-001	DataFax Database Change Control Form
539-002	Clinical Systems Hardware and Software Change Control Documentation

Schedule C-2: Additional SOPs

SOP Number	SOP Title
539-004	Study Volume Access Form
539-006	Security Questionnaire
539-007	Event Qualification Form
539-008	Study Volume Freeze Form
539-009	dsNavigator User Access Form
539-011	dsNavigator Database Change Control Form
Preclinical	
0-018	Employee Training
0-027	Records Retention
8-108	Toxicology Department Training
8-109	Animal Welfare/USDA Employee Training
8-202	Protocol Approval Procedures
8-203	Protocol Amendments and Protocol Deviations for Nonclinical Good Laboratory Practice Studies
8-205	Raw Data Procedures
8-212	Biological Research (BIO) Studies: Protocols, Study Conduct, and Reports
8-300	Documenting Animal Orders and Receipt
8-301	Husbandry of Rats and Mice
8-302	Husbandry of Rabbits and Guinea Pigs
8-303	Animal Husbandry of Dogs and Pigs
8-305	Laboratory Animal Identification Procedures
8-307	Verifying Animal Identification Upon Cage Transfer and Manipulation
8-311	Daily Animal Health Evaluations and Documentation
8-312	Euthanasia and Disposal of Laboratory Animals
8-314	Environmental Conditions of Animal Rooms and Support Areas
8-315	Cage Cleaning and Room Maintenance
8-316	Animal Feed, Water, and Bedding
8-320	Animal Vendor and Intermediate Handler Qualification
8-338	Veterinary Resource Center Dress and Protection Procedures
8-405	Controlled Substances

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Schedule C-2: Additional SOPs

SOP Number	SOP Title
8-509	Blood Collection from Rats and Mice
8-510	Blood Collection in Rabbits and Guinea Pigs
8-515	Administration of Fluids Via Hypodermic Syringe
8-517	Disposal of Sharps, and Biohazardous, Drug, Chemical, and Radioactive Waste
8-518	Anesthesia and Analgesia of Laboratory Animals
8-543	Gross Pathology Procedure
8-547	Animal Randomization
8-555	Implantation of Catheters in Laboratory Rodents
8-564	Blood Collection — Swine
8-571	Clinical Observations
8-572	Survival Surgery and Perioperative Care
8-573	Delivery of Inhalation Agents to Laboratory Animals
9-041	Laboratory Procedures for Handling Controlled Substances

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Schedule D: Forms

Form Number	Form Title
Process Development and Manufacturing	
05-001-007	Supplement material and Equipment Received and In Process Data Sheet
231-502	Screening Study Plan Approval and Release
531-1039	Microbiology Report for Test for indicator Organisms .
531-1041	Microbiology Report
531-1075	Micro Report for LAL
531-1230	Microbiology Report for Microbial Content Assay
531-1251	Microbiology Report for Final Rinse Water Bioburden Assay
531-1305	Macroflux® Cleaning In Process Sheet
531-1306	Macroflux® Forming In Process Sheet
531-507	ALZA Clinical Batch Review
531-514	Pre Production Checklist
531-524	Label Accountability Log
531-796	Macroflux® Housing In Process Sheet

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Schedule E: Technical Reports

Report No.	Report Title
Preclinical	
TR-1340	[**]
TR-1347	[**]
TR-1364	[**]
TR-1367	[**]
TR-1379	[**]
TR-1380	[**]
TR-1409	[**]
TR-1547	[**]
TR-1557	[**]
TR-1583	[**]
TR-1607	Determination of Transdermal Delivery of human Parathyroid Hormone (hPTH) 1-34 in [**].
TR-1635	[**]
TR-1636	Pharmacokinetic Profiles of hPTH (1-34) (TH0229) and Forteo Administered in [**]
TR-2191	[**]
TR-2205	[**]
TR-2236	[**]
TR-2332	Optimization of Commercial Human PTH (1-34) EIA From Peninsula Laboratories For Use with [**] Plasma

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Schedule E: Technical Reports

Report No.	Report Title
TR-2467	[**]
TR-2702	Testing of Physical Stability of Macroflux® PTH Systems in [**] Model
TR-2703	Effect of Patch Wearing Time of Macroflux® PTH Systems In Vivo Using [**] Model
Formulation & Analytical	
TR-1331	Formulation Development Report
TR-1348	Oxidation of PTH(1-34) *in* the solid state
TR-1349	Solution Stability of PTH(1-34)
TR-1350	Solid State Stability of PTH
TR-1479	[**]
TR-1483	[**]
TR-1511	[**]
TR-1512	[**]
TR-1531	hPTH(1-34) Macroflux® formulation development report
TR-1584	Determination of Coating Variability
TR-1709	[**]
TR-2192	Macroflux® Human B-type Naturetic Peptide (hBNP) Formulation Development Report
TR-2326	IVP-1 Packaging Configuration Long Term Stability: 6 Month Data Summary
TR-2510	Determination of Residual Human Parathyroid Hormone (hPTH) 1-34 on [**] Skin
Process Development and Manufacturing	
TR-1454	Identification and Handling of Dedicated Equipment for PDP-1 In Phase I Clinical Builds
TR-1555	PDP-09: Macroflux® hPTH (1-34) Phase I Process Development Report
TR-1568	PDP-09 (hPTH) Coating Process Development

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Schedule F: Toxicology Reports

Study Number	Toxicology Study Title	
TR-06-0576-003#	4-Week Subcutaneous Injection Toxicity and Toxicokinetic Study with Teriparatide (Human Parathyroid Hormone, 1-34) in Rats	transfer to occur by 12/31/06
TR-05-7106-021#	Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells	transfer to occur by 12/31/06
TR-05-7106-022#	Salmonella-Escherichia coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay	transfer to occur by 12/31/06
TR-05-016	A Primary and Cumulative Irritation Study of Macroflux® (hPTH) [**]	
TR-05-003	A Primary and Cumulative Irritation Study of Macroflux® (hBNP) [**]	
TR-03-035	[**]	
TR-03-026	A Primary Skin Irritation Study of Macroflux® (Parathyroid Hormone) in [**]	
TR-02-034	A Primary Skin Irritation Study of Macroflux® (desmopressin) in [**]	
TR-02-031	In Vitro Evaluation of Macroflux® Circular Array, 2B200LS, 2cm2, 321/cm2, Unformed, Code No. 0012734, Control No. MV0214344: ISO Cytotoxicity Testing	
TR-02-029	A Primary Skin Irritation Study of Macroflux® (Desmopressin) Systems in [**]	
TR-02-027	[**]	
TR-02-026	[**]	
TR-02-003	[**]	

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Schedule G: Design History Files

Report Number	Report Title
DHF - Applicator - All Sections	
TR-1510-DHF	Macroflux® Gen 3i Applicator (code no. 0013490) Design and Development Plan
TR-1525-DHF	Development Team and Approval Matrix for the Macroflux® Applicator (Code No. 0013490)
TR-1292-DHF	Macroflux® Applicator (Code No. 0011864) User / Stakeholder Needs
TR-1294-DHF	Hold-down Force Criterion
TR-1295-DHF	Impact Criterion
TR-1497-DHF	Macroflux® Applicator (Code No. 0013490) User/Stakeholder Needs
TR-1511-DHF	Macroflux® *Gen* 3i Applicator (Code No. 0013490) System Requirements
TR-1293-DHF	Process Validation
TR-1296-DHF	Macroflux® Applicator Code No. 0011864 Technical File
TR-1297-DHF	Evaluation of the Conformity with the Essential Requirements (Directive 93/42/EEC, Annex 1)
TR-1454-DHF -	Macroflux® Identification and Handling of Dedicated Equipment for PDP-1 in Phase I Clinical Builds
TR-1508-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Material Selection
TR-1509-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) FEA Report
TR-1513-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Tooling
TR-1519-DHF	Macroflux® Gen3i Applicator Tolerance Analysis and Geometry Check
TR-1769-DHF	Macroflux® Gen3i Applicator Component First Article Inspection Report (Code No. 0013490)
TR-1795-DHF	Hold Down Force Generation and Tolerability Measurements in Healthy Elderly Volunteers for Macroflux® Applicator Design (C-2003-014)
TR-2039-DHF	Biocompatibility Assessment of Macroflux® Applicator (code no. 0013490) and Retainer (code no. 0013491)
TR-2041-DHF	Clinical Performance of the Gen. 3 Macroflux® Applicator (Code No. 0011864)
TR-2046-DHF	Macroflux® Gen4 Applicator Market Research by Timely Data Resources in 2003
TR-2074-DH F	The Effect of Applicator Piston Angle on Macroflux® System Performance
TR-1505-DHF	Macroflux® Gen3i Applicator - Technical Development Review
TR-1774-DHF	Macroflux® Gen3i Applicator

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Schedule G: Design History Files

Report Number	Report Title
TR-1284-DHF	Macroflux® Applicator (Code No. 0011864) Impact Energy
TR-1285-DHF	Macroflux® Applicator (Code No. 0011864) Hold-down Force
TR-1286-DHF	Macroflux® Applicator (Code No. 0011864) Cycle Life
TR-1287-DHF	Macroflux® Applicator (Code No. 0011864) Retainer Attachment Cycle Life
TR-1288-DHF	Macroflux® Applicator (Code No. 0011864) Retainer Detachment Force
TR-1289-DHF	Macroflux® Applicator (Code No. 0011864) Temperature Cycling
TR-1290-DHF	Macroflux® Applicator (Code no 0011864) Chemical Resistance
TR-1291-DHF	Macroflux® Applicator (Code No. 0011864) Shipping
TR-1299-DHF	Declaration of Conformity - Macroflux® Applicator
TR-1780-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Design Verification Testing General Tests
TR-1781-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Design Verification Testing Environmental Tests
TR-1782-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Design Verification Testing Life Cycle Tests
TR-1794-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Design Verification Testing Video Protocol
TR-1796-DHF	Macroflux® Gen3i Applicator Design Verification Report Code No. 0013490
TR-1797-DHF	Macroflux® Gen3i Applicator Design Verification Matrix Code No. 0013490
TR-2049-DHF	Macroflux® Gen4 Applicator (0013490) Design for the Environment
TR-2058-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Design Verification Testing Audible *and* Tactile
TR-1418-DHF	Non-Drug Macroflux® Manufacturing
TR-2050-DHF	Macroflux® Applicator Code No. 0011864 Design History File Index
TR-1300-DHF	Risk Analysis Worksheet (RAW) Form
TR-1504-DHF	Risk Analysis for Macroflux® Applicator (Code 0013490)
TR-1770-DHF	Macroflux® Gen3i Applicator (Code No. 0013490) Risk Analysis Meeting Minutes
DHF Array - Design Output	
TR-1503-DHF	The Effect of Number of Passes on Coating of 0012907
TR-1507-DHF	Evaluation of 2cm2 Macroflux® Array Designs: MF1004, MF1033, MF1034, MF1035, MF1037, MF1039, MF1040, S250

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Schedule G: Design History Files

Report Number	Report Title
TR-1783	Coating Linearity to Array Size
TR-1814-DHF	MF1035 Depth of Penetration Sensitivity to Coating
TR-1815-DHF	Acceptability of Tecomet as a Macroflux® Array Supplier
DHF - Housing - Design Output	
TR-1536-DHF	Identification of Macroflux® Product Contacting Equipment
TR-1537-DH F	Process Parameters that Effect Film Thickness on the Macroflux® Center
DHF - IVP-1	
TR-2598-DHF	Film Thickness Measurement Using the Keyence LT-900, LS-7030
TO-1205-DHF	[**]
TR-2529-DHF	[**]
TO-1208-DHF	[**]
TD-1212-DHF	[**]
TR-2299-DHF	[**]
TR-2314-TR	Macroflux® Identification and Handling of Dedicated Equipment for IVP-1 (hBNP) in Phase **I** Clinical Builds
TR-2530-TR	Macroflux® IVP-1 Package. Integrity Protocol
TD-1223-DHF	[**]
TD-1226-TR	[**]
TR-2192-DHF	[**]
TR-2321-DHF	Macroflux® Forming Elastomer Life Expectancy
TR-2326-DHF	IVP-1 Final Product Packaging Configuration Long Term Stability - 6 Month Data Summary
TR-2538-DHF	Macroflux® IVP-1 Package Integrity Report
TR-2539-DHF	[**]
TR-2595-DHF	RAM Optical Formed Length/Angle Inspection Gage R&R
TR-2629-DHF	Film Thickness Measurement Using the Keyence LT-900, LS-7030

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Schedule G: Design History Files

Report Number	Report Title
TD-1209-DHF	[**]
TD-1215-DHF	[**]
TD-1227-DHF	[**]
DHF - IVP-6	
TD-1302-DHF	Dose Mapping Protocol for Irradiated Macroflux® Aseptic Processing Components—Equipment
TD-1303-DHF	Mapping Protocol for Irradiated Macroflux® Aseptic Processing Components—Product Components
TR-2871-DHF	Dose Mapping Report for Irradiated Macroflux® Aseptic Processing Components—Equipment
TR-2332-DHF	[**]
TR-2510-DHF	[**]
TR-2874-DHF	RAM Optical Sprint CNC 200 Formed Length/Angle Inspection Gage R&R
DHF - PDP-1	
03102000-060702	Change Document No. 31020000-060702, Amendment No. 1
03102000-101503	Change Document 31020000-101503, Amendment #3
03102000-112603	Change Document 3102000-112603, Amendment 4
PDP-1, 2/16/01	[**]
TR-1340-DHF	[**]
TR-1347-DH F	[**]
TR-1364-DHF	[**]
TR-1367-DHF	[**]
TR-1379-DHF	[**]

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Schedule G: Design History Files

Report Number	Report Title
TR-1380-DHF	[**]
TR-1409-DHF	[**]
TR-1523-DHF	Formulation and Macroflux® Delivery System Development
TR-1547-DHF	[**]
TR-1557-DHF	[**]
TR-1583-DHF	[**]
TR-1635-DHF	[**]
DHF - PDP-9	
5112-121102	Change Document 5112-121102, Amendment 1
PDP-9, 10/12/01	Macroflux® PTH Analog Delivery System
TR-1573	PDP-09: Macroflux® hPTH (1-34) Phase I Process Development Report
TR-1791-DHF	Macroflux® PDP-9 Human Parathyroid hormone (1-34) User/Stakeholder Needs
TR-2042-DHF	Penetration of hPTH Coated Macroflux® Systems in Excised [**]
TR-1348-DHF	Oxidation of PTH(1-34) in the Solid State
TR-1349-DHF	Solution Stability of PTH(1-34)
TR-1350-DHF	Solid State Stability of PTH
TR-1351-DHF	hPTH(1-34) Macroflux® Formulation Development Report
TR-1803-DHF	Macroflux® hPTH Microbiological Control Program

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Schedule H: Training Modules

TM Number	TM Title
02-012-004	ExRx Reporting System Training Module: Overview
03-032-017	ExRx ANA Investigation Origin for Laboratory Testing and Procedural Deviation
03-032-018	Laboratory Glassware and Utensils Pre-cleaning Procedure *in* Analytical Sciences
03-032-019	Cleaning Procedure for Analytical Sciences Laboratory Glassware and Lab Ware
03-032-020	Analytical Laboratory Safety Orientation
03-032-022	Analytical Sciences Empower CDS - Getting Started
03-032-023	Analytical Sciences Empower CDS - Creating a New Project
03-032-024	Analytical Sciences Empower CDS - The Instrument Method
03-032-025	Analytical Sciences Empower CDS - The Processing Method
03-032-026	Analytical Sciences Empower CDS - The Method Set
03-032-027	Analytical Sciences Empower CDS - The Sample Set Method
03-032-028	Analytical Sciences Empower CDS - Running Samples
03-032-029	Analytical Sciences Empower CDS - Viewing Data and Optimizing Methods
03-032-030	Analytical Sciences Empower CDS - Data Processing
03-032-031	Analytical Sciences Empower CDS - Reports and Electronic Signatures
03-032-037	Operation of Advanced Software for the Agilent ChemStation with Security Pack for UV-visible Spectroscopy
03-032-039	Administration of The Analytical Sciences Reference Standard Program
03-032-045	Handling Analytical Records in Analytical Sciences Document Control Center

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Schedule I: ALZA Analytical Methods (AAM)

AAM No.	AAM Title
1.710	identity and Purity of Parathyroid Hormone (PTH 1-34) by Reversed Phase High Performance Liquid Chromatography (RP-HPLC)
1,760	[**]
1.775	Determination of Parathyroid Hormone (hPTH 1-34) Content of Macroflux® Finished Product and In-Process Control Sample by Liquid Chromatography
3.305	Identification by IR Spectroscopy (ATR Technique)
3.307	Identification by Infrared Spectroscopy—Film from Chlorinated Solvent Solution
3.339	Determination of PTH (1-34) in Swabbing Material by Micro BCA
3.340	Determination of (1-34) Human Parathyroid Hormone Content of Macroflux® hPTH In-Process Samples by UV Spectrophotometry
5.102	Physical Dimensions
5.104	Thickness
5.141	Appearance of Injection Molded Parts
5.639	Activation Force Measurement of Macroflux® Applicator
5.640	Impact Peak Force and Duration Measurement of Macroflux® Applicator
5.719	Dimensional Inspection of Macroflux® Arrays with View Voyager
6.441	USP Microbial Content Assay for Polysorbate 20
6.443	Kinetic LAL Bacterial Endotoxins Test for Polysorbate 20
6.444	USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Polysorbate 20
6.483	Kinetic LAL Bacterial Endotoxins Test for Sucrose
6.484	USP Microbial Content Assay for Sucrose
6.523	USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Sucrose
6.550	USP Microbial Content Assay for Edetate Disodium
6.552	Kinetic LAL Bacterial Endotoxins Test for Edetate Disodium

6.553 USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Edetate Disodium

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Schedule I: ALZA Analytical Methods (AAM)

AAM No.	AAM Title
6.576	USP Microbial Content Assay for Human Parathyroid Hormone
6.577	Kinetic LAL Bacterial Endotoxins Test for Human Parathyroid Hormone
6.578	USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Human Parathyroid Hormone
6.586	USP Microbial Content Assay for Macroflux® Sucrose Placebo
6.587	Kinetic LAL Bacterial Endotoxins Test for Macroflux® Sucrose Placebo
6.588	USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Macroflux® Sucrose Placebo
6.589	[**]
6.591	Bioburden Testing of Final Rinse Water
6.592	USP Microbial Content Assay for Macroflux® Human Parathyroid Hormone
6.593	Kinetic LAL Bacterial Endotoxins Test for Macroflux® Human Parathyroid Hormone
6.594	USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Macroflux® Human Parathyroid Hormone
6.595	[**]
6.596	[**]
6.597	[**]
6.599	USP Microbial Content Assay for Macroflux® Adhesive Patch
6.600	USP Microbial Content Assay for Macroflux® Polyurethane Disk
6.601	Kinetic LAL Bacterial Endotoxins Test for Macroflux® Polyurethane Disk
6.602	USP Test for Staphylococcus aureus and Pseudomonas aeruginosa from Macroflux® Polyurethane Disk
8.001	Amino Acid Composition Analysis of Proteins and Peptides
8.003	Molecular Weight Determination of Peptides by Electrospray Mass Spectrometry .
8.010	[**]
8.016	[**]
9.001	Appearance
9.002	Certificate Verification
9.003	Attribute Verification

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Schedule I: ALZA Analytical Methods (AAM)

AAM No.	AAM Title
9.004	Document Review
9.030	Certificate Verification for Reference Standards
9.038	Appearance of Components
9.045	Appearance of Raw Material Powders or Granules

Attachment 1.6 - ALZA Know-How Index

Schedule J: ALZA Quality Specification (AQS)

AQS Number	AQS Title
0002654	[**]
0008541	[**]
0009083	Hydrochloric Acid, NF, Ph Eur
0009895	Water for Injection, USP, (Bulk Package)
0011513	[**]
0012191	[**]
0012490	[**]
0012512	[**]
0012514	[**]
0012602	Centrifuge Tubes, 250 mL, Polypropylene
0012608	Pipette tip, 1000uL, positive displacement, sterile
0012636	Centrifuge tube, 15 ml, Sterile
0012663	Pipette tip, 10mL, sterile
0012664	Pipette tip, 100uL, positive displacement, sterile
0013359	[**]
0013379	Edetate Disodium, USP, Ph Eur, Dihydrate, (Low Endotoxin)
0013429	[**]
0013430	[**]
0013431	[**]
0013490	[**]
0013652	Parathyroid Hormone (1-34) Human, Acetate Salt
0013673	Detergent CIP-100 (1 gallon)
0013712	[**]
0013854	Pipette Tip, 10uL, Positive Displacement, Steri
0013882	[**]
0013889	Centrifuge Tubes, 2.0mL sterile/non-pyrogenic
0013911	[**]
0013933	Tubing, Polypropylene, 1/8 in ID x 1/4 in OD

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Schedule J: ALZA Quality Specification (AQS)

AQS Number	AQS Title
0014056	[**]
0014360	[**]
0014793	[**]
0014859	[**]
0014860	[**]
0014889	[**]
0014941	Sucrose, NF (low endotoxin), Beet Derived
0015010	[**]
0015011	[**]
0015029	[**]
0015081	HOPE, Separator
0015186	[**]
0015187	[**]
0015188	[**]
0015189	[**]
0015207	[**]
0015340	[**]
0015346	[**]
0015403	[**]
0015540	[**]
0015594	[**]
0015618	Bag, Unprinted, Nylon/LLDPE 14.5 x 7”
0015619	Bag, Unprinted, Tyvek/film 15 x 19.5
0015620	Shipper, Corrugated, RSC, 16 x 10 x 8”
0015621	Bag, Unprinted, Tyvek/film, 15.5 x 13.25”
0015634	[**]
0015662	[**]

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Schedule J: ALZA Quality Specification (AQS)

AQS Number	AQS Title
0015663	Bag, Unprinted, Nylon/LLDPE, 9 x 14”
0015664	Shipper, Corrugated, RSC, 22 x 15 x 10”
0015665	Bag, Unprinted, Nylon/LLDPE, 7 x 6.5”
0015666	Bag, Unprinted, Nylon/LLDPE, 19 x 16 “
0015667	Shipper, Corrugated, RSC, 20 x 12 x 8”
0015668	Bag, Unprinted, Tyvek/film, 12 x 8.75”
0015669	Bag, Unprinted, Tyvek/film 16 x 37”
0015670	Bag, Unprinted, Nylon/LLDPE 16 x 8.5”
0015671	Shipper, Corrugated, RSC, 36 x 16 x 7”
0015672	Label, Identification, Process 3” x 2”
0015691	Polypropylene filter disk, 7.5”
0015692	Autoclave Indicator, 1/2” Circle
0015693	Polyethylene Foam Cushioning and Mailer
0015694	Poly Cushion/Shipper Macroflux® Reservoir
0015695	Poly Cushion/Shipper 16x10x8”
0015696	Carton, Folding, Plastic, 5 Side
0015697	Indicator, Irradiation, 1/2” Circle
0015698	Poly Cushion/Shipper,Macroflux® Filters
0015699	Poly Cushion/Shipper for Macroflux® Tubes
0015708	[**]
0015712	[**]
0015713	[**]
0015781	Cap, Protective, Plastisol, Black 1/2” x 1 3/4”
0015782	Tray, Thermoformed, PETG
0015783	Poly Cushion/Shipper, MFL Metal Tube
0015803	Bag, Unprinted, Tyvek/Film, 6 1/4 x 9 5/8 inch
0015804	Lid, Tyvek, 13 1/2 x 7 1/4 inch
0015805	Bag, Unprinted, Tyvek/Film, 18 x 23 1/2 inch
0015806	Pouch, Unprinted, Tyvek 3 7/8 x 5 7/8”

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Schedule J: ALZA Quality Specification (AQS)

AQS Number	AQS Title
0015819	Bag, Unprinted, Tyvek/film, 4 3/4 x 6 1/4 inch
0015820	Pouch, Unprinted, 5 1/4 x 8 1/2 inch
0015821	Letter Opener, White
0015860	Tubing, Silicone 0.030 I.D. x 0.066 O.D.
0015863	[**]
0015864	Syringe, 3mI Sterile
0015865	Syringe, 10 ml Sterile
0015866	*Syringe,* 5 ml Sterile
0015868	Gasket, Viton
0015884	[**]
0015885	Shipper, Corrugated, RSC, 14 1/2 x 11x110”
0015886	Bag, Unprinted, Nylon/LLDPE, 20 1/2 x 18”
0015887	Poly Cushion/Shipper, Media Filter
0015888	Shipper, Corrugated, RSC 27 x 7 1/2 x 5”
0015889	Bag, Unprinted, Nylon/LLDPE, 8 1/2 x 12”
0015890	Bag, Unprinted, Nylon/LLDPE, 8 x 27”
0015891	Bag, Unprinted, Nylon/LLDPE, 12 1/2 x 17”
0016086	Tapered Y Connector
0016109	Cable Tie, Nylon, 5 1/2”
0016162	[**]
0016163	[**]
0016164	[**]
0016165	[**]
0016166	[**]
0016167	[**]
0016180	Bag, Unprinted, Tyvek/Film, 22 x 29-1/2”
0016181	Poly Cushion/Mailer/Shipper
0016182	Bag, Unprinted, Tyvek/Film, 15.5 x 10.625”
0016256	[**]

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Schedule J: ALZA Quality Specification (AQS)

AQS Number	AQS Title
0016262	Argon
0016397	Pouch, Unprinted, Foil Pouch, 5.50 x 8.50”
0016404	Plastic Box, PS, Hinged 5 1/8“x 3 1/8 “x 1 5/16”
0016497	Tip Cap, Sterile
0016498	Tube, PETG 1 1/2 x 9 inch
0016524	Sodium Hydroxide Pellets, NF
0016527	Pouch, Printed, Tyvek 3 7/8” x 5 7/8”
0016528	Syringe Filter Connector, Stainless Steel
0016536	MFL Subassemblies in MACAP Infeed Tube
0016545	Needle, 16 gauge x 1.5 inch Sterile
0016668	Tyvek Pouch, Irr 3 7/8 inch x 5 7/8 inch
0016669	[**]
0016670	[**]
0016671	[**]
0016707	[**]
00319	Nitrogen, NF (liquid)
009895	Water for Injection, USP, (Bulk Package)

Attachment 1.6 - ALZA Know-How Index

Schedule K: CPR

CPR Number	CPR Title
0002654	Foil Pouch, 3 718 x 5 7/8 inch
0012191	[**]
0012514	Polyurethane Disk, 70A, 5/8” Diameter, 1/8” Thick, Amber
0013359	[**]
0013372	[**]
0013432	[**]
0013433	[**]
0013434	[**]
0013911	[**]
0015186	Polyurethane DiSk, 54A, 0.8 inch diameter
0015634	Polyurethane Disk, 54A 5/8 inch Diameter
0015708	[**]
0016536	[**]

Attachment 1.6 - ALZA Know-How Index

Schedule L: Packaging Material Specifications (PMS)

PMS Number	PMS Title
0015692	Autoclave Indicator, 1/2” Circle
0015891	Bag, Unprinted, Nylon/LLDPE, 12 1/2 x 17”
0015886	Bag, Unprinted, Nylon/LLDPE, 20 1/2.x 18”
0015889	Bag, Unprinted, Nylon/LLDPE, 8 1/2 x 12”
0015890	Bag, Unprinted, Nylon/LLDPE, 8 x 27”
0016182	Bag, Unprinted, Tyvek/Film, 15.5 x 10.625”
0016180	Bag, Unprinted, Tyvek/Film, 22 x 29-1/2’
0015803	Bag, Unprinted, Tyvek/Film, 6 1/4 x 9 5/8 inch
0015805	Bag, Unprinted, Tyvek/Film, 18 x 23 1/2 inch
0015819	Bag, Unprinted, Tyvek/Film, 4 3/4 x 6 1/4 inch
0013164	Box, Polystyrene, Hinged
0016109	Cable Tie, Nylon, 5 1/2”
0015781	Cap, Protective, Plastisol, Black 1/2” x 1 3/4”
0015696	Carton, Folding, Plastic, 5 Side
0015697	Indicator, Irradiation, 1/2” Circle
0013163	Interleaving, High Impact Polystyrene
0015821	Letter Opener, White
0015804	Lid, Tyvek, 13 1/2 x 7 1/4 inch
0016181	Poly Cushion/Mailer/Shipper
0015695	Poly Cushion/Shipper 16x10x8”
0015699	Poly Cushion/Shipper for Macroflux® Tubes
0015694	[**]
0015884	[**]
0015887	Poly Cushion/Shipper, Media Filter
0015783	Poly Cushion/Shipper, MFL Metal Tube
0015698	Poly Cushion/Shipper, Macroflux® Filters
0015693	Polyethylene Foam Cushioning and Mailer
0015691	Polypropylene filter disk, 7.5”

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Schedule L: Packaging Material Specifications (PMS)

PMS Number	PMS Title
0015820	Pouch, Unprinted, 5 1/4 x 8 112 inch
0015806	Pouch, Unprinted, Tyvek 3 7/8 x 5 718”
0015888	Shipper, Corrugated, RSC, 27 x 7 1/2 x 5”
0015885	Shipper, Corrugated, RSC, 14 1/2 x 11x110”
0016497	Tip Cap, Sterile
0015782	Tray, Thermoformed, PETG
0016498	Tube, PETG 1 1/2 x 9 inch
000783	Pouch Stock, Unprinted, 12”
0016527	Pouch, Printed, Tyvek 3 7/8” x 5 7/8”
0016397	Pouch, Unprinted, Foil Pouch, 5.50 x 8.50”

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Schedule M: Clinical Files

Clinical Study Number and Title

[**] **-** Tolerability of Skin Interface Technology Designs and Application Methods in Healthy Volunteers

[**] **-** Assessment of Tolerability and Penetration of Macroflux® Non-Drug Systems in Healthy Volunteers

[**] **-** Assessment of Penetration and Tolerability of Macroflux® Non-Drug Systems in Healthy Volunteers

[**] **-** Assessment of Safety and Bioavailability of Macroflux® TH0229 in Healthy Volunteers

[**] # - Pharmacokinetics, Pharmacodynamics and Tolerability of Macroflux® hPTH via Three Application Sites in Healthy, Postmenopausal Women [**]

[**] **# -** Dose-Finding Study of Macroflux® hPTH in Healthy Postmenopausal Women [**]

[**]

The documents from <u>each</u> clinical study <u>must, at a minimum, include</u> the following (except as noted for study [**] **above:**

Raw data

Final study report

Approved Final Protocol

All Protocol Amendments

Protocol Signature Pages

All Protocol Amendment(s) Signature Pages

If not included in protocol, a document describing unblinding procedure in case of an emergency, (if applicable)

Institutional Review Board (IRB)/ Independent Ethics Committee (IEC) approved Informed Consent Forms (original and amended versions)

Signed FDA Form 1572 (and all updated 1572s)

Curricula vitae (CV) for the principal investigator, subinvestigators, and others listed on the 1572.

One page CV summaries for investigator and sub investigators

Attachment 1.6 - ALZA Know-How Index

Schedule M: Clinical Files

The documents from <u>each</u> clinical study <u>must, at a minimum, include</u> the following (except as noted for study [**] above):

Financial Disclosure Forms (if applicable)

Insurance statement (if applicable)

Declaration of Helsinki, (if applicable)

DEA forms (if applicable)

IRB/IEC membership list or Department of Health and Human Services (DHHS) ID number

Initial IRB/IEC approval letter for the protocol, consent form and any subsequent amendments

IRB/IEC approval for advertisements and copy of advertisement (if applicable)

IRB/IEC approval for any other written information given to subjects and copy of information (if applicable)

IRB/IEC continuing review and reapproval (if applicable)

Each edition of the Investigator's Brochure

Package Insert/Summary of Product Characteristics, (if applicable)

Clinical laboratory information (certifications, accreditation, normal ranges, CV of laboratory director)

Documents concerning investigational drug shipments and accountability

Documentation concerning disposition of any unused investigational drug at study termination

Monitoring Log

Subject Screening/Enrollment Log

Signature Verification Form/Staff Delegation Log

Contact reports, correspondence, monitoring reports

Serious Adverse Event Report Form (if applicable)

Notification to investigators of IND safety reports (if applicable)

IRB/IEC notification of IND safety reports (if applicable)

Clinical Safety Team Checklist

Approved version of Case Report Forms (CRFs)

DataFax QC reports (returned by sites) documenting CRF corrections

Subjects' completed signed and dated CRFs

Case Reports

Clinical Research Organization (CRO) file, (if applicable)

CRO Audit reports

Protocol specific training manuals, (if applicable)

Any other study related documents ***except for financial records***

Attachment 1.6 - ALZA Know-How Index

Schedule N: Bioanalytical - CRO documents

Per provision 3.4 of the License Agreement, ALZA will not be required to transfer or make available any ALZA Know-How that would require ALZA to breach any obligation it may have to a Third Party or violate any law, statute, ordinance or regulation.

Note: Audit reports and quotes required for all CROs listed

Data and documents in this Section N to be transferred at the end of the transition services period

CRO Name

[**]

Attachment 1.6 - ALZA Know-How Index

Schedule O: Vendor Files

Per provision 3.4 of the License Agreement, ALZA will not be required to transfer or make available any ALZA Know-How that would require ALZA to breach any obligation it may have to a Third Party or violate any law, statute, ordinance or regulation. ALZA agrees to transfer to TMC any equipment files, equipment manuals; drawing files and vendor audit files in its possession for the vendors listed in this Schedule O at the end of the transition services period provided that TMC has obtained any permission required from such vendors for such transfers.

Item Number(s)	Vendor Name	GMP PO Number
11696	[**]	None
None	[**]	None
None	[**]	None
None	[**]	None
15708	[**]	Various (4)
12512	[**]	70110457
None	[**]	None
13164	[**]	Various (2)
13712	[**]	70110041
14793	[**]	70110604
15863, 16669, 16670	[**]	70110687
15010 & 15011	[**]	Various (3)
15340	[**]	Various (2)
15619 & 15621	[**]	None
13827	[**]	Pending
16523	[**]	70110650
13163 & 15081	[**]	70110546
14941	[**]	Various
None	[**]	Pending
14889	[**]	70110631
13827	[**]	None
13827	[**]	Various
15618, 15663, 15665, 15666, 15670, 15886, 15889, 15891	[**]	Various (2)
15699, 15693, 15694, 15695 15696, 15698, 15884, 15887	[**]	70110494

15696	[**]	Various (3)

15668, 15669, 15804, 16527	[**]	Various (8)
4657, 4661, 8556, 9083 9895, 13673, 14977, 15403	[**]	Various (11)

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

Attachment 1.6 - ALZA Know-How Index

Schedule P: Completed Batch Records

Requirements: Completed Batch Records for the following programs listed below.

Program name

Macroflux® PTH

Macroflux® Desmopressin

[**]

Attachment 1.12 - Development Agreements

1. Interim Development Agreement between ALZA Corporation and [**].
2. Interim Development Agreement between ALZA Corporation and [**].
3. Interim Development Agreement between ALZA Corporation and [**].
4. Termination Agreement between ALZA Corporation and [**] terminating all three of the above [**].
5. Interim Development Agreement between ALZA Corporation and [**].
6. Material Evaluation Agreement between ALZA Corporation and [**].

Attachment 1.23 - Licensed Patents

CATEGORY A

6,050,988 ARC2758R1 AU, CA, CN, EP, JP, KR, MX	Device for Enhancing Transdermal Agent Flux
6,230,051 ARC2466CIP1 CA, EP, JP, KR	Device and Method for Enhancing Transdermal Sampling
6,855,372 ARC3116R1	Method and Apparatus for Coating Skin Piercing Microprojections
6,855,131 ARC3014R1 AU, BR, CA, CZ, EP, HU, HK, IL, IN, JP, KR, MA, MX, NO, NZ, PL, RU, VN, ZA	Microprotrusion Member Retainer for Impact Applicator
6,953,589 ARC2685N1	Device For Enhancing Transdermal Agent Flux
09/733,305 ARC2864R1 AU, CA, CN, EP, HK, HU, IL, JP, KR, MX, NO, NZ, ZA	Skin Treatment Method and Apparatus for Sustained Transdermal Drug Delivery
10/794,637 ARC2864N1	Skin Treatment Method and Apparatus for Sustained Transdermal Drug Delivery
09/733,506 ARC2877R1 EP, HK	Device and Method for Enhancing skin Piercing by Microprotrusions
10/984,499 ARC2877DIV I	Device and Method for Enhancing skin Piercing by Microprotrusions
09/976,763 ARC2972R1 AU, BR, CA, CN, CZ, EP, HK, HU, IL, IN, JP, KR, MA, MX, NO, NZ, PL, RU, VN, ZA	Microblade Array Impact Applicator
11/251,488 ARC2972USCNT	Microblade Array Impact Applicator
10/978,807 ARC3014CON1	Microprotrusion Member Retainer for Impact Applicator
10/045,842 ARC3036R1 AU, BR, CA, CN, CZ, EP, HK, HU, IL, IN, JP, KR, MA, MX, NO, NZ, PL, RU, VN, ZA	Transdermal Drug Delivery Devices Having Coated Microprotrusions
11/347,779 ARC3036USD1V	Transdermal Drug Delivery Devices Having Coated Microprotrusions
10/984,510 ARC3116D1V1	Method and Apparatus for Coating Skin Piercing Microprojections
10/127,171 ARC3092R1 AU, BR, CA, CN. EP, IL, JP, KR, MX, NO, NZ, ZA	Microprojection Array Immunization Patch and Method

11/267,563 ARC3092USCNT	Microprojection Array Immunization Patch and Method
10/127,108 ARC3056R1 AU, BR, CA, CN, EP, EP DIV, IL, JP, KR, MX, NO, NZ, NZ DIV, ZA	Microprojection Array Having a Beneficial agent Containing Coating
10/305,641 ARC3089R1 EP	Method and Apparatus for Forming Microprojection Arrays
10/327,330 ARC2909R1 AU, EP, HU, IN, NO, RU, ZA	Skin-Piercing Microprojections Having Piercing Depth Control
10/674,626 ARC3061R1 CA, EP	Drug Delivery Device and Method Having Coated Microprojections Incorporating Vasoconstrictors
10/608,304 ARC3074R1 AR, AU, BR, CA, CN, EP, JP, KR, MX, SG, TW	Transdermal Drug Delivery Devices Having Coated Microprotrusions
10/637,909 ARC3149R1 AR, AU, BR, CA, CN, EP, HK, JP, KR, MX, SG, TW	Transdermal Vaccine Delivery Device Having Coated Microprotrusions
10/745,995 ALZ5103R1 AR, AU, BR, CA, CL, CN, EP, HK, JP, KR, MX, SG, TW, VE	Active Agent Delivery Device Having Composite Members
10/884,603 ARC3077USANP AR, AU, BR, CA, CL, CN, EP, JP, KR, MX, MY, NZ, PE, PK, SG, TH, TW, UY, VE	Microprojection Array Immunization Patch and Method
10/880,702 ALZ5049USNP AR, AU, BR, CA, CN, EP, JP, KR, TH, MX, MY, NZ, SG, TW, VE	Formulations for Coated Microprotrusions Containing Non-Volatile Counterions
11/034,891 ALZ5049CIP1 WO, AR, MY, TH, TW, VE	Formulations for Coated Microprojections Having Controlled Solubility
10/880,701 ALZ5050USANP AR, AU, BR, CA, CN, EP, JP, KR, MX, MY, NZ, SG, TH, TW, VE	Method for Coating Skin Piercing Microprojections
10/925,518 ALZ5056USANP AR, AU, BR, CA, CN, EP, JP, KR, MX, MY, NZ, SG, TW, TH, VE	Device and Method For Intradermal cell Implantation
10/910,889 ALZ5037USANP AR, AU, BR, CA, CN, EP, JP, KR, MY, MX, NZ, SG, TH, TW, VE	Device For Enhancing Transdermal Agent Flux
10/910,915 ALZ5037USANP2 AR, AU, BR, CA, CN, EP, JP, KR, MY, MX, NZ, SG, TH, TW, VE	Device For Enhancing Transdermal Agent Flux
10/911,299 ALZ5037USANP3	Device For Enhancing Transdermal Agent Flux
10/972,230 ALZ5074NP AR, MY, TH, TW, VE, AU, BR, CA, CN, EP, JP, KR, MX, SG	Compositions of Stabilized DNA for Coating Microprojections
10/971,224 ALZ5075NP AR, MY, TH, TW, VE, AU, BR, CA, CN, EP, JP, KR, MX, SG	Method and Apparatus for Reducing the Incidence of Tobacco Use

10/972,231 ALZ5076NP AR, MY, TH, TW, VE, AU, BR, CA, CN, EP, KR JP, MX, SG	Delivery of Polymer Conjugates of Therapeutic Peptides and Proteins via a Microprojection Apparatus
10/971,871 ALZ5084NP AR, MY, TH, VE, AU, BR, CA, CN, EP, KR, JP, MX, SG	Self-Actuating Applicator for Microprojection Array
10/970,890 ALZ5095NP AR, MY, TH, TW, VE, AU, BR, CA, CN, EP, KR, JP, MX, SG	Composition and Apparatus for Transdermal Delivery
11/084,631 ALZ5123NP AR, AU, BR, CA, CN, EP, JP, KR, MY, MX, SG, TH, TW, VE	Apparatus and Method for Transdermal delivery of Influenza Vaccine
11/084,635 ALZ5 I 24NP WO, AR, MY, TH, TW, VE	Apparatus and Method for Transdermal Delivery of Multiple Vaccines
11/084,634 ALZ5133NP WO, AR, MY, TH, TW, VE	Method and Apparatus for Transdermal Delivery of hPTH(1-34)
11/222,297 ALZ5154USNP WO, AR, MY, TH, TW, VE	Microprojection Array with Improved Skin Adhesion and Compliance
11/259,010 ALZ5159USNP	Method and Apparatus for Transdermal Delivery of Desmopressin
11/341,832 ALZ5170USNP WO, AR, MY, TH, TW, VE	Coated Microprojections Having Reduced Variability and Method for Producing Same
11/391,609 ALZ5171USNP WO	Microprojections with Capillary Control Features and Method
11/446,530 ALZ5 I 93USANP WO	Method for Terminal Sterilization of Transdermal Delivery Devices
11/446,487 ALZ5194USANP WO	Method for Terminal Sterilization of Transdermal Delivery Devices
11/472,165 ALZ5173USANP WO	Method And Device for Coating a Continuous Strip of Microprojections Members
11/ ALZ5216USAPSP WO	Coatable Transdermal Delivery Microprojection Assembly
60/754,948 ALZ5234USPSP	Therapeutic Formulations With Improved Stability
60/781,049 ALZ5237USPSP	Microprojection Array Application with High Barrier Retainer
60/782,939 ALZ5240USPSP	Apparatus and Methods for Transdermal Delivery of Parathyroid Hormone Agents to Prevent or Treat Osteopenia
60/784,883 ALZ5243USPSP	Apparatus and Methods for Transdermal Delivery of a Triptan Agonist

60/784,743 ALZ5244USPSP	Apparatus and Methods for Transdermal Delivery of a 5-Hydroxytritamine Antagonist
60/784,850 ALZ5245USPSP	Apparatus and Methods for Transdermal Delivery of a Benzodiazepine
60/817,499 ALZ5259USPSP	Apparatus and Methods for Transdermal Delivery of Insulin
60/817,563 ALZ5260USPSP	Apparatus and Methods for Transdermal Delivery of Gonadotropins
60/795,009 ALZ5247USPSP	Microprojection Array Application with Sculptured Microprojections for High Drug Loading
60/794,941 ALZ5251 U SPSP	Microprojection Array Application with Grouped Microprojections for High Drug Loading
60/794,960 ALZ5252USPSP	Microprojection Array Application with Multilayered Microprojection Member for High Drug Loading
11/477,045 ALZ5084USCNT	Self-Actuating Applicator for Microprojection Array

CATEGORY B

6083196 ARC2685R2 AU, CA, CN, EP, JP, KR, MX	Device for Enhancing Transdermal Agent Flux
6322808 ARC2685RI AU, CA, CN, EP, JP, MX DIV, KR, MX	Device for Enhancing Transdermal Agent Flux
08/877,155 ARC2466R1 AR, AR DIV, CA, EP, JP, KR, TW	Device and Method for Enhancing Transdermal Flux
6,918.901 ARC2600R1 AU, CA, CN, EP, JP, KR, MX	Device and Method for Enhancing Transdermal Agent Flux
10/881,440 ARC2600N1	Device and Method for Enhancing Transdermal Agent Flux
09/950,436 ARC2911 AU, BR, CA, CN, CZ, EP, IL, JP, KR, MA, MX, NO, NZ, RU, VN, ZA	Methods for Inhibiting Decrease in Transdermal Drug Flux by Inhibition of Pathway Closure
09/976,798 ARC3043R1 AU, BR, CA, CN, CZ, EP, HK, HU, IL, IN, JP, KR, MA, MX, NO, NZ, PL, RU, VN, ZA	Apparatus and Method for Piercing Skin with Microprotrusions
11/092,800 ARC3043CIP	Apparatus and Method for Piercing Skin with Microprotrusions
11/092,202 ARC3043DIV1	Apparatus and Method for Piercing Skin with Microprotrusions
10/971,430 ALZ5070NP IAR, MY, TH, TW, VE, AU, BR, CA, CN, EP, KR, JP, MX, SG	Apparatus and Method for Enhancing Transdermal Drug Delivery
10/970,901 ALZ5071NP AR, MY, TH, TW, VE, AU, BR, CA, CN, EP, KR, JP, MX, SG	Pretreatment Method and System for Enhancing Transdermal Drug Delivery
11/084,636 ALZ5125NP WO, AR, MY, TH, TW, VE	Apparatus and Method for Transdermal Delivery of FentanylBased Agents
11/201,617 ALZ5150NP WO, AR, MY, TH, TW, VE	Microprojection Apparatus and System with Low Infection Potential
I 1/237,200 ALZ5156NP WO, AR, MY, TH, TW, VE	Method and Formulation for Stabilizing Alum-Adsorbed Vaccines
11/336,134 ALZ5169NP WO, AR, MY, TH, TW, VE	Therapeutic Peptide Formulations With Improved Stability
11/355,729 ALZ5174NP WO, AR, MY, TH, TW, VE	Microprojection Arrays with Improved Biocompatibilty
11/112,311 ALZ5134NP WO, AR, MY, TH, TW, VE	Method and formulation for Transdermal Delivery of Immunologically Active Agents

Attachment 1.46 - Trademark

TRADEMARK	COUNTRY	FILING NO,	REGISTRATION NO.
MACROFLUX	ARGENTINA	2648182	
MACROFLUX	ARGENTINA	2648183	
MACROFLUX	ARGENTINA	2648184	
MACROFLUX	AUSTRALIA	1050824	
MACROFLUX	AUSTRALIA	1099430	
MACROFLUX	BENELUX	1102532	790811
MACROFLUX	BRAZIL	828132097	
MACROFLUX	BRAZIL	828132062	
MACROFLUX	BRAZIL	828132070	
MACROFLUX	BULGARIA	880221	880221
MACROFLUX	CANADA	875880	
MACROFLUX	EUROPEAN COMMUNITY (EUROPEAN UNION)	819730	819730
MACROFLUX	HONG KONG	300572751	
MACROFLUX	INDIA	1419150	
MACROFLUX	INDIA	1419151	
MACROFLUX	INDIA	1419152	
MACROFLUX	- ISRAEL	187772	
MACROFLUX	ISRAEL	187773	
MACROFLUX	ISRAEL	187774	
MACROFLUX	JAPAN	52553/98	4410279
MACROFLUX	KOREA (NORTH)	880221	880221
MACROFLUX	KOREA (SOUTH)	0450	
MACROFLUX	MALAYSIA	04863	
MACROFLUX	MALAYSIA	04864	
MACROFLUX	MALAYSIA	04865	
MACROFLUX	MEXICO	768540	
MACROFLUX	NEW ZEALAND	741896	
MACROFLUX	NORWAY	01277	
MACROFLUX	NORWAY	02451	
MACROFLUX	RUSSIAN FEDERATION (formerly USSR)	880221	880221
MACROFLUX	SINGAPORE	028591	
MACROFLUX	SINGAPORE	02858J	02858J

MACROFLUX	SINGAPORE	02860B	
MACROFLUX	SOUTH AFRICA	02108	
MACROFLUX	SOUTH AFRICA	02109	
MACROFLUX	SOUTH AFRICA	02110	
MACROFLUX	SWITZERLAND	880221	880221
MACROFLUX	TAIWAN	5192	
MACROFLUX	TAIWAN	5193	
MACROFLUX	TAIWAN	5194	
MA CROFLUX	THAILAND	624920	
MACROFLUX	THAILAND	616583	
MACROFLUX	THAILAND	616584	
MACROFLUX	UNITED STATES OF AMERICA	76/232982	2872091
MACROFLUX	VENEZUELA	01523	
MACROFLUX	VENEZUELA	01522	
MACROFLUX	VENEZUELA	01524	
MACROFLUX	VIETNAM	01518	

www.macroflux.com and www.macroflux.info

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

Attachment 3.3.1 — Existing Agreements

Service and Consulting Agreements

1. Service Agreement between ALZA Corporation and [**] regarding Contract #20060455, dated July 25, 2006
2. Service Agreement between ALZA Corporation and [**] regarding Contract #20060120, dated March 9, 2006
3. Service Agreement between ALZA Corporation and [**] regarding Contract #20050611, dated September 6, 2005
4. Service Agreement between ALZA Corporation and [**] regarding Contract #20060046 and Purchase Order #991532361, dated February 2, 2006
5. Service Agreement between ALZA Corporation and [**] regarding Contract #20060215 and Purchase Order #991595923, dated April 20, 2006
6. Service Agreement between ALZA Corporation and [**] regarding Contract #20060353, dated May 22, 2006.
7. Service Agreement between ALZA Corporation and [**] regarding Contract #20060192, dated April 21, 2006
8. Master Services Agreement between ALZA Corporation and [**], regarding Contract #20060346, dated May 2, 2006; Clinical Agreement Request dated May 9, 2006; Work Order regarding Work Order #20060346-1, dated May 9, 2006
9. Service Agreement between ALZA Corporation and [**] regarding Contract #20050949 and Purchase Order #991520371, dated December 20, 2005

Attachment 3.3.1 — Agreements Transferring to TMC

10. Service Agreement between ALZA Corporation and [**] regarding Contract #20060365, and Purchase Order #991618313, dated May 25, 2006

11. Consultant Agreement between ALZA Corporation and Lane, Nancy E., M.D. regarding Contract #20050556, dated August 25, 2005, as amended on August 24, 2006.

12. Consultant Agreement between ALZA Corporation and [**] regarding Contract #20060330 and Purchase Order #991622895, dated May 22, 2006

13. Service Agreement between ALZA Corporation and [**] regarding Contract #20060191, dated March 30, 2006

14. Service Agreement between ALZA Corporation and [**] regarding Contract #20060108, dated May 3, 2006

15. Service Agreement between ALZA Corporation and [**] regarding Contract #20060034, dated January 23, 2006

16. Service Agreement between ALZA Corporation and [**] regarding Contract #20050869, dated December 12, 2005, as amended on September 14, 2006

17. Service Agreement between ALZA Corporation and [**] regarding Contract #20060388 and Purchase Order #991638161, dated June 7, 2006

18. Service Agreement between ALZA Corporation and [**] regarding Contract #20050858 and Purchase Order #991489623, dated November 18, 2005, as amended on February 16, 2006

19. Service Agreement between ALZA Corporation and [**] regarding Contract #20060467, dated August 8, 2006

Attachment 3.3.1 — Agreements Transferring to TMC

Secrecy/Confidentiality Agreements

1. Confidentiality Agreement between ALZA Corporation and ACE USA regarding Contract #20060382, dated June 12, 2006
2. Secrecy Agreement between ALZA Corporation and Alliance Capital Ventures regarding Contract #20060234, dated April 11, 2006
3. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060422, dated June 22, 2006
4. Secrecy Agreement between ALZA Corporation and Babington Consulting, LLC regarding Contract #20060538 dated September 6, 2006.
5. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20050444, dated August 1, 2005
6, Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060172, dated May 2, 2006
7. Secrecy Agreement between ALZA Corporation and Continental Casualty Company regarding Contract #20060381, dated June 19, 2006
8. Secrecy Agreement between ALZA Corporation and CRESA Partners, LLC regarding Contract #20060390, dated June 12, 2006
9. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060516, dated September 1, 2006.
10. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060077, dated February 14, 2006

11. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060497, dated August 18, 2006
12. Secrecy Agreement between ALZA Corporation and Frazier Management LLC regarding Contract # 20060071, dated January 31, 2006
13. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20050960, dated March 10, 2006
14. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060479, dated August 9, 2006
15. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060424, dated June 22, 2006
16. Secrecy Agreement between ALZA Corporation and [**]regarding Contract #20060341, dated May 17, 2006
17. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060533, dated September 6, 2006.
18. Secrecy Agreement between ALZA Corporation and Kleiner Perkins Caufield & Byers regarding Contract #20060075, dated March 6, 2006
19. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060344, dated May 17, 2006
20. Secrecy Agreement between ALZA Corporation and Marsh Risk and Insurance, Inc. regarding Contract #20060354, dated May 22, 2006

Attachment 3.3.1 — Agreements Transferring to TMC

21. Mutual Non-Disclosure Agreement between ALZA Corporation and [**], regarding Contract #20060379, dated September 16, 2004
22. Secrecy Agreement between ALZA Corporation and Mercer Health Resource Consulting, Inc. regarding Contract #20060235, dated April 12, 2006, as amended on May 9, 2006
23. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060039, dated February 10, 2006
24. Secrecy Agreement between ALZA Corporation and National Union Fire Insurance Company regarding Contract #20060425, dated June 21, 2006
25. Secrecy Agreement between ALZA Corporation and New Enterprise Associates regarding Contract #20060460, dated July 24, 2006
26. Secrecy Agreement between ALZA Corporation and Nomura Phase 4 Ventures LP regarding Contract #20060076, dated February 7, 2006
27. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060036, dated January 18, 2006
28. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060271, dated May 3, 2006
29, Secrecy Agreement between ALZA Corporation and OrbiMed Advisors, LLC regarding Contract #20060095, dated February 16, 2006
30. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060366, dated May 2006

31. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20040368, dated May 4, 2004
32. Secrecy Agreement between ALZA Corporation and [**] regarding Contract # 20050053, dated January 27, 2005
33. Secrecy Agreement between ALZA Corporation and Robust Network Solutions regarding Contract #20060378, dated June 6, 2006
34. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20060302, dated May 17, 2006
35. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20050929, dated January 9, 2006
36. Confidentiality Agreement between ALZA Corporation and St. Paul Travelers regarding Contract #20060395, dated June 7, 2006
37. Secrecy Agreement between ALZA Corporation and The Tech Group regarding Contract #20060423, dated June 22, 2006
38. Secrecy Agreement between ALZA Corporation and [**] regarding Contract #20050430, dated August 10, 2005
39. Secrecy Agreement between ALZA Corporation and Warburg Pincus, LLC regarding Contract #20060088, dated February 28, 2006

Attachment 4.1 - GENERAL TRADEMARK ASSIGNMENT

WHEREAS, **ALZA CORPORATION,** a Delaware corporation, having its place of business at 1900 Charleston Road, Mountain View, California 94043 (hereinafter called "Assignor"), has established certain rights in various countries in and to the trademarks identified in the attached Exhibit A (together with any registrations and applications for registration therefor, hereinafter "Trademarks"); and

WHEREAS, **THE MACROFLUX CORPORATION,** a Delaware Corporation, (hereinafter called "Assignee"), desires to acquire all of Assignor's right, title and interest in and to the Trademarks; and

NOW THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, Assignor does hereby assign and transfer unto Assignee, and Assignee does hereby accept, all of Assignor's rights, title and interest in and to the Trademarks in all countries where such rights exist together with the goodwill of the business symbolized by the Trademarks, Assignor undertakes within two years hereof to duly execute, or have duly executed by its subsidiaries, any further documents reasonably necessary to record the transfer of title effected hereby, as prepared by Assignee.

IN WITNESS WHEREOF, Assignor and Assignee have caused these presents to be executed by their duly authorized officers or agents on this day of , 2006.

ASSIGNOR: **ALZA CORPORATION**

BY: _____

TITLE: _____

NOTARIZATION

ASSIGNEE: **THE MACROFLUX CORPORATION**

BY: _____

TITLE: _____

NOTARIZATION

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

EXHIBIT A

Mark	Class	Country	App./Reg. No.	App./Reg. Date
MACROFLUX	05	ARGENTINA	2648182	May 17, 2006
MACROFLUX	10	ARGENTINA	2648183	May 18, 2006
MACROFLUX	42	ARGENTINA	2648184	May 19, 2006
MACROFLUX	05,10,42	AUSTRALIA	1099430	February 16, 2006
MACROFLUX	05,10	AUSTRALIA	1050824	February 16, 2006
MACROFLUX	05	BRAZIL	828132097	February 07, 2006
MACROFLUX	10	BRAZIL	828132070	February 07, 2006
MACROFLUX	42	BRAZIL	828132062	February 07, 2006
MACROFLUX		CANADA	875880	April 22, 1998
MACROFLUX	05,10,42	E.U.	819730	April 19, 2006
MACROFLUX	05,10,42	HONG KONG	300572751	January 26, 2006
MACROFLUX	05	INDIA	1419150	February 06, 2006
MACROFLUX	42	INDIA	1419152	February 06, 2006
MACROFLUX	10	INDIA	1419151	February 06, 2006
MACROFLUX	05	ISRAEL	187772	February 22, 2006
MACROFLUX	10	ISRAEL	187773	February 22, 2006
MACROFLUX	42	ISRAEL	187774	February 22, 2006
MACROFLUX	05,10,42	JAPAN	4410279	August 01, 2000
MACROFLUX	05,10,42	S. KOREA	0450	February 08, 2006
MACROFLUX	05	MALAYSIA	04863	March 28, 2006
MACROFLUX	42	MALAYSIA	04865	March 28, 2006
MACROFLUX	10	MALAYSIA	04864	March 28, 2006

MACROFLUX	42	MEXICO	924368	February 28, 2006
MACROFLUX	05,10,42	NEW ZEALAND	741896	January 25, 2006
MACROFLUX	05,10,42	NORWAY	01277	February 7, 2006
MACROFLUX	05,10,42	NORWAY	02451	March 9, 2006
MACROFLUX	05	SINGAPORE	02858J	February 14, 2006
MACROFLUX	10	SINGAPORE	028591	February 14, 2006
MACROFLUX	42	SINGAPORE	02860B	February 14, 2006
MACROFLUX	05	SOUTH AFRICA	02108	February 01, 2006
MACROFLUX	10	SOUTH AFRICA	02109	February 01, 2006
MACROFLUX	42	SOUTH AFRICA	02110	February 01, 2006
MACROFLUX	05	TAIWAN	5192	February 03, 2006
MACROFLUX	10	TAIWAN	5193	February 03, 2006
MACROFLUX	42	TAIWAN	5194	February 03, 2006
MACROFLUX	05	THAILAND	624920	March 28, 2006
MACROFLUX	10	THAILAND	616583	January 31, 2006
MACROFLUX	42	THAILAND	616584	January 31, 2006
MACROFLUX	05,10	U.S.	2872091	August 10, 2004
MACROFLUX	05	VENEZUELA	01523	January 30, 2006
MACROFLUX	10	VENEZUELA	01524	January 30, 2006
MACROFLUX	42	VENEZUELA	01522	January 30, 2006
MACROFLUX	05,10,42	VIETNAM	01518	February 06, 2006

TRADEMARK ASSIGNMENT

WHEREAS, **JANSSEN PHARMACEUTICA N.V.,** a Belgium corporation, having its place of business at Turnhoutseweg 30 B-2340 Beerse, Belgium (hereinafter called "Assignor"), has established certain rights in various countries in and to the trademarks identified in the attached Exhibit A (together with any registrations and applications for registration therefor, hereinafter "Trademarks"); and

WHEREAS, **THE MACROFLUX CORPORATION**, a Delaware Corporation, (hereinafter called "Assignee"), desires to acquire all of Assignor's right, title and interest in and to the Trademarks; and

NOW THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, Assignor does hereby assign and transfer unto Assignee, and Assignee does hereby accept, all of Assignor's rights, title and interest in and to the Trademarks in all countries where such rights exist together with the goodwill of the business symbolized by the Trademarks. Assignor undertakes within two years hereof to duly execute, or have duly executed by its subsidiaries, any further documents reasonably necessary to record the transfer of title effected hereby, as prepared by Assignee.

IN WITNESS WHEREOF, Assignor and Assignee have caused these presents to be executed by their duly authorized officers or agents on this day of , 2006.

ASSIGNOR: **JANSSEN PHARMACEUTICA N.V.**

BY: _____

TITLE: _____

NOTARIZATION:

ASSIGNEE: **THE MACROFLUX CORPORATION**

BY: _____

TITLE: _____

NOTARIZATION:

EXHIBIT A

Mark	Class	Country	App./Reg. No.	App./Reg. Date
MACROFLUX	05, 10, 42	BENELUX	1102532	February 1, 2006
MACROFLUX	05, 10, 42	INTERNATIONAL REGISTRATION (Valid in Bulgaria, N. Korea, Russia, Switzerland)	880221	March 1, 2006

Attachment 4.5 - Trademark Assignment Form

THIS TRADEMARK ASSIGNMENT (the "Assignment") is made and entered into as of this _____ day of _____, 2006 and is made effective as of _____, 2006 ("Effective Date", from **ASSIGNOR NAME AND ADDRESS** ("Assignor") to **ASSIGNEE NAME AND ADDRESS** ("Assignee").

WHEREAS, Assignor is the sole and exclusive owner of the entire right, title and interest in, to and under the trademarks and the trademark registration set forth on the Exhibit A (collectively, the "Trademark"), and the goodwill of the business associated therewith;

WHEREAS, Assignee wishes to acquire and Assignor wishes to assign all right, title and interest in and to the Trademark, together with the goodwill of the business in connection with which the Trademark is used;

NOW, THEREFORE, for the good and valuable consideration, the receipt and sufficiency of which are hereby expressly acknowledged, the Assignor hereby sells, assigns and transfers to Assignee, all of the Assignor's right, title and interest in and to said Trademark, together with the good will of the business symbolized by said Trademark, and the Assignor's entire right, title and interest in and to any and all claims and demands it may have, at law or in equity, for past infringement of Trademark.

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

IN WITNESS WHEREOF, the Assignor and Assignee have caused this Assignment of Trademarks to be executed and sealed by their respective duly authorized officers as of the dates noted below.

ASSIGNOR

By: _____

Name: _____

Title: _____

Date: _____

ASSIGNEE

By: _____

Name: _____

Title: _____

Date: _____

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

EXHIBIT A — TRADEMARKS

Title	Issue Date	Registration No.

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

Attachment 10.1 - Key Terms for a

Product Development and Commercialization Agreement

Macroflux® Nesiritide

Parties:	ALZA Corporation or its affiliated company designated by ALZA ("ALZA") and NewCo ("NewCo").
Agreement:	A Product Development and Commercialization Agreement (the "Agreement") incorporating the terms and conditions set forth herein, and other terms and conditions as the parties may agree, governing the development and commercialization of a Macroflux® nesiritide product.
Drug:	Nesiritide, or any analog or derivative thereof, in its pure form or in the formulation(s) provided to NewCo by ALZA.
System:	NewCo's proprietary system for the passive, diffusion-mediated delivery of therapeutic or prophylactic agents into or through the skin from a microprojection array having a plurality of microprojections which pierce at least through the outmost layer (i.e., the stratum corneum layer) of the skin (a "Microprojection System"), which array is coated with such therapeutic or prophylactic agents; or (b) NewCo's proprietary system for diffusion-mediated delivery of therapeutic or prophylactic agents into or through the skin by way of pathways formed by a Microprojection System.
Product:	A product combining the Drug with the System developed by NewCo pursuant to the Agreement.
License Grant:	NewCo would grant ALZA an exclusive license under any and all intellectual property, patents, trade secrets and know-how now or hereafter owned or controlled by NewCo which are reasonably necessary or useful to make, have made, use, import, offer for sale and sell the Product, solely for purposes of making, having made, using (including performing development work), importing, offering for sale and selling the Product in the Territory during the term of, and in accordance with, the Agreement.
Territory:	Worldwide.

Product Development:	NewCo would undertake the technical development of the Product in accordance with work plans and cost estimates prepared by NewCo and pre-approved by ALZA. ALZA would supply Drug to NewCo at no cost, and would reimburse NewCo on a monthly basis for its internal development costs at the NewCo FTE Rate plus [**] of any out-of-pocket costs incurred by NewCo in connection with such development activities. "NewCo FTE Rate" would mean an annual FTE rate of [**] (which would be adjusted on an annual basis in accordance with the U.S. Department of Labor, Bureau of Labor Statistics Consumer Price Index-Urban Wage Earners and Clerical Workers for the San Francisco-Oakland-San Jose, CA metropolitan area). ALZA would be responsible for clinical development and regulatory activities for the Product in the Territory, and would bear related expenses. ALZA would use commercially reasonable efforts to perform the Product development activities consistent with the efforts ALZA devotes to products of similar market potential and in similar product lifecycle positions and based on conditions then prevailing with respect to the applicable Product and the relevant markets.
Commercialization Rights and Term:	ALZA would be granted the exclusive right (including the right to sublicense such right to a third party) to market the Product in the Territory. Upon receipt of regulatory approvals, ALZA would use commercially reasonable efforts (consistent with the efforts ALZA devotes to products of similar market potential and in similar product lifecycle positions and based on conditions then prevailing with respect to the applicable Product and the relevant markets) to commence and continue diligent commercialization of the Product during the term of the Agreement. The term of the Agreement would be for the commercial life of the Product.
Exclusivity:	During the term of the Agreement, NewCo would not conduct (itself or with a third party) any material development or commercialization activities with respect to any product (other than the Product) incorporating a natriuretic peptide, stresscopin, urocortin, or any analog or derivative of a natriuretic peptide, stresscopin, or urocortin, into any System.
Upfront Payment:	None.

Milestone Payments:	ALZA would pay NewCo the following one-time Milestone Payments within forty five (45) days of each noted occurrence: [**]

* "Net Sales" would mean the total amount billed or invoiced in United States dollars (or converted thereto in accordance with the Agreement) on sales of the Product by ALZA, its affiliates or sublicensees to independent, unrelated third parties (other than sublicensees) such as wholesalers in bona fide arm's length transactions, less the following deductions, in each case related specifically to the Product and actually allowed and taken by such third parties or accrued in accordance with generally accepted accounting principles as consistently applied across ALZA's and its

Product Payments: ALZA would make quarterly payments ("Product Payments") to NewCo within 45 days after the end of each calendar quarter, until, on a country-by-country basis, the date of expiry of the last to expire of patents owned or licensed by NewCo having a valid claim covering the Product in such country, at which point ALZA would have a fully paid-up license in such country. Product Payments would be determined by multiplying the aggregate worldwide Net Sales of the Product during each calendar year by the applicable percentage rates, determined based on the cumulative, aggregate worldwide Net Sales of the Product for the then current calendar year as follows:

For cumulative, aggregate worldwide Net Sales of the Product in the then current calendar year within the respective intervals below ($U.S. Million):	The Product Payment Rate as a percentage of worldwide, aggregate Net Sales within such intervals during the then current calendar year would be:
[**]	[**]
[**]	[**]
[**]	[**]

The total Product Payment for each calendar quarter would be the sum of the amounts calculated in each interval set forth above. For example, if in the first quarter in a calendar year, aggregate worldwide Net Sales were [**], the Product Payment percentage rate for such quarter would be [**], resulting in a quarterly Product Payment of [**]. If in the second quarter of such calendar year,

affiliates' products (as adjusted from time to time to reflect amounts actually incurred) and not otherwise recovered by or reimbursed to ALZA: [**] In the case of any sale or other disposal for value, such as barter or counter-trade, of any Product other than in an arm's length transaction exclusively for money, Net Sales would be calculated as above on a fair market price of the Product in the country of sale or disposal. For clarity, Net Sales would not include the value of Product provided by ALZA for clinical trials, or donations.

aggregate worldwide Net Sales were [**], the Product Payment percentage rates for such quarter would be as follows: [**] for [**] of such Net Sales, and [**] for [**] of such Net Sales, resulting in a quarterly Product Payment of [**]. If in the third quarter of such calendar year, aggregate worldwide Net Sales were [**], the Product Payment percentage rates for such quarter would be as follows: [**] for [**] of such Net Sales, and [**] for [**] of such Net Sales, resulting in a quarterly Product Payment of [**].

Net Sales of the Product would be excluded from the aggregate worldwide net sales of products used to calculate the product payments paid to ALZA by NewCo under the terms of the Macroflux® technology licensing agreement.

Manufacture and Supply:

NewCo would use commercially reasonable efforts to manufacture ALZA's requirements of the Product through completion of Phase II clinical studies. ALZA would supply Drug to NewCo at no cost, and would reimburse NewCo on a monthly basis for NewCo's costs associated with manufacture of ALZA's Preclinical, and Phase I and Phase II clinical requirements of the Product with such costs calculated as the sum of the NewCo FTE Rate plus [**] of any out-of-pocket costs plus [**] of the cost of any new capital assets acquired by NewCo specifically for, and exclusively dedicated to the manufacture of Product (collectively, the "Manufacturing Costs"). Any capital assets (i) acquired by NewCo specifically for, and exclusively dedicated to the manufacture of Product, and (ii) for which ALZA had reimbursed NewCo would be owned by ALZA.

At ALZA's request, NewCo also would be responsible for manufacturing ALZA's Phase III clinical requirements of the Product, provided that such manufacturing could be accomplished using NewCo's existing manufacturing facilities and without compromising NewCo's ability to manufacture its existing requirements of its own products or to satisfy its prior manufacturing obligations to third parties (if any). ALZA would supply Drug to NewCo at no cost, and would reimburse NewCo on a monthly basis for its Manufacturing Costs associated with manufacture of ALZA's Phase III clinical requirements of the Product. In the event that manufacture of ALZA's Phase III clinical requirements of Product could not be accomplished using NewCo's existing manufacturing facilities, the parties would discuss in good faith commercially reasonable alternative

arrangements for manufacturing the Product including the following options:

(A) NewCo would be responsible for development and scale-up of manufacturing processes for the Product and would transfer to a third party contract manufacturing organization ("CMO") selected by ALZA and reasonably acceptable to NewCo, such manufacturing technology and know-how as would be necessary or reasonably useful to enable such CMO to manufacture ALZA's Phase III clinical requirements and commercial requirements of the Product. ALZA would be responsible for all costs associated with the manufacture of its Phase III clinical requirements of the Product and its commercial requirements of the Product by such CMO and would reimburse NewCo for all internal costs incurred by NewCo in connection with the transfer of manufacturing technology and know-how to such CMO at the NewCo FTE Rate plus [**] of any out-of-pocket costs incurred by NewCo in connection with such activities; and,

(B) ALZA would provide capital and infrastructure investments required for any necessary incremental expansion of NewCo's existing Phase III and/or commercial-scale manufacturing facilities, and NewCo would be responsible for manufacturing ALZA's Phase III clinical and/or commercial requirements of the Product. ALZA would supply Drug to NewCo at no cost, and would reimburse NewCo on a monthly basis for its Manufacturing Costs associated with manufacture of Phase III clinical requirements of the Product. The parties would negotiate in good faith commercially reasonable terms for the manufacture and supply of ALZA's commercial requirements of the Product. Until the parties agreed upon fixed supply prices (which would be negotiated promptly after the manufacture and acceptance of three ICH batches of the Product, and which would include annual price increases in accordance with the U.S. Producers' Price Index), the supply price would be [**] of NewCo's fully allocated manufacturing cost. ALZA would supply Drug to NewCo at no cost.

Proprietary Rights: Inventions arising out of the Agreement would be the property of ALZA if and to the extent related to the Drug itself, or the manufacture

	or use thereof (including the use of the Drug with the System). All other inventions arising out of the Agreement would be the property of NewCo, including those related to the System, or the manufacture or use thereof without the Drug (including the use of the System with drugs other than the Drug).
Indemnification:	ALZA would indemnify NewCo for claims arising from the manufacture, use or sale of the Product, except to the extent due to NewCo's negligence or intentional misconduct. NewCo would warrant that, at the time of shipment, Product manufactured by NewCo would meet the then agreed-upon specifications, would be manufactured in accordance with cGMP, and would not be adulterated or misbranded due to any action, or failure to act, of NewCo. NewCo would indemnify ALZA for breach of this warranty; provided, however, that NewCo would not be liable for (i) misbranding with respect to any Product labeling or package insert text provided or used by ALZA or its Affiliates, subcontractors or agents, or any translation thereof; or (ii) any adulteration, misbranding, failure to meet agreed-upon specifications or GMP violation due to handling or packaging of the Product by ALZA or its Affiliates, subcontractors or agents. NewCo's warranty would not apply to or cover any Product that had not been stored under the required conditions after leaving NewCo or to any product handling by anyone other than NewCo, or any adulteration occurring after the Product leaves NewCo.
Termination:	ALZA would be able to terminate the Agreement at any time upon 90 days' written notice to NewCo. NewCo would be able to terminate the Agreement on 30 days' written notice to ALZA for ALZA's material breach of the Agreement. If NewCo notified ALZA that it was terminating the Agreement due to breach, ALZA would have the rights to cure the breach or, if such breach could not be cured within such notification period, such additional reasonable amount of time, prior to the termination becoming effective.

THIS DOCUMENT OUTLINES THE GENERAL BUSINESS TERMS FOR THE AGREEMENT. OTHER TERMS AND CONDITIONS WOULD APPLY. ALL TERMS ARE SUBJECT TO APPROVAL BY ALZA AND JOHNSON & JOHNSON MANAGEMENT, AND NEGOTIATION AND EXECUTION OF A DEFINITIVE AGREEMENT.

Attachment 16.3.4-
Disclosures

1. Interactions and communications relating to the Interim Development Agreement between ALZA Corporation and [**] and its affiliates [**] and [**] regarding Contract [**], and any research and development conducted pursuant to such agreement.

2. Interactions and communications relating to the Material Evaluation Agreement between ALZA Corporation and [**] dated [**], and any research and development conducted pursuant to such Agreement.

3. Interactions and communications relating to the opposition filed by [**] in connection with [**].

Attachment 17.2 - Arbitration Proceedings

(a) Any dispute, claim or controversy arising from or related in any way to this Agreement or the interpretation, application, breach, termination or validity thereof, including any claim of inducement of this Agreement by fraud or otherwise, will be submitted for resolution to arbitration pursuant to the rules then pertaining of the CPR Institute for Dispute Resolution for Non-Administered Arbitration (available at www.cpradr.org/arb-rules.htm), or successor ("CPR"), except where those rules conflict with these provisions, in which case these provisions control. The arbitration will be held in Los Angeles, California.

(b) The panel will consist of three arbitrators chosen from the CPR Panels of Distinguished Neutrals (or, by agreement, from another provider of arbitrators) each of whom is a lawyer with at least 15 years experience with a law firm or corporate law department of over 25 lawyers or who was a judge of a court of general jurisdiction. In the event the aggregate damages sought by the claimant are stated to be less than $5 million, and the aggregate damages sought by the counter claimant are stated to be less than $5 million, and neither side seeks equitable relief, then a single arbitrator will be chosen, having the same qualifications and experience specified above. Each arbitrator will be neutral, independent, disinterested, impartial and will abide by The CPR-Georgetown Commission Proposed Model Rule for the Lawyer as Neutral available at www.cpradr.org/cpr-george.html.

(c) The parties agree to cooperate (1) to attempt to select the arbitrator(s) by agreement within 45 days of initiation of the arbitration, including jointly interviewing the final candidates, (2) to meet with the arbitrator(s) within 45 days of selection and (3) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than nine (9) months after selection of the arbitrator(s) and in the award being rendered within 60 days of the conclusion of the hearings, or of any post hearing briefing, which briefing will be completed by both sides within 45 days after the conclusion of the hearings.

(d) In the event the parties cannot agree upon selection of the arbitrator(s), the CPR will select arbitrator(s) as follows: CPR will provide the parties with a list of no less than 25 proposed arbitrators (15 if a single arbitrator is to be selected) having the credentials referenced above. Within 25 days of receiving such list, the parties will rank at least 65% of the proposed arbitrators on the initial CPR list, after exercising cause challenges. The parties may then interview the five candidates (three if a single arbitrator is to be selected) with the highest combined rankings for no more than one

hour each and, following the interviews, may exercise one peremptory challenge each. The panel will consist of the remaining three candidates (or one, if one arbitrator is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, CPR will select the appropriate number of arbitrators from among the members of the various CPR Panels of Distinguished Neutrals, allowing each side challenges for cause and three peremptory challenges each. In the event the dispute, claim or controversy relates to the validity or infringement of the Licensed Patents, Future ALZA Patents and TMC Patents, the arbitrator will be registered before the United States Patent and Trademark Office and have experience in patent litigation.

(e) In the event the parties cannot agree upon procedures for discovery and conduct of the hearing meeting the schedule set forth in paragraph c above, then the arbitrator(s) will set dates for the hearing, any post hearing briefing, and the issuance of the award in accord with the paragraph c schedule. The arbitrator(s) will provide for discovery according to those time limits, giving recognition to the understanding of the parties that they contemplate reasonable discovery, including document demands and depositions, but that such discovery be limited so that the paragraph c schedule may be met without difficulty. In no event will the arbitrator(s), absent agreement of the parties, allow more than a total of ten days for the hearing or permit either side to obtain more than a total of 40 hours of deposition testimony from all witnesses, including both fact and expert witnesses, or serve more than 20 individual requests for documents, including subparts, or 20 individual requests for admission or interrogatories, including subparts. Multiple hearing days will be scheduled consecutively to the greatest extent possible.

(f) The arbitrator(s) must render their award by application of the substantive law of Pennsylvania and are not free to apply "amiable compositeur" or "natural justice and equity." The arbitrator(s) will render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing will be made and will, upon request, be made available to either party. The arbitrator(s) will have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award will be overturned by reason of such ruling on evidence. To the extent possible, the arbitration hearings and award will be maintained in confidence.

(g) In the event the panel's award exceeds $5 million in monetary damages or includes or consists of equitable relief, or rejects a claim in excess of that amount or for that relief, then the losing party may obtain review of the arbitrators' award or decision by a single appellate arbitrator (the "Appeal Arbitrator") selected from the CPR Panels of Distinguished Neutrals by agreement or,

failing agreement within seven working days, pursuant to the selection procedures specified in paragraph d above. If CPR cannot provide such services, the parties will together select another provider of arbitration services that can. No Appeal Arbitrator will be selected unless he or she can commit to rendering a decision within forty five days following oral argument as provided in this paragraph. Any such review must be initiated within thirty (30) days following the rendering of the award referenced in f above.

(h) The Appeal Arbitrator will make the same review of the arbitration panel's ruling and its bases that the U.S. Court of Appeals of the Circuit where the arbitration hearings are held would make of findings of fact and conclusions of law rendered by a district court after a bench trial and then modify, vacate or affirm the arbitration panel's award or decision accordingly, or remand to the panel for further proceedings. The Appeal Arbitrator will consider only the arbitration panel's findings of fact and conclusions of law, pertinent portions of the hearing transcript and evidentiary record as submitted by the parties, opening and reply briefs of the party pursuing the review, and the answering brief of the opposing party, plus a total of no more than four (4) hours of oral argument evenly divided between the parties. The party seeking review must submit its opening brief and any reply brief within seventy five (75) and one hundred thirty (130) days, respectively, following the date of the award under review, whereas the opposing party must submit its responsive brief within one hundred ten (110) days of that date. Oral argument will take place within five (5) months after the date of the award under review, and the Appeal Arbitrator will render a decision within forty five (45) days following oral argument. That decision will be final and not subject to further review, except pursuant to the Federal Arbitration Act.

(i) The parties consent to the jurisdiction of the Federal District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder (including after review by the Appeal Arbitrator where such an appeal is pursued). Should such court for any reason lack jurisdiction, any court with jurisdiction will act in the same fashion.

(j) Each party has the right before or, if the arbitrator(s) cannot hear the matter within an acceptable period, during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration.

(k) EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

CONFIDENTIAL MATERIALS OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. DOUBLE ASTERISKS [**] DENOTE OMISSIONS.

(l) EACH PARTY HERETO WAIVES ANY CLAIM TO PUNITIVE, EXEMPLARY OR MULTIPLIED DAMAGES FROM THE OTHER.

(m) EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL DAMAGES FROM THE OTHER.

(n) EACH PARTY HERETO WAIVES ANY CLAIM FOR ATTORNEYS' FEES AND COSTS AND PREJUDGMENT INTEREST FROM THE OTHER.

13.2 Mediation.

(a) Any dispute, controversy or claim arising out of or related to this agreement, or the interpretation, application, breach, termination or validity thereof, including any claim of inducement by fraud or otherwise, which claim would, but for this provision, be submitted to arbitration will, before submission to arbitration, first be mediated through non binding mediation in accordance with The CPR Mediation Procedure then in effect of the CPR Institute for Dispute Resolution (CPR) available at www.cpradr.org/m_proced.htm, except where that procedure conflicts with these provisions, in which case these provisions control. The mediation will be conducted in Philadelphia, Pennsylvania and will be attended by a senior executive with authority to resolve the dispute from each of the operating companies that are parties.

(b) The mediator will be neutral, independent, disinterested and will be selected from a professional mediation firm such as ADR Associates or JAMS/ENDISPUTE or CPR.

(c) The parties will promptly confer in an effort to select a mediator by agreement. In the absence of such an agreement within 10 days of initiation of the mediation, the mediator will be selected by CPR as follows: CPR will provide the parties with a list of at least 15 names from the CPR Panels of Distinguished Neutrals. Each party will exercise challenges for cause, two peremptory challenges, and rank the remaining candidates within 5 working days of receiving the CPR list. The parties may together interview the three top ranked candidates for no more than one hour each and, after the interviews, may each exercise one peremptory challenge. The mediator will be the remaining candidate with the highest aggregate ranking.

(d) The mediator will confer with the parties to design procedures to conclude the mediation within no more than 45 days after initiation. Under no circumstances may the commencement of arbitration above be delayed more than 45 days by the mediation process specified herein absent contrary agreement of the parties.

(e) Each party agrees not to use the period or pendency of the mediation to disadvantage the other party procedurally or otherwise. No statements made by either side during the mediation may be used by the other or referred to during any subsequent proceedings.

(f) Each party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed.