-----BEGIN PRIVACY-ENHANCED MESSAGE----- Proc-Type: 2001,MIC-CLEAR Originator-Name: webmaster@www.sec.gov Originator-Key-Asymmetric: MFgwCgYEVQgBAQICAf8DSgAwRwJAW2sNKK9AVtBzYZmr6aGjlWyK3XmZv3dTINen TWSM7vrzLADbmYQaionwg5sDW3P6oaM5D3tdezXMm7z1T+B+twIDAQAB MIC-Info: RSA-MD5,RSA, UpdukwVnACTlGANk/HZy7W4TkelENMMGGtPpm+h5sgh7X8K6tEgihF4THprNZjtF anv8oaJmzxmZ6t4VDnV+YQ== 0000921895-99-000789.txt : 19991103 0000921895-99-000789.hdr.sgml : 19991103 ACCESSION NUMBER: 0000921895-99-000789 CONFORMED SUBMISSION TYPE: 8-K PUBLIC DOCUMENT COUNT: 9 CONFORMED PERIOD OF REPORT: 19991018 ITEM INFORMATION: ITEM INFORMATION: FILED AS OF DATE: 19991102 FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 8-K SEC ACT: SEC FILE NUMBER: 001-12584 FILM NUMBER: 99739791 BUSINESS ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 BUSINESS PHONE: 3145799899 MAIL ADDRESS: STREET 1: 425 WOODSMILL RD CITY: ST LOUIS STATE: MO ZIP: 63017 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606
8-K
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FORM 8-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 18, 1999

SHEFFIELD PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	1-12584	13-3808303
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

425 South Woodsmill Road, St. Louis, Missouri 63017

(Address of Principal executive offices) (Zip Code)

(314) 579-9899

Registrant's telephone number, including area code

(Former Name or Former Address; if Changed Since Last Report)

Item 5. Other Events.

On October 18, 1999, Sheffield Pharmaceuticals, Inc. (the "Company") consummated a license and financing transaction with Elan International Services, Ltd. ("Elan") (an affiliate of Elan Corporation plc, an Irish pharmaceutical company) in accordance with the terms of the binding letter of intent dated September 30, 1999 (the "Letter of Intent").

As part of the transaction, the Company has formed a Bermuda subsidiary ("Newco") and entered into several agreements with Elan, including a Securities Purchase Agreement dated October 18, 1999 (the "Purchase Agreement") a Subscription, Joint Development and Operating Agreement dated October 18, 1999 (the "Operating Agreement"), and a Registration Rights Agreement dated October 18, 1999 (the "Registration Rights Agreement"). Elan and the Company have also licensed certain of their intellectual property rights to Newco relating to certain pulmonary drug delivery systems pursuant to license agreements. Copies of the Purchase Agreement, the Operating Agreement, the Registration Rights Agreement and the license agreements are attached hereto as exhibits and are incorporated herein by reference.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits

(4.5) Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series D Cumulative Convertible Exchangeable Preferred Stock.

(4.6) Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable

to the Company's Series E Convertible Non-Exchangeable Preferred Stock.

(4.7) Certificate of Designations defining the powers, designations, rights, preferences, limitations and restrictions applicable to the Company's Series F Convertible Exchangeable Preferred Stock.

(10.25) Securities Purchase Agreement, dated as of October 18, 1999, by and between the Company and Elan (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

(10.26) Subscription, Joint Development and Operating Agreement dated as of October 18, 1999 by and among Elan Pharma International Limited, Elan, the Company and Newco. (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

(10.27) License Agreement dated October 19, 1999 by and between the Company and Newco (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

(10.28) License Agreement dated October 20, 1999 by and between Elan Pharma International Limited and Newco (portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to the Company's application requesting confidential treatment in accordance with Rule 24b-2 as promulgated under the Securities Exchange Act of 1934, as amended).

(10.29) Registration Rights Agreement dated as of October 18, 1999 by and between Elan and the Company.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SHEFFIELD PHARMACEUTICALS INC.

Date: November 2, 1999 By: /s/ Loren Peterson

Loren Peterson
President and
Chief Executive Officer

EX-4.5
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CERTIFICATE OF DESIGNATIONS

CERTIFICATE OF DESIGNATIONS,
PREFERENCES AND RIGHTS

OF

SERIES D CUMULATIVE CONVERTIBLE EXCHANGEABLE
PREFERRED STOCK

OF

SHEFFIELD PHARMACEUTICALS, INC.

Pursuant to Section 151 of
the General Corporation Law of the State of Delaware

Sheffield Pharmaceuticals, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), hereby certifies that the following resolutions were duly adopted by the Board of Directors of the Corporation at a meeting duly called and held on October 15, 1999 pursuant to authority of the Board of Directors as required by Section 151 of the General Corporation Law of the State of Delaware:

RESOLVED, that pursuant to the authority expressly granted to and vested in the Board of Directors of the Corporation (the "Board" or the "Board

of Directors") by the provisions of the Certificate of Incorporation of the Corporation (the "Certificate of Incorporation"), out of the 3,000,000 shares of preferred stock of the Corporation authorized in Article FOURTH of the Certificate of Incorporation (the "Preferred Stock"), there hereby is created a series of Preferred Stock consisting of 21,000 shares, which series shall have the following powers, designations, preferences and relative, participating, optional or other rights, and the following qualifications, limitations and restrictions (in addition to the powers, designations, rights, and the qualifications, limitations and restrictions, set forth in the Certificate of Incorporation which are applicable to the Preferred Stock).

ARTICLE 1
DESIGNATION AND AMOUNT

The shares of such series shall be designated as "Series D Cumulative Convertible Exchangeable Preferred Stock" (the "Series D Preferred Stock") and the authorized number of shares constituting such series shall be 21,000 shares. The par value of the Series D Preferred Stock shall be $.01 per share. The stated value of the Series D Preferred Stock shall be One Thousand Dollars ($1,000) per share (the "Stated Value").

ARTICLE 2
DEFINITIONS

The terms defined in this Article whenever used in this Certificate of Designations have the following respective meanings:

(a) "AMEX" means the American Stock Exchange.

(b) "Business Day" means a day other than Saturday, Sunday or any day on which banks located in the State of New York are authorized or obligated to close.

(c) "Common Shares" or "Common Stock" means shares of common stock, $.01 par value, of the Corporation.

(d) "Conversion Date" means any day on which all or any portion of shares of the Series D Preferred Stock is converted in accordance with the provisions hereof.

(e) "Conversion Notice" has the meaning set forth in Section 6.1.

(f) "Conversion Price" has the meaning set forth in Section 6.1.

(g) "Corporation" means Sheffield Pharmaceuticals, Inc., a Delaware corporation, and any successor or resulting corporation by way of merger, consolidation, sale or exchange of all or substantially all of the Corporation's assets, or otherwise.

(h) "Current Market Price" on any date of determination means

the closing price of a Common Share on such day as reported on the AMEX, or, if such security is not listed or admitted to trading on the AMEX, on the principal national security exchange or quotation system on which such security is quoted or listed or admitted to trading, or, if not quoted or listed or admitted to trading on any national securities exchange or quotation system, the average of the closing bid and ask prices of such security on the over-the-counter market on the day in question as reported by the National Quotation Bureau Incorporated, or a similar generally accepted reporting service, or if not so available, in such manner as furnished by any Nasdaq member firm of the National Association of Securities Dealers, Inc. selected from time to time by the Board

of Directors of the Corporation for that purpose, or a price determined in good faith by the Board of Directors of the Corporation as being equal to the fair market value thereof, as the case may be.

(i) "Dividend Notes" have the meaning set forth in Section 4.1.

(j) "Dividend Payment Date" has the meaning set forth in Section 4.1.

(k) "Dividend Period" has the meaning set forth in Section 4.1.

(l) "Dividend Shares" means the shares of Series D Preferred Stock issued as dividends on outstanding shares of Series D Preferred Stock in accordance with Article 4 hereof.

(m) "Dollars" or "$" means currency of the United States of America.

(n) "Exchange Date" has the meaning set forth in Section 7.01.

(o) "Exchange Note" has the meaning set forth in Section 7.02.

(p) "Exchange Notice" has the meaning set forth in Section 7.01.

(q) "Holder" or "Holders" means Elan International Services, Ltd., a Bermuda corporation, any successor thereto, or any Person(s) to whom the Series D Preferred Stock is subsequently transferred in accordance with the provisions hereof.

(r) "Issue Date" means the date of original issuance of the applicable share of Series D Preferred Stock.

(s) "Junior Securities" has the meaning set forth in Article 3.

(t) "Liquidation Preference" has the meaning set forth in Section 5.1(b).

(u) "Newco" means Sheffield Newco Ltd. a Bermuda exempted

limited liability company incorporated under the laws of Bermuda.

(v) "Newco Capital Stock" means all outstanding shares of Newco Common Stock and all securities convertible or exchangeable into shares of Newco Common Stock (including, Newco Preferred Stock).

(w) "Newco Common Stock" means the ordinary shares of the common stock, par value $1.00 per share, of Newco.

(x) "Newco Preferred Stock" means the preferred stock, par value $1.00 per share, of Newco.

(y) "Original Holder" means Elan International Services, Ltd, a Bermuda

exempted limited liability company incorporated under the laws of Bermuda and its affiliates (as that term is defined under the Securities Exchange Act of 1934, as amended).

(z) "Original Issue Date" means the date of the initial issuance of shares of Series D Preferred Stock.

(aa) "Pari Passu Securities" has the meaning set forth in Article 3.

(bb) "Person" means an individual, a corporation, a partnership, an association, a limited liability company, a unincorporated business organization, a trust or other entity or organization, and any government or political subdivision or any agency or instrumentality thereof.

(cc) "Rights" has the meaning set forth in Section 6.2(e).

(dd) "Securities Purchase Agreement" means the Securities Purchase Agreement, dated as of October 18, 1999, between the Corporation and Elan International Services, Ltd.

(ee) "Stated Value" has the meaning set forth in Article 1.

(ff) "Trading Day" means any day on which purchases and sales of securities authorized for quotation on the AMEX are reported thereon or, if the Common Stock is not listed or admitted to trading on the AMEX, a day on which the principal national securities exchange on which the Common Stock is listed or admitted to trading is open for the transaction of business, or, if the Common Stock is not so listed or admitted to trading on any national securities exchange, a day on which the Nasdaq National Market (or any successor thereto) or such other system then in use is open for the transaction of business, or, if the Common Stock is not quoted by any such organization, any day other than a Saturday, Sunday or a day on which banking institutions in the State of New York are authorized or obligated by law or executive order to close.

ARTICLE 3

RANK

The Series D Preferred Stock shall rank (i) prior to the Common Stock; (ii) prior to any class or series of capital stock of the Corporation hereafter created other than Pari Passu Securities (collectively, with the Common Stock, the "Junior Securities"); (iii) pari passu with the Corporation's Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock"); (iv) pari passu with the Corporation's Series E Convertible Non-Exchangeable Preferred Stock (the "Series E Preferred Stock"); (v) pari passu with the Corporation's Series F Convertible Non-Exchangeable Preferred Stock (the "Series F Preferred Stock"); and (vi) pari passu with any class or series of capital stock of the Corporation hereafter created specifically

ranking on parity with the Series D Preferred Stock (collectively, with the Series C Preferred Stock, the Series E Preferred Stock and the Series F Preferred Stock, the "Pari Passu Securities").

ARTICLE 4
DIVIDENDS

SECTION 4.1

(a) (i) Subject to Article 6, the Holder shall be entitled to receive, out of funds legally available for the payment of dividends, dividends at the rate of 7.0% per annum (computed on the basis of a 360-day year) (the "Dividend Rate") on the Stated Value of each outstanding share of Series D Preferred Stock payable on and as of the most recent Dividend Payment Date with respect to each Dividend Period. Dividends on the Series D Preferred Stock shall be cumulative from the date of issue or the most recent Dividend Payment Date upon which dividends have been paid on the Series D Preferred Stock by the Corporation.

(ii) Dividends on the Series D Preferred Stock shall be payable in equal semi-annual installments on April 18 and October 18 of each year (each, a "Dividend Payment Date"), commencing April 18, 2000 and ending October 18, 2005, to the holders of record of shares of the Series D Preferred Stock, as they appear on the stock records of the Corporation at the close of business on any record date, not more than 60 days or less than 10 days preceding the payment dates thereof, as shall be fixed by the Board of Directors. For the purposes hereof, "Dividend Period," in respect of any share of Series D Preferred Stock, shall mean the period commencing on April 18, 2000 and, thereafter, the semiannual period commencing on and including the day after the immediately preceding Dividend Payment Date and ending on and including the immediately subsequent Dividend Payment Date. Accrued and unpaid dividends for any past Dividend Period may be declared and paid at any time, without reference to any Dividend Payment Date, to holders of record on such date, not more than 15 days preceding the payment date thereof, as may be fixed by the Board of Directors.

(iii) Dividends on the outstanding shares of Series D Preferred Stock shall be paid through the issuance of duly and validly

authorized and issued, fully paid and non-assessable shares of Series D Preferred Stock to be issued at the rate of one (1) share of Series D Preferred Stock for each $1,000 of dividend due and payable. No fractional shares of the Series D Preferred Stock shall be issued as Dividend Shares. Instead of any fractional shares of Series D Preferred Stock which would otherwise be issuable as Dividend Shares, the Corporation shall pay a cash adjustment in respect of such fractional interest in an amount equal to $1,000 times the fractional interest.

(b) The Holder shall not be entitled to any dividends in excess of the cumulative dividends, as herein provided, on the Series D Preferred Stock. Except as provided in this Article 4, no interest, or sum of money in lieu of interest, shall be payable in respect of any dividend payment or payments on the Series D Preferred Stock that may be in arrears.

(c) In the event that, after the first anniversary of the Original Issue Date, the payment of any Dividend Shares upon the Series D Preferred Stock to the Original Holder would result in the Original Holder's fully-diluted ownership of Common Stock (assuming the conversion into Common Stock of all options, warrants and other securities convertible or exchangeable into Common Stock beneficially owned by the Original Holder) to exceed 49.9% of the then outstanding

Common Stock, such excess dividends shall be paid to the Original Holder through issuance by the Corporation of promissory notes with an aggregate principal amount equal to each dividend payment amount then payable (collectively, the "Dividend Notes"). Each Dividend Note shall be issued in substantially the form attached as Exhibit B to this Certificate of Designations. It shall be a condition to the Corporation's obligation to issue Dividend Notes in respect of any such excess dividends that the Original Holder deliver to the Corporation, at least 15 days before the applicable Dividend Payment Date, a certificate (i) certifying that the Dividend Shares otherwise issuable on such Dividend Payment Date shall cause the Original Holder's beneficial ownership to exceed such 49.9% amount and (ii) demonstrating the calculation of the principal amount of the Dividend Note to be issued in lieu of the applicable excess Dividend Shares.

ARTICLE 5
LIQUIDATION PREFERENCE

SECTION 5.1

(a) If the Corporation shall commence a voluntary case under the Federal bankruptcy laws or any other applicable Federal or State bankruptcy, insolvency or similar law, or consent to the entry of an order for relief in an involuntary case under any law or to the appointment of a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Corporation or of any substantial part of its property, or make an assignment for the benefit of its creditors, or admit in writing its inability to pay its debts generally as they become due, or if a decree or order for relief in respect of the Corporation shall be entered by a court having jurisdiction in the premises in an involuntary case under the Federal bankruptcy laws or any other applicable Federal or state bankruptcy, insolvency or similar law

resulting in the appointment of a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Corporation or of any substantial part of its property, or ordering the winding up or liquidation of its affairs, and any such decree or order shall be unstayed and in effect for a period of ninety (90) consecutive days and, on account of any such event, the Corporation shall liquidate, dissolve or wind up, or if the Corporation shall otherwise liquidate, dissolve or wind up (each such event being considered a "Liquidation Event"), no distribution shall be made to the holders of any Junior Securities of the Corporation upon liquidation, dissolution or winding up unless prior thereto, the Holders, subject to Article 5, shall have received the Liquidation Preference (as defined in Article 5.1(b)) with respect to each share. If upon the occurrence of a Liquidation Event, the assets and funds available for distribution among the Holders and holders of shares of Pari Passu Securities shall be insufficient to permit the payment to such holders of the

preferential amounts payable thereon, then the entire assets and funds of the Corporation legally available for distribution to the Series D Preferred Stock and the Pari Passu Securities shall be distributed ratably among such shares in proportion to the ratio that the preferential amounts payable on each such share bears to the aggregate preferential amounts payable on all such shares.

(b) For purposes hereof, the "Liquidation Preference" with respect to a share of the Series D Preferred Stock shall mean an amount equal to (i) the Stated Value thereof, plus (ii) the aggregate of all accrued and unpaid dividends on such share of Series D Preferred Stock until the most recent Dividend Payment Date; provided that, in the event of an actual liquidation, dissolution or winding up of the Corporation, the amount referred to in clause (ii) above shall be calculated by including accrued and unpaid stock dividends to the actual date of such liquidation, dissolution or winding up, rather than the applicable Dividend Payment Due Date referred to above.

ARTICLE 6
CONVERSION OF SERIES D PREFERRED STOCK

SECTION 6.1 Conversion.

(a) Holders of shares of the Series D Preferred Stock shall have the right, exercisable at any time after the second anniversary of the Original Issue Date and prior to the sixth anniversary of the Original Issue Date, to convert all or any such shares of the Series D Preferred Stock into the number of shares of Common Stock (calculated as to each conversion to the nearest 1/100th of a share) determined by dividing (1) the aggregate Liquidation Preference of the shares of Series D Preferred Stock to be converted by (2) $4.86 (the "Conversion Price"). Upon conversion, no adjustment or payment will be made for dividends, but if any holder surrenders a share of the Series D Preferred Stock for conversion after the close of business on the record date for the payment of a dividend and prior to the opening of business on the next Dividend Payment Date, then, notwithstanding such conversion, the dividend payable on such Dividend Payment Date will be paid to the registered holder of such share on such record date. In such event, such share, when surrendered for conversion during the period between the close of business on any dividend payment record date and the opening of business on the corresponding Dividend Payment Date, must be accompanied by payment of an amount equal to the dividend

payable on such Dividend Payment Date on the share so converted.

(b) Any holder of a share or shares of the Series D Preferred Stock electing to convert such share or shares thereof shall deliver the certificate or certificates therefor to the principal office of the Corporation or any transfer agent for the Common Stock, with the form of notice of election to convert attached as Exhibit C to this Certificate of Designations (the "Conversion Notice"), fully completed and duly executed and (if such required by the Corporation or any conversion agent) accompanied by instruments of transfer in form satisfactory to the Corporation and to any conversion agent, duly executed by the registered Holder of his duly authorized attorney. The conversion right with respect to any such shares shall be deemed to have been

exercised at the date upon which the certificates therefore accompanied by such duly executed notice of election and instruments of transfer and such taxes, stamps, funds, or evidence of payment shall have been so delivered, and the Person or Persons entitled to receive the shares of the Common Stock issuable upon such conversion shall be treated for all purposes as the record Holder or Holders of such shares of the Common Stock upon said date.

(c) From and after the delivery of the Conversion Notice in respect of any conversion of shares of Series D Preferred Stock, all such shares of Series D Preferred Stock shall be deemed to have been converted into shares of Common Stock as of the applicable Conversion Date at the applicable conversion rate, all stock dividends on such shares of the Series D Preferred Stock shall cease to accrue, and all rights of the Holders thereof as holders of Series D Preferred Stock, except the right to receive all accrued and unpaid stock dividends to such Conversion Date at the applicable rate for such shares of Series D Preferred Stock and the right to receive certificates representing shares of Common Stock issuable upon the conversion of such shares (including, without limitation, with respect to such stock dividends, as applicable), shall cease and terminate, such shares of Series D Preferred Stock shall not thereafter be transferred (except with the consent of the Corporation) and such shares shall not be deemed to be outstanding for any purpose whatsoever.

(d) No fractional shares of the Common Stock or scrip representing fractional shares shall be issued upon conversion of shares of the Series D Preferred Stock. If more than one share of the Series D Preferred Stock shall be surrendered for conversion at one time by the same holder, the number of full shares of the Common Stock which shall be issuable upon conversion thereof shall be computed on the basis of the aggregate number of shares of the Series D Preferred Stock so surrendered. Instead of any fractional shares of the Common Stock which would otherwise be issuable upon conversion of any shares of the Series D Preferred Stock, the Corporation shall pay a cash adjustment in respect of such fraction in an amount equal to the same fraction of the Current Market Price for the Common Stock on the last Trading Day preceding the applicable date of conversion.

(e) Each Conversion Notice under this Section 6.1 shall request the conversion of at least 500 shares of Series D Preferred Stock or the remaining balance of Series D Preferred Stock held by the converting Holder, whichever is less.

SECTION 6.2 Adjustments. The Conversion Price and the number of shares issuable upon conversion of the Series D Preferred Stock are subject to adjustment from time to time as follows:

(a) Merger, Sale of Assets, Etc. Notwithstanding any other limitation whatsoever contained herein, if at any time while the Series D Preferred Stock, or any portion thereof, is outstanding there shall be (i) a reorganization (other than a combination, reclassification, exchange or subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Corporation with or into another corporation in which the Corporation is the surviving entity but the shares of the Corporation's capital stock outstanding immediately prior to the merger are converted by virtue of the

merger into other property, whether in the form of securities, cash or otherwise, or (iii) a sale or transfer of the Corporation's properties and assets as, or substantially as, an entirety to any other Person, then as a part of such reorganization, merger, consolidation, sale or transfer lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon conversion of the Series D Preferred Stock, during the period specified herein, the number of shares of stock or other securities or property of the successor corporation resulting from such reorganization, merger, consolidation, sale or transfer that the Holder would have been entitled to receive in such reorganization, consolidation, merger, sale or transfer if the Series D Preferred Stock had been converted immediately before such reorganization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 6.2(a). The foregoing provisions of this Section 6.2(a) shall similarly apply to successive reclassification, changes, consolidations, mergers, mandatory share exchanges and sales and transfers. If the per share consideration payable to the holder hereof for shares in connection with any such transaction is in a form other than cash or marketable securities, then the value of such consideration shall be determined in good faith by the Board of Directors. In all events, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions of this Certificate of Designations with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this Certificate of Designations shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable after that event upon conversion of the Series D Preferred Stock.

(b) Reclassification, Etc. If the Corporation, at any time while the Series D Preferred Stock, or any portion thereof, remains outstanding, shall change any of the securities as to which conversion rights under this Certificate of Designations exist into the same or a different number of securities of any other class or classes, the Series D Preferred Stock shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities that were subject to the conversion rights under this Certificate of Designations immediately prior to such reclassification or other change and the Conversion Price therefor shall be appropriately adjusted, all subject to further adjustment as provided in this Certificate of Designations.

(c) Split, Subdivision or Combination of Shares. If the

Corporation at any time while the Series D Preferred Stock, or any portion thereof, remains outstanding shall split, subdivide or combine the securities as to which conversion rights under this Certificate of Designations exist, into a different number of securities of the same class, the Conversion Price shall be proportionately decreased in the case of a split or subdivision or proportionately increased in the case of a combination.

(d) Adjustments for Dividends in Stock and Other Securities or Property. If while the Series D Preferred Stock, or any portion hereof, remains outstanding, the holders of the securities as to which conversion rights under this Certificate of Designations exist at the time shall have received, or, on or after the record date fixed for the determination of eligible stockholders of the Corporation, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than

cash) of the Corporation by way of dividend, then and in each case, the Series D Preferred Stock shall represent the right to acquire, upon conversion, in addition to the number of shares of the security receivable upon conversion of the Series D Preferred Stock, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) of the Corporation that the Holder would hold on the date of such conversion had it been the holder of record of the security receivable upon conversion of the Series D Preferred Stock on the date hereof and had thereafter, during the period from the date hereof to and including the date of such conversion, retained such shares and/or additional stock available by it as aforesaid during such period, giving effect to all adjustments called for during such period by the provisions of this Section 6.2.

(e) Repurchases or Redemptions of Common Stock or Options. If the Corporation at any time while shares of Series D Preferred Stock are outstanding, shall repurchase or redeem any outstanding shares of Common Stock or rights, options or warrants granting the holder thereof the right to acquire shares of Common Stock (collectively, the "Rights") in a single transaction or a series of related transactions involving an aggregate repurchase or redemption price in excess of $500,000 at a price (on a per share basis) which is greater than 150% of the Current Market Price as of the day prior to such repurchase or redemption, the Conversion Price shall thereupon be adjusted by multiplying the Conversion Price in effect immediately prior to the applicable repurchase or redemption by a fraction (i) the numerator of which shall be the Conversion Price in effect immediately prior to such repurchase or redemption and (ii) the denominator of which shall be the fair market value of the consideration paid by the Corporation for each share of Common Stock (or each share of Common Stock issuable upon exercise of the Right(s) subject to such repurchase or redemption) in such repurchase or redemption.

(f) Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment pursuant to this Section 6.2, the Corporation at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to the Holder a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based.

(g) Cumulative Adjustments. No adjustment in the Conversion Price shall be required until cumulative adjustments result in a concomitant change of 1% or more of the Conversion Price as in effect prior to the last adjustment of the Conversion Price; provided, however, that any adjustments which by reason of this Section 6.2 are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 6.2 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be. No adjustment to the Conversion Price shall be made for cash dividends.

ARTICLE 7

EXCHANGE RIGHTS

SECTION 7.01 Optional Exchange. (a) Original Holders of at least a majority of the then outstanding shares of Series D Preferred Stock shall have the right, by written notice delivered to the Corporation in the form of notice of election to exchange attached to this Certificate of Designations as Exhibit D (the "Exchange Notice"), fully completed and duly executed by the requisite Original Holders, to require the Corporation to exchange all outstanding shares of Series D Preferred Stock and all outstanding Dividend Notes as of any Dividend Payment Date (such date being the "Exchange Date") for the greater of (i) 7,224 shares of Newco Preferred Stock, subject to adjustment for split, stock dividends and similar events occurring in respect of Newco Capital Stock after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date, with such capital stock to be delivered to all Holders on a pro rata basis based on their respective holdings of Series D Preferred Stock on the Exchange Date. The Exchange Notice shall be delivered at least 30 days prior to the Exchange Date. Upon receipt of the Exchange Notice, the Corporation shall promptly notify all Holders of its receipt of thereof and all Holders will promptly deliver the certificate or certificates therefor to the principal office of the Corporation or any transfer agent for the Common Stock for cancellation.

(b) From and after the delivery of the Exchange Notice, all shares of Series D Preferred Stock (including Dividend Shares) shall be deemed to have been exchanged for the greater of (i) 7,224 shares of Newco Preferred Stock, subject to adjustment for split, stock dividends and similar events occurring in respect of Newco Capital Stock after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date, all stock dividends on such shares of the Series D Preferred Stock shall cease to accrue, all interest on the Dividend Notes shall cease to accrue, and all rights of the Holders thereof as holders of Series D Preferred Stock and Dividend Notes, except the right to receive all accrued and unpaid stock dividends on the Series D Preferred Stock to the Exchange Date at the applicable rate for such shares of such shares of Series D Preferred Stock, and the right to receive all accrued and unpaid interest on the Dividend Note to the Exchange Date at the applicable rate for such notes, and the right to receive

certificates representing the applicable shares of Newco Capital Stock issuable in respect of the exchange, shall cease and terminate, such shares of Series D Preferred Stock and Dividend Notes shall not thereafter be transferred (except with the consent of the Corporation) and such shares shall not be deemed to be outstanding for any purpose whatsoever.

(c) The rights of Holders under this Article 7 shall terminate and such Holders shall not be entitled to exchange shares of Series D Preferred Stock under this Article 7 upon the earlier of (i) the sixth anniversary of the Original Issue Date and (ii) the delivery to the Corporation of a Conversion Notice pursuant to this Section 6.1.

SECTION 7.02. Mandatory Exchange. On or before the first anniversary of the Original Issue Date, the Corporation shall notify each Holder, in writing, (i) that the issuance of the Series D Preferred Stock, and the issuance and

listing upon the American Stock Exchange ("AMEX") of the shares of Common Stock issuable upon conversion of the Series D Preferred Stock, has been approved or ratified by the stockholders of the Corporation in accordance with the General Corporation Law of the State of Delaware and the rules and regulation of the AMEX or (ii) that such approval or ratification is not required by the applicable rules of the AMEX. In the event that the Corporation fails to provide such written notice on or before the first anniversary of the Original Issue Date, (A) all outstanding shares of Series D Preferred Stock shall be deemed exchanged for promissory note(s) in substantially the form of Exhibit A attached to this Certificate of Designations (the "Exchange Notes"), in the respective principal amounts equal to the aggregate Liquidation Preference of all shares of Series D Preferred Stock held by each respective Holder as of the date of such exchange and (B) from and after the first anniversary of the Original Issue Date, all shares of Series D Preferred Stock (including Dividend Shares) shall be deemed to have been exchanged for Exchange Notes, all dividends on the Series D Preferred Stock shall cease to accrue, and all rights of Holders thereof as holders of Series D Preferred Stock shall cease and terminate and all shares of Series D Preferred Stock shall not be deemed outstanding for any purpose whatsoever, except the right to receive the Exchange Notes issuable to them as determined above.

ARTICLE 8
VOTING RIGHTS

The holders of the Series D Preferred Stock shall have no voting rights, except as otherwise provided by the General Corporation Law of the State of Delaware ("DGCL") and in this Article 8, and in Article 9 below.

The Corporation shall provide each Holder of Series D Preferred Stock with prior notification of any meeting of the shareholders of the Corporation (and copies of proxy materials and other information sent to shareholders). In the event of any taking by the Corporation of a record of its shareholders for the purpose of determining shareholders who are entitled to receive payment of any dividend or other distribution, any right to subscribe for, purchase or

otherwise acquire (including by way of merger, consolidation or recapitalization) any share of any class or any other securities or property, or to receive any other right, or for the purpose of determining shareholders who are entitled to vote in connection with any proposed liquidation, dissolution or winding up of the Corporation, the Corporation shall mail a notice to each Holder, at least thirty (30) days prior to the consummation of the transaction or event, whichever is earlier), of the date on which any such action is to be taken for the purpose of such dividend, distribution, right or other event, and a brief statement regarding the amount and character of such dividend, distribution, right or other event to the extent known at such time.

To the extent that under the DGCL the vote of the Holders of the Series D Preferred Stock, voting separately as a class or series as applicable, is required to authorize a given action of the Corporation, the affirmative vote or consent of the Holders of at least a majority of the shares of the Series D Preferred Stock represented at a duly held meeting at which a quorum is present or by written consent of a majority of the shares of Series D Preferred Stock

(except as otherwise may be required under the DGCL) shall constitute the approval of such action by the class. To the extent that under the DGCL Holders of the Series D Preferred Stock are entitled to vote on a matter with Holders of Common Stock, voting together as one class, each share of Series D Preferred Stock shall be entitled to a number of votes equal to the number of shares of Common Stock into which such shares are convertible as of the record date for the taking of such vote of shareholders. Holders of the Series D Preferred Stock shall be entitled to notice of all shareholder meetings or written consents (and copies of proxy materials and other information sent to shareholders) with respect to which they would be entitled as of right under the DGCL, which notice would be provided pursuant to the Corporation's bylaws and the DGCL.

ARTICLE 9
PROTECTIVE PROVISIONS

So long as shares of Series D Preferred Stock are outstanding, the Corporation shall not, without first obtaining the approval (by vote or written consent, as provided by the DGCL) of the Holders of at least a majority of the then outstanding shares of Series D Preferred Stock:

(a) create any new class or series of capital stock having a preference superior to the Series D Preferred Stock as to distribution of assets upon liquidation, dissolution or winding up of the Corporation ("Senior Securities") or alter or change the rights, preferences or privileges of any Senior Securities so as to affect adversely the Series D Preferred Stock; or

(b) amend or alter whether by merger, consolidation or otherwise, any of the provisions of the Certificate of Incorporation (including this Certificate of Designations) that would change the preferences, rights or privileges with respect to the Series D Preferred Stock so as to affect the Series D Preferred Stock adversely.

In the event holders of at least a majority of the then outstanding shares of Series D Preferred Stock agree to allow the Corporation to amend or

alter the preferences, rights or privileges of the shares of Series D Preferred Stock, pursuant to subsection (b) above, so as to affect adversely the Series D Preferred Stock, then the Corporation will deliver notice of such approved change to the Holders of the Series D Preferred Stock that did not agree to such amendment or change (the "Dissenting Holders") and the Dissenting Holders shall have the right for a period of thirty (30) days to convert pursuant to Section 6.1 of this Certificate of Designations as they exist prior to such alteration or continue to hold their shares of Series D Preferred Stock. The Holders' rights under this Article 9 shall terminate on the sixth anniversary of the Original Issue Date.

ARTICLE 10
MISCELLANEOUS

SECTION 10.1 Loss, Theft, Destruction of Series D Preferred Stock. Upon receipt of evidence satisfactory to the Corporation of the loss, theft, destruction or mutilation of shares of Series D Preferred Stock and, in the case of any such loss, theft or destruction, upon receipt of indemnity or security reasonably satisfactory to the Corporation, or, in the case of any such mutilation, upon surrender and cancellation of the Series D Preferred Stock, the Corporation shall make, issue and deliver, in lieu of such lost, stolen, destroyed or mutilated shares of Series D Preferred Stock, new shares of Series D Preferred Stock of like date and tenor.

SECTION 10.2 Who Deemed Absolute Owner. The Corporation may deem the Person in whose name the Series D Preferred Stock shall be registered upon the registry books of the Corporation to be, and may treat it as, the absolute owner of the Series D Preferred Stock for the purpose of receiving payment of dividends on the Series D Preferred Stock, for the conversion of the Series D Preferred Stock and for all other purposes, and the Corporation shall not be affected by any notice to the contrary. All such payments and such conversion shall be valid and effectual to satisfy and discharge the liability upon the Series D Preferred Stock to the extent of the sum or sums so paid or the conversion so made.

SECTION 10.3 Register. The Corporation shall keep at its principal office a register in which the Corporation shall provide for the registration of the Series D Preferred Stock. Upon any transfer of the Series D Preferred Stock in accordance with the provisions hereof, the Corporation shall register such transfer on the Series D Preferred Stock register.

SECTION 10.4 Withholding. To the extent required by applicable law, the Corporation may withhold amounts for or on account of any taxes imposed or levied by or on behalf of any taxing authority in the United States having jurisdiction over the Corporation from any payments made pursuant to the Series D Preferred Stock.

SECTION 10.5 Headings. The headings of the Articles and Sections of this Certificate of Designations are inserted for convenience only and do not constitute a part of this Certificate of Designations. IN WITNESS WHEREOF, the Corporation has caused this Certificate of Designations, Preferences and Rights to be signed by Loren G. Peterson, its President and Chief Executive Officer, and attested by Scott A. Hoffmann, its Secretary, on this 18th day of October, 1999.

SHEFFIELD PHARMACEUTICALS, INC.

By:/s/ Loren G. Peterson

Loren G. Peterson
President and Chief Executive Officer

Attested:

By: /s/ Scott A. Hoffman

Scott A. Hoffmann
Secretary

Exhibit A

FORM OF EXCHANGE NOTE

SHEFFIELD PHARMACEUTICALS, INC.

U.S. $_____ _____, 20__

The undersigned, Sheffield Pharmaceuticals, Inc., a Delaware corporation ("Sheffield"), for value received, hereby promises to pay to the order of _____ (the "Investor") or its permitted assigns (the "Holder"), at such place as may be designated by the Holder to Sheffield, the sum of _____ dollars ($_____), plus interest on the unpaid principal balance at the rate specified below, in accordance with the provisions set forth herein. During the term of this Note, interest shall accrue at the rate of 7.0% per annum (calculated on the basis of a year of 360 days comprised of 12 30-day months). Accrued interest shall be payable (i) quarterly in arrears on the first day of January, April, July and October of each year and (ii) in-kind through the issuance of additional notes in like tenor to this Note (the "Interest Notes"). The full principal amount of this Note and all Interest Notes, including any accrued interest thereon, shall be due and payable on October 18, 2005 (the "Maturity Date"). This Note is originally being issued in exchange for shares of Series D Preferred Stock, par value $.01 per share, of Sheffield (the "Series D Preferred Stock"), the rights of which are designated in the Certificate of Designations of the Series D Preferred Stock of Sheffield (the "Certificate of Designations"), and pursuant to a certain Securities Purchase Agreement, dated October 18, 1999 (the "Original Issue Date"), between Sheffield and Elan International Services, Ltd. (the "Purchase Agreement"). All Notes issued in exchange for shares of Series D Preferred Stock, including the Interest Notes, or upon transfer or exchange of other Notes are referred to herein as the "Notes."

All capitalized terms used in this Note and not otherwise defined herein shall have the meaning assigned to such terms in the Certificate of Designations.

The following is a statement of the rights of the Holder and the conditions to which this Note is subject, and to which the Holder hereof, by the acceptance of this Note, agrees:

1. Mandatory Exchange.

(a) Upon the delivery by holders of at least a majority of the then outstanding principal balance of Notes of written notice delivered to Sheffield in the form of notice of election to exchange attached as Annex A to this Note (the "Exchange Notice"), the Holder of this Note shall be required to surrender this Note in exchange for a pro rata portion of the greater of (i) 7,224 shares of Newco Preferred Stock, subject to adjustment for split, stock dividends and similar events occurring after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which,

together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date.

(b) From and after the delivery of the Exchange Notice, this Note shall be deemed to have been exchanged for a pro rata portion of the greater of (i) 7,224 shares of Newco Preferred Stock, subject to adjustment for split, stock dividends and similar events occurring after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date, all interest on the Note shall cease to accrue, and all rights of the Holder as a holder of the Note, except the right to receive all accrued and unpaid interest to such Exchange Date at the applicable rate for such Note and the right to receive certificates representing shares of Newco Capital Stock issuable upon the exchange of the Note (including, without limitation, with respect to such Notes issued as interest paid in kind stock), shall cease and terminate, the Note shall not thereafter be transferred (except with the consent of Sheffield) and the Note shall not be deemed to be outstanding for any purpose whatsoever.

2. Exchange or Replacement of Note.

(a) The Holder, at its option, may in person or by duly authorized attorney surrender this Note for exchange, at the office or agency of Sheffield and receive in exchange therefor a new Note in the same aggregate principal amount as the unpaid principal amount of the Note so surrendered, each such new Note to be dated as of the date to which interest has been paid on the Note so surrendered and payable to the Holder or its assignee, as the Holder may designate in writing (subject to the restrictions on transfer set forth in this Note and in the Purchase Agreement).

(b) Upon receipt by Sheffield of evidence satisfactory to it of the loss, theft, destruction, or mutilation of this Note, and (in case of loss, theft or destruction) of indemnity reasonably satisfactory to it, and upon reimbursement to Sheffield of all reasonable expenses incidental thereto, and

upon surrender and cancellation of this Note, if mutilated, Sheffield shall make and deliver a new Note of like tenor in lieu of this Note. Any Note made and delivered in accordance with this paragraph shall be dated the date hereof.

3. Amendments. This Note may not be amended, modified or waived in any respect unless set forth in writing and signed by the Holder, in the case of any change hereto, including any change in the amount or timing of any payment to be made hereunder or any adverse change in conversion rights hereunder. Any such amendment, modification or waiver shall be binding upon each future holder of this Note.

4. Costs and Expenses. Sheffield agrees to pay all reasonable costs and expenses, including reasonable attorneys' fees, incurred by the Holder in collecting or enforcing this Note.

5. No Waivers. No delay by the Holder in exercising any power or right hereunder shall operate as a waiver of any power or right, nor shall any single or partial exercise of any power or right preclude other or further exercise thereof, or the exercise of any other power or right hereunder or otherwise.

6. Events of Default

The occurrence of any of the following events shall constitute an event of default (an "Event of Default"):

(a) A default in the payment of the principal amount of this Note, when and as the same shall become due and payable;

(b) a default in the payment of any accrued and unpaid interest on this Note, when and as the same shall become due and payable;

(c) a default in the performance, or a breach of any other covenant or agreement of Sheffield in this Note on any other Transaction Document (as defined in the Purchase Agreement), and continuance of such default or breach for a period of 10 days after the Holder has notified Sheffield of its occurrence;

(d) any representation, warranty, or certification made by Sheffield pursuant to this Note or any other Transaction Document shall prove to have been false or misleading as of the date made in any material respect; or

(e) (i) the entry of a decree or order by a court having jurisdiction adjudging Sheffield bankrupt or insolvent, or approving a petition seeking reorganization, arrangement, adjustment or composition of or in respect of Sheffield, and the continuance of any such decree or order unstayed and in effect for a period of 60 days; (ii) the commencement by Sheffield of a voluntary case under United States bankruptcy law, as now or hereafter constituted, or the consent by Sheffield to the institution of bankruptcy or insolvency proceedings against it; (iii) the filing by Sheffield of a petition or answer or consent seeking reorganization or relief under United States bankruptcy law; (iv) the appointment of a receiver, liquidator, assignee, trustee, sequestrator, or similar official of Sheffield or of any substantial part of its property which is not discharged within 30 days; (v) the making by Sheffield of an assignment for the benefit of creditors, or the admission by it

in writing of its inability to pay its debts generally as they become due, or the taking of corporate action by Sheffield in furtherance of any such action.

7. Remedies in the Event of Default

(a) In the case of any Event of Default by Sheffield, the principal amount of this Note and accrued and unpaid interest thereon shall, in addition to all other rights and remedies of the Holder hereunder and under applicable law, be and become immediately due and payable.

(b) Sheffield hereby waives grace, demand and presentment for payment, notice of nonpayment, protest and notice of protest, diligence, filing suit, and all other notice and promises to pay the Holder its costs of collection of all amounts due hereunder, including reasonable attorneys' fees.

(c) Upon the occurrence and during the continuation of any Event of Default or breach of this Note by Sheffield this Note shall bear interest at the interest rate otherwise in effect hereunder plus 3% per annum (but in any event not in excess of the maximum rate of interest permitted by applicable law).

8. Seniority

This Note shall constitute senior indebtedness of Sheffield, and Sheffield shall not incur any indebtedness for money borrowed which shall rank senior to, or pari passu with, this Note without the prior consent of the holders of a majority in principal amount of the Notes; provided, that nothing contained herein shall be construed as to prevent Sheffield from incurring and paying obligations in the ordinary course of business, in accordance with past practice.

9. Miscellaneous

(a) The Investor may assign this Note to its affiliates (as such term is defined in the Securities Exchange Act of 1934, as amended). This Note and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, subject to compliance by such assignee with the representations and warranties contained in Section 3(a) of the Purchase Agreement.

(b) All notices, demands and requests of any kind to be delivered to the other party in connection with this Note shall be in writing and shall be deemed to have been duly given if personally delivered or if sent by nationally-recognized overnight courier or by registered or certified airmail, return receipt requested and postage prepaid, addressed as follows:

to Sheffield:

Sheffield Pharmaceuticals, Inc.
South Winton Court
3136 Winton Road South
Suite 306
Rochester, NY 14623
Attn: Chairman

and

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017-3441
Attention: Chief Executive Officer

with a copy to:

Olshan Grundman Frome, Rosenzweig & Wolosky LLP
505 Park Avenue
New York, NY 10022
Attention: Daniel J. Gallagher

to Holder:

at the address provided to Sheffield by the Holder.

Each party, by written notice given to the other in accordance with this Section may change the address to which notices, other communication or documents are to be sent to such party. All notices, other communications or documents shall be deemed to have been duly given when received. Any such notice or communication shall be deemed to have been received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of nationally-recognized overnight courier, on the second business day after the date when sent and (iii) in the case of mailing, on the fifth business day following that day on which the piece of mail containing such communication is posted. Notice hereunder may be given on behalf of the parties by their respective attorneys.

(c) This Note shall be governed by and construed in accordance with the laws of the state of New York, without reference to the principles of conflicts of laws thereof.

IN WITNESS WHEREOF, Sheffield has caused this Note to be issued as of the date first set forth hereinabove.

SHEFFIELD PHARMACEUTICALS, INC.

By:_____
Name:
Title:

to Exchange Note

FORM OF EXCHANGE NOTICE

TO: Sheffield Pharmaceuticals, Inc.
Attention: Chief Financial Officer

The undersigned owner(s) of Exchange Notes ("Notes") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercise(s) its option to cause the Corporation to exchange $_____ of outstanding principal balance of the Notes for a pro rata portion of the greater of (i) 7,224 shares of preferred stock, par value $1.00 per share, of Sheffield Newco, Limited, a Bermuda corporation ("Newco"), subject to adjustment for split, stock dividends and similar events occurring after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date, in accordance with the terms of the Note originally issued in exchange for shares of Series D Cumulative Convertible Exchangeable Non-Redeemable Preferred Stock, par value $.01 per share of, the Corporation issued pursuant to the Certificate of Designations of the Series D Preferred Stock. The undersigned hereby instructs the Corporation to advise all other holders of Notes, if any, of this exercise by the undersigned owner(s). The undersigned directs that the Newco Capital Stock issuable and certificates therefor deliverable to the undersigned upon such exchange be issued in the name of and delivered to the undersigned unless a different name has been indicated below. All capitalized terms used and not defined herein have the respective meanings assigned to them in the Notes.

Dated:

---

by:_____
Name:
Title:

Please print name and address
(including zip code number) :

- ---
- ---
- ---

Exhibit B

FORM OF DIVIDEND NOTE

SHEFFIELD PHARMACEUTICALS, INC.

U.S. $_____ _____, 20__

The undersigned, Sheffield Pharmaceuticals, Inc., a Delaware corporation ("Sheffield"), for value received, hereby promises to pay to the order of _____ (the "Investor") or its permitted assigns (the "Holder"), at such place as may be designated by the Holder to Sheffield, the sum of _____ dollars ($_____), plus interest on the unpaid principal balance at the rate specified below, in accordance with the provisions set forth herein. During the term of this Note, interest shall accrue at the rate of 7.0% per annum (calculated on the basis of a year of 360 days comprised of 12 30-day months). Accrued interest shall be payable (i) quarterly in arrears on the first day of January, April, July and October of each year and (ii) in-kind through the issuance of additional notes in like tenor to this Note (the "Interest Notes"). The full principal amount of this Note and all Interest Notes, including any accrued interest thereon, shall be due and payable on October 18, 2005 (the "Maturity Date"). This Note is originally being issued as payment of dividends due on shares of Series D Preferred Stock, par value $.01 per share, of Sheffield (the "Series D Preferred Stock"), the rights of which are designated in the Certificate of Designations of the Series D Preferred Stock of Sheffield (the "Certificate of Designations"), and pursuant to a certain Securities Purchase Agreement, dated October 18, 1999 (the "Original Issue Date"), between Sheffield and Elan International Services, Ltd. (the "Purchase Agreement"). All Notes issued as payment of dividends due on shares of Series D Preferred Stock, including the Interest Notes, or upon transfer or exchange of other Notes are referred to herein as the "Notes."

All capitalized terms used in this Note and not otherwise defined herein shall have the meaning assigned to such terms in the Certificate of Designations.

The following is a statement of the rights of the Holder and the conditions to which this Note is subject, and to which the Holder hereof, by the acceptance of this Note, agrees:

1. Mandatory Exchange.

(a) Upon the delivery by holders of at least a majority of the then outstanding shares of Series D Preferred Stock of written notice delivered to Sheffield in the form of notice of election to exchange attached to the Certificate of Designations as Exhibit D (the "Exchange Notice"), the Holder of this Note shall be required to surrender this Note in exchange for a pro rata portion of the greater of (i) 7,224 shares of Newco Preferred Stock, subject to adjustment for split, stock dividends and similar events occurring after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date.

(b) From and after the delivery of the Exchange Notice, this Note shall be deemed to have been exchanged for a pro rata portion of the greater of (i) 7,224 shares of Newco Preferred Stock, subject to adjustment for a split, stock dividends and similar events occurring after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares

of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date, all interest on the Note shall cease to accrue, and all rights of the Holder as a holder of the Note, except the right to receive all accrued and unpaid interest to such Exchange Date at the applicable rate for such Note and the right to receive certificates representing shares of Newco Capital Stock issuable upon the exchange of the Note (including, without limitation, with respect to such Notes issued as interest paid in kind stock), shall cease and terminate, the Note shall not thereafter be transferred (except with the consent of Sheffield) and the Note shall not be deemed to be outstanding for any purpose whatsoever.

2. Exchange or Replacement of Note.

(a) The Holder, at its option, may in person or by duly authorized attorney surrender this Note for exchange, at the office or agency of Sheffield and receive in exchange therefor a new Note in the same aggregate principal amount as the unpaid principal amount of the Note so surrendered, each such new Note to be dated as of the date to which interest has been paid on the Note so surrendered and payable to the Holder or its assignee, as the Holder may designate in writing (subject to the restrictions on transfer set forth in this Note and in the Purchase Agreement).

(b) Upon receipt by Sheffield of evidence satisfactory to it of the loss, theft, destruction, or mutilation of this Note, and (in case of loss, theft or destruction) of indemnity reasonably satisfactory to it, and upon reimbursement to Sheffield of all reasonable expenses incidental thereto, and upon surrender and cancellation of this Note, if mutilated, Sheffield shall make and deliver a new Note of like tenor in lieu of this Note. Any Note made and delivered in accordance with this paragraph shall be dated the date hereof.

3. Amendments. This Note may not be amended, modified or waived in any respect unless set forth in writing and signed by the Holder, in the case of any change hereto, including any change in the amount or timing of any payment to be made hereunder or any adverse change in conversion rights hereunder. Any such amendment, modification or waiver shall be binding upon each future holder of this Note.

4. Costs and Expenses. Sheffield agrees to pay all reasonable costs and expenses, including reasonable attorneys' fees, incurred by the Holder in collecting or enforcing this Note.

5. No Waivers. No delay by the Holder in exercising any power or right hereunder shall operate as a waiver of any power or right, nor shall any single or partial exercise of any power or right preclude other or further exercise thereof, or the exercise of any other power or right hereunder or otherwise.

6. Events of Default

The occurrence of any of the following events shall constitute an event of default (an "Event of Default"):

(a) A default in the payment of the principal amount of this Note, when and as the same shall become due and payable;

(b) a default in the payment of any accrued and unpaid interest on this Note, when and as the same shall become due and payable;

(c) a default in the performance, or a breach of any other covenant or agreement of Sheffield in this Note on any other Transaction Document (as defined in the Purchase Agreement), and continuance of such default or breach for a period of 10 days after the Holder has notified Sheffield of its occurrence;

(d) any representation, warranty, or certification made by Sheffield pursuant to this Note or any other Transaction Document shall prove to have been false or misleading as of the date made in any material respect; or

(e) (i) the entry of a decree or order by a court having jurisdiction adjudging Sheffield bankrupt or insolvent, or approving a petition seeking reorganization, arrangement, adjustment or composition of or in respect of Sheffield, and the continuance of any such decree or order unstayed and in effect for a period of 60 days; (ii) the commencement by Sheffield of a voluntary case under United States bankruptcy law, as now or hereafter constituted, or the consent by Sheffield to the institution of bankruptcy or insolvency proceedings against it; (iii) the filing by Sheffield of a petition or answer or consent seeking reorganization or relief under United States bankruptcy law; (iv) the appointment of a receiver, liquidator, assignee, trustee, sequestrator, or similar official of Sheffield or of any substantial part of its property which is not discharged within 30 days; or (v) the making by Sheffield of an assignment for the benefit of creditors, or the admission by it in writing of its inability to pay its debts generally as they become due, or the taking of corporate action by Sheffield in furtherance of any such action;

7. Remedies in the Event of Default

(a) In the case of any Event of Default by Sheffield, the principal amount of this Note and accrued and unpaid interest thereon shall, in addition to all other rights and remedies of the Holder hereunder and under applicable law, be and become immediately due and payable. (b) Sheffield hereby waives grace, demand and presentment for payment, notice of nonpayment, protest and notice of protest, diligence, filing suit, and all other notice and promises to pay the Holder its costs of collection of all amounts due hereunder, including reasonable attorneys' fees.

(c) Upon the occurrence and during the continuation of any Event of Default or breach of this Note by Sheffield this Note shall bear interest at the interest rate otherwise in effect hereunder plus 3% per annum (but in any event not in excess of the maximum rate of interest permitted by applicable law).

8. Seniority

This Note shall constitute senior indebtedness of Sheffield, and Sheffield shall not incur any indebtedness for money borrowed which shall rank senior to, or pari passu with, this Note without the prior consent of the

holders of a majority in principal amount of the Notes; provided, that nothing contained herein shall be construed as to prevent Sheffield from incurring and paying obligations in the ordinary course of business, in accordance with past practice.

9. Miscellaneous

(a) The Investor may assign this Note to its affiliates (as such term is defined in the Securities Exchange Act of 1934, as amended). This Note and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, subject to compliance by such assignee with the representations and warranties contained in Section 3(e) of the Purchase Agreement.

(b) All notices, demands and requests of any kind to be delivered to the other party in connection with this Note shall be in writing and shall be deemed to have been duly given if personally delivered or if sent by nationally-recognized overnight courier or by registered or certified airmail, return receipt requested and postage prepaid, addressed as follows:

to Sheffield:

Sheffield Pharmaceuticals, Inc.
South Winton Court
3136 Winton Road South
Suite 306
Rochester, NY 14623
Attn: Chairman

and

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017-3441
Attention: Chief Executive Officer

with a copy to:

Olshan Grundman Frome, Rosenzweig & Wolosky LLP
505 Park Avenue
New York, NY 10022
Attention: Daniel J. Gallagher

to Holder:

at the address provided to Sheffield by the Holder.

Each party, by written notice given to the other in accordance with this Section may change the address to which notices, other communication or documents are to be sent to such party. All notices, other communications or documents shall be deemed to have been duly given when received. Any such notice or communication shall be deemed to have been received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of nationally-recognized overnight courier, on the second business day after the date when sent and (iii) in the case of mailing, on the fifth business day following that day on which the piece

of mail containing such communication is posted. Notice hereunder may be given on behalf of the parties by their respective attorneys.

(c) This Note shall be governed by and construed in accordance with the laws of the state of New York, without reference to the principles of conflicts of laws thereof.

IN WITNESS WHEREOF, Sheffield has caused this Note to be issued as of the date first set forth hereinabove.

SHEFFIELD PHARMACEUTICALS, INC.

By:_____
Name:
Title:

Exhibit C

FORM OF CONVERSION NOTICE

TO: Sheffield Pharmaceuticals, Inc.
Attention: Chief Financial Officer

The undersigned owner of shares of Series D Cumulative Convertible Exchangeable Preferred Stock, par value $.01 per share (the "Series D Preferred Stock") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercises its option to convert _____ shares of the Series D Preferred Stock into shares of the common stock, $.01 par value, of the Corporation ("Common Stock"), in accordance with the terms of the Certificate of Designations of the Series D Preferred Stock. The undersigned hereby instructs the Corporation to convert the number of shares of the Series D Preferred Stock specified above into shares of Common Stock in accordance with the provisions of Article 6 of such Certificate of Designations. The undersigned directs that the Common Stock issuable and certificates therefor deliverable upon conversion, the Series D Preferred Stock recertificated, if any, not being surrendered for conversion hereby, together with any check in payment for fractional Common Stock, be issued in the name of and delivered to the undersigned unless a different name has been indicated below. All capitalized terms used and not defined herein have the respective meanings assigned to them in such Certificate of Designations.

Dated:_____

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by:_____

Name:
Title:

Fill in for registration of Series D Preferred Stock:

Please print name and address
(including zip code number) :

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Exhibit D

FORM OF EXCHANGE NOTICE

TO: Sheffield Pharmaceuticals, Inc.
Attention: Chief Financial Officer

The undersigned owner(s) of shares of Series D Cumulative Convertible Exchangeable Preferred Stock, par value $.01 per share (the "Series D Preferred Stock") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercise(s) its option to cause the Corporation to exchange _____ shares of Series D Preferred Stock for a pro rata portion of the greater of (i) 7,224 shares of preferred stock, par value $1.00 per share, of Sheffield Newco, Limited, a Bermuda corporation ("Newco"), subject to adjustment for split, stock dividends and similar events occurring after the Original Issue Date, or (ii) a number of shares of Newco Capital Stock which, together with the shares of Newco Capital Stock issued to the Original Holder on the Original Issue Date, equals fifty percent (50%) of the then outstanding Newco Capital Stock as of the Exchange Date, in accordance with the terms of the Certificate of Designations of the Series D Preferred Stock. The undersigned hereby instructs the Corporation to advise all other holders of Series D Preferred Stock, if any, of this exercise by the undersigned owner(s). The undersigned directs that the Newco Capital Stock issuable and certificates therefor deliverable to the undersigned upon such exchange be issued in the name of and delivered to the undersigned unless a different name has been indicated below. All capitalized terms used and not defined herein have the respective meanings assigned to them in such Certificate of Designations.

Dated: _____

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by:_____
Name:
Title:

Fill in for registration of Series D Preferred Stock:

Please print name and address
(including zip code number) :

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EX-4.6
3
SERIES E CERTIFICATE OF DESIGNATION

CERTIFICATE OF DESIGNATIONS,
PREFERENCES AND RIGHTS

OF

SERIES E CUMULATIVE CONVERTIBLE NON-EXCHANGEABLE
PREFERRED STOCK

OF

SHEFFIELD PHARMACEUTICALS, INC.

Pursuant to Section 151 of
the General Corporation Law of the State of Delaware

Sheffield Pharmaceuticals, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), hereby certifies that the following resolutions were duly adopted by the Board of Directors of the Corporation at a meeting duly called and held on October 15, 1999 pursuant to authority of the Board of Directors as required by Section 151 of the General Corporation Law of the State of Delaware:

RESOLVED, that pursuant to the authority expressly granted to and vested in the Board of Directors of the Corporation (the "Board" or the "Board of Directors") by the provisions of the Certificate of Incorporation of the Corporation (the "Certificate of Incorporation"), out of the 3,000,000 shares of preferred stock of the Corporation authorized in Article FOURTH of the Certificate of Incorporation (the "Preferred Stock"), there hereby is created a series of Preferred Stock consisting of 9,000 shares, which series shall have the following powers, designations, preferences and relative, participating, optional or other rights, and the following qualifications, limitations and restrictions (in addition to the powers, designations, rights, and the qualifications, limitations and restrictions, set forth in the Certificate of Incorporation which are applicable to the Preferred Stock).

ARTICLE 1
DESIGNATION AND AMOUNT

The shares of such series shall be designated as "Series E Cumulative Convertible Non-Exchangeable Preferred Stock" (the "Series E Preferred Stock") and the authorized number of shares constituting such series shall be 9,000 shares. The par value of the Series E Preferred Stock shall be $.01 per share. The stated value of the Series E Preferred Stock shall be One Thousand Dollars ($1,000) per share (the "Stated Value").

ARTICLE 2
DEFINITIONS

The terms defined in this Article whenever used in this Certificate of Designations have the following respective meanings:

(a) "AMEX" means the American Stock Exchange.

(b) "Business Day" means a day other than Saturday, Sunday or any day on which banks located in the State of New York are authorized or obligated to close.

(c) "Common Shares" or "Common Stock" means shares of common stock, $.01 par value, of the Corporation.

(d) "Conversion Date" means any day on which all or any portion of shares of the Series E Preferred Stock is converted in accordance with the provisions hereof.

(e) "Conversion Notice" has the meaning set forth in Section 6.1.

(f) "Conversion Price" has the meaning set forth in Section 6.1.

(g) "Corporation" means Sheffield Pharmaceuticals, Inc., a Delaware corporation, and any successor or resulting corporation by way of merger, consolidation, sale or exchange of all or substantially all of the Corporation's assets, or otherwise.

(h) "Current Market Price" on any date of determination means the closing price of a Common Share on such day as reported on the AMEX, or, if such security is not listed or admitted to trading on the AMEX, on the principal national security exchange or quotation system on which such security is quoted or listed or admitted to trading, or, if not quoted or listed or admitted to trading on any national securities exchange or quotation system, the average of the closing bid and ask prices of such security on the over-the-counter market on the day in question as reported by the National Quotation Bureau Incorporated, or a similar generally accepted reporting service, or if not so available, in such manner as furnished by any Nasdaq member firm of the National Association of Securities Dealers, Inc. selected from time to time by the Board of Directors of the Corporation for that purpose, or a price determined in good faith by the Board of Directors of the Corporation as being equal to the fair

market value thereof, as the case may be.

(i) "Dividend Notes" have the meaning set forth in Section 4.1.

(j) "Dividend Payment Date" has the meaning set forth in Section 4.1.

(k) "Dividend Period" has the meaning set forth in Section 4.1.

(l) "Dividend Shares" means the shares of Series E Preferred Stock issued as dividends on outstanding shares of Series E Preferred Stock in accordance with Article 4 hereof.

(m) "Dollars" or "$" means currency of the United States of America.

(n) "Exchange Note" has the meaning set forth in Section 7.01.

(o) "Holder" or "Holders" means Elan International Services, Ltd., a Bermuda corporation, any successor thereto, or any Person(s) to whom the Series E Preferred Stock is subsequently transferred in accordance with the provisions hereof.

(p) "Issue Date" means the date of original issuance of the applicable share of Series E Preferred Stock.

(q) "Junior Securities" has the meaning set forth in Article 3.

(r) "Liquidation Preference" has the meaning set forth in Section 5.1(b).

(s) "Original Holder" means Elan International Services, Ltd, a Bermuda exempted limited liability company incorporated under the laws of Bermuda and its affiliates (as that term is defined under the Securities Exchange Act of 1934, as amended).

(t) "Original Issue Date" means the date of the initial issuance of shares of Series E Preferred Stock.

(u) "Pari Passu Securities" has the meaning set forth in Article 3.

(v) "Person" means an individual, a corporation, a partnership, an association, a limited liability company, a unincorporated business organization, a trust or other entity or organization, and any government or political subdivision or any agency or instrumentality thereof.

(w) "Rights" has the meaning set forth in Section 6.2(e).

(x) "Securities Purchase Agreement" means the Securities Purchase Agreement, dated as of October 18, 1999, between the Corporation and Elan International Services, Ltd.

(y) "Stated Value" has the meaning set forth in Article 1.

(z) "Trading Day" means any day on which purchases and sales of securities authorized for quotation on the AMEX are reported thereon or, if the Common Stock is not listed or admitted to trading on the AMEX, a day on which the principal national securities exchange on which the Common Stock is listed or admitted to trading is open for the transaction of business, or, if the Common Stock is not so listed or admitted to trading on any national securities exchange, a day on which the Nasdaq National Market (or any successor thereto) or such other system then in use is open for the transaction of business, or, if the Common Stock is not quoted by any such organization, any day other than a Saturday, Sunday or a day on which banking institutions in the State of New York are authorized or obligated by law or executive order to close.

ARTICLE 3
RANK

The Series E Preferred Stock shall rank (i) prior to the Common Stock; (ii) prior to any class or series of capital stock of the Corporation hereafter created other than Pari Passu Securities (collectively, with the Common Stock, the "Junior Securities"); (iii) pari passu with the Corporation's Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock"); (iv) pari passu with the Corporation's Series D Convertible Exchangeable Preferred Stock (the "Series D Preferred Stock"); (v) pari passu with the Corporation's Series F Convertible Non-Exchangeable Preferred Stock (the "Series F Preferred Stock"); and (vi) pari passu with any class or series of capital stock of the Corporation hereafter created specifically ranking on parity with the Series E Preferred Stock (collectively, with the Series C Preferred Stock, the Series D Preferred Stock and the Series F Preferred Stock, the "Pari Passu Securities").

ARTICLE 4
DIVIDENDS

SECTION 4.1

(a) (i) Subject to Article 6, the Holder shall be entitled to receive, out of funds legally available for the payment of dividends, dividends at the rate of 9.0% per annum (computed on the basis of a 360-day year) (the "Dividend Rate") on the Stated Value of each outstanding share of Series E Preferred Stock payable on and as of the most recent Dividend Payment Date with respect to each Dividend Period. Dividends on the Series E Preferred Stock shall be cumulative from the date of issue or the most recent Dividend Payment Date upon which dividends have been paid on the Series E Preferred Stock by the Corporation.

(ii) Dividends on the Series E Preferred Stock shall be payable in equal semi-annual installments on April 18 and October 18 of each year (each, a "Dividend Payment Date"), commencing April 18, 2000 and ending

October 18, 2005, to the holders of record of shares of the Series E Preferred Stock, as they appear on the stock records of the Corporation at the close of business on any record date, not more than 60 days or less than 10 days preceding the payment dates thereof, as shall be fixed by the Board of Directors. For the purposes hereof, "Dividend Period," in respect of any share of Series E Preferred Stock, shall mean the period commencing on April 18, 2000 and, thereafter, the semiannual period commencing on and including the day after the immediately preceding Dividend Payment Date and ending on and including the immediately subsequent Dividend Payment Date. Accrued and unpaid dividends for any past Dividend Period may be declared and paid at any time, without reference to any Dividend Payment Date, to holders of record on such date, not more than 15 days preceding the payment date thereof, as may be fixed by the Board of Directors.

(iii) Dividends on the outstanding shares of Series E Preferred Stock shall be paid through the issuance of duly and validly authorized and issued, fully paid and non-assessable shares of Series E Preferred Stock to be issued at the rate of one (1) share of Series E Preferred Stock for each $1,000 of dividend due and payable. No fractional shares of the Series E Preferred Stock shall be issued as Dividend Shares. Instead of any fractional shares of Series E Preferred Stock which would otherwise be issuable as Dividend Shares, the Corporation shall pay a cash adjustment in respect of such fractional interest in an amount equal to $1,000 times the fractional interest.

(b) The Holder shall not be entitled to any dividends in excess of the cumulative dividends, as herein provided, on the Series E Preferred Stock. Except as provided in this Article 4, no interest, or sum of money in lieu of interest, shall be payable in respect of any dividend payment or payments on the Series E Preferred Stock that may be in arrears.

(c) In the event that, after the first anniversary of the Original Issue Date, the payment of any Dividend Shares upon the Series E Preferred Stock to the Original Holder would result in the Original Holder's fully-diluted ownership of Common Stock (assuming the conversion into Common Stock of all options, warrants and other securities convertible or exchangeable into Common Stock beneficially owned by the Original Holder) to exceed 49.9% of the then outstanding Common Stock, such excess dividends shall be paid to the Original Holder through issuance by the Corporation of promissory notes with an aggregate principal amount equal to each dividend payment amount then payable (collectively, the "Dividend Notes"). Each Dividend Note shall be issued in substantially the form attached as Exhibit A to this Certificate of Designations. It shall be a condition to the Corporation's obligation to issue Dividend Notes in respect of any such excess dividends that the Original Holder deliver to the Corporation, at least 15 days before the applicable Dividend Payment Date, a certificate (i) certifying that the Dividend Shares otherwise issuable on such Dividend Payment Date shall cause the Original Holder's beneficial ownership to exceed such 49.9% amount and (ii) demonstrating the calculation of the principal amount of the Dividend Note to be issued in lieu of the applicable excess Dividend Shares.

ARTICLE 5

LIQUIDATION PREFERENCE

SECTION 5.1

(a) If the Corporation shall commence a voluntary case under the Federal bankruptcy laws or any other applicable Federal or State bankruptcy, insolvency or similar law, or consent to the entry of an order for relief in an involuntary case under any law or to the appointment of a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Corporation or of any substantial part of its property, or make an assignment for the benefit of its creditors, or admit in writing its inability to pay its debts generally as they become due, or if a decree or order for relief in respect of the Corporation shall be entered by a court having jurisdiction in the premises in an involuntary case under the Federal bankruptcy laws or any other applicable Federal or state bankruptcy, insolvency or similar law resulting in the appointment of a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Corporation or of any substantial part of its property, or ordering the winding up or liquidation of its affairs, and any such decree or order shall be unstayed and in effect for a period of ninety (90) consecutive days and, on account of any such event, the Corporation shall liquidate, dissolve or wind up, or if the Corporation shall otherwise liquidate, dissolve or wind up (each such event being considered a "Liquidation Event"), no distribution shall be made to the holders of any Junior Securities of the Corporation upon liquidation, dissolution or winding up unless prior thereto, the Holders, subject to Article 5, shall have received the Liquidation Preference (as defined in Article 5.1(b)) with respect to each share. If upon the occurrence of a Liquidation Event, the assets and funds available for distribution among the Holders and holders of shares of Pari Passu Securities shall be insufficient to permit the payment to such holders of the preferential amounts payable thereon, then the entire assets and funds of the Corporation legally available for distribution to the Series E Preferred Stock and the Pari Passu Securities shall be distributed ratably among such shares in proportion to the ratio that the preferential amounts payable on each such share bears to the aggregate preferential amounts payable on all such shares.

(b) For purposes hereof, the "Liquidation Preference" with respect to a share of the Series E Preferred Stock shall mean an amount equal to (i) the Stated Value thereof, plus (ii) the aggregate of all accrued and unpaid dividends on such share of Series E Preferred Stock until the most recent Dividend Payment Date; provided that, in the event of an actual liquidation, dissolution or winding up of the Corporation, the amount referred to in clause (ii) above shall be calculated by including accrued and unpaid stock dividends to the actual date of such liquidation, dissolution or winding up, rather than the applicable Dividend Payment Due Date referred to above.

ARTICLE 6
CONVERSION OF SERIES E PREFERRED STOCK

SECTION 6.1 Conversion.

(a) Holders of shares of the Series E Preferred Stock shall have the right, exercisable at any time after the second anniversary of the Original Issue Date and prior to the sixth anniversary of the Original Issue Date, to

convert all or any such shares of the Series E Preferred Stock into the number of shares of Common Stock (calculated as to each conversion to the nearest 1/100th of a share) determined by dividing (1) the aggregate Liquidation Preference of the shares of Series E Preferred Stock to be converted by (2) $3.89 (the "Conversion Price"). Upon conversion, no adjustment or payment will be made for dividends, but if any holder surrenders a share of the Series E Preferred Stock for conversion after the close of business on the record date for the payment of a dividend and prior to the opening of business on the next Dividend Payment Date, then, notwithstanding such conversion, the dividend payable on such Dividend Payment Date will be paid to the registered holder of such share on such record date. In such event, such share, when surrendered for conversion during the period between the close of business on any dividend payment record date and the opening of business on the corresponding Dividend Payment Date, must be accompanied by payment of an amount equal to the dividend payable on such Dividend Payment Date on the share so converted.

(b) Any holder of a share or shares of the Series E Preferred Stock electing to convert such share or shares thereof shall deliver the certificate or certificates therefor to the principal office of the Corporation or any transfer agent for the Common Stock, with the form of notice of election to convert attached as Exhibit C to this Certificate of Designations (the "Conversion Notice"), fully completed and duly executed and (if such required by the Corporation or any conversion agent) accompanied by instruments of transfer in form satisfactory to the Corporation and to any conversion agent, duly executed by the registered Holder of his duly authorized attorney. The conversion right with respect to any such shares shall be deemed to have been exercised at the date upon which the certificates therefore accompanied by such duly executed notice of election and instruments of transfer and such taxes, stamps, funds, or evidence of payment shall have been so delivered, and the Person or Persons entitled to receive the shares of the Common Stock issuable upon such conversion shall be treated for all purposes as the record Holder or Holders of such shares of the Common Stock upon said date.

(c) From and after the delivery of the Conversion Notice in respect of any conversion of shares of Series E Preferred Stock, all such shares of Series E Preferred Stock shall be deemed to have been converted into shares of Common Stock as of the applicable Conversion Date at the applicable conversion rate, all stock dividends on such shares of the Series E Preferred Stock shall cease to accrue, and all rights of the Holders thereof as holders of Series E Preferred Stock, except the right to receive all accrued and unpaid stock dividends to such Conversion Date at the applicable rate for such shares of Series E Preferred Stock and the right to receive certificates representing shares of Common Stock issuable upon the conversion of such shares (including, without limitation, with respect to such stock dividends, as applicable), shall cease and terminate, such shares of Series E Preferred Stock shall not thereafter be transferred (except with the consent of the Corporation) and such shares shall not be deemed to be outstanding for any purpose whatsoever.

(d) No fractional shares of the Common Stock or scrip representing fractional shares shall be issued upon conversion of shares of the Series E Preferred Stock. If more than one share of the Series E Preferred Stock

shall be surrendered for conversion at one time by the same holder, the number of full shares of the Common Stock which shall be issuable upon conversion thereof shall be computed on the basis of the aggregate number of shares of the Series E Preferred Stock so surrendered. Instead of any fractional shares of the Common Stock which would otherwise be issuable upon conversion of any shares of the Series E Preferred Stock, the Corporation shall pay a cash adjustment in respect of such fraction in an amount equal to the same fraction of the Current Market Price for the Common Stock on the last Trading Day preceding the applicable date of conversion.

(e) Each Conversion Notice under this Section 6.1 shall request the conversion of at least 500 shares of Series E Preferred Stock or the remaining balance of Series E Preferred Stock held by the converting Holder, whichever is less.

SECTION 6.2 Adjustments. The Conversion Price and the number of shares issuable upon conversion of the Series E Preferred Stock are subject to adjustment from time to time as follows:

(a) Merger, Sale of Assets, Etc. Notwithstanding any other limitation whatsoever contained herein, if at any time while the Series E Preferred Stock, or any portion thereof, is outstanding there shall be (i) a reorganization (other than a combination, reclassification, exchange or subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Corporation with or into another corporation in which the Corporation is the surviving entity but the shares of the Corporation's capital stock outstanding immediately prior to the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (iii) a sale or transfer of the Corporation's properties and assets as, or substantially as, an entirety to any other Person, then as a part of such reorganization, merger, consolidation, sale or transfer lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon conversion of the Series E Preferred Stock, during the period specified herein, the number of shares of stock or other securities or property of the successor corporation resulting from such reorganization, merger, consolidation, sale or transfer that the Holder would have been entitled to receive in such reorganization, consolidation, merger, sale or transfer if the Series E Preferred Stock had been converted immediately before such reorganization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 6.2(a). The foregoing provisions of this Section 6.2(a) shall similarly apply to successive reclassification, changes, consolidations, mergers, mandatory share exchanges and sales and transfers. If the per share consideration payable to the holder hereof for shares in connection with any such transaction is in a form other than cash or marketable securities, then the value of such consideration shall be determined in good faith by the Board of Directors. In all events, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions of this Certificate of Designations with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this Certificate of Designations shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable after that event upon conversion of the Series E Preferred Stock.

(b) Reclassification, Etc. If the Corporation, at any time while the Series E Preferred Stock, or any portion thereof, remains outstanding, shall change any of the securities as to which conversion rights under this Certificate of Designations exist into the same or a different number of securities of any other class or classes, the Series E Preferred Stock shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities that were subject to the conversion rights under this Certificate of Designations immediately prior to such reclassification or other change and the Conversion Price therefor shall be appropriately adjusted, all subject to further adjustment as provided in this Certificate of Designations.

(c) Split, Subdivision or Combination of Shares. If the Corporation at any time while the Series E Preferred Stock, or any portion thereof, remains outstanding shall split, subdivide or combine the securities as to which conversion rights under this Certificate of Designations exist, into a different number of securities of the same class, the Conversion Price shall be proportionately decreased in the case of a split or subdivision or proportionately increased in the case of a combination.

(d) Adjustments for Dividends in Stock and Other Securities or Property. If while the Series E Preferred Stock, or any portion hereof, remains outstanding, the holders of the securities as to which conversion rights under this Certificate of Designations exist at the time shall have received, or, on or after the record date fixed for the determination of eligible stockholders of the Corporation, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than cash) of the Corporation by way of dividend, then and in each case, the Series E Preferred Stock shall represent the right to acquire, upon conversion, in addition to the number of shares of the security receivable upon conversion of the Series E Preferred Stock, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) of the Corporation that the Holder would hold on the date of such conversion had it been the holder of record of the security receivable upon conversion of the Series E Preferred Stock on the date hereof and had thereafter, during the period from the date hereof to and including the date of such conversion, retained such shares and/or additional stock available by it as aforesaid during such period, giving effect to all adjustments called for during such period by the provisions of this Section 6.2.

(e) Repurchases or Redemptions of Common Stock or Options. If the Corporation at any time while shares of Series E Preferred Stock are outstanding, shall repurchase or redeem any outstanding shares of Common Stock or rights, options or warrants granting the holder thereof the right to acquire shares of Common Stock (collectively, the "Rights") in a single transaction or a series of related transactions involving an aggregate repurchase or redemption price in excess of $500,000 at a price (on a per share basis) which is greater than 150% of the Current Market Price as of the day prior to such repurchase or redemption, the Conversion Price shall thereupon be adjusted by multiplying the Conversion Price in effect immediately prior to the applicable repurchase or redemption by a fraction (i) the numerator of which shall be the Conversion Price in effect immediately prior to such repurchase or redemption and (ii) the

denominator of which shall be the fair market value of the consideration paid by the Corporation for each share of Common Stock (or each share of Common Stock issuable upon exercise of the Right(s) subject to such repurchase or redemption) in such repurchase or redemption.

(f) Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment pursuant to this Section 6.2, the Corporation at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to the Holder a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based.

(g) Cumulative Adjustments. No adjustment in the Conversion Price shall be required until cumulative adjustments result in a concomitant change of 1% or more of the Conversion Price as in effect prior to the last adjustment of the Conversion Price; provided, however, that any adjustments which by reason of this Section 6.2 are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 6.2 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be. No adjustment to the Conversion Price shall be made for cash dividends.

ARTICLE 7

EXCHANGE RIGHTS

SECTION 7.01 Mandatory Exchange. On or before the first anniversary of the Original Issue Date, the Corporation shall notify each Holder, in writing, (i) that the issuance of the Series E Preferred Stock, and the issuance and listing upon the American Stock Exchange ("AMEX") of the shares of Common Stock issuable upon conversion of the Series E Preferred Stock, has been approved or ratified by the stockholders of the Corporation in accordance with the General Corporation Law of the State of Delaware and the rules and regulation of the AMEX or (ii) that such approval or ratification is not required by the applicable rules of the AMEX. In the event that the Corporation fails to provide such written notice on or before the first anniversary of the Original Issue Date, (A) all outstanding shares of Series E Preferred Stock shall be deemed exchanged for promissory note(s) in substantially the form of Exhibit B attached to this Certificate of Designations (the "Exchange Notes"), in the respective principal amounts equal to the aggregate Liquidation Preference of all shares of Series E Preferred Stock held by each respective Holder as of the date of such exchange and (B) from and after the first anniversary of the Original Issue Date, all shares of Series E Preferred Stock (including Dividend Shares) shall be deemed to have been exchanged for Exchange Notes, all dividends on the Series E Preferred Stock shall cease to accrue, and all rights of Holders thereof as holders of Series E Preferred Stock shall cease and terminate and all shares of Series E Preferred Stock shall not be deemed outstanding for any purpose whatsoever, except the right to receive the Exchange Notes issuable to them as determined above.

ARTICLE 8
VOTING RIGHTS

The holders of the Series E Preferred Stock shall have no voting rights, except as otherwise provided by the General Corporation Law of the State of Delaware ("DGCL") and in this Article 8, and in Article 9 below.

The Corporation shall provide each Holder of Series E Preferred Stock with prior notification of any meeting of the shareholders of the Corporation (and copies of proxy materials and other information sent to shareholders). In the event of any taking by the Corporation of a record of its shareholders for the purpose of determining shareholders who are entitled to receive payment of any dividend or other distribution, any right to subscribe for, purchase or otherwise acquire (including by way of merger, consolidation or recapitalization) any share of any class or any other securities or property, or to receive any other right, or for the purpose of determining shareholders who are entitled to vote in connection with any proposed liquidation, dissolution or winding up of the Corporation, the Corporation shall mail a notice to each Holder, at least thirty (30) days prior to the consummation of the transaction or event, whichever is earlier), of the date on which any such action is to be taken for the purpose of such dividend, distribution, right or other event, and a brief statement regarding the amount and character of such dividend, distribution, right or other event to the extent known at such time.

To the extent that under the DGCL the vote of the Holders of the Series E Preferred Stock, voting separately as a class or series as applicable, is required to authorize a given action of the Corporation, the affirmative vote or consent of the Holders of at least a majority of the shares of the Series E Preferred Stock represented at a duly held meeting at which a quorum is present or by written consent of a majority of the shares of Series E Preferred Stock (except as otherwise may be required under the DGCL) shall constitute the approval of such action by the class. To the extent that under the DGCL Holders of the Series E Preferred Stock are entitled to vote on a matter with Holders of Common Stock, voting together as one class, each share of Series E Preferred Stock shall be entitled to a number of votes equal to the number of shares of Common Stock into which such shares are convertible as of the record date for the taking of such vote of shareholders. Holders of the Series E Preferred Stock shall be entitled to notice of all shareholder meetings or written consents (and copies of proxy materials and other information sent to shareholders) with respect to which they would be entitled as of right under the DGCL, which notice would be provided pursuant to the Corporation's bylaws and the DGCL.

ARTICLE 9
PROTECTIVE PROVISIONS

So long as shares of Series E Preferred Stock are outstanding, the Corporation shall not, without first obtaining the approval (by vote or written consent, as provided by the DGCL) of the Holders of at least a majority of the then outstanding shares of Series E Preferred Stock:

(a) create any new class or series of capital stock having a preference superior to the Series E Preferred Stock as to distribution of assets upon liquidation, dissolution or winding up of the Corporation ("Senior

Securities") or alter or change the rights, preferences or privileges of any Senior Securities so as to affect adversely the Series E Preferred Stock; or

(b) amend or alter whether by merger, consolidation or otherwise, any of the provisions of the Certificate of Incorporation (including this Certificate of Designations) that would change the preferences, rights or privileges with respect to the Series E Preferred Stock so as to affect the Series E Preferred Stock adversely.

In the event holders of at least a majority of the then outstanding shares of Series E Preferred Stock agree to allow the Corporation to amend or alter the preferences, rights or privileges of the shares of Series E Preferred Stock, pursuant to subsection (b) above, so as to affect adversely the Series E Preferred Stock, then the Corporation will deliver notice of such approved change to the Holders of the Series E Preferred Stock that did not agree to such amendment or change (the "Dissenting Holders") and the Dissenting Holders shall have the right for a period of thirty (30) days to convert pursuant to Section 6.1 of this Certificate of Designations as they exist prior to such alteration or continue to hold their shares of Series E Preferred Stock. The Holders' rights under this Article 9 shall terminate on the sixth anniversary of the Original Issue Date.

ARTICLE 10
MISCELLANEOUS

SECTION 10.1 Loss, Theft, Destruction of Series E Preferred Stock. Upon receipt of evidence satisfactory to the Corporation of the loss, theft, destruction or mutilation of shares of Series E Preferred Stock and, in the case of any such loss, theft or destruction, upon receipt of indemnity or security reasonably satisfactory to the Corporation, or, in the case of any such mutilation, upon surrender and cancellation of the Series E Preferred Stock, the Corporation shall make, issue and deliver, in lieu of such lost, stolen, destroyed or mutilated shares of Series E Preferred Stock, new shares of Series E Preferred Stock of like date and tenor.

SECTION 10.2 Who Deemed Absolute Owner. The Corporation may deem the Person in whose name the Series E Preferred Stock shall be registered upon the registry books of the Corporation to be, and may treat it as, the absolute owner of the Series E Preferred Stock for the purpose of receiving payment of dividends on the Series E Preferred Stock, for the conversion of the Series E Preferred Stock and for all other purposes, and the Corporation shall not be affected by any notice to the contrary. All such payments and such conversion shall be valid and effectual to satisfy and discharge the liability upon the Series E Preferred Stock to the extent of the sum or sums so paid or the conversion so made.

SECTION 10.3 Register. The Corporation shall keep at its principal office a register in which the Corporation shall provide for the registration of the Series E Preferred Stock. Upon any transfer of the Series E Preferred Stock in accordance with the provisions hereof, the Corporation shall register such transfer on the Series E Preferred Stock register.

SECTION 10.4 Withholding. To the extent required by applicable law, the Corporation may withhold amounts for or on account of any taxes imposed or levied by or on behalf of any taxing authority in the United States having jurisdiction over the Corporation from any payments made pursuant to the Series E Preferred Stock.

SECTION 10.5 Headings. The headings of the Articles and Sections of this Certificate of Designations are inserted for convenience only and do not constitute a part of this Certificate of Designations.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Designations, Preferences and Rights to be signed by Loren G. Peterson, its President and Chief Executive Officer, and attested by Scott A. Hoffmann, its Secretary, on this 18th day of October, 1999.

SHEFFIELD PHARMACEUTICALS, INC.

By:/s/ Loren G. Peterson

Loren G. Peterson
President and Chief Executive Officer

Attested:

By: /s/ Scott A. Hoffman

Scott A. Hoffmann
Secretary

Exhibit A

FORM OF DIVIDEND NOTE

SHEFFIELD PHARMACEUTICALS, INC.

U.S. $_____ _____, 20__

The undersigned, Sheffield Pharmaceuticals, Inc., a Delaware corporation

("Sheffield"), for value received, hereby promises to pay to the order of _____ (the "Investor") or its permitted assigns (the "Holder"), at such place as may be designated by the Holder to Sheffield, the sum of _____ dollars ($_____), plus interest on the unpaid principal balance at the rate specified below, in accordance with the provisions set forth herein. During the term of this Note, interest shall accrue at the rate of 9.0% per annum (calculated on the basis of a year of 360 days comprised of 12 30-day months). Accrued interest shall be payable (i) quarterly in arrears on the first day of January, April, July and October of each year and (ii) in-kind through the issuance of additional notes in like tenor to this Note (the "Interest Notes"). The full principal amount of this Note and all Interest Notes, including any accrued interest thereon, shall be due and payable on October 18, 2005 (the "Maturity Date"). This Note is originally being issued as payment of dividends due on shares of Series E Preferred Stock, par value $.01 per share, of Sheffield (the "Series E Preferred Stock"), the rights of which are designated in the Certificate of Designations of the Series E Preferred Stock of Sheffield (the "Certificate of Designations"), and pursuant to a certain Securities Purchase Agreement, dated October 18, 1999 (the "Original Issue Date"), between Sheffield and Elan International Services, Ltd. (the "Purchase Agreement"). All Notes issued as payment of dividends due on shares of Series E Preferred Stock, including the Interest Notes, or upon transfer or exchange of other Notes are referred to herein as the "Notes."

All capitalized terms used in this Note and not otherwise defined herein shall have the meaning assigned to such terms in the Certificate of Designations.

The following is a statement of the rights of the Holder and the conditions to which this Note is subject, and to which the Holder hereof, by the acceptance of this Note, agrees:

1. Exchange or Replacement of Note.

(a) The Holder, at its option, may in person or by duly authorized attorney surrender this Note for exchange, at the office or agency of Sheffield and receive in exchange therefor a new Note in the same aggregate principal amount as the unpaid principal amount of the Note so surrendered, each

such new Note to be dated as of the date to which interest has been paid on the Note so surrendered and payable to the Holder or its assignee, as the Holder may designate in writing (subject to the restrictions on transfer set forth in this Note and in the Purchase Agreement).

(b) Upon receipt by Sheffield of evidence satisfactory to it of the loss, theft, destruction, or mutilation of this Note, and (in case of loss, theft or destruction) of indemnity reasonably satisfactory to it, and upon reimbursement to Sheffield of all reasonable expenses incidental thereto, and upon surrender and cancellation of this Note, if mutilated, Sheffield shall make and deliver a new Note of like tenor in lieu of this Note. Any Note made and delivered in accordance with this paragraph shall be dated the date hereof.

2. Amendments. This Note may not be amended, modified or waived in any respect unless set forth in writing and signed by the Holder, in the case of any change hereto, including any change in the amount or timing of any payment to be

made hereunder or any adverse change in conversion rights hereunder. Any such amendment, modification or waiver shall be binding upon each future holder of this Note.

3. Costs and Expenses. Sheffield agrees to pay all reasonable costs and expenses, including reasonable attorneys' fees, incurred by the Holder in collecting or enforcing this Note.

4. No Waivers. No delay by the Holder in exercising any power or right hereunder shall operate as a waiver of any power or right, nor shall any single or partial exercise of any power or right preclude other or further exercise thereof, or the exercise of any other power or right hereunder or otherwise.

5. Events of Default

The occurrence of any of the following events shall constitute an event of default (an "Event of Default"):

(a) A default in the payment of the principal amount of this Note, when and as the same shall become due and payable;

(b) a default in the payment of any accrued and unpaid interest on this Note, when and as the same shall become due and payable;

(c) a default in the performance, or a breach of any other covenant or agreement of Sheffield in this Note on any other Transaction Document (as defined in the Purchase Agreement), and continuance of such default or breach for a period of 10 days after the Holder has notified Sheffield of its occurrence;

(d) any representation, warranty, or certification made by Sheffield pursuant to this Note or any other Transaction Document shall prove to have been false or misleading as of the date made in any material respect; or

(e) (i) the entry of a decree or order by a court having jurisdiction adjudging Sheffield bankrupt or insolvent, or approving a petition seeking reorganization, arrangement, adjustment or composition of or in respect of Sheffield, and the continuance of any such decree or order unstayed and in effect for a period of 60 days; (ii) the commencement by Sheffield of a voluntary case under United States bankruptcy law, as now or hereafter constituted, or the consent by Sheffield to the institution of bankruptcy or insolvency proceedings against it; (iii) the filing by Sheffield of a petition or answer or consent seeking reorganization or relief under United States bankruptcy law; (iv) the appointment of a receiver, liquidator, assignee, trustee, sequestrator, or similar official of Sheffield or of any substantial part of its property which is not discharged within 30 days; or (v) the making by Sheffield of an assignment for the benefit of creditors, or the admission by it in writing of its inability to pay its debts generally as they become due, or the taking of corporate action by Sheffield in furtherance of any such action;

6. Remedies in the Event of Default

(a) In the case of any Event of Default by Sheffield, the principal amount of this Note and accrued and unpaid interest thereon shall, in addition to all other rights and remedies of the Holder hereunder and under applicable law, be and become immediately due and payable.

(b) Sheffield hereby waives grace, demand and presentment for payment, notice of nonpayment, protest and notice of protest, diligence, filing suit, and all other notice and promises to pay the Holder its costs of collection of all amounts due hereunder, including reasonable attorneys' fees.

(c) Upon the occurrence and during the continuation of any Event of Default or breach of this Note by Sheffield this Note shall bear interest at the interest rate otherwise in effect hereunder plus 3% per annum (but in any event not in excess of the maximum rate of interest permitted by applicable law).

7. Seniority

This Note shall constitute senior indebtedness of Sheffield, and Sheffield shall not incur any indebtedness for money borrowed which shall rank senior to, or pari passu with, this Note without the prior consent of the holders of a majority in principal amount of the Notes; provided, that nothing contained herein shall be construed as to prevent Sheffield from incurring and paying obligations in the ordinary course of business, in accordance with past practice.

8. Miscellaneous

(a) The Investor may assign this Note to its affiliates (as such term is defined in the Securities Exchange Act of 1934, as amended). This Note and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, subject to compliance by such assignee with the representations and warranties contained in Section 3(e) of the Purchase Agreement.

(b) All notices, demands and requests of any kind to be delivered to the other party in connection with this Note shall be in writing and shall be deemed to have been duly given if personally delivered or if sent by nationally-recognized overnight courier or by registered or certified airmail, return receipt requested and postage prepaid, addressed as follows:

to Sheffield:

Sheffield Pharmaceuticals, Inc.
South Winton Court
3136 Winton Road South
Suite 306
Rochester, NY 14623
Attention: Chairman

and

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017-3441
Attention: Chief Executive Officer

with a copy to:

Olshan Grundman Frome, Rosenzweig & Wolosky LLP
505 Park Avenue
New York, NY 10022
Attention: Daniel J. Gallagher

to Holder:

at the address provided to Sheffield by the Holder.

Each party, by written notice given to the other in accordance with this Section may change the address to which notices, other communication or documents are to be sent to such party. All notices, other communications or documents shall be deemed to have been duly given when received. Any such notice or communication shall be deemed to have been received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of nationally-recognized overnight courier, on the second business day after the date when sent and (iii) in the case of mailing, on the fifth business day following that day on which the piece of mail containing such communication is posted. Notice hereunder may be given on behalf of the parties by their respective attorneys.

(c) This Note shall be governed by and construed in accordance with the laws of the state of New York, without reference to the principles of conflicts of laws thereof.

IN WITNESS WHEREOF, Sheffield has caused this Note to be issued as of the date first set forth hereinabove.

SHEFFIELD PHARMACEUTICALS, INC.

By:_____
Name:
Title:

Exhibit B

FORM OF EXCHANGE NOTE

SHEFFIELD PHARMACEUTICALS, INC.

U.S. $_____ _____, 20__

The undersigned, Sheffield Pharmaceuticals, Inc., a Delaware corporation ("Sheffield"), for value received, hereby promises to pay to the order of _____ (the "Investor") or its permitted assigns (the "Holder"), at such place as may be designated by the Holder to Sheffield, the sum of _____ dollars ($_____), plus interest on the unpaid principal balance at the rate specified below, in accordance with the provisions set forth herein. During the term of this Note, interest shall accrue at the rate of 9.0% per annum (calculated on the basis of a year of 360 days comprised of 12 30-day months). Accrued interest shall be payable (i) quarterly in arrears on the first day of January, April, July and October of each year and (ii) in-kind through the issuance of additional notes in like tenor to this Note (the "Interest Notes"). The full principal amount of this Note and all Interest Notes, including any accrued interest thereon, shall be due and payable on October 18, 2005 (the "Maturity Date"). This Note is originally being issued in exchange for shares of Series E Preferred Stock, par value $.01 per share, of Sheffield (the "Series E Preferred Stock"), the rights of which are designated in the Certificate of Designations of the Series E Preferred Stock of Sheffield (the "Certificate of Designations"), and pursuant to a certain Securities Purchase Agreement, dated October 18, 1999 (the "Original Issue Date"), between Sheffield and Elan International Services, Ltd. (the "Purchase Agreement"). All Notes issued in exchange for shares of Series E Preferred Stock, including the Interest Notes, or upon transfer or exchange of other Notes are referred to herein as the "Notes."

All capitalized terms used in this Note and not otherwise defined herein shall have the meaning assigned to such terms in the Certificate of Designations.

The following is a statement of the rights of the Holder and the conditions to which this Note is subject, and to which the Holder hereof, by the acceptance of this Note, agrees:

1. Exchange or Replacement of Note.

(a) The Holder, at its option, may in person or by duly authorized attorney surrender this Note for exchange, at the office or agency of Sheffield and receive in exchange therefor a new Note in the same aggregate principal amount as the unpaid principal amount of the Note so surrendered, each such new Note to be dated as of the date to which interest has been paid on the Note so surrendered and payable to the Holder or its assignee, as the Holder may designate in writing (subject to the restrictions on transfer set forth in this Note and in the Purchase Agreement).

(b) Upon receipt by Sheffield of evidence satisfactory to it of the loss, theft, destruction, or mutilation of this Note, and (in case of loss, theft or destruction) of indemnity reasonably satisfactory to it, and upon reimbursement to Sheffield of all reasonable expenses incidental thereto, and

upon surrender and cancellation of this Note, if mutilated, Sheffield shall make and deliver a new Note of like tenor in lieu of this Note. Any Note made and delivered in accordance with this paragraph shall be dated the date hereof.

2. Amendments. This Note may not be amended, modified or waived in any respect unless set forth in writing and signed by the Holder, in the case of any change hereto, including any change in the amount or timing of any payment to be made hereunder or any adverse change in conversion rights hereunder. Any such amendment, modification or waiver shall be binding upon each future holder of this Note.

3. Costs and Expenses. Sheffield agrees to pay all reasonable costs and expenses, including reasonable attorneys' fees, incurred by the Holder in collecting or enforcing this Note.

4. No Waivers. No delay by the Holder in exercising any power or right hereunder shall operate as a waiver of any power or right, nor shall any single or partial exercise of any power or right preclude other or further exercise thereof, or the exercise of any other power or right hereunder or otherwise.

5. Events of Default

The occurrence of any of the following events shall constitute an event of default (an "Event of Default"):

(a) A default in the payment of the principal amount of this Note, when and as the same shall become due and payable;

(b) a default in the payment of any accrued and unpaid interest on this Note, when and as the same shall become due and payable;

(c) a default in the performance, or a breach of any other covenant or agreement of Sheffield in this Note on any other Transaction Document (as defined in the Purchase Agreement), and continuance of such default or breach for a period of 10 days after the Holder has notified Sheffield of its occurrence;

(d) any representation, warranty, or certification made by Sheffield pursuant to this Note or any other Transaction Document shall prove to have been false or misleading as of the date made in any material respect; or

(e) (i) the entry of a decree or order by a court having jurisdiction adjudging Sheffield bankrupt or insolvent, or approving a petition seeking reorganization, arrangement, adjustment or composition of or in respect of Sheffield, and the continuance of any such decree or order unstayed and in effect for a period of 60 days; (ii) the commencement by Sheffield of a voluntary case under United States bankruptcy law, as now or hereafter constituted, or the consent by Sheffield to the institution of bankruptcy or insolvency proceedings against it; (iii) the filing by Sheffield of a petition or answer or consent seeking reorganization or relief under United States bankruptcy law; (iv) the appointment of a receiver, liquidator, assignee, trustee, sequestrator, or similar official of Sheffield or of any substantial part of its property which is not discharged within 30 days; (v) the making by

Sheffield of an assignment for the benefit of creditors, or the admission by it in writing of its inability to pay its debts generally as they become due, or the taking of corporate action by Sheffield in furtherance of any such action.

6. Remedies in the Event of Default

(a) In the case of any Event of Default by Sheffield, the principal amount of this Note and accrued and unpaid interest thereon shall, in addition to all other rights and remedies of the Holder hereunder and under applicable law, be and become immediately due and payable.

(b) Sheffield hereby waives grace, demand and presentment for payment, notice of nonpayment, protest and notice of protest, diligence, filing suit, and all other notice and promises to pay the Holder its costs of collection of all amounts due hereunder, including reasonable attorneys' fees.

(c) Upon the occurrence and during the continuation of any Event of Default or breach of this Note by Sheffield this Note shall bear interest at the interest rate otherwise in effect hereunder plus 3% per annum (but in any event not in excess of the maximum rate of interest permitted by applicable law).

7. Seniority

This Note shall constitute senior indebtedness of Sheffield, and Sheffield shall not incur any indebtedness for money borrowed which shall rank senior to, or pari passu with, this Note without the prior consent of the holders of a majority in principal amount of the Notes; provided, that nothing contained herein shall be construed as to prevent Sheffield from incurring and paying obligations in the ordinary course of business, in accordance with past practice.

8. Miscellaneous

(a) The Investor may assign this Note to its affiliates (as such term is defined in the Securities Exchange Act of 1934, as amended). This Note and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, subject to compliance by such assignee with the representations and warranties contained in Section 3(a) of the Purchase Agreement.

(b) All notices, demands and requests of any kind to be delivered to the other party in connection with this Note shall be in writing and shall be deemed to have been duly given if personally delivered or if sent by nationally-recognized overnight courier or by registered or certified airmail, return receipt requested and postage prepaid, addressed as follows:

to Sheffield:

Sheffield Pharmaceuticals, Inc.
South Winton Court
3136 Winton Road South
Suite 306
Rochester, NY 14623

Attention: Chairman

and

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017-3441
Attention: Chief Executive Officer

with a copy to:

Olshan Grundman Frome, Rosenzweig & Wolosky LLP
505 Park Avenue
New York, NY 10022
Attention: Daniel J. Gallagher

to Holder:

at the address provided to Sheffield by the Holder.

Each party, by written notice given to the other in accordance with this Section may change the address to which notices, other communication or documents are to be sent to such party. All notices, other communications or documents shall be deemed to have been duly given when received. Any such notice or communication shall be deemed to have been received (i) in the case of personal delivery, on the date of such delivery, (ii) in the case of nationally-recognized overnight courier, on the second business day after the date when sent and (iii) in the case of mailing, on the fifth business day following that day on which the piece of mail containing such communication is posted. Notice hereunder may be given on behalf of the parties by their respective attorneys.

(c) This Note shall be governed by and construed in accordance with the laws of the state of New York, without reference to the principles of conflicts of laws thereof.

IN WITNESS WHEREOF, Sheffield has caused this Note to be issued as of the date first set forth hereinabove.

SHEFFIELD PHARMACEUTICALS, INC.

By:_____
Name:
Title:

FORM OF CONVERSION NOTICE

TO: Sheffield Pharmaceuticals, Inc.
Attention: Chief Financial Officer

The undersigned owner of shares of Series E Cumulative Convertible Preferred Stock, par value $.01 per share (the "Series E Preferred Stock") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercises its option to convert _____ shares of the Series E Preferred Stock into shares of the common stock, $.01 par value, of the Corporation ("Common Stock"), in accordance with the terms of the Certificate of Designations of the Series E Preferred Stock. The undersigned hereby instructs the Corporation to convert the number of shares of the Series E Preferred Stock specified above into shares of Common Stock in accordance with the provisions of Article 6 of such Certificate of Designations. The undersigned directs that the Common Stock issuable and certificates therefor deliverable upon conversion, the Series E Preferred Stock recertificated, if any, not being surrendered for conversion hereby, together with any check in payment for fractional Common Stock, be issued in the name of and delivered to the undersigned unless a different name has been indicated below. All capitalized terms used and not defined herein have the respective meanings assigned to them in such Certificate of Designations.

Dated:_____

---

by:_____
Name:
Title:

Fill in for registration of Series E Preferred Stock:

Please print name and address
(including zip code number):

- ---
- ---
- ---
- ---

EX-4.7
4
SERIES F CERTIFICATE OF DESIGNATION

CERTIFICATE OF DESIGNATIONS,
PREFERENCES AND RIGHTS

OF

SERIES F CONVERTIBLE NON-EXCHANGEABLE

PREFERRED STOCK

OF

SHEFFIELD PHARMACEUTICALS, INC.

Pursuant to Section 151 of
the General Corporation Law of the State of Delaware

Sheffield Pharmaceuticals, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), hereby certifies that the following resolutions were duly adopted by the Board of Directors of the Corporation at a meeting duly called and held on October 15, 1999 pursuant to authority of the Board of Directors as required by Section 151 of the General Corporation Law of the State of Delaware:

RESOLVED, that pursuant to the authority expressly granted to and vested in the Board of Directors of the Corporation (the "Board" or the "Board of Directors") by the provisions of the Certificate of Incorporation of the Corporation (the "Certificate of Incorporation"), out of the 3,000,000 shares of preferred stock of the Corporation authorized in Article FOURTH of the Certificate of Incorporation (the "Preferred Stock"), there hereby is created a series of Preferred Stock consisting of 5,000 shares, which series shall have the following powers, designations, preferences and relative, participating, optional or other rights, and the following qualifications, limitations and restrictions (in addition to the powers, designations, rights, and the qualifications, limitations and restrictions, set forth in the Certificate of Incorporation which are applicable to the Preferred Stock).

ARTICLE 1
DESIGNATION AND AMOUNT

The shares of such series shall be designated as "Series F Convertible Non-Exchangeable Preferred Stock" (the "Series F Preferred Stock") and the authorized number of shares constituting such series shall be 5,000 shares. The par value of the Series F Preferred Stock shall be $.01 per share. The stated value of the Series F Preferred Stock shall be One Thousand Dollars ($1,000) per share (the "Stated Value").

ARTICLE 2
DEFINITIONS

The terms defined in this Article whenever used in this Certificate of Designations have the following respective meanings:

(a) "AMEX" means the American Stock Exchange.

(b) "Business Day" means a day other than Saturday, Sunday or any day on which banks located in the State of New York are authorized or obligated to close.

(c) "Common Shares" or "Common Stock" means shares of common stock, $.01 par value, of the Corporation.

(d) "Conversion Date" means any day on which all or any portion of shares of the Series F Preferred Stock is converted in accordance with the provisions hereof.

(e) "Conversion Notice" has the meaning set forth in Section 6.1.

(f) "Conversion Price" has the meaning set forth in Section 6.1.

(g) "Corporation" means Sheffield Pharmaceuticals, Inc., a Delaware corporation, and any successor or resulting corporation by way of merger, consolidation, sale or exchange of all or substantially all of the Corporation's assets, or otherwise.

(h) "Current Market Price" on any date of determination means the closing price of a Common Share on such day as reported on the AMEX, or, if such security is not listed or admitted to trading on the AMEX, on the principal national security exchange or quotation system on which such security is quoted or listed or admitted to trading, or, if not quoted or listed or admitted to trading on any national securities exchange or quotation system, the average of the closing bid and ask prices of such security on the over-the-counter market on the day in question as reported by the National Quotation Bureau Incorporated, or a similar generally accepted reporting service, or if not so available, in such manner as furnished by any Nasdaq member firm of the National Association of Securities Dealers, Inc. selected from time to time by the Board of Directors of the Corporation for that purpose, or a price determined in good faith by the Board of Directors of the Corporation as being equal to the fair market value thereof, as the case may be.

(i) "Dollars" or "$" means currency of the United States of America.

(j) "Holder" or "Holders" means Elan International Services, Ltd., a Bermuda corporation, any successor thereto, or any Person(s) to whom the Series F Preferred Stock is subsequently transferred in accordance with the provisions hereof.

(k) "Issue Date" means the date of original issuance of the applicable share of Series F Preferred Stock.

(l) "Junior Securities" has the meaning set forth in Article 3.

(m) "Liquidation Preference" has the meaning set forth in Section 5.1(b).

(n) "Original Holder" means Elan International Services, Ltd, a Bermuda exempted limited liability company incorporated under the laws of Bermuda and its affiliates (as that term is defined under the Securities Exchange Act of 1934, as amended).

(o) "Original Issue Date" means the date of the initial issuance of shares of Series F Preferred Stock.

(p) "Pari Passu Securities" has the meaning set forth in Article 3.

(q) "Person" means an individual, a corporation, a partnership, an association, a limited liability company, a unincorporated business organization, a trust or other entity or organization, and any government or political subdivision or any agency or instrumentality thereof.

(r) "Rights" has the meaning set forth in Section 6.2(e).

(s) "Securities Purchase Agreement" means the Securities Purchase Agreement, dated as of October 18, 1999, between the Corporation and Elan International Services, Ltd.

(t) "Stated Value" has the meaning set forth in Article 1.

(u) "Trading Day" means any day on which purchases and sales of securities authorized for quotation on the AMEX are reported thereon or, if the Common Stock is not listed or admitted to trading on the AMEX, a day on which the principal national securities exchange on which the Common Stock is listed or admitted to trading is open for the transaction of business, or, if the Common Stock is not so listed or admitted to trading on any national securities exchange, a day on which the Nasdaq National Market (or any successor thereto) or such other system then in use is open for the transaction of business, or, if the Common Stock is not quoted by any such organization, any day other than a Saturday, Sunday or a day on which banking institutions in the State of New York are authorized or obligated by law or executive order to close.

ARTICLE 3
RANK

The Series F Preferred Stock shall rank (i) prior to the Common Stock; (ii) prior to any class or series of capital stock of the Corporation hereafter created other than Pari Passu Securities (collectively, with the Common Stock, the "Junior Securities"); (iii) pari passu with the Corporation's Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock"); (iv) pari passu with the Corporation's Series E Convertible Non-Exchangeable Preferred Stock (the "Series E Preferred Stock"); (v) pari passu with the Corporation's Series D Convertible Exchangeable Preferred Stock (the "Series D Preferred Stock"); and (vi) pari passu with any class or series of capital stock of the Corporation hereafter created specifically ranking on parity with the Series F Preferred Stock (collectively, with the Series C Preferred Stock, the Series E Preferred Stock and the Series D Preferred Stock,

the "Pari Passu Securities").

ARTICLE 4
DIVIDENDS

SECTION 4.1

(a) Subject to Article 6, the Holder shall be entitled to receive, out of funds legally available for the payment of dividends, dividends on a pari passu basis with the holders of Common Stock. No interest, or sum of money in lieu of interest, shall be payable in respect of any dividend payment or payments on the Series F Preferred Stock that may be in arrears.

(b) No dividends or distributions may be paid with respect to the Common Stock, and the Company shall not repurchase, redeem or otherwise acquire any Common Stock, unless such dividends, distribution or repurchase, redemption or acquisition payment are paid on a pro rata basis to holders of Series F Preferred Stock, on an as converted basis, at the same time and upon the same terms as such payments with respect to the Common Stock.

ARTICLE 5
LIQUIDATION PREFERENCE

SECTION 5.1

(a) If the Corporation shall commence a voluntary case under the Federal bankruptcy laws or any other applicable Federal or State bankruptcy, insolvency or similar law, or consent to the entry of an order for relief in an involuntary case under any law or to the appointment of a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Corporation or of any substantial part of its property, or make an assignment for the benefit of its creditors, or admit in writing its inability to pay its debts generally as they become due, or if a decree or order for relief in respect of the Corporation shall be entered by a court having jurisdiction in the premises in an involuntary case under the Federal bankruptcy laws or any other applicable Federal or state bankruptcy, insolvency or similar law resulting in the appointment of a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Corporation or of any substantial part of its property, or ordering the winding up or liquidation of its affairs, and any such decree or order shall be unstayed and in effect for a period of ninety (90) consecutive days and, on account of any such event, the Corporation shall liquidate, dissolve or wind up, or if the Corporation shall otherwise liquidate, dissolve or wind up (each such event being considered a "Liquidation Event"), no distribution shall be made to the holders of any Junior Securities of the Corporation upon liquidation, dissolution or winding up unless prior thereto, the Holders, subject to Article 5, shall have received the Liquidation Preference (as defined in Article 5.1(b)) with respect to each share. If upon the occurrence of a Liquidation Event, the assets and funds available for distribution among the Holders and holders of shares of Pari Passu Securities shall be insufficient to permit the payment to such holders of the preferential amounts payable thereon, then the entire assets and funds of the

Corporation legally available for distribution to the Series F Preferred Stock and the Pari Passu Securities shall be distributed ratably among such shares in proportion to the ratio that the preferential amounts payable on each such share bears to the aggregate preferential amounts payable on all such shares.

(b) For purposes hereof, the "Liquidation Preference" with respect to a share of the Series F Preferred Stock shall mean an amount equal to the Stated Value thereof plus the aggregate of all accrued and unpaid dividends on such share of Series F Preferred Stock.

ARTICLE 6
CONVERSION OF SERIES F PREFERRED STOCK

SECTION 6.1 Conversion.

(a) Holders of shares of the Series F Preferred Stock shall have the right, exercisable at any time after the second anniversary of the Original Issue Date and prior to the sixth anniversary of the Original Issue Date, to convert all or any such shares of the Series F Preferred Stock into the number of shares of Common Stock (calculated as to each conversion to the nearest 1/100th of a share) determined by dividing (1) the aggregate Liquidation Preference of the shares of Series F Preferred Stock to be converted by (2) $3.40 (the "Conversion Price").

(b) Any holder of a share or shares of the Series F Preferred Stock electing to convert such share or shares thereof shall deliver the certificate or certificates therefor to the principal office of the Corporation or any transfer agent for the Common Stock, with the form of notice of election to convert attached as Exhibit A to this Certificate of Designations (the

"Conversion Notice"), fully completed and duly executed and (if such required by the Corporation or any conversion agent) accompanied by instruments of transfer in form satisfactory to the Corporation and to any conversion agent, duly executed by the registered Holder of his duly authorized attorney. The conversion right with respect to any such shares shall be deemed to have been exercised at the date upon which the certificates therefore accompanied by such duly executed notice of election and instruments of transfer and such taxes, stamps, funds, or evidence of payment shall have been so delivered, and the Person or Persons entitled to receive the shares of the Common Stock issuable upon such conversion shall be treated for all purposes as the record Holder or Holders of such shares of the Common Stock upon said date.

(c) From and after the delivery of the Conversion Notice in respect of any conversion of shares of Series F Preferred Stock, all such shares of Series F Preferred Stock shall be deemed to have been converted into shares of Common Stock as of the applicable Conversion Date at the applicable conversion rate, all stock dividends on such shares of the Series F Preferred Stock shall cease to accrue, and all rights of the Holders thereof as holders of Series F Preferred Stock, except the right to receive all accrued and unpaid stock dividends to such Conversion Date at the applicable rate for such shares of Series F Preferred Stock and the right to receive certificates representing shares of Common Stock issuable upon the conversion of such shares (including,

without limitation, with respect to such stock dividends, as applicable), shall cease and terminate, such shares of Series F Preferred Stock shall not thereafter be transferred (except with the consent of the Corporation) and such shares shall not be deemed to be outstanding for any purpose whatsoever.

(d) No fractional shares of the Common Stock or scrip representing fractional shares shall be issued upon conversion of shares of the Series F Preferred Stock. If more than one share of the Series F Preferred Stock shall be surrendered for conversion at one time by the same holder, the number of full shares of the Common Stock which shall be issuable upon conversion thereof shall be computed on the basis of the aggregate number of shares of the Series F Preferred Stock so surrendered. Instead of any fractional shares of the Common Stock which would otherwise be issuable upon conversion of any shares of the Series F Preferred Stock, the Corporation shall pay a cash adjustment in respect of such fraction in an amount equal to the same fraction of the Current Market Price for the Common Stock on the last Trading Day preceding the applicable date of conversion.

(e) Each Conversion Notice under this Section 6.1 shall request the conversion of at least 500 shares of Series F Preferred Stock or the remaining balance of Series F Preferred Stock held by the converting Holder, whichever is less.

SECTION 6.2 Adjustments. The Conversion Price and the number of shares issuable upon conversion of the Series F Preferred Stock are subject to adjustment from time to time as follows:

(a) Merger, Sale of Assets, Etc. Notwithstanding any other limitation whatsoever contained herein, if at any time while the Series F Preferred Stock, or any portion thereof, is outstanding there shall be (i) a reorganization (other than a combination, reclassification, exchange or

subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Corporation with or into another corporation in which the Corporation is the surviving entity but the shares of the Corporation's capital stock outstanding immediately prior to the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (iii) a sale or transfer of the Corporation's properties and assets as, or substantially as, an entirety to any other Person, then as a part of such reorganization, merger, consolidation, sale or transfer lawful provision shall be made so that the Holder shall thereafter be entitled to receive upon conversion of the Series F Preferred Stock, during the period specified herein, the number of shares of stock or other securities or property of the successor corporation resulting from such reorganization, merger, consolidation, sale or transfer that the Holder would have been entitled to receive in such reorganization, consolidation, merger, sale or transfer if the Series F Preferred Stock had been converted immediately before such reorganization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 6.2(a). The foregoing provisions of this Section 6.2(a) shall similarly apply to successive reclassification, changes, consolidations, mergers, mandatory share exchanges and sales and transfers. If the per share consideration payable to the holder hereof for shares in connection with any such transaction is in a form other than cash or marketable securities, then the

value of such consideration shall be determined in good faith by the Board of Directors. In all events, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions of this Certificate of Designations with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this Certificate of Designations shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable after that event upon conversion of the Series F Preferred Stock.

(b) Reclassification, Etc. If the Corporation, at any time while the Series F Preferred Stock, or any portion thereof, remains outstanding, shall change any of the securities as to which conversion rights under this Certificate of Designations exist into the same or a different number of securities of any other class or classes, the Series F Preferred Stock shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities that were subject to the conversion rights under this Certificate of Designations immediately prior to such reclassification or other change and the Conversion Price therefor shall be appropriately adjusted, all subject to further adjustment as provided in this Certificate of Designations.

(c) Split, Subdivision or Combination of Shares. If the Corporation at any time while the Series F Preferred Stock, or any portion thereof, remains outstanding shall split, subdivide or combine the securities as to which conversion rights under this Certificate of Designations exist, into a different number of securities of the same class, the Conversion Price shall be proportionately decreased in the case of a split or subdivision or proportionately increased in the case of a combination.

(d) Adjustments for Dividends in Stock and Other Securities or Property. If while the Series F Preferred Stock, or any portion hereof, remains outstanding, the holders of the securities as to which conversion rights under this Certificate of Designations exist at the time shall have received, or, on

or after the record date fixed for the determination of eligible stockholders of the Corporation, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than cash) of the Corporation by way of dividend, then and in each case, the Series F Preferred Stock shall represent the right to acquire, upon conversion, in addition to the number of shares of the security receivable upon conversion of the Series F Preferred Stock, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) of the Corporation that the Holder would hold on the date of such conversion had it been the holder of record of the security receivable upon conversion of the Series F Preferred Stock on the date hereof and had thereafter, during the period from the date hereof to and including the date of such conversion, retained such shares and/or additional stock available by it as aforesaid during such period, giving effect to all adjustments called for during such period by the provisions of this Section 6.2.

(e) Repurchases or Redemptions of Common Stock or Options. If the Corporation at any time while shares of Series F Preferred Stock are outstanding, shall repurchase or redeem any outstanding shares of Common Stock

or rights, options or warrants granting the holder thereof the right to acquire shares of Common Stock (collectively, the "Rights") in a single transaction or a series of related transactions involving an aggregate repurchase or redemption price in excess of $500,000 at a price (on a per share basis) which is greater than 150% of the Current Market Price as of the day prior to such repurchase or redemption, the Conversion Price shall thereupon be adjusted by multiplying the Conversion Price in effect immediately prior to the applicable repurchase or redemption by a fraction (i) the numerator of which shall be the Conversion Price in effect immediately prior to such repurchase or redemption and (ii) the denominator of which shall be the fair market value of the consideration paid by the Corporation for each share of Common Stock (or each share of Common Stock issuable upon exercise of the Right(s) subject to such repurchase or redemption) in such repurchase or redemption.

(f) Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment pursuant to this Section 6.2, the Corporation at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to the Holder a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based.

(g) Cumulative Adjustments. No adjustment in the Conversion Price shall be required until cumulative adjustments result in a concomitant change of 1% or more of the Conversion Price as in effect prior to the last adjustment of the Conversion Price; provided, however, that any adjustments which by reason of this Section 6.2 are not required to be made shall be carried forward and taken into account in any subsequent adjustment. All calculations under this Section 6.2 shall be made to the nearest cent or to the nearest one-hundredth of a share, as the case may be. No adjustment to the Conversion Price shall be made for cash dividends.

ARTICLE 7
VOTING RIGHTS

The holders of the Series F Preferred Stock shall have no voting rights, except as otherwise provided by the General Corporation Law of the State of Delaware ("DGCL") and in this Article 7, and in Article 8 below.

The Corporation shall provide each Holder of Series F Preferred Stock with prior notification of any meeting of the shareholders of the Corporation (and copies of proxy materials and other information sent to shareholders). In the event of any taking by the Corporation of a record of its shareholders for the purpose of determining shareholders who are entitled to receive payment of any dividend or other distribution, any right to subscribe for, purchase or otherwise acquire (including by way of merger, consolidation or recapitalization) any share of any class or any other securities or property, or to receive any other right, or for the purpose of determining shareholders who are entitled to vote in connection with any proposed liquidation, dissolution or winding up of the Corporation, the Corporation shall mail a notice to each Holder, at least thirty (30) days prior to the consummation of the transaction or event, whichever is earlier), of the date on which any such action is to be taken for the purpose of such dividend, distribution, right or other event, and a brief statement regarding the amount and character of such dividend,

distribution, right or other event to the extent known at such time.

To the extent that under the DGCL the vote of the Holders of the Series F Preferred Stock, voting separately as a class or series as applicable, is required to authorize a given action of the Corporation, the affirmative vote or consent of the Holders of at least a majority of the shares of the Series F Preferred Stock represented at a duly held meeting at which a quorum is present or by written consent of a majority of the shares of Series F Preferred Stock (except as otherwise may be required under the DGCL) shall constitute the approval of such action by the class. To the extent that under the DGCL Holders of the Series F Preferred Stock are entitled to vote on a matter with Holders of Common Stock, voting together as one class, each share of Series F Preferred Stock shall be entitled to a number of votes equal to the number of shares of Common Stock into which such shares are convertible as of the record date for the taking of such vote of shareholders. Holders of the Series F Preferred Stock shall be entitled to notice of all shareholder meetings or written consents (and copies of proxy materials and other information sent to shareholders) with respect to which they would be entitled as of right under the DGCL, which notice would be provided pursuant to the Corporation's bylaws and the DGCL.

ARTICLE 8
PROTECTIVE PROVISIONS

So long as shares of Series F Preferred Stock are outstanding, the Corporation shall not, without first obtaining the approval (by vote or written consent, as provided by the DGCL) of the Holders of at least a majority of the then outstanding shares of Series F Preferred Stock:

(a) create any new class or series of capital stock having a preference superior to the Series F Preferred Stock as to distribution of assets upon liquidation, dissolution or winding up of the Corporation ("Senior

Securities") or alter or change the rights, preferences or privileges of any Senior Securities so as to affect adversely the Series F Preferred Stock; or

(b) amend or alter whether by merger, consolidation or otherwise, any of the provisions of the Certificate of Incorporation (including this Certificate of Designations) that would change the preferences, rights or privileges with respect to the Series F Preferred Stock so as to affect the Series F Preferred Stock adversely.

In the event holders of at least a majority of the then outstanding shares of Series F Preferred Stock agree to allow the Corporation to amend or alter the preferences, rights or privileges of the shares of Series F Preferred Stock, pursuant to subsection (b) above, so as to affect adversely the Series F Preferred Stock, then the Corporation will deliver notice of such approved change to the Holders of the Series F Preferred Stock that did not agree to such amendment or change (the "Dissenting Holders") and the Dissenting Holders shall have the right for a period of thirty (30) days to convert pursuant to Section 6.1 of this Certificate of Designations as they exist prior to such alteration or continue to hold their shares of Series F Preferred Stock. The Holders' rights under this Article 8 shall terminate on the sixth anniversary of the

Original Issue Date.

ARTICLE 9
MISCELLANEOUS

SECTION 9.1 Loss, Theft, Destruction of Series F Preferred Stock. Upon receipt of evidence satisfactory to the Corporation of the loss, theft, destruction or mutilation of shares of Series F Preferred Stock and, in the case of any such loss, theft or destruction, upon receipt of indemnity or security reasonably satisfactory to the Corporation, or, in the case of any such mutilation, upon surrender and cancellation of the Series F Preferred Stock, the Corporation shall make, issue and deliver, in lieu of such lost, stolen, destroyed or mutilated shares of Series F Preferred Stock, new shares of Series F Preferred Stock of like date and tenor.

SECTION 9.2 Who Deemed Absolute Owner. The Corporation may deem the Person in whose name the Series F Preferred Stock shall be registered upon the registry books of the Corporation to be, and may treat it as, the absolute owner of the Series F Preferred Stock for the purpose of receiving payment of dividends on the Series F Preferred Stock, for the conversion of the Series F Preferred Stock and for all other purposes, and the Corporation shall not be affected by any notice to the contrary. All such payments and such conversion shall be valid and effectual to satisfy and discharge the liability upon the Series F Preferred Stock to the extent of the sum or sums so paid or the conversion so made.

SECTION 9.3 Register. The Corporation shall keep at its principal office a register in which the Corporation shall provide for the registration of the Series F Preferred Stock. Upon any transfer of the Series F Preferred Stock in accordance with the provisions hereof, the Corporation shall register such transfer on the Series F Preferred Stock register.

SECTION 6.4 Withholding. To the extent required by applicable law, the Corporation may withhold amounts for or on account of any taxes imposed or levied by or on behalf of any taxing authority in the United States having jurisdiction over the Corporation from any payments made pursuant to the Series F Preferred Stock.

SECTION 6.5 Headings. The headings of the Articles and Sections of this Certificate of Designations are inserted for convenience only and do not constitute a part of this Certificate of Designations.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Designations,

Preferences and Rights to be signed by Loren G. Peterson, its President and Chief Executive Officer, and attested by Scott A. Hoffmann, its Secretary, on this 18th day of October, 1999.

SHEFFIELD PHARMACEUTICALS, INC.

By:/s/ Loren G. Peterson

Loren G. Peterson
President and Chief Executive Officer

Attested:

By: /s/ Scott A. Hoffman

Scott A. Hoffmann
Secretary

Exhibit C

FORM OF CONVERSION NOTICE

TO: Sheffield Pharmaceuticals, Inc.
Attention: Chief Financial Officer

The undersigned owner of shares of Series F Convertible Non-Exchangeable Preferred Stock, par value $.01 per share (the "Series F Preferred Stock") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercises its option to convert _____ shares of the Series F Preferred Stock into shares of the common stock, $.01 par value, of the Corporation ("Common Stock"), in accordance with the terms of the Certificate of Designations of the Series F Preferred Stock. The undersigned hereby instructs the Corporation to convert the number of shares of the Series F Preferred Stock specified above into shares of Common Stock in accordance with the provisions of Article 6 of such Certificate of Designations. The undersigned directs that the Common Stock issuable and certificates therefor deliverable upon conversion, the Series F Preferred Stock recertificated, if any, not being surrendered for conversion hereby, together with any check in payment for fractional Common Stock, be issued in the name of and delivered to the undersigned unless a different name has been indicated below. All capitalized terms used and not defined herein have the respective meanings assigned to them in such Certificate of Designations.

Dated: _____

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by:_____
Name:
Title:

Fill in for registration of Series F Preferred Stock:

Please print name and address
(including zip code number) :

- ---
- ---
- ---

EX-10.25
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SECURITIES PURCHASE AGREEMENT

SECURITIES PURCHASE AGREEMENT

SECURITIES PURCHASE AGREEMENT, dated as of October 18, 1999 between Elan International Services, Ltd., a Bermuda exempted limited liability company incorporated under the laws of Bermuda ("EIS"), and Sheffield Pharmaceuticals, Inc., a Delaware corporation (the "Company").

R E C I T A L S:

A. The Company desires to issue and sell to EIS, and EIS desires to purchase from the Company, for aggregate consideration of $12,015,000 (the "Original Series D Issue Price"), 12,015 shares of a newly-created series of cumulative convertible exchangeable preferred stock, par value $0.01 per share, of the Company (the "Series D Preferred Stock"), which shall be issued to EIS pursuant to a Certificate of Designations in the form attached hereto as Exhibit A (the "Series D Certificate of Designations"), at a per share purchase price of $1,000.

B. The Company desires to issue and sell to EIS, and EIS desires to purchase from the Company, for aggregate consideration that shall not exceed $4,005,000 (the "Original Series E Issue Price"), up to 4,005 shares of a newly-created series of cumulative convertible non-exchangeable preferred stock, par value $0.01 per share, of the Company (the "Series E Preferred Stock"), which, if issued, shall be issued to EIS pursuant to a Certificate of Designations in the form attached hereto as Exhibit B (the "Series E Certificate of Designations"), at a per share purchase price of $1,000.

C. The Company desires to issue and sell to EIS, and EIS desires to purchase from the Company, for aggregate consideration of $5,000,000 (the "Original Series F Issue Price"), (i) 5,000 shares of a newly-created series of the Company's convertible, non-exchangeable preferred stock, par value

$0.01 per share, of the Company (the "Series F Preferred Stock"), which shall be issued to EIS pursuant to a Certificate of Designations in the form attached hereto as Exhibit C (the "Series F Certificate of Designations", and together with the Series D Certificate of Designations and the Series E Certificate of Designations, the "Certificates of Designations") and (ii) a warrant to acquire 150,000 shares (subject to adjustment) of the common stock, par value $0.01 per share, of the Company (the "Sheffield Common Stock"), at an exercise price of $6.00 per share, pursuant to a warrant certificate in the form attached hereto as Exhibit D (the "Warrant", and together with the Series D Preferred Stock, the Series E Preferred Stock and the Series F Preferred, collectively, the "Securities").

D. The Company has previously caused to be formed Sheffield Newco, Ltd., a Bermuda exempted limited liability company incorporated under the laws of Bermuda ("Newco"). The Company will acquire from Newco, for an aggregate purchase price of $12,015,000, (i) 12,000 shares of Newco's voting common stock (the "Newco Common Stock"), representing 100% of the outstanding shares of such class of stock, and (ii) 7,224 shares of Newco's non-voting, convertible preferred stock (the "Newco Preferred Stock"), representing, on a fully diluted basis, 30.1% of the outstanding shares of such class of stock. EIS will acquire from Newco, for an aggregate purchase price of $2,985,000, 4,776 shares of Newco Preferred Stock, representing, on a fully diluted basis, 19.9% of the outstanding shares of such class of stock. Newco has entered into license arrangements (the "License Arrangements") with Elan Pharma International Limited, an Irish private company ("EPIL"), and with the Company for the purpose of developing and commercializing certain medical products as set forth in the documents that evidence the License Arrangements.

E. The parties intend, as provided herein, that all of the proceeds from the sale of (i) the Series D Preferred Stock shall be applied by the Company solely to fund the Company's initial investment in Newco and (ii) the Series E Preferred Stock shall be applied by the Company solely to fund the Company's subsequent development funding obligations in connection with Newco, in each case, as provided herein and as set forth in the Subscription, Joint Development and Operating Agreement, dated as of the date hereof, by and between Newco, Elan Pharma International Limited, EIS and the Company (the "Development Agreement").

F. The Company and EIS are executing and delivering on the date hereof a Registration Rights Agreement (the "Sheffield Registration Rights Agreements") in respect of the purchase of the Series D Preferred Stock, Series E Preferred Stock, Series F Preferred Stock and the Sheffield Common Stock underlying the Securities and any other shares of Sheffield capital stock (including shares of preferred stock issued as dividends upon the Series D Preferred Stock or Series E Preferred Stock) that may, at any time, be acquired or owned by EIS or its affiliates.

G. The Company, EIS and Newco are executing and delivering on the date hereof a Registration Rights Agreement (the "Newco Registration Rights Agreements"), in respect of the purchase of Newco Common Stock and Newco Preferred Stock by the Company and EIS. This Agreement, the Securities, the Certificates of Designations, the Development Agreement, the Sheffield Registration Rights Agreements, the Newco Registration Rights Agreements, the Dividend Notes (as defined below) and each other document, promissory notes or

instrument executed and delivered, or to be executed and delivered as contemplated hereby or thereby, in connection with the transactions contemplated hereby, (the "Transaction Documents").

A G R E E M E N T:

The parties agree as follows:

SECTION 1. Closings. (a) Time and Place. The closing of the transactions contemplated hereby (the "Closing") shall occur on the date hereof (the "Closing Date") at such place as the parties may agree.

(b) Issuance of Securities. At the Closing, (x) the Company shall issue and sell to EIS, and EIS shall purchase from the Company (i) 12,015 shares of Series D Preferred Stock for an aggregate purchase price of $12,015,000 and (ii) 5,000 shares of Series F Preferred Stock and the Warrant for an aggregate purchase price of $4,397,500 and the surrender and cancellation of the Promissory Note, dated September 30, 1999, issued by the Company to EIS in the principal amount of $600,000.

(c) Delivery. At the Closing, EIS shall pay the purchase price for the Series D Preferred Stock, the Series F Preferred Stock and the Warrant by wire transfer to an account or accounts designated by the Company and the parties hereto shall execute and deliver to each other, as applicable: (i) a certificate or certificates for the shares of Series D Preferred Stock; (ii) the Warrant; (iii) a certificate or certificates for the shares of the Series F Preferred Stock; (iv) certificates as to the incumbency of the officers executing this Agreement; and (v) each of the other documents or instruments executed in connection herewith. In addition, at the Closing, the Company shall cause to be delivered to EIS an opinion of counsel in form and substance satisfactory to EIS.

(d) Additional Closings - Series E Preferred Stock. EIS shall be obligated, subject to the conditions set forth in Section 6, during the first 36 months immediately after the Closing Date, to purchase from the Company all or a portion of 4,005 shares of the Series E Preferred Stock for a purchase price per share of $1,000, in accordance with Section 6 hereof.

(e) Exemption from Registration. The Securities will be issued under an exemption or exemptions from registration under the Securities Act of 1933, as amended (the "Securities Act"); accordingly, the certificate or certificates evidencing the Securities, and any shares of Sheffield Common Stock, Newco Common

Stock or Newco Preferred Stock issuable upon the exercise, exchange or conversion of any of the Securities shall, upon issuance, contain the following legend:

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), AND MAY NOT UNDER ANY CIRCUMSTANCES BE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE ACT OF AND ANY APPLICABLE STATE SECURITIES LAWS OR AN OPINION OF COUNSEL SATISFACTORY TO THE

CORPORATION THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR APPLICABLE STATE SECURITIES LAWS.

(f) Registration Rights Agreement. On the date hereof, the Company and EIS shall execute and deliver (i) the Sheffield Registration Rights Agreement, covering the resale by EIS of the Sheffield Common Stock issuable upon conversion, exercise or exchange of any of the Securities and (ii) the Newco Registration Rights Agreement, covering the resale by EIS and the Company of the Newco Common Stock issuable, directly or indirectly, upon exchange of any of the Securities.

SECTION 2. Representations and Warranties of the Company. (a) Organization. The Company is duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own and lease its properties, to carry on its business as presently conducted and as proposed to be conducted and to consummate the transactions contemplated hereby. As of the date hereof, the Company is qualified and in good standing to do business in jurisdictions set forth on Schedule 2(a), which constitute all of the jurisdictions in which the nature of the business conducted or the property owned by it requires such qualification, except where the failure to so qualify would not have a material adverse effect on the business, prospects, properties or condition (financial or otherwise) of the Company (a "Material Adverse Effect").

(b) Capitalization. As of the date hereof, (i) the authorized capital stock of the Company consists of (A) 60,000,000 shares of Sheffield Common Stock, par value $0.01 per share and (B) 3,000,000 shares of Preferred Stock, par value $0.01 per share, (w) 23,000 shares of which have been designated as Series C Cumulative Preferred Stock, par value $0.01 per share ("Series C Preferred Stock"), (x) 21,000 shares of which have been designated Series D Preferred Stock, (y) 9,000 shares of which have been designated as Series E Preferred Stock and (z) 5,000 shares of which have been designated as Series F Preferred Stock. As of the date hereof, 27,296,346 shares of Sheffield Common Stock were issued and outstanding; 12,556 shares of Series C Preferred Stock were issued and outstanding; and no shares of Series D Preferred Stock, Series E Preferred Stock or Series F Preferred Stock were issued and outstanding.

(ii) Except as listed in Schedule 2(b), as of the date hereof, there are no options, warrants or other rights outstanding to purchase or otherwise acquire, or any securities convertible into, any of the Company's authorized capital stock. Other than as set forth in this Agreement and as described in Schedule 2(b), there are no agreements, arrangements or understandings concerning the voting, acquisition or disposition of any of the Company's outstanding securities to which the Company is a party or of which it is otherwise aware entered into since June 30, 1998. Other than as set forth in Schedule 2(b) or in the Registration Rights Agreements, since June 30, 1998 the Company has not entered into any agreement to register any of the Company's outstanding securities under the U.S. federal securities laws relating to securities that have not already been registered under the Securities Act.

(iii) All of the outstanding shares of capital stock of the Company have been issued in accordance with applicable state, federal and foreign laws and regulations governing the sale and purchase of securities, all of such shares have been duly and validly issued and all such shares are fully paid and non-assessable, and none of such shares carries preemptive or similar

rights.

(c) Authorization of Transaction Documents. The Company has full corporate power and authority to execute and deliver this Agreement and each of the other Transaction Documents, and to perform its obligations hereunder and thereunder. The execution, delivery and performance by the Company of the Transaction Documents (including the issuance and sale of the Securities) have been authorized by all requisite corporate actions by the Company; and the Transaction Documents, including the issuance and sale of the Securities, have been duly executed and delivered by the Company and are the valid and binding obligations of the Company, enforceable against the Company in accordance with their respective terms.

(d) No Violation. The execution, delivery and performance by the Company of the Transaction Documents (including the issuance and sale of the Securities and the issuance of all securities issuable upon the conversion, exchange or exercise of any of the Securities), and compliance with the provisions thereof, will not (i) violate any provision of applicable law, statute, rule or regulation applicable to the Company or any ruling, writ, injunction, order, judgment or decree of any court, arbitrator, administrative agency or other governmental body applicable to the Company or any of their respective properties or assets or (ii) conflict with or result in a breach of any of the terms, conditions or provisions of, or constitute (with notice or lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of, any Encumbrance (as defined below) upon any of the properties or assets of the Company under its Certificate of Incorporation, as amended, its Certificates of Designations (in the various forms to be filed as provided herein) or By-laws, or any material contract to which the Company is a party, except where such violation, conflict or breach would not, individually or in the aggregate, have a Material Adverse Effect. As used herein, "Encumbrance" shall mean any liens, charges, encumbrances, equities, claims, options, proxies, pledges, security interests, or other similar rights of any nature, except for such conflicts, breaches or defaults which would not, individually or in the aggregate, have a Material Adverse Effect.

(e) Approvals. Except as set forth on Schedule 2(e), no material permit, authorization, consent or approval of or by, or any notification of or filing with, any person or entity (governmental or otherwise) is required in connection with the execution, delivery or performance of the Transaction Documents, including the issuance and sale of the Securities and the securities issuable upon the conversion, exchange or exercise of any of the Securities, by the Company. Except as set forth on Schedule 2(e), there is no approval of the Company's stockholders required under any applicable statute, rule or regulation in connection with the execution and delivery the Transaction Documents or the consummation of the transactions contemplated thereby, including the filing of the Certificates of Designations, the issuance of the Securities and the securities issuable upon the conversion, exchange or exercise of any of the Securities and the listing of the shares of Sheffield Common Stock issuable upon the conversion, exercise or exchange of any of the Securities on the American Stock Exchange.

(f) Filings, Taxes and Financial Statements. (i) The Company has filed its annual report on Form 10-K for the year ended December 31, 1998

(the "Annual Report"), its related proxy materials and the quarterly report on Form 10-Q for the quarter ended June 30, 1999 (the "Quarterly Report," together with the Annual Report, including all exhibits and schedules required to be filed in connection therewith, the "SEC Filings") with the Securities and Exchange Commission, the American Stock Exchange, Inc., and any other required person or entity (governmental or otherwise) in a timely manner and as otherwise required by applicable laws and regulations, including the federal securities laws. The audited financial statements of the Company for the fiscal year ended December 31, 1998 included in the Annual Report (the "Audited Financial Statements"), and the Company's unaudited balance sheet for the period ending June 30, 1999, together with the accompanying statements of operations and cash flows including the notes thereto in the Quarterly Report (the "June Financial Statements"; collectively, with the Audited Financial Statements, the "Financial Statements") are accurate and complete in all material respects and fairly present the financial condition of the Company as at the dates thereof and have been prepared in accordance with generally accepted accounting principles applied on a consistent basis throughout the periods indicated (except as may be otherwise indicated in such financial statements or the notes thereto), subject, in the case of the June Financial Statements, to normal year-end audit adjustments (which shall not be material in the aggregate) and the absence of footnote disclosures.

(ii) The Company has filed in a timely manner all material federal, state, local and foreign tax returns, reports and filings (collectively, "Returns"), including income, franchise,

property and other taxes, and has paid or accrued the appropriate amounts reflected on such Returns. None of the Returns have been, or as of the date hereof and to the knowledge of the Company, are currently being, audited or challenged, nor has the Company received any notice of challenge nor have any of the amounts or other data included in the Returns been challenged or reviewed by any governmental authority.

(iii) Except as disclosed in the SEC Filings or listed in Schedule 2(f), which sets forth a true and accurate list and description of any employee benefit plans maintained or sponsored by the Company or to which the Company is required to make contributions, the Company does not maintain, sponsor, and is not required to make contributions to or otherwise have any liability with respect to any pension, profit sharing, thrift or other retirement plan, employee stock ownership plan, deferred compensation, stock ownership, stock purchase, performance share, bonus or other incentive plan, severance plan, health or group insurance plan, welfare plan, or other similar plan, agreement, policy or understanding (whether written or oral), whether or not such plan is intended to be qualified under Section 401(a) of the Code, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended, which plan covers any employee or former employee of the Company.

(g) Absence of Changes. Except as set forth on Schedule 2(g), since June 30, 1999 there has not been (a) any material adverse change in the business, properties, condition (financial or otherwise), operations or prospects of the Company; (b) any damage, destruction or loss, whether or not

covered by insurance, materially and adversely affecting the business, properties, condition (financial or otherwise), operations or prospects of the Company; (c) any declaration, setting aside or payment of any dividend or other distribution or payment (whether in cash, stock or property) in respect of the capital stock of the Company (other than in respect of the Company's outstanding Series C Preferred Stock), or any redemption or other acquisition of such stock by the Company; (d) any disposal or lapse of any trade secret, invention, patent, trademark, trademark registration, service mark, service mark registration, copyright, copyright registration, or any application therefor or filing in respect thereof that had a Material Adverse Effect; (e) loss of the services of any of the key officers or key employees of the Company that had a Material Adverse Effect; (f) other than with EIS, its subsidiaries and affiliates, any incurrence of or entry into any liability, mortgage, lien, commitment or transaction, including without limitation, any borrowing (or assumption or guarantee thereof) or guarantee of a third party's obligations, or capital expenditure (or lease in the nature of a conditional purchase of capital equipment) in excess of $100,000; or (g) any material change by the Company in accounting methods or principles or (h) any change in the assets, liabilities, condition (financial or otherwise), results or operations or prospects of the Company from those reflected on the Quarterly Report, except changes in the ordinary course of business that have not, individually or in the aggregate, had a Material Adverse Effect.

(h) No Liabilities. Except as set forth in the Quarterly Report attached hereto, the Company has not incurred or suffered any liability or obligation, matured or unmatured, contingent or otherwise, except in the ordinary course of business that have individually or in the aggregate, had a Material Adverse Effect.

(i) Properties and Assets; Etc. (i) The SEC Filings disclose all patents and other intellectual property material to the business and operations of the Company and all applications therefore and licenses, sublicenses or agreements in respect thereof which the Company owns or has the right to use or to which the Company is a party (the "Proprietary Rights"). The Proprietary Rights are adequate for the conduct of the Company's business. Except as set forth in the SEC Filings, the agreements evidencing the License Arrangements, the licenses of Proprietary Rights to or from Systemic Pulmonary Delivery, Ltd. or where the absence of which would not have a Material Adverse Effect, (A) the Company is the sole and exclusive owner of all rights, title and interest to all Proprietary Rights free and clear of all liens, claims, charges, equities, rights of use, encumbrances and restrictions whatsoever, (B) the Company does not have knowledge of any basis for any claim of infringement or misappropriation contesting the validity or Company's right to use any Proprietary Rights; (C) all of such patents, trademark registrations, service mark registrations, trade name registrations and copyrights and copyright registrations, whether foreign or domestic, have been duly issued and have not been canceled, abandoned, or otherwise terminated; and (D) all of the Company's patent applications, trademark applications, service mark applications, trade name applications and copyright applications have been duly filed.

(ii) Each of the contracts listed as an exhibit to the Company's SEC Filings is a legal and valid agreement binding upon each of the

parties thereto and is in full force and effect except where the expiration or termination have not, individually or in the aggregate, had a Material Adverse Effect. To the best knowledge of the Company, there is no breach or default by any party thereunder that had a Material Adverse Effect. Such contracts constitute all material agreements, arrangements or understandings required to be included as an exhibit in such reports under Item 601 of the Securities and Exchange Commission Regulations.

(iii) The Company has and maintains adequate and sufficient insurance, including liability, casualty and products liability insurance, covering risks associated with its business, properties and assets, including insurance that is customary for companies similarly situated.

(iv) The Company, its business and properties and assets are in compliance, in all material respects, with all applicable laws and regulations, including without limitation, those relating to (a) health, safety and employee relations, (b) environmental matters, including the discharge of any hazardous or potentially hazardous materials into the environment, and (c) the development, commercialization and sale of pharmaceutical and biotechnology products, including all applicable regulations of the U.S. Food and Drug Administration and comparable foreign regulatory authorities.

(j) Legal Proceedings, etc. Except as set forth on Schedule 2(j), there is no legal, administrative, arbitration or other action or proceeding or governmental investigation pending or, to the Company's best knowledge, threatened against the Company, or any director, officer or employee of the Company, which is required to be described in the SEC Filings and is not so described. The Company is not in violation of, or default under, any material laws, judgments, injunctions, orders or decrees of any court, governmental department, commission, agency, instrumentality or arbitrator applicable to its business.

(k) Disclosure. The Company's SEC Filings and periodic reports subsequently filed under Section 13 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the representations and warranties set forth herein and the Transaction Documents, when viewed collectively, do not contain any untrue statement of a material fact or omit to state any material fact necessary to make the statements contained herein and therein not misleading in light of circumstances in which they were made.

(l) Brokers or Finders. The Company has not retained any investment banker, broker or finder in connection with the transactions contemplated by the Transaction Documents, other than Tucker Anthony Cleary Gull, the fee of which are payable solely by the Company.

SECTION 3. Representation and Warranties of EIS. EIS hereby represents and warrants to the Company as follows:

(a) Organization. EIS is a corporation duly organized, validly existing and in good standing under the laws of Bermuda and has all requisite corporate power and authority to own and lease its properties, to carry on its business as presently conducted and as proposed to be conducted and to consummate the transactions contemplated hereby. EIS is qualified and in good standing to do business in each jurisdiction in which the nature of the business conducted or the property owned by it requires such qualification, except where the failure to so qualify would not reasonably be expected to have a material

adverse effect on the business or condition (financial or otherwise) of EIS.

(b) Authorization of Agreement. EIS has full legal right, power and authority to enter into this Agreement and perform its obligations hereunder, which have been duly authorized by all requisite corporate action. This Agreement and the purchase of the Securities are the valid and binding obligations of EIS, enforceable against them in accordance with their terms.

(c) No Conflicts. The execution, delivery and performance by EIS of this Agreement, the purchase and acceptance of the Securities and compliance with provisions hereof by EIS, will not (i) violate any provisions of applicable law, statute, rule or regulation applicable to EIS or any ruling, writ, injunction, order, judgment or decree of any court, arbitration, administrative agency or other governmental body applicable to EIS or any of its properties or assets or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute (with notice or lapse of time to both) a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any Encumbrance upon any of the properties or assets of EIS under its Certificate of Incorporation or By-laws or any material contract to which EIS is party, except where such violation, conflict or breach would not, individually or in the aggregate, have a material adverse effect on EIS.

(d) Approvals. No permit, authorization, consents or approval of or by, or any notification of or filing with, any person or entity (governmental or otherwise) is required in connection with the execution, delivery or performance of this Agreement (including the funding and acceptance thereof) by EIS.

(e) Investment Representations. (i) EIS is an "accredited investor" as defined in Rule 501(a) of Regulation D. EIS is sophisticated in transactions of this type and capable of evaluating the merits and risks of the transactions described herein and in the other Transaction Documents, has the capacity to protect its own interests, has reviewed the SEC Filings, and is aware of the risk factors relating to an investment in the Company as disclosed in such filings. EIS has not been formed solely for the purpose of entering into the transactions described herein and therein and is acquiring the Securities for investment for its own account, not as a nominee or agent, and not with the view to distribute or sell any part thereof; provided, that EIS shall be permitted to convert, exchange or exercise such Securities and/or transfer them as permitted herein and under applicable law. EIS has been afforded the opportunity to ask questions of, and receive information about, the Company and its business and prospects, from management and representatives of the Company, and has relied on its own independent judgment in making a judgment about an investment in the Securities.

(ii) Nothing contained in this Section 3(e) shall limit any of the Company's representations or warranties or limit EIS's recourse in respect thereof.

(iii) EIS has not retained any investment banker, broker or finder in connection with the transactions contemplated by the Transaction Documents.

SECTION 4. Covenants of the Company. (a) Non-disclosure. From and after the date hereof, neither the Company nor EIS shall disclose to any person or entity (other than its directors, officers and agents who need to know such information in connection with the transactions described herein and the other Transaction Documents, each of whom shall be informed of this confidentiality provision and in respect of whose breaches the Company shall be responsible) the content of this Agreement or any of the other Transaction Documents or the substance of the transactions described herein, without the prior written consent of the other party (which consent shall not be unreasonably withheld or delayed), except to the extent required by applicable laws, regulations or administrative or judicial processes in respect of press releases, periodic reports or other public disclosure prepared in good faith by the Company or EIS; provided, that EIS and the Company shall each provide the other with a reasonable opportunity to review such releases or reports prior to release. This Section 4(a) shall not be construed to prohibit disclosure of any information which has not been previously determined to be confidential by EIS or the Company, or which shall have become publicly disclosed (other than by breach obligations of the Company or EIS hereunder).

(b) Fully-diluted Stock Ownership. (i) Notwithstanding any other provision of this Agreement, in the event that EIS shall have determined that at any time it (together with its affiliates, if applicable) holds or has the right to receive Sheffield Common Stock (or securities or rights, options or warrants exercisable, exchangeable or convertible for or into Sheffield Common Stock) representing in the aggregate in excess of 19.9% of the outstanding Sheffield Common Stock (assuming any such exercise, exchange or conversion, but not the exercise, exchange or conversion of any other similar securities) or EIS has otherwise determined that Elan would be required to equity account for its investment in Sheffield, EIS shall have the right (but not the obligation), in its sole discretion, rather than acquiring such securities from the Company, to exchange such number of securities as are

necessary so that Elan shall not have to equity account, for non-voting, convertible, liquidation preferred stock of the Company on terms mutually acceptable to the Company and EIS such that EIS will not be required to account for its investments under the equity method. In the event that EIS shall undertake to exercise such right, EIS shall retain the additional right to assign all or a portion of such convertible securities (including Sheffield Common Stock issuable upon conversion thereof) to its affiliates. Each of EIS and the Company shall use commercially reasonable efforts to effect such transactions and any required subsequent conversions or adjustments to EIS's securities position, on a quarterly basis, within 15 business days of the end of each of EIS's fiscal quarter.

(ii) In the event that, after the first anniversary of the date hereof, the payment to EIS of any dividend in kind upon the Series D Preferred Stock or the Series E Preferred Stock would result in EIS's fully-diluted ownership of Sheffield Common Stock to exceed 49.9%, such excess dividends (I.E., dividends paid in kind, the payment of which would result in EIS's fully-diluted ownership of Sheffield Common Stock exceeding 49.9%) shall be paid to EIS through the issuance by the Company to EIS, in lieu of dividends, of promissory notes with an aggregate principal amount equal to the amount of such excess dividend that would otherwise be paid in kind (collectively, the

"Dividend Notes"). The Dividend Notes shall (i) bear interest of 7.0% per annum, compounded semi-annually, compounding to commence six months after issuance, which shall be payable through the issuance of additional Notes of like tenor and (ii) mature and become immediately due and payable in full in cash on the sixth anniversary of the date thereof.

(c) Certain Preemptive Rights. For a period of four years from and after the date hereof, EIS shall be entitled to participate in any convertible or exchangeable debt, equity, warrant or convertible securities financing (the "Preemptive Right") undertaken by the Company (each, a "Capital Raising"), in order that EIS may maintain its then current PRO RATA percentage equity ownership interest (on a fully diluted basis) of the Company. Notwithstanding the foregoing, the Preemptive Right shall terminate and be of no further force and effect at such time as equity ownership interest of EIS and its affiliates in the Company falls below 5%, on a fully-diluted basis. Such participation by EIS shall be on terms no less attractive to EIS than those offered to any other potential investor in a Capital Raising financing; provided, that such Preemptive Right shall not apply to (i) any BONA FIDE offering to the public pursuant to the Securities Act, or (ii) an offering of securities solely in connection with (A) an acquisition of assets, merger, consolidation or similar transaction with an unaffiliated third party, or (B) an employee stock option plan.

(d) Use of Proceeds. The Company shall use all of the aggregate proceeds of the sale of the Series D Preferred Stock and the Series E Preferred Stock solely for the purpose of meeting its capitalization and funding commitments to Newco.

SECTION 5. Additional Covenants of the Parties. (a) Right of Conversion. (i) EIS may, pursuant to the Series D Certificate of Designations, after the second anniversary of the date hereof and prior to the sixth anniversary of the date hereof, convert the Series D Preferred Stock into Sheffield Common Stock as set forth in the Series D Certificate of Designations (the "Series D Conversion Right").

(ii) EIS may, pursuant to the Series E Certificate of Designations, after the second anniversary of the date hereof and prior to the sixth anniversary of the date hereof, convert the Series E Preferred Stock into Sheffield Common Stock as set forth in the Series E Certificate of Designations (the "Series E Conversion Right", and together with the Series D Conversion Right, collectively, the "Conversion Rights").

(b) Rights of Exchange. (i) NEWCO EQUITY EXCHANGE RIGHT. (A) EIS may, at its option and in accordance with the Series D Certificate of Designations, exchange in whole the originally issued shares of Series D Preferred Stock, any Series D Preferred Stock issued as a dividend upon outstanding Series D Preferred Stock, and all outstanding Dividend Notes held by EIS, its subsidiaries and affiliates, for all shares of Newco Preferred Stock issued by Newco to the Company pursuant to the Development Agreement, thereby increasing EIS's fully-diluted ownership of outstanding Newco Common Stock to [REDACTED], on a fully converted basis, assuming the conversion of such exchanged shares of Newco Preferred Stock and all shares of Newco Preferred Stock previously issued to EIS as described in Recital D above (the "Equity Exchange Right"). After the exercise of the Equity Exchange Right and the receipt by EIS of Newco Preferred Stock convertible, together with all shares of Newco Preferred Stock previously issued to EIS, into [REDACTED] of the

outstanding Newco Common Stock, (I) the shares of Series D Preferred

Stock exchanged shall be cancelled and no longer entitle the holder thereof to any rights with respect to the Company, and (II) all Dividend Notes shall be immediately cancelled.

(B) The Equity Exchange Right shall terminate upon the earlier of (x) exercise of the Series D Conversion Right by EIS and (y) the sixth anniversary of the date hereof.

(C) If EIS exercises the Equity Exchange Right, EIS shall, at its option, either (i) cause to be paid to the Company within thirty days of the consummation of such equity exchange an amount equal to [REDACTED] of the aggregate amount provided to Newco (by or on behalf of the Company and EIS and their respective affiliates and subsidiaries) to fund the agreed upon initial research and development budget of Newco (the "Development Funding") from and after the Closing Date and prior to the date of exercise of the Equity Exchange Right, (ii) surrender to the Company for cancellation shares of the Series E Preferred Stock with an aggregate liquidation preference equal to [REDACTED] of the aggregate amount of Development Funding provided to Newco (by or on behalf of the Company and EIS and their respective affiliates and subsidiaries) from and after the Closing Date and prior to the date of exercise of the Equity Exchange Right, or (iii) elect to satisfy such obligation with a combination of the payment methods set forth in clauses (i) and (ii) above.

(ii) SHEFFIELD DEBT EXCHANGE. All shares of Series D Preferred Stock (including all shares issued as dividends thereon), all shares of Series E Preferred (including all shares issued as dividends thereon) and all outstanding Dividend Notes shall be exchanged by the Company for one or more promissory notes with an aggregate principal amount equal to the sum of (A) the aggregate principal amount of all outstanding Dividend Notes and all accrued and unpaid interest thereon, (B) the aggregate liquidation preference of all shares of Series D Preferred Stock (including all shares issued as dividends thereon and all accrued but unpaid dividends thereon) and (C) the aggregate liquidation preference of all shares of Series E Preferred Stock (including all shares issued as dividends thereon and all accrued but unpaid dividends thereon) (the "Debt Exchange"), unless on or before the first anniversary of the Closing Date, the Company has provided to EIS (and any permitted transferee of EIS) written evidence that (I) the issuance of the Series D Preferred Stock and the Series E Preferred Stock and the issuance and listing upon the American Stock Exchange ("AMEX") of the shares of Sheffield Common Stock to be issued upon the conversion of the Series D Preferred Stock and the Series E Preferred Stock has been approved or ratified by the stockholders of the Company in accordance with the General Corporation Law of the State of Delaware and the rules and regulations of the AMEX or (II) that such approval or ratification is not required by the applicable rules of the AMEX. The promissory notes to be issued upon the consummation of the Debt Exchange shall be in the form attached to the Series D Certificate of Designations, the Series E Certificate of Designations and the Dividend Notes.

(c) Further Assurances. From and after the date hereof, each of the parties hereto agree to do or cause to be done such further acts and things and deliver or cause to be delivered to each other such additional assignments, agreements, powers and instruments, as each may reasonably require

or deem advisable, to carry into effect the purposes of this Agreement and the other Transaction Documents or to better to assure and confirm unto each other their respective rights, powers and remedies hereunder and thereunder.

SECTION 6. Series E Preferred Stock. (a) Issuance. (i) As of the date hereof and until the date which is the 36 month anniversary of the date hereof, EIS shall be required, at the Company's option as exercised by written notice to EIS, to purchase shares of Series E Preferred Stock, to be issued pursuant to the Series E Certificate of Designations, for aggregate consideration of up to $4,005,000, at a price per share of $1,000 and [REDACTED].

(b) Conditions to the Purchase of Series E Preferred Stock. It shall be a condition to EIS's obligation to purchase the Series E Preferred Stock that (A) each of the representations and warranties set forth in Section 2 of this Agreement shall be true and correct in all material respects as if the date hereof were the proposed funding date thereof; provided, that any reference to the Quarterly Report shall refer to the most recent quarterly report on Form 10-Q and/or any report filed pursuant to Section 13 of the Exchange Act, required to be filed by the Company under applicable law immediately prior to such funding date and SEC Filings shall refer to all filings required to be made by the Company under applicable law on or prior to such date, (B) there shall be no default or breach in any material respect by the Company or Newco of a material obligation under any of the Transaction Documents or any other agreement between the Company or Newco or any of its affiliates, on the one hand, and EIS or any of their affiliates, on the other hand, and [REDACTED].

SECTION 7. Survival and Indemnification. (a) Survival Period. The representations and warranties of the Company and EIS contained herein shall survive for a period of one year from and after the date hereof.

(b) Indemnification. In addition to all rights and remedies available to the parties hereunder at law or in equity, each party hereto (in such capacity, an "Indemnifying Party") shall indemnify each other party hereto, and its respective affiliates, and its respective affiliates' stockholders, officers, directors, employees, agents, representatives, successors and assigns (collectively, the "Indemnified Person"), and save and hold each Indemnified Person harmless from and against and pay on behalf of or reimburse each such Indemnified Person, as and when incurred, for any and all loss, liability, demand, claim, action, cause of action, cost, damage, deficiency, tax, penalty, fine or expense, whether or not arising out of any claims by or on behalf of such Indemnified Person or any third party, including interest, penalties, reasonable attorneys' fees and expenses and all amounts paid in investigation, defense or settlement of any of the foregoing (collectively, "Losses"), that any such Indemnified Person may suffer, sustain, incur or become subject to, as a result of, in connection with, relating, or incidental, to or by virtue of:

(i) any misrepresentation or breach of warranty on the part of the Indemnifying Party under Section 2 or 3 of this Agreement; or

(ii) any nonfulfillment, default or breach of any covenant or agreement on the part of the Indemnifying Party under Section 4, 5 or 6 of this Agreement.

(c) Maximum Recovery. Notwithstanding anything in this Agreement to the contrary, in no event shall the Company be liable for indemnification under this Section 7, the Transaction Documents, or otherwise, in an amount in excess of [REDACTED] in the aggregate. No Indemnified Party shall assert any such claim unless Losses in respect thereof incurred by any Indemnified Party, when aggregated with all previous Losses hereunder, equal or exceed $50,000; and after the $50,000 threshold is reached, each Indemnified Person shall be entitled to be indemnified for the amount of all claims arising hereunder in excess of $50,000.

(d) Exception. Notwithstanding the foregoing, and subject to the following sentence, upon judicial determination that is final and no longer appealable that the act or omission giving rise to the indemnification set forth above resulted primarily out of or was based primarily upon the Indemnified Person's negligence (unless such Indemnified Person's negligence was based upon the Indemnified Person's reliance in good faith upon any of the representations, warranties, covenants or promises made by the Indemnifying Party herein) the Indemnifying Party shall not be responsible for any Losses sought to be indemnified in connection therewith, and the Indemnifying Party shall be entitled to recover from the Indemnified Person all amounts previously paid in full or partial satisfaction of such indemnity, together with all costs and expenses (including reasonable attorney's fees)

of the Indemnifying Party reasonably incurred in connection with the Indemnified Party's claim for indemnity, together with interest at the rate per annum publicly announced by Morgan Guaranty Trust Company as its prime rate from the time of payment of such amounts to the Indemnified Person until repayment to the Indemnifying Party.

(e) Investigation. All indemnification rights hereunder shall survive the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby to the extent provided in Section 7(b) above, irrespective of any investigation, inquiry or examination made for or on behalf of the Indemnified Person or the acceptance of any certificate or opinion.

(f) Contribution. If the indemnity provided for in this Section 7 is in whole or in part unavailable to any Indemnified Person due to Section 7(b) being declared unenforceable by a court of competent jurisdiction based upon reasons of public policy, so that Section 7(b) shall be insufficient to hold each such Indemnified Person harmless from Losses which would otherwise be indemnified hereunder, then the Indemnifying Party and the Indemnified Person shall each contribute to the amount paid or payable for such Loss in such proportion as is appropriate to reflect not only the relative benefits received by the Indemnifying Party on the one hand and the Indemnified Person on the other, but also the relative fault of the Indemnifying Party and be in addition to any liability that the Indemnifying Party may otherwise have. Subject to Section 7(g) hereunder, the indemnity, contribution and expense reimbursement obligations that the Indemnifying Party has under this Section 7 shall survive the expiration of the Transaction Documents. The parties hereto further agree that the indemnification and reimbursement commitments set forth in this Agreement shall apply whether or not the Indemnified Person is a formal party to any such lawsuit, claims or other proceedings.

(g) Limitation. No claim shall be brought by an Indemnified Person in respect of any misrepresentation or breach of warranty under this Agreement after one year from and after the date hereof; and any claim for nonfulfillment, default or breach of any covenant shall be brought within one year of the date that such Indemnified Person became aware or should have become aware of the nonfulfillment, default or breach. Except as set forth in the previous sentence and in Section 7(c) above, this Section 7 is not intended to limit the rights or remedies otherwise available to any party hereto with respect to this Agreement or the other Transaction Documents.

SECTION 8. Notices. All notices, demands and requests of any kind to be delivered to any party in connection with this Agreement shall be in writing and shall be deemed to have been duly given if personally or hand delivered or if sent by an internationally-recognized overnight delivery service or by registered or certified airmail, return receipt requested and postage prepaid, addressed as follows:

(i) if to the Company:

Sheffield Pharmaceuticals, Inc.
South Winton Court
3136 Winton Road South
Suite 306
Rochester, NY 14623
Attention: Chairman

and

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017-3441
Attention: Chief Executive Officer

with a copy to:

Olshan Grundman Frome, Rosenzweig & Wolosky LLP
505 Park Avenue
New York, NY 10022
Attention: Daniel J. Gallagher

(ii) if to EIS:

Elan International Services, Ltd.
Flatts, Smiths Parish
Bermuda, FL04
Attention: Director

with a copy to:

Brock Silverstein LLC
800 Third Avenue, 21st Floor
New York, New York 10022

Attention: Scott Rosenblatt

or to such other address as the party to whom notice is to be given may have furnished to the other party hereto in writing in accordance with provisions of this Section 8. Any such notice or communication shall be deemed to have been received (i) in the case of personal or hand delivery, on the date of such delivery, (ii) in the case of an internationally-recognized overnight delivery service, on the second business day after the date when sent and (iii) in the case of mailing, on the fifth business day following that day on which the piece of mail containing such communication is posted. Notice hereunder may be given on behalf of the parties by their respective attorneys.

SECTION 9. Entire Agreement. This Agreement and the other Transaction Documents contain the entire understanding of the parties with respect to the subject matter hereof and supersede all prior agreements and understandings among the parties with respect thereto.

SECTION 10. Amendments. This Agreement may not be modified or amended, or any of the provisions hereof waived, except by written agreement of the Company and EIS.

SECTION 11. Counterparts and Facsimile. The Transaction Documents may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute one agreement. Each of the Transaction Documents may be signed and delivered to the other party by facsimile transmission.

SECTION 12. Headings. The section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of the Agreement.

SECTION 13. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to principles of conflicts of laws. Each of the parties hereby irrevocably submits to the jurisdiction of any New York State or United States Federal court sitting in the county, city and state of New York over any action or proceeding arising out of or relating to this Agreement or the other Transaction Documents; and each hereby waives the defense of an inconvenient forum for the maintenance of such an action.

SECTION 14. Expenses. Each of the parties hereto shall be responsible for its own costs and expenses incurred in connection with the transactions contemplated hereby and by the other Transaction Documents.

SECTION 15. Public Releases; Etc. The parties shall reasonably agree upon the contents of any press release or releases and other public disclosure in respect of the transactions contemplated hereby, and except as may otherwise be required by applicable law or judicial or administrative process or which the Company concludes in good faith is required by applicable securities laws and regulations.

SECTION 16. Schedules, etc. All statements contained in any exhibit or schedule delivered by or on behalf of the parties hereto, or in connection with the transactions contemplated hereby, are an integral part of this Agreement and shall be deemed representations and warranties hereunder.

SECTION 17. Assignments. This Agreement and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, subject to compliance with the representations and warranties contained in Section 3(e) of this Agreement. This Agreement, the Transaction Documents, and the Securities may be assigned by EIS to its affiliates and subsidiaries.

SECTION 18. Currency. All references to "$" or dollars herein shall mean United States dollars.

IN WITNESS WHEREOF, each of the undersigned has duly executed this Securities Purchase Agreement as of the date first written above.

SHEFFIELD PHARMACEUTICALS, INC.

By: /s/ Loren G. Peterson

Name:
Title:

ELAN INTERNATIONAL SERVICES, LTD.

By:/s/ Kevin Insley

Name:
Title:

EX-10.26
6
ELAN JOINT DEVELOPMENT AND OPERATING AGREEMENT

SUBSCRIPTION, JOINT DEVELOPMENT AND OPERATING AGREEMENT

ELAN PHARMA INTERNATIONAL LIMITED

ELAN INTERNATIONAL SERVICES, LTD.

AND

SHEFFIELD PHARMACEUTICALS, INC.

AND

SHEFFIELD NEWCO, LTD.

INDEX

THIS SUBSCRIPTION, JOINT DEVELOPMENT AND OPERATING AGREEMENT made this 18th day of October, 1999

BETWEEN:

(1) ELAN PHARMA INTERNATIONAL LIMITED, a public limited company incorporated under the laws of Ireland, and having its registered office at WIL House, Shannon Business Park, Shannon, County Clare, Ireland ("EPIL")

(2) ELAN INTERNATIONAL SERVICES, LTD., a private limited company incorporated under the laws of Bermuda, and having its registered office at Clarendon House, 2 Church St., Hamilton, Bermuda ("EIS");

(3) SHEFFIELD PHARMACEUTICALS, INC. a corporation duly incorporated and validly existing under the laws of Delaware and having its principal place of business at 425 South Woodsmill Road, Suite 270, St. Louis, MO 63017, United States of America; and

(4) SHEFFIELD NEWCO, LTD., a private limited company incorporated under the laws of Bermuda, and having its registered office at Clarendon House, 2 Church St., Hamilton, Bermuda ("Newco").

RECITALS:

A. Newco desires to issue and sell to the Stockholders (as defined below), and the Stockholders desire to purchase from Newco, for aggregate consideration of $7,500,000 apportioned between them as set forth

herein, 12,000 ordinary shares of Newco's common stock, par value $1.00 per share (the "Common Stock"), allocated to Sheffield. Additionally, Newco desires to issue and sell to the Stockholders, and the Stockholders desire to purchase from Newco, for aggregate consideration of $7,500,000, apportioned between them as set forth herein, 12,000 shares of Newco's preferred stock, par value $1.00 per share (the "Preferred Stock"), allocated 7,224 shares to Sheffield for aggregate consideration of $4,515,000 and 4,776 shares to EIS for aggregate consideration of $2,985,000.

B. As of the date hereof, EPIL has entered into a license agreement with Newco, and Sheffield has entered into a license agreement with Newco, in connection with the license to Newco of the Elan Intellectual Property and the Sheffield Intellectual Property, respectively (each as defined below).

C. Elan and Sheffield have agreed to co-operate in the research, development and commercialization of the Products (as defined below) based on their respective technologies.

D. Elan and Sheffield have agreed to enter into this Agreement for the purpose of recording the terms and conditions regulating their relationship with each other, with respect to the Licensed Technologies and with Newco.

NOW IT IS HEREBY AGREED AS FOLLOWS:

CLAUSE 1

DEFINITIONS

1.1 In this Agreement, the following terms shall, where not inconsistent with the context, have the following meanings respectively.

"Affiliate" shall mean any corporation or entity controlling, controlled or under the common control of Elan or Sheffield, as the case may be. For the purpose of this definition, "control" shall mean direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors. Newco is not an Affiliate of Elan or EIS.

"Agreement" shall mean this agreement (which expression shall be deemed to include the Recitals and the Schedules hereto).

"Board" shall mean the board of directors of Newco.

"Business" shall mean the business specified in the Business Plan.

"Business Plan" shall mean the business plan and program of development to be agreed by Elan and Sheffield pursuant to Clause 6 that shall contain, among other things, to the extent practicable, the research and development objectives, desired Product specifications, clinical

indications, preliminary clinical trial designs (Phase I/II), development timelines, budgeted costs and the relative responsibilities of Sheffield and Elan as it relates to the implementation of the R&D Plan.

"Certificate of Designations" shall mean that certain certificate of designations, preferences and rights of the Series D Preferred Stock issued on the Closing Date.

"Closing Date" shall mean the date upon which the Transaction Documents are executed and delivered by the Parties and the transactions effected thereby are closed.

"Combined Fields" shall mean Field A, Field B and Field C.

"Common Stock Equivalents" shall mean any options, warrants, rights or any other securities convertible, exercisable or exchangeable, in whole or in part, for or into Common Stock.

"Compounds" shall mean the Field A Compound, the Field B Compound and/or the Field C Compound.

"Directors" shall mean, at any time, the directors of Newco.

"Dividend Notes" shall mean promissory notes issued by Sheffield to holders of Series D Preferred Stock as payment for dividends pursuant to the Certificate of Designations.

"EIS Director" has the meaning set forth in Clause 5.

"Elan" shall mean EPIL and Affiliates and includes EIS and subsidiaries of Elan Corporation, Plc. within the division of Elan Corporation, Plc. carrying on business as Elan Pharmaceutical Technologies but shall not include Affiliates and subsidiaries (present or future) of Elan Corporation Plc within the division of Elan Corporation, Plc carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

"Elan Improvements" shall mean improvements relating to the Elan Patents and/or the Elan Know-How, developed (i) by Elan whether or not pursuant to the Project, (ii) by Newco or Sheffield or by a third party (under contract with Newco) whether or not pursuant to the Project, and/or (iii) jointly by any combination of Elan, Sheffield or Newco pursuant to the Project, except as limited by agreements with third Parties. Subject to third party agreements, Elan Improvements shall constitute part of Elan Intellectual Property and be included in the license of the Elan Intellectual Property pursuant to Clause 2.1 of the Elan License Agreement solely for the purposes set forth therein. If the inclusion of an Elan Improvement in the license of Elan Intellectual Property is restricted or limited by a third party agreement, Elan shall use reasonable commercial efforts to minimize any such restriction or limitation.

"Elan Intellectual Property" shall mean the Elan Know-How, the Elan Patents and the Elan Improvements. For the avoidance of doubt, Elan Intellectual Property shall exclude (i) Elan's patent rights and know-how relating to protein or peptide agents or peptodomimetics, derivatives or analogs thereof, designed to target a pharmaceutically active agent to a certain site or sites in the body (targeting technology) and (ii) inventions, patents and know-how owned, licensed or controlled by Axogen Limited and Neuralab Limited, and by all Affiliates and subsidiaries (present or future) of Elan Corporation, Plc. carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

"Elan Know-How" shall mean any and all rights owned, licensed or controlled by Elan to any discovery, invention (whether patentable or not), know-how, substances, data, techniques, processes, systems, formulations and designs relating to Nanocrystal(TM) Technology.

"Elan License Agreement" shall mean the license agreement between Elan and Newco, of even date herewith, attached hereto in Schedule 1.

"Elan Patents" shall mean any and all rights under any and all patents applications and/or patents, now existing, currently pending or hereafter filed or obtained by Elan relating to Nanocrystal(TM) Technology as set forth in Schedule 1 of the Elan License Agreement, and any foreign counterparts thereof and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"Encumbrance" shall mean any liens, charges, encumbrances, equities, claims, options, proxies, pledges, security interests, or other similar rights of any nature.

"EPIL Patents" shall mean the Elan Patents owned by EPIL.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

"Exchange Note" shall mean promissory notes issued by Sheffield to holders of the Series D Preferred Stock in exchange for share of Series D Preferred Stock pursuant to the Certificate of Designations.

"Exchange Right" shall mean the Equity Exchange Right (as such term is defined in the Certificate of Designations in effect on the date hereof.)

"Field A" shall mean the topical pulmonary delivery of Formulations of the Field A Compound by means of the Field A Device.

"Field B" shall mean the topical pulmonary delivery of Formulations of

the Field B Compound by means of the Field B Device.

"Field C" shall mean the topical pulmonary delivery of Formulations of the Field C Compound by means of the Field C Device.

"Field A Device" shall mean a third party table top unit dose nebulizer having a reservoir capable of holding a unit dose (a device and a compressor to nebulize a unit dose shall be deemed a device), which is a device having any one the following characteristics:

(i) [REDACTED]

(ii) [REDACTED]

(iii) [REDACTED]

(iv) [REDACTED]

(v) [REDACTED]

For the avoidance of doubt, Field A Device does not include [REDACTED]

"Field B Device" shall mean the Aerosol Drug Delivery System ("ADDS"), owned by Systemic Pulmonary Delivery Limited and exclusively licensed to Sheffield for topical pulmonary applications.

"Field C Device" shall mean the handheld multi-dose nebulizer ("MSI") which was licensed exclusively by Siemens to Sheffield pursuant to the Siemens Agreements and which was subsequently sub-licensed by Sheffield to Zambon (on an exclusive basis for delivery of various medicines for humans in treating respiratory disease and/or other lung diseases including, but not limited to, anti-infectives) provided that Newco, through the Management Committee, is successful in obtaining a sub-license from Zambon to Newco enabling the development and use of the Field C Compounds for use with a Field C Device, as described in more detail in Clause 2.2 of the Elan License.

"Field A Compound" shall mean [REDACTED.]

"Field B Compound" shall mean [REDACTED] for therapeutic use to be nominated by the Management Committee pursuant to Clause 2.3, and with reference to Clause 2.3, any Substitute Field B Compound.

"Field C Compound" shall mean [REDACTED] and with reference to Clause 2.4, any Substitute Field C Compound and/or any Additional Field C Compound".

"Field A Products" shall mean Formulations of the Field A Compound delivered by means of any Field A Device in Field A.

"Field B Products" shall mean Formulations of the Field B Compound delivered by means of the Field B Device in Field B.

"Field C Products" shall mean Formulations of the Field C Compound delivered by means of the Field C Device in Field C.

"Financial Year" shall mean each year commencing on January 1 (or in the case of the first Financial Year, the date hereof) and expiring on December 31 of each year.

"Formulations" shall mean Nanocrystal(TM) Technology formulations of Compounds for use in Field A, Field B or Field C, as applicable.

"Fully Diluted Common Stock" shall mean all of the issued and outstanding Common Stock, assuming the conversion, exercise or exchange of all outstanding Common Stock Equivalents.

"Funding Agreement" shall mean the Funding Agreement, dated as of the date hereof, between EIS and Sheffield.

"License Agreements" shall mean the Elan License Agreement and the Sheffield License Agreement.

"Licensed Technologies" shall mean, collectively, the Elan Intellectual Property and the Sheffield Intellectual Property.

"Nanocrystal(TM) Technology" shall mean the Elan proprietary technology directed to nanoparticulate formulations of compounds used in the manufacturing and/or formulation process, and methods of making the same.

"Newco By-Laws" shall mean the By-Laws of Newco.

"Newco Intellectual Property" shall mean all rights to patents, know-how and other intellectual property arising out of the conduct of the Project by any person, including any technology acquired by Newco from a third party, that does not constitute Elan Intellectual Property or Sheffield Intellectual Property.

"Newco Patents" shall mean any and all patents now existing, currently pending or hereafter filed or obtained relating to the Newco Intellectual Property, and any foreign counterparts thereof and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"Participant" shall mean Sheffield or Elan, as the case may be, and "Participants" shall mean both Sheffield and Elan together as the context requires.

"Party" shall mean Elan, Sheffield, or Newco, as the case may be, and "Parties" shall mean all three together.

"Permitted Transferee" shall mean any Affiliate or subsidiary of Elan, EIS or Sheffield, to whom this Agreement may be assigned, in whole or in part, pursuant to the terms hereof or in the case of Elan/EIS, a

special purpose financing entity created by Elan or EIS provided such are not competitors of Sheffield.

"Person" shall mean an individual, partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, governmental entity or authority or other entity of whatever nature.

"Products" shall mean the Field A Products, the Field B Products and/or the Field C Products.

"Project" shall mean all activities as undertaken by or on behalf of Newco in order to develop the Products.

"Registration Rights Agreements" shall mean the Registration Rights Agreements of even date herewith relating to the common shares and the common stock of Newco and Sheffield, respectively.

"Regulatory Application" shall mean any regulatory application or any other application for marketing approval for a Product, which Newco will file in any country of the Territory, including any supplements or amendments thereto.

"Regulatory Approval" shall mean the final approval to market a Product in any country of the Territory, and any other approval which is required to launch the Product in the normal course of business.

"Research and Development Term" shall refer to the period of time from the date hereof until the third anniversary of the date hereof.

"RHA" shall mean any relevant government health authority (or successor agency thereof) in any country of the Territory whose approval is necessary to market a Product in the relevant country of the Territory.

"R&D Program" shall mean any research and development program commenced by Newco pursuant to the Project.

"R&D Plan" shall mean the program of work, including the budget, agreed by the Management Committee as part of the Business Plan that relates to the formulation, biopharmaceutical and clinical development of the Products and such further research and development work as may be agreed by the Management Committee from time to time.

"Securities Act" shall mean the United States Securities Act of 1933, as amended.

"Series D Preferred Stock" shall mean the Series D Cumulative Convertible Exchangeable Preferred Stock, par value $.01 per share, of Sheffield.

"Shares" shall mean the shares of Common Stock and the shares of Preferred Stock issued or issuable (directly or upon conversion) to the Participants pursuant to this Agreement or the Newco Bye-Laws.

"Sheffield" shall mean Sheffield Pharmaceuticals, Inc and its Affiliates.

"Sheffield Devices" shall mean the Field B Device and the Field C Device.

"Sheffield Directors" has the meaning set forth in Clause 5.

"Sheffield Improvements" shall mean improvements relating to the Sheffield Patents and/or the Sheffield Know-How, developed (i) by Sheffield whether or not pursuant to the Project, (ii) by Newco or Elan or by a third party (under contract with Newco) whether or not pursuant to the Project, and/or (iii) jointly by any combination of Sheffield, Elan or Newco pursuant to the Project, except as limited by agreements with third Parties.

Subject to third party agreements, Sheffield Improvements shall constitute part of Sheffield Intellectual Property and be included in the license of the Sheffield Intellectual Property pursuant to Clause 2.1 of the Sheffield License solely for the purposes set forth therein. If the inclusion of a Sheffield Improvement in the license of Sheffield Intellectual Property is restricted or limited by a third party agreement, Sheffield shall use reasonable commercial efforts to minimize any such restriction or limitation.

"Sheffield Intellectual Property" shall mean the Sheffield Know-How, the Sheffield Patents and the Sheffield Improvements.

"Sheffield Know-How" shall mean any and all rights owned, licensed or controlled by Sheffield to any discovery, invention (whether patentable or not), know-how, substances, data, techniques, processes, systems, formulations and designs relating exclusively to the Sheffield Devices.

"Sheffield License Agreement" shall mean the license agreement between Sheffield and Newco, of even date herewith, attached hereto in Schedule 2.

"Sheffield Patents" shall mean any and all rights under any and all patents applications and/or patents, now existing, currently pending or hereafter filed or obtained by Sheffield relating to the Sheffield Devices and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"Sheffield Securities Purchase Agreement" shall mean that certain Securities Purchase Agreement, of even date herewith, by and between Sheffield and EIS.

"Siemens" shall mean Siemens Aktiengesellschaft.

"Siemens Agreements" shall mean the License Agreement (as amended)

dated 21 March 1997 and the Basic Supply Agreement dated 21 March 1997, both between Sheffield Medical Technologies Inc. and Siemens Aktiengesellschaft.

"Stockholder" shall mean any of EIS, Sheffield, any Permitted Transferee or any other Person who subsequently becomes bound by this Agreement as a holder of the Shares, and

"Stockholders" shall mean all of the Stockholders together.

"Subsidiary" shall mean any company that is a subsidiary of Newco within the meaning of applicable laws.

"Technological Competitor of Elan" shall mean a company, corporation or person listed in Schedule 3 and successors thereof or any additional broad-based technological competitor of Elan added to such Schedule 3 from time to time upon mutual agreement of the Parties

"Technological Competitor of Sheffield" shall mean a company, corporation or person listed in Schedule 4 and successors thereof or any additional broad-based technological competitor of Sheffield added to such Schedule 4 from time to time upon mutual agreement of the Parties.

"Term" shall mean the term of this Agreement.

"Territory" shall mean all of the countries of the world.

"Transaction Documents" shall mean this Agreement, the Funding Agreement, the Elan License Agreement, the Sheffield License Agreement, the Sheffield Securities Purchase Agreement, the Exchange Notes, the Dividend Notes, the Registration Rights Agreements, the Certificate of Designations and associated documentation of even date herewith, by and between Sheffield, Elan, EIS and Newco, as applicable.

"United States Dollar" and "US$" and "$" shall mean the lawful currency of the United States of America.

"Zambon" shall mean Inpharzam International, S.A..

"Zambon Agreement" shall mean the agreement dated June 15, 1998 between Sheffield and Zambon.

1.2 In addition, the following definitions have the meanings in the Clauses corresponding thereto, as set forth below.

Definition	Clause
"AAA"	20.6
"Buyout Option"	20.4
"Closing"	4.3
"Common Stock"	Recital

"Confidential Information" 22.1
"Co-sale Notice" 17.4
"Expert" 19.3
"Management Committee" 5.2.1
"Notice of Exercise" 17.3
"Notice of Intention" 17.3

"Offered Shares" 17.3
"Offer Price" 17.3
"Preferred Stock" Recital
"Proposing Participant" 20.4
"Proposing Participant Price" 20.6
"Purchase Price" 20.6
"R&D Committee" 5.2.3
"Recipient Participant" 20.4
"Recipient Participant Price" 20.6
"Remaining Stockholders" 17.4
"Relevant Event" 20.2
"Selling Stockholder" 17.3
"Tag-Along Right" 17.4
"Transaction Proposal" 17.3
"Transfer" 17.1
"Transferee Terms" 17.4
"Transferring Stockholder" 17.4

1.3 Words importing the singular shall include the plural and vice versa.

1.4 Unless the context otherwise requires, reference to a recital, article, paragraph, provision, clause or schedule is to a recital, article, paragraph, provision, clause or schedule of or to this Agreement.

1.5 Reference to a statute or statutory provision includes a reference to it as from time to time amended, extended or re-enacted.

1.6 The headings in this Agreement are inserted for convenience only and do not affect its construction.

1.7 Unless the context or subject otherwise requires, references to words in one gender include references to the other genders.

1.8 Capitalized terms used but not defined herein shall have the meanings ascribed in the Transaction Documents, if defined therein.

CLAUSE 2

BUSINESS

2.1 This Agreement shall regulate the business of the development, testing, registration, manufacture, commercialization and licensing of Products in the Territory and to achieve the other objectives set out in this Agreement. The focus of the Business will be to develop the Products in

the Combined Fields (subject to the provisions outlined in Clause 2.3 and Clause 2.4 of this

Agreement and Clause 1 of the Funding Agreement) using the Elan Intellectual Property, the Sheffield Intellectual Property and the Newco Intellectual Property to agreed upon specifications and timelines.

2.2 The central management and control of Newco shall be exercised in Bermuda and shall be vested in the Directors and such Persons as they may delegate the exercise of their powers in accordance with the Newco By-Laws. The Stockholders shall use their best endeavors to ensure that to the extent required pursuant to the laws of Bermuda, and to ensure the sole residence of Newco in Bermuda, all meetings of the Directors are held in Bermuda or other jurisdictions outside the United States and generally to ensure that Newco is treated as resident for taxation purposes in Bermuda.

2.3 Nomination procedures in Field B

The Management Committee shall nominate the Field B Compound as soon as practicable following the Effective Date provided that the Management Committee shall in no circumstances be entitled to nominate [REDACTED] as the Field B Compound without the prior consent in writing of Elan.

Upon nomination of the Field B Compound, the R&D Committee shall carry out, or have carried out on its behalf by a third party agreed by the R&D Committee, a feasibility study ("Field B Feasibility Study") to determine the feasibility of the Field B Compound initially nominated for an R&D Program in Field B.

Subject to Clause 6.3 and Clause 1 of the Funding Agreement, if the Management Committee is satisfied with the results of the Field B Feasibility Study, the Management Committee will consider whether and when Newco will commence an R&D Program in Field B with such Field B Compound having regard to the other R&D Programs being undertaken by Newco and the personnel resources and funding which Newco has allocated thereto. If the Management Committee determines that such Field B Compound represents a more valuable opportunity for Newco than Field A, the

Management Committee, to the extent necessary, will re-prioritize any R&D Program(s) already commenced in Field A or proposed to be commenced by Newco in such Field.

If the Management Committee is not satisfied with the results of the Field B Feasibility Study, no R&D Program will be commenced by Newco in respect of such Field B Compound and the Management Committee will nominate a substitute [REDACTED] for therapeutic use in Field B (the

"Substitute Field B Compound") (provided that the Management Committee shall in no circumstances be entitled to nominate [REDACTED] as the Field B Compound without the prior consent in writing of Elan) which will be subject to a new Field B Feasibility Study and all other applicable provisions of this Clause 2.3.

Prior to Newco commencing any R&D Program in Field B with the Field B Compound, or the Substitute Field B Compound, the Parties shall negotiate in good faith such amendments as are required to the Licenses and/or the Development Agreement, such as amending the provisions regulating non-competition.

The Management Committee shall not be entitled to nominate more than one Substitute Field B Compound hereunder.

With reference to Clause 6.3 and Clause 1 of the Funding Agreement, in the event that either Elan or Sheffield determines not to fund any amounts required for an R&D Program in Field B, but the other Party desires to fund such R&D Program in Field B, the Party desiring to continue such funding shall be entitled to enter into an agreement with Newco to obtain the relevant R&D Program in Field B from Newco and to enter into any necessary license agreements with Newco which will be negotiated in good faith with Newco and based on the then current fair market value of such R&D Program in Field B and other customary terms.

2.4 Nomination procedures in Field C

As provided in Clause 2.2 of the Elan License Agreement, on the date which is [REDACTED] days following the Effective Date, or such extended date as may be agreed in writing by Elan and Newco, Elan shall, at its sole discretion, be entitled forthwith to terminate the license to Newco described in Clause 2.1.3 of the Elan License, upon notice in writing to Newco, in the event that Newco has not, prior to such date, executed a written sub-license with Zambon for the development by Newco of the Field C Formulation in Field C.

Prior to the execution by Newco of the written sub-license with Zambon, as described herein, within the period specified herein, the Management Committee will consider whether and when Newco will commence an R&D Program in Field C having regard to the other R&D Programs being undertaken by Newco and the personnel resources which Newco has allocated thereto and the funding available from Zambon for such proposed R&D Program.

If Newco commences an R&D Program in Field C with the Field C Compound under this Clause 2.4 and such R&D Program is subsequently terminated by the Management Committee within one year of commencement because the Field C Compound cannot be

formulated in a manner suitable for delivery with the Field C Device, the Management Committee will consider the nomination of a substitute

[REDACTED] in Field C (the "Substitute Field C Compound").

After a period of 1 year following the later of the commencement date of the R&D Program commenced by Newco for the Field C Compound or the Substitute Field C Compound, on a semi-annual basis, the Management Committee will consider whether it should nominate and consider one additional [REDACTED] in Field C ("Additional Field C Compound") for an one additional R&D Program in Field C having regard to the other R&D Programs being undertaken by Newco and the personnel resources and funding which Newco has allocated thereto and the funding available from Zambon for such an additional R&D Program.

Prior to Newco commencing any R&D Program in Field C with a Substitute Field C Compound or with an Additional Field C Compound, the Parties shall negotiate in good faith such amendments as are required to the Licenses and/or the Development Agreement, such as amending the provisions regulating non-competition and as are required to the agreement between Newco and Zambon described herein (assuming that such agreement has been executed in accordance with the provisions hereof).

CLAUSE 3

REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of Newco: Newco hereby represents and warrants to each of the Stockholders as follows, as of the date hereof:

3.1.1 Organization: Newco is an exempted company duly organized, validly existing and in good standing under the laws of Bermuda, and has all the requisite corporate power and authority to own and lease its properties, to carry on its business as presently conducted and as proposed to be conducted.

3.1.2 Capitalization: As of the date hereof, the authorized capital stock of Newco consists of 12,000 shares of Common Stock and 12,000 shares of Preferred Stock. Prior to the date hereof, no shares of capital stock of Newco have been issued.

3.1.3 Authorization: The execution, delivery and performance by Newco of this Agreement, including the issuance of the Shares, have been duly authorized by all requisite corporate actions; this Agreement has been duly executed and delivered by Newco and is the valid and binding obligation of Newco, enforceable against it in accordance with its terms except as limited by applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting the enforcement of creditors' rights generally, and except as enforcement of rights to indemnity and contribution hereunder may be limited by United States federal or state securities laws or principles of public policy. The Shares, when issued as

contemplated hereby or in the Newco By-Laws, will be validly issued and outstanding, fully paid and non-assessable and not subject to preemptive or any other similar rights of the Stockholders or others.

3.1.4 No Conflicts: The execution, delivery and performance by Newco of this Agreement, the issuance, sale and delivery of the Shares, and compliance with the provisions hereof by Newco, will not:

(i) violate any provision of applicable Bermuda law, statute, rule or regulation applicable to Newco or any ruling, writ, injunction, order, judgment or decree of any court, arbitrator, administrative agency or other governmental body applicable to Newco or any of its properties or assets;

(ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute (with notice or lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under its charter or organizational documents or any material contract to which Newco is a party, except where such violation, conflict or breach would not, individually or in the aggregate, have a material adverse effect on Newco; or

(iii) result in the creation of, any Encumbrance upon any of the properties or assets of Newco.

3.1.5 Approvals: As of the date hereof, no permit, authorization, consent or approval of or by, or any notification of or filing with, any Person is required in connection with the execution, delivery or performance of this Agreement by Newco. Newco has full authority to conduct its business as contemplated in the Business Plan and the Transaction Documents.

3.1.6 Disclosure: This Agreement does not contain any untrue statement of a material fact or omit to state any material fact necessary to make the statements contained herein not misleading. Newco is not aware of any material contingency, event or circumstance relating to its business or prospects, which could have a material adverse effect thereon, in order for the disclosure herein relating to Newco not to be misleading in any material respect.

3.1.7 No Business; No Liabilities: Newco has not conducted any business or incurred any liabilities or obligations prior to the date hereof, except solely in connection with its organization and formation.

3.2 Representations and Warranties of the Stockholders: Each of the Stockholders hereby severally represents and warrants to Newco as follows as of the date hereof:

3.2.1 Organization: Such Stockholder is a corporation duly organized and validly existing under the laws of its jurisdiction of organization and has all the requisite corporate power and authority to own and lease its respective properties, to carry on its respective business as presently conducted and as proposed to be conducted and to carry out the transactions contemplated hereby.

3.2.2 Authority: Such Stockholder has full legal right, power and authority to enter into this Agreement and to perform its obligations hereunder, which have been duly authorized by all requisite corporate action. This Agreement is the valid and binding obligation of such Stockholder, enforceable against it in accordance with its terms except as limited by applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting the enforcement of creditors' rights generally, and except as enforcement of rights to indemnity and contribution hereunder may be limited by United States federal or state securities laws or principles of public policy.

3.2.3 No Conflicts: The execution, delivery and performance by such Stockholder of this Agreement, purchase of the Shares, and compliance with the provisions hereof by such Stockholder will not:

(i) violate any provision of applicable law, statute, rule or regulation known by and applicable to such Stockholder or any ruling, writ, injunction, order, judgment or decree of any court, arbitrator, administrative agency or other governmental body applicable to such Stockholder or any of its properties or assets;

(ii) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute (with notice or lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under the charter or organizational documents of such Stockholder or any material contract to which such Stockholder is a party, except where such violation, conflict or breach would not, individually or in the aggregate, have a material adverse effect on such Stockholder; or

(iii) result in the creation of, any Encumbrance upon any of the properties or assets of such Stockholder.

3.2.4 Approvals: As of the date hereof, no permit, authorization, consent or approval of or by, or any notification of or filing with, any Person is required in connection with the execution, delivery or performance of this Agreement by such Stockholder.

3.2.5 Investment Representations: Such Stockholder is sophisticated in transactions of this type and capable of evaluating the merits and risks of its investment in Newco. Such Stockholder has not been formed solely for the purpose of making this investment and such Stockholder is acquiring the Common Stock and/or Preferred Stock for investment for its own account, not as a nominee or agent, and not with the view to, or for resale in connection with, any distribution of any part thereof. Such

Stockholder understands that the Shares have not been registered under the Securities Act or applicable state and foreign securities laws by reason of a specific exemption from the registration provisions of the Securities Act and applicable state and foreign securities laws, the availability of which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of such Stockholders' representations as expressed herein. Such Stockholder understands that no public market now exists for any of the Shares and that there is no assurance that a public market will ever exist for such Shares.

CLAUSE 4

AUTHORIZATION AND CLOSING

4.1 Newco has authorized the issuance to (i) EIS of 4,776 shares of Preferred Stock and (ii) Sheffield of 12,000 shares of Common Stock and 7,224 shares of Preferred Stock, issuable as provided in Clause 4.3 hereof.

4.2 Sheffield and EIS hereby subscribe for the number of Shares set forth in Clause 4.1 and shall pay to the Newco in consideration therefor, by wire transfer of immediately available funds (to a bank account established by Newco in connection with Completion) the subscription amounts each as provided in Clause 4.4.1.

4.3 The closing (the "Closing") shall take place at the offices of Brock Silverstein LLC at 800 Third Avenue, New York, New York 10022 on the date hereof or such other places if any, as the Parties may agree and shall occur contemporaneously with the closing under the Sheffield Securities Purchase Agreement.

4.4 At the Closing, each of the Stockholders shall take or (to the extent within its powers) cause to be taken the following steps at directors and shareholder meetings of the Newco, or such other meetings or locations, as appropriate:

4.4.1 Newco shall issue and sell to EIS, and EIS shall purchase from Newco, upon the terms and subject to the conditions set forth herein, 4,776 shares of Preferred Stock for an aggregate purchase price of $2,985,000 Newco shall issue and sell to Sheffield, and Sheffield shall purchase from Newco, upon the terms and conditions set forth herein, (i) 12,000 shares of Common Stock for an aggregate purchase price of $7,500,000 and (ii) 7,224 shares of Preferred Stock for an aggregate purchase price of $4,515,000;

4.4.2 the Parties shall execute and deliver to each other, as applicable, certificates in respect of the Common Stock and Preferred Stock described above and any other certificates, resolutions or documents which the Parties shall reasonably require;

4.4.3. the adoption by the Newco of Newco's By-Laws;

4.4.4. the appointment of Kevin Insley, Loren G. Peterson, and Thomas M. Fitzgerald as Directors of Newco; and

4.4.5. the resignation of all directors and the secretary of Newco holding office prior to the execution of this Agreement and delivery of written confirmation under seal by each Person so resigning that he has no claim or right of action against Newco and that Newco is not in any way obligated or indebted to him.

4.5 Exemption from Registration:

The Shares will be issued under an exemption or exemptions from registration under the Securities Act. Accordingly, the certificates evidencing the Shares shall, upon issuance, contain the following legend:

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY SECURITIES LAWS OF A STATE OR OTHER JURISDICTION AND MAY NOT UNDER ANY CIRCUMSTANCES BE SOLD, TRANSFERRED, OR OTHERWISE DISPOSED OF EXCEPT PURSUANT TO (i) AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT AND ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS, (ii) TO THE EXTENT APPLICABLE, RULE 144 UNDER THE SECURITIES ACT (OR ANY SIMILAR RULE UNDER THE SECURITIES ACT RELATING TO THE DISPOSITION OF SECURITIES) OR ANY OTHER AVAILABLE EXCEPTION TO OR EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF SUCH ACT AND ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS, TOGETHER WITH AN OPINION

OF COUNSEL REASONABLY SATISFACTORY TO THE CORPORATION THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR APPLICABLE STATE SECURITIES LAWS.

4.6. Newco shall use reasonable efforts to file any documents that require filing with the Registrar of Companies in Bermuda within the prescribed time limits. EIS and Sheffield shall provide all reasonable co-operation to Newco in relation to the matters set forth in this Clause 4.6.

4.7. In the event that EIS exercises the Exchange Right prior to the second anniversary of the Closing Date and Sheffield is required to transfer to EIS any shares of Common Stock (in addition to the shares of Preferred Stock otherwise transferable), Newco shall, immediately upon such exercise, take all necessary steps to ensure that each share to be transferred by Sheffield to EIS upon the exercise of the Exchange Right is a duly and validly issued share

of Preferred Stock (including the conversion of existing shares of Common Stock held by Sheffield prior to the exercise of the Exchange Right for newly created shares of Preferred Stock for purposes of the exercise of the Exchange Right) and that EIS shall have full legal right, title and interest in and to such shares of Preferred Stock thereby exchanged. All shares of Newco capital stock transferred by Sheffield to EIS upon exercise of the Exchange Right prior to the second anniversary of the Closing Date shall be (or pursuant to this clause 4.7, shall be converted from common into) shares of Preferred Stock.

CLAUSE 5

DIRECTORS; MANAGEMENT AND R&D COMMITTEES

5.1. Directors:

Prior to the exercise of the Exchange Right, the Board shall be composed of three Directors. Sheffield shall have the right to nominate two directors of Newco ("Sheffield Directors") and EIS shall have the right to nominate one Director of Newco ("EIS Director"), which Director, save as further provided herein, shall only be entitled to 15% of the votes of the Board. To the extent required by applicable Bermuda law, in the event that the EIS Director is not a resident of Bermuda, at least one of the Sheffield Directors shall be a resident of Bermuda. Sheffield may appoint one of the Sheffield Directors to be the chairman of Newco. In the event that the Exchange Right is exercised by EIS within 2 years following the Closing Date, the EIS Director shall only be entitled to 15% of the votes of the Board until the expiry of 2 years from the Closing Date.

In the event that the Exchange Right is exercised by EIS at any time

after two years following the Closing Date or upon the expiry of 2 years following the Closing Date where the Exchange Right has been exercised by EIS within 2 years following the Closing Date, each of Sheffield, and EIS shall cause the Board to be reconfigured so that an equal number of Directors are designated by EIS and Sheffield and that each of the Directors has equal voting power.

5.1.1 If EIS removes the EIS Director, or Sheffield removes any of the Sheffield Directors, EIS or Sheffield, as the case may be, shall indemnify the other Stockholder against any claim by such removed Director arising from such removal.

5.1.2 The Directors shall meet not less than three times in each Financial Year and Board meetings shall be held in Bermuda to the extent required pursuant to the laws of Bermuda or to ensure the sole residence of Newco in Bermuda.

5.1.3 At any such meeting, the presence of at least one EIS Director and at least one Sheffield Director shall be required to constitute a quorum and, subject to Clause 18 hereof, the affirmative vote of a majority of the Directors present at a meeting at which such a quorum is present shall constitute an action of the Directors. In the event of any meeting being

inquorate, the meeting shall be adjourned for a period of seven days. A notice shall be sent to the EIS Director(s) and the Sheffield Directors specifying the date, time and place where such adjourned meeting is to be held and reconvened.

5.1.4 The chairman of Newco shall hold office until the first meeting of the Board after the exercise by EIS of the Exchange Right, provided that the Exchange Right is exercised by EIS at any time after two years from the date hereof. If the Exchange Right is exercised by EIS within two years from the date hereof, the chairman of Newco shall continue to hold office. If the chairman is unable to attend any meeting of the Board, the Sheffield Directors shall be entitled to appoint another Director to act as chairman in his place at the meeting. After exercise of the Exchange Right by EIS, each of EIS and Sheffield, beginning with EIS, shall have the right, exercisable alternatively, of nominating one Director to be chairman of Newco for a term of one year. If the chairman of Newco is unable to attend any meeting of the Board held after the exercise of the Exchange Right by EIS, the Directors shall be entitled to appoint another Director to act as chairman of Newco in his place at the meeting.

5.1.5. In case of an equality of votes at a meeting of the Board, the chairman of Newco shall not be entitled to a second or casting vote. In the event of continued deadlock, the Board shall resolve the deadlock pursuant to the provisions set forth in Clause 19.

5.2 Management and R&D Committees:

5.2.1 The Board shall appoint a management committee (the "Management Committee") to consist initially of four members, two of whom shall be nominated by Elan and two of whom shall be nominated by Sheffield, and each of whom shall be entitled to one vote, whether or not present at any Management Committee meeting. Decisions of the Management Committee shall require approval of at least one Elan nominee on the Management Committee and one Sheffield nominee on the Management Committee.

5.2.2 Each of Elan and Sheffield shall be entitled to remove any of their nominees to the Management Committee and appoint a replacement in place of any nominees so removed. The number of members of the Management Committee may be altered if agreed to by a majority of the Directors; provided that, each of Elan and Sheffield shall be entitled to appoint an equal number of members to the Management Committee. The Management Committee shall be responsible for, inter alia, devising, implementing and reviewing strategy for the Project.

5.2.3 The Management Committee shall appoint a research and development committee (the "R&D Committee"), which shall initially be comprised of four members, two of whom shall be nominated by Elan and two of whom shall be nominated by Sheffield, and each of whom shall have one vote, whether or not present at an R&D Committee meeting during which research and development issues are discussed. Decisions of the R&D Committee shall require approval of at least one Elan nominee

on the R&D Committee and one Sheffield nominee on the R&D Committee.

5.2.4 Each of Elan and Sheffield shall be entitled to remove any of their nominees to the R&D Committee and appoint a replacement in place of any nominees so removed. The number of members of the R&D Committee may be altered if agreed to by a majority of the Directors provided that each of Elan and Sheffield shall be entitled to appoint an equal number of members to the R&D Committee.

5.2.5 The Management Committee shall be responsible for the preparation of the Business Plan. The Management Committee shall also be responsible for monitoring and conducting periodic reviews of Elan Intellectual Property and Sheffield Intellectual Property.

5.2.6 The R&D Committee shall be responsible for:-

(i) designing that portion of the Business Plan that relates to the Project for consideration by the

Management Committee;

(ii) establishing a joint Project team consisting of an equal number of team members from Elan and Sheffield, including one Project leader from each of Elan and Sheffield; and

(iii) implementing such portion of the Business Plan that relates to the Project, as approved by the Management Committee.

5.2.7 In the event of any dispute amongst the R&D Committee, the R&D Committee shall refer such dispute to the Management Committee whose decision on the dispute shall be binding on the R&D Committee.

If the Management Committee cannot resolve the matter after 15 days or such other period as may be agreed by the Management Committee, the dispute will be referred to a designated senior officer of each of Elan and Sheffield, and thereafter, in the event of continued deadlock, pursuant to the deadlock provisions to be set forth in Clause 19, involving inter alia, the referral of the dispute to an expert, whose decision will be binding on the Participants. This process shall also apply to any dispute within the Management Committee.

5.2.8 Elan and Sheffield shall permit Newco or its duly authorized representative on reasonable notice and at any reasonable time during normal business hours to have access to inspect and audit the accounts and records of Elan or Sheffield and any other book, record, voucher, receipt or invoice relating to the calculation or the cost of the R&D Program and to the accuracy of the reports which accompanied them. Any such inspection of Elan's or Sheffield's records, as the case may be, shall be at the expense of Newco, except that if such inspection reveals an overpayment in the amount paid to Elan or Sheffield, as the

case may be, for the R&D Program hereunder in any Financial Year of 5% or more of the amount due to Elan or Sheffield, as the case may be, then the expense of such inspection shall be borne solely by Elan or Sheffield, as the case may be, instead of by Newco. Any surplus over the sum properly payable by Newco to Elan or Sheffield, as the case may be, shall be paid promptly by Elan or Sheffield, as the case may be, to Newco. If such inspection reveals a deficit in the amount of the sum properly payable to Elan or Sheffield, as the case may be, by Newco, Newco shall pay the deficit to Elan or Sheffield, as the case may be.

CLAUSE 6

THE BUSINESS PLAN AND REVIEWS

6.1 The Directors shall meet together as soon as reasonably practicable after the Closing Date hereof and shall agree upon and approve the Business Plan for the current Financial Year within [REDACTED] days of the Closing Date.

6.2. The Business Plan shall be reviewed and mutually agreed to by the unanimous approval of the EIS Director and the Sheffield Directors on a semi-annual basis.

6.3. Neither Participant shall be obliged to provide funding to Newco in the absence of the semi-annual approval of the Business Plan and a determination by each Participant, in its sole discretion, that Subsequent Funding (as such term is defined in the Funding Agreement) shall be provided for the development of the Products.

6.4. Future Business Plans prepared pursuant to Clause 5 shall be reviewed and mutually agreed to by the EIS Director and the Sheffield Directors.

CLAUSE 7

RESEARCH AND DEVELOPMENT WORK

7.1 Subject to Clause 6.3, Elan and Sheffield, at Newco's request, may undertake research and development work related to the development and commercialization of the Products, at the request of Newco and as articulated in the Business Plan, in furtherance of the development and commercialization of the Products and cultivation of patent rights and know-how related to the Elan Intellectual Property, Sheffield Intellectual Property and Newco Intellectual Property.

7.2 Elan and Sheffield shall use reasonable efforts in undertaking any such research and development work undertaken for Newco hereunder to conduct such research and development work in a professional and timely manner, in accordance with relevant RHA guidelines and regulations.

7.3 The cost of such development work shall be Elan's and Sheffield's, as the case may be, fully-burdened actual costs in respect thereof, plus [REDACTED] of such costs. Research and development work that is sub-contracted by Elan or Sheffield to third party providers and/or any other materials or other services purchased from a third party provider on Newco's behalf shall be charged by Elan or Sheffield to Newco at the amount invoiced by the relevant third party provider.

CLAUSE 8

COMMERCIALIZATION

8.1 Newco shall diligently pursue the research, development, prosecution and commercialization of the Products, as provided in the Business

Plan.

8.2 Subject to Clause 2 of the Sheffield License Agreement, at any time during the development of the Products, Newco may, subject to the Licenses and Clause 8.3, license the marketing rights to the Products to one or more marketing partners, or otherwise commercialize the Products under an alternative strategy to be agreed upon by Elan and Sheffield.

8.3 Newco shall be responsible for negotiating with third Parties commercially reasonable terms (including, inter alia, royalties, milestones, fees, profit sharing, manufacturing rights, supply terms) for the rights to be granted, but shall do so under the commercial strategy agreed with Elan and Sheffield and shall keep Elan and Sheffield informed throughout the negotiation process.

CLAUSE 9

SUBLICENSE AND ASSIGNMENT RIGHTS

9.1 Newco shall not be permitted to assign, license or sublicense any of its rights in respect of the Newco Intellectual Property without the prior written consent of Elan and Sheffield which consent will not be unreasonably withheld or delayed; provided that:

9.1.1 Elan shall in all cases, in its sole discretion, be entitled to withhold its consent in the case of a proposed sublicense to any Technological Competitor of Elan;

9.1.2 Sheffield shall in all cases, in its sole discretion, be entitled to withhold its consent in the case of a proposed sublicense to any Technological Competitor of Sheffield provided that for the avoidance of doubt, this Clause 9.1.2 shall not impact in any way Elan's right to grant sub-licenses of Newco Intellectual Property pursuant to Clause 12.

9.2 The Parties acknowledge and agree to be bound by the provisions of Clause 2.7 of the Elan License Agreement and the provisions of Clause 2.7 of the Sheffield License Agreement which set forth the agreement between the Parties thereto in relation to sub-licensing of the Elan Intellectual Property and the Sheffield Intellectual Property respectively.

CLAUSE 10

OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS/NON-COMPETITION

10.1. The Parties acknowledge and agree to be bound by the provisions of Clause 3.1 of the Elan License Agreement and Clause 3.1 of the Sheffield License Agreement set forth the agreement between the parties

thereto in relation to the ownership of the Elan Intellectual Property, the Sheffield Intellectual Property and the Newco Intellectual property respectively.

10.2 The Parties acknowledge and agree to be bound by the provisions of Clause 4 of the Elan License Agreement and the provisions of Clause 4 of the Sheffield License Agreement which set forth the agreement between the parties thereto in relation to the non-competition obligations of Elan and Sheffield, respectively.

CLAUSE 11

INTELLECTUAL PROPERTY RIGHTS

11.1 Newco shall remain the owner of the Newco Intellectual Property.

11.1.1 Each Party shall be responsible for the preparation, prosecution and maintenance of all patent applications and issued patents relating to its own intellectual property. Prior to filing for any patent protection on any Newco Intellectual Property, Newco shall inform Elan and Sheffield of its intention to do so.

11.1.2 Upon request, Elan or Sheffield shall provide information regarding its activities set forth in 11.1.1.

11.2 Enforcement of Intellectual Property Rights; third party infringement

11.2.1 Sheffield, Newco and Elan shall promptly inform the other in writing of any alleged infringement or unauthorized use of which it shall become aware by a third party of Newco

Intellectual Property, Elan Intellectual Property or Sheffield Intellectual Property, and provide such other with any available evidence of such unauthorized activity.

11.2.2 Elan shall have the right to pursue at its own expense any enforcement activities of the Elan Intellectual Property. Sheffield shall have the right to pursue at its own expense any enforcement activities of the Sheffield Intellectual Property. Both Elan and Sheffield agree to reasonably co-operate with each other in any such action. Any expenses borne by the co-operating party shall be reimbursed by the enforcing party. Should either Elan or Sheffield decide not to enforce the Elan Intellectual Property or the Sheffield Intellectual Property as the case may be within the Combined Fields, Newco may do so at its expense and for its own benefit, and the parties will reasonably co-operate with such action. If an enforcement action is successful, the Party taking such enforcement action shall be entitled to any proceeds recovered.

11.3 Infringement of third party patents

11.3.1 In the event that a claim or proceeding is brought against Newco by a third party alleging that the manufacture, use, offer for sale, sale or other activity relating to any of the Products constitute an unauthorized use of an intellectual property right owned by such a third party in the Territory, Newco shall promptly advise Elan and Sheffield of such threat or suit.

11.3.2 Newco shall indemnify, defend and hold Elan and Sheffield harmless against all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys fees) relating directly or indirectly to all such claims or proceedings directed to Products; provided that Elan or Sheffield shall not acknowledge to the third party or to any other person the validity of any claims of such a third party, and shall not compromise or settle any claim or proceedings relating thereto without the prior written consent of Newco, not to be unreasonably withheld or delayed. At its option, in the event the claim is directed primarily to Compounds, Elan may elect to take over the conduct of such proceedings from Newco, or in the event the claim is directed primarily at Sheffield Devices, Sheffield may elect to take over the conduct of such proceedings from Newco; provided that Newco's indemnification obligations shall continue; the costs of defending such claim shall be borne by the Party assuming control over such proceedings; and Elan or Sheffield shall not compromise or settle any such claim or proceeding without the prior written consent of Newco, not to be unreasonably withheld or delayed.

CLAUSE 12

CROSS-LICENSES/EXPLOITATION OF PRODUCTS OUTSIDE FIELDS A, B AND C

12.1 Solely for the purpose of and insofar as is necessary, in each case, for Elan to perform its obligations under the Elan License Agreement, Newco shall grant to Elan a non-exclusive, worldwide, royalty-free, fully paid-up license for the term of the License Agreements:

12.1.1 to use the Newco Intellectual Property in the Combined Fields, and

12.1.2 subject to the terms and conditions of the Sheffield License Agreement, a sublicense to use the Sheffield Intellectual Property in the Combined Fields.

12.2 Solely for the purpose of and insofar as is necessary, in each case, for Sheffield to perform its obligations under the Sheffield License Agreement, Newco shall grant to Sheffield a non-exclusive, worldwide, royalty-free, fully paid-up license for the term of the Licenses:

12.2.1 to use the Newco Intellectual Property in the Combined Fields, and

12.2.2 subject to the terms and conditions of the Elan License Agreement, a sublicense to use the Elan Intellectual Property in the Combined Fields.

12.3 Elan shall be entitled to exploit the Newco Intellectual Property in Field B and/or Field C outside Field B and/or Field C respectively subject to the Parties negotiating a license agreement in good faith (including all material provisions thereof, including as to whether the license should be exclusive or non-exclusive), pursuant to which Newco will grant Elan a license under the Newco Intellectual Property in Field B and/or Field C outside Field B and/or Field C respectively on a Product by Product basis. The financial terms of the said license agreement shall have regard, inter alia, to:

12.3.1 the amount of monies expended by Newco in developing the Newco Intellectual Property;

12.3.2 the materiality of the Newco Intellectual Property in Field B and/or Field C by comparison to the further research and development work to be conducted, and of the Elan Intellectual Property and the Sheffield Intellectual Property; and

12.3.3 the financial return likely to be earned by Elan from the proposed exploitation outside Field B and/or Field C; and

12.3.4 the impact of the proposed exploitation of the Newco Intellectual Property in Field B and/or Field C outside Field B and/or Field C respectively on the exploitation of the Newco Intellectual Property in Field B and/or Field C within Field B and/or Field C respectively.

12.4 Sheffield shall be entitled to exploit the Newco Intellectual Property in Field B and/or Field C outside Field B and/or Field C respectively subject to the Parties negotiating a license agreement in good faith (including all material provisions thereof, including as to whether the license should be exclusive or non-exclusive), pursuant to which Newco will grant Sheffield a license under the Newco Intellectual Property

outside Field B and/or Field C respectively on a Product by Product basis. The financial terms of the said license agreement shall have regard, inter alia, to:

12.4.1 the amount of monies expended by Newco in developing the Newco Intellectual Property;

12.4.2 the materiality of the Newco Intellectual Property in Field B and/or Field C by comparison to the further research and development work to be conducted, and of the Elan Intellectual Property and the Sheffield Intellectual Property; and

12.4.3 the financial return likely to be earned by Sheffield from the proposed exploitation of outside Field B and/or Field C; and

12.4.4 the impact of the proposed exploitation of the Newco Intellectual Property in Field B and/or Field C outside Field B and/or Field C respectively on the exploitation of the Newco Intellectual Property in Field B and/or Field C within Field B and/or Field C respectively.

12.5 Newco hereby grants to Elan a worldwide, perpetual, fully-paid and royalty-free license, with the right to grant sublicenses, to the Newco Intellectual Property in Field A for use outside Field A.

CLAUSE 13

REGULATORY

13.1 Newco shall keep the other Parties promptly and fully advised of Newco's regulatory activities, progress and procedures. Newco shall inform the other Parties of any dealings it shall have with an RHA, and shall furnish the other Parties with copies of all correspondence relating to the Products. The Parties shall collaborate with a view to obtaining any required regulatory approval of the RHA to market the Products.

13.2 Newco shall, at its own cost, file, prosecute and maintain any and all Regulatory Applications for the Products in the Territory in accordance with the Business Plan, except where such obligations are by contract undertaken by a third party.

13.3 Subject to Clause 13.5, and subject to a determination by Newco that one or more regulatory approvals should be held in the name of Newco's commercial partner such as a sub-licensee, any and all Regulatory Approvals obtained hereunder for any Product shall be prosecuted and owned by Newco, provided that Newco shall allow Elan and Sheffield access thereto to enable Elan and Sheffield to fulfill their respective obligations and exercise their respective rights under this Agreement. Newco shall maintain such Regulatory Approvals at its own cost.

13.4 It is hereby acknowledged that there are inherent uncertainties involved in the registration of pharmaceutical products with the RHA's insofar as obtaining approval is concerned and such uncertainties form part of the business risk involved in undertaking the form of commercial collaboration as set forth in this Agreement.

13.5 The DMF (Drug Master File) relating to Formulations shall be processed by and be the property of Elan and at all times held in Elan's sole name. Elan grants Newco for Field A, Field B and Field C, a right to reference Elan's DMF, as described herein, with the FDA to the extent necessary for Newco's regulatory purposes. Elan grants Sheffield for Field B and Field C a right to reference Elan's DMF, as described

herein, with the FDA to the extent necessary for Sheffield's regulatory purposes.

CLAUSE 14

MANUFACTURING

Elan will supply Nanocrystal Compounds to Newco at Elan's fully burdened cost plus [REDACTED] of such cost; provided, however, that Elan shall have the right to subcontract the manufacture and supply of the Nanocrystal Compounds. Elan shall have the first right to manufacture and supply, and/or subcontract the manufacture and supply of Formulations, subject to the Zambon Agreement.

Any such supply agreement shall be negotiated and agreed by the Parties not later than the date of completion of Phase II (as such term is commonly used in connection with FDA applications) of the R&D Program. The terms of the said supply agreements shall be on Elan's normal commercial terms, and shall be negotiated in good faith by the Parties thereto provided that Elan agrees that the cost which would to be invoiced by Elan to Newco in respect of such manufacture would be Elan's fully-burdened actual costs plus [REDACTED] of such costs.

If Elan does not exercise its first right hereunder to manufacture and supply, and/or subcontract the manufacture and supply of Formulations, then Newco shall be free to enter into negotiations with a third party (other than a Technological Competitor of Elan) to agree to terms upon which the third party would be licensed by Elan (on licensing terms satisfactory to Elan) and by Newco to the extent necessary (on licensing terms satisfactory to Newco) to manufacture the relevant Formulation(s) in the Territory, which terms when taken as a whole, are not more favourable to the third party than the principal terms of the last written proposal offered by Newco to Elan or by Elan to Newco, as the case may be.

CLAUSE 15

TECHNICAL SERVICES AND ASSISTANCE

15.1 Whenever commercially and technically feasible, Newco shall contract with Sheffield or Elan, as the case may be, to perform such other services as Newco may require, other than those specifically dealt with hereunder or in the License Agreements. In determining which Party should provide such services, the Management Committee shall take into account the respective infrastructure, capabilities and experience of Elan and Sheffield. There shall be no obligation upon either of Sheffield or Elan to perform such services.

15.2 Newco shall, if the Participants so agree, conclude an administrative support agreement with Elan and/or Sheffield on such terms as the Parties thereto shall in good faith negotiate. The administrative services shall include one or more of the following administrative services as requested by Newco:

15.2.1 accounting, financial and other services;

15.2.2 tax services;

15.2.3 insurance services;

15.2.4 human resources services;

15.2.5 legal and company secretarial services;

15.2.6 patent and related intellectual property services; and

15.2.7 all such other services consistent with and of the same type as those services to be provided pursuant to this Agreement, as may be required.

The foregoing list of services shall not be deemed exhaustive and may be changed from time to time upon written request by Newco.

15.3. The Parties agree that each Party shall effect and maintain comprehensive general liability insurance in respect of all clinical trials and other activities performed by them on behalf of Newco. The Stockholders and Newco shall ensure that the industry standard insurance policies shall be in place for all activities to be carried out by Newco.

15.4 If Elan or Sheffield so requires, Sheffield or Elan, as the case may be, shall receive, at times and for periods mutually acceptable to the Parties, employees of the other Party (such employees to be acceptable to the receiving Party in the matter of qualification and competence) for instruction in respect of the Elan Intellectual Property or the Sheffield Intellectual Property, as the case may be, as necessary to further the Project.

15.5 The employees received by Elan or Sheffield, as the case may be, shall be subject to obligations of confidentiality no less stringent than those set out in Clause 22 and such employees shall observe the rules, regulations and systems adopted by the Party receiving the said employees for its own employees or visitors.

CLAUSE 16

AUDITORS, BANKERS, REGISTERED OFFICE, ACCOUNTING REFERENCE DATE; SECRETARY

Unless otherwise agreed by the Stockholders and save as may be provided to the contrary herein:

16.1 the auditors of Newco shall be Ernst & Young or as designated by the Directors;

16.2 the bankers of Newco shall be as designated by the Directors; there shall be established at a U.S. bank mutually agreed to by the parties a

bank account managed by Sheffield for the benefit of Newco;

16.3 the accounting reference date of Newco shall be December 31 in each Financial Year; and

16.4 the secretary of Newco shall be I.S. Outerbridge or such other Person as may be appointed by the Directors from time to time.

CLAUSE 17

TRANSFERS OF SHARES;
RIGHT OF FIRST OFFER; TAG ALONG RIGHTS

General:

17.1. No Stockholder shall, directly or indirectly, sell or otherwise transfer (each, a "Transfer") any Shares held by it except in as expressly permitted by and accordance with the terms of this Agreement. Newco shall not, and shall not permit any transfer agent or registrar for any Shares to, transfer upon the books of Newco any Shares from any Stockholder to any transferee, in any manner, except in accordance with this Agreement, and any purported transfer not in compliance with this Agreement shall be void.

During the Research and Development Term, no Stockholder shall, directly or indirectly, sell or otherwise Transfer any of its legal and/or beneficial interest in the Shares held by it to any other Person. After completion of the Research and Development Term, a Stockholder may Transfer Shares provided such Stockholder complies with the provisions of Clauses 17.2 and 17.3.

Notwithstanding anything contained herein to the contrary (i) at all times, EIS and/or Sheffield shall have the right to Transfer any Shares

to their Affiliates provided, however, that such assignment does not result in adverse tax consequences for any other Parties and (ii) Sheffield may not Transfer or allow any Encumbrance in, or to, any Shares that are subject to the Exchange Right, other than to EIS or its Affiliates. EIS shall have the right to Transfer any Shares to an affiliate; provided, that such Affiliates shall agree to be expressly subject to and bound by all the limitations and provisions which are embodied in this Agreement.

17.2 No Stockholder shall, except with the prior written consent of the other Stockholder, create or permit to subsist any pledge, lien or charge over, or grant any option or other rights or Encumbrance in, or to, all or any of the Shares held by it (other than by a Transfer of such Shares in accordance with the provisions of this Agreement) made by it to Newco unless any Person in whose favour any such pledge, lien, or charge is created or permitted to subsist or such option or rights are granted or such interest is disposed of shall be expressly subject

to and bound by all the limitations and provisions which are embodied in this Agreement.

17.3 Rights of First Offer:

If, at any time after the end of the Research and Development Term, a Stockholder shall desire to Transfer any Shares owned by it (a "Selling Stockholder"), in any transaction or series of related transactions other than a Transfer to an Affiliate or subsidiary or in the case of EIS permitted by the Agreement to a special purpose financing or similar entity established by EIS, then such Selling Stockholder shall deliver prior written notice of its desire to Transfer (a "Notice of Intention") (i) to Newco and (ii) to the Stockholders who are not the Selling Stockholder (and any transferee thereof permitted hereunder, if any), as applicable, setting forth such Selling Stockholder's desire to make such Transfer, the number of Shares proposed to be transferred (the "Offered Shares") and the proposed form of transaction (the "Transaction Proposal"), together with any available documentation relating thereto, if any, and the consideration to be paid and the terms and conditions, at which such Selling Stockholder proposes to Transfer the Offered Shares (the "Offer Price"). The "Right of First Offer" provided for in this Clause 17 shall be subject to any "Tag Along Right" benefiting a Stockholder which may be provided for by Clause 17, subject to the exceptions set forth therein.

Upon receipt of the Notice of Intention, the Stockholders who are not the Selling Stockholder shall have the right to purchase at the Offer Price the Offered Shares, exercisable by the delivery of notice to the Selling Stockholder (the "Notice of Exercise"), with a copy to Newco, within 10 business days from the date of receipt of the Notice of Intention. If no such Notice of Exercise has been delivered by the Stockholders who are not the Selling Stockholder within such 10-business day period, or such Notice of Exercise does not relate to all of the Offered Shares covered by the Notice of Intention, then the Selling Stockholder shall be entitled to Transfer all of the Offered Shares to the intended transferee. In the event that all of the Offered Shares are not purchased by the non-selling Stockholders, the Selling Stockholder shall sell the available Offered Shares within 30 days after the delivery of such Notice of Intention on terms no more favorable to a third party than those presented to the non-selling

Stockholders. If such sale does not occur, the Offered Shares shall again be subject to the Right of First Refusal set forth in Clause 17.3.

In the event that any of the Stockholders who are not the Selling Stockholder exercise their right to purchase all of the Offered Shares (in accordance with this Clause 17), then the Selling Stockholder shall sell all of the Offered Shares to such Stockholder(s), in the amounts set forth in the Notice of Intention, after not less than 20 business days and not more than 30 business days from the date of the delivery of the Notice of Exercise. In the event that more than one of the

Stockholders who are not the Selling Stockholders wish to purchase the Offered Shares, the Offered Shares shall be allocated to such Stockholders on the basis of their pro rata equity interests in Newco, taken as a whole.

The rights and obligations of each of the Stockholders pursuant to the Right of First Offer provided herein shall terminate upon the date that the Common Stock is registered under Section 12(b) or 12(g) of the Exchange Act.

At the closing of the purchase of all of the Offered Shares by the Stockholders who are not the Selling Stockholder (scheduled in accordance with Clause 17), the Selling Stockholder shall deliver certificates evidencing the Offered Shares being sold, duly endorsed, or accompanied by written instruments of transfer in form reasonably satisfactory to the Stockholders who are not the Selling Stockholder, duly executed by the Selling Stockholder, free and clear of any adverse claims, against payment of the purchase price therefor in cash, and such other customary documents as shall be necessary in connection therewith.

17.4 Tag Along Rights:

Subject to Clause 17.3, a Stockholder (the "Transferring Stockholder") shall not Transfer (either directly or indirectly), in any one transaction or series of related transactions, to any Person or group of Persons, any Shares, unless the terms and conditions of such Transfer shall include an offer to the other Stockholders (the "Remaining Stockholders"), to sell Shares at the same price and on the same terms and conditions as the Transferring Stockholder has agreed to sell its Shares (the "Tag Along Right").

In the event a Transferring Stockholder proposes to Transfer any Shares in a transaction subject to this Clause 17.4, it shall notify, or cause to be notified, the Remaining Stockholders in writing of each such proposed Transfer. Such notice shall set forth: (i) the name of the transferee and the amount of Shares proposed to be transferred, (ii) the proposed amount and form of consideration and terms and conditions of payment offered by the transferee (the "Transferee Terms") and (iii) that the transferee has been informed of the Tag Along Right provided for in this Clause 17, if such right is applicable, and the total number of Shares the transferee has agreed to purchase from the Stockholders in accordance with the terms hereof.

The Tag Along Right may be exercised by each of the Remaining Stockholders by delivery of a written notice to the Transferring Stockholder (the "Co-sale Notice") within 20 business days following

receipt of the notice specified in the preceding subsection. The Co-sale Notice shall state the number of Shares owned by such Remaining Stockholder which the Remaining Stockholder wishes to include in such Transfer; provided, however, that without the written consent of the

Transferring Stockholder, the amount of such securities belonging to the Remaining Stockholder included in such Transfer may not be greater than such Remaining Stockholder's percentage beneficial ownership of Fully Diluted Common Stock multiplied by the total number of shares of Fully Diluted Common Stock to be sold by both the Transferring Stockholder and all Remaining Stockholders. Upon receipt of a Co-sale Notice, the Transferring Stockholder shall be obligated to transfer at least the entire number of Shares set forth in the Co-sale Notice to the transferee on the Transferee Terms; provided, however, that the Transferring Stockholder shall not consummate the purchase and sale of any Shares hereunder if the transferee does not purchase all such Shares specified in all Co-sale Notices. If no Co-sale Notice has been delivered to the Transferring Stockholder prior to the expiration of the 20 business day period referred to above and if the provisions of this Section have been complied with in all respects, the Transferring Stockholder shall have the right for a 45-day period to Transfer Shares to the transferee on the Transferee Terms without further notice to any other party, but after such 45-day period, no such Transfer may be made without again giving notice to the Remaining Stockholders of the proposed Transfer and complying with the requirements of this Clause 17. At the closing of any Transfer of Shares subject to this Clause 17, the Transferring Stockholder, and the Remaining Stockholder, in the event such Tag Along Right is exercised, shall deliver certificates evidencing such securities as have been Transferred by each, duly endorsed, or accompanied by written instruments of transfer in form reasonably satisfactory to the transferee, free and clear of any adverse claim, against payment of the purchase price therefor.

Notwithstanding the foregoing, this Clause 17 shall not apply to any sale of Common Stock pursuant to an effective registration statement under the Securities Act in a bona fide public offering.

CLAUSE 18

MATTERS REQUIRING PARTICIPANTS' APPROVAL

18.1 Subject to the provisions of Clause 18.2, in consideration of Sheffield and Elan agreeing to enter into the License Agreements, the Parties hereby agree that Newco shall not without the prior approval of the EIS Director and the Sheffield Directors:

18.1.1. make a material Newco determination outside the ordinary course of business, including, among other things, acquisitions or dispositions of intellectual property and licenses or sublicenses, changes in the Business or the Newco budget; entry into joint ventures and similar arrangements as they relate to the Licensed Technologies and changes to the Business Plan as they relate to the Licensed Technologies;

18.1.2. issue any unissued Shares or unissued Common Stock Equivalents, or create, authorize or issue any new shares

(including a split of the Shares) or Common Stock Equivalents, except as expressly permitted by the Newco By-Laws in effect as of the date hereof;

18.1.3. alter any rights attaching to any class of share in the capital of Newco or alter the Newco By-Laws;

18.1.4. consolidate, sub-divide or convert any of Newco's share capital or in any way alter the rights attaching thereto;

18.1.5. dispose of all or substantially all of the assets of Newco;

18.1.6. do or permit or suffer to be done any act or thing whereby Newco may be wound up (whether voluntarily or compulsorily), save as otherwise expressly provided for in this Agreement;

18.1.7. enter into any contract or transaction except in the ordinary and proper course of the Business on arm's length terms;

18.1.8. license or sub-license any of the Elan Intellectual Property, Sheffield Intellectual Property, Newco Intellectual Property;

18.1.9. amend or vary the terms of the Sheffield License Agreement or the Elan License Agreement;

18.1.10. permit a person other than Newco to own a regulatory approval relating to the Product(s);

18.1.11. approve, amend or vary the Business Plan or the Newco budget; and

18.1.12. alter the number of Directors.

CLAUSE 19

DISPUTES

19.1 Should any dispute or difference arise between Elan and Sheffield, or between Elan or Sheffield and Newco, during the period that this Agreement is in force, other than a dispute or difference relating to (i) the interpretation of any provision of this Agreement, (ii) the interpretation or application of law, or (iii) the ownership of any intellectual property, then any Party may forthwith give notice to the

other Parties that it wishes such dispute or difference to be referred to the Chief Executive Officer of Sheffield and the President of Elan Pharmaceutical Technology, a division of Elan Corporation, Plc ("EPT").

19.2 In any event of a notice being served in accordance with Clause 19.1, each of the Participants shall within 14 days of the service of such notice prepare and circulate to the chief executive officer of each Participant a memorandum or other form of statement setting out its

position on the matter in dispute and its reasons for adopting that position. Each memorandum or statement shall be considered by the chief executive officers of the Participants who shall endeavor to resolve the dispute. If the chief executive officers of the Participants agree upon a resolution or disposition of the matter, they shall each sign a statement which sets out the terms of their agreement. The Participants agree that they shall exercise the voting rights and other powers available to them in relation to Newco to procure that the agreed terms are fully and promptly carried into effect.

19.3 In the event the chief executive officers of the Participants are unable to resolve a dispute or difference when it is referred to them under Clause 19.1 which relates to the interpretation of this Agreement or any other Transaction Document or the compliance of the Parties with their legal obligations thereunder, such dispute or difference shall be referred to arbitration in accordance with Clause 24.8.3 hereof. If the dispute or difference does not relate to the interpretation of this Agreement or any other Transaction Document or the compliance of the Parties with their legal obligations thereunder, the provisions of Clause 24.8.2 shall govern.

CLAUSE 20

TERMINATION

20.1 This Agreement shall govern the operation and existence of Newco until

20.1.1 terminated by written agreement of all Parties hereto or

20.1.2 otherwise terminated in accordance with this Clause 20.

20.2 For the purpose of this Clause 20, a "Relevant Event" is committed or suffered by a Participant if:

20.2.1 [REDACTED]

20.2.2 [REDACTED]

20.2.3 [REDACTED]

20.2.4 [REDACTED]

20.2.5 [REDACTED]

20.2.6 [REDACTED]

20.4 If either Participant commits or suffers a Relevant Event, the other Participant shall be entitled, within three months of the occurrence of the Relevant Event, to require the defaulting Participant (the "Recipient Participant") to sell on reasonable terms of payment to the non-defaulting Participant (the "Proposing Participant") all (but not some only) of the Shares, held or beneficially owned by the Recipient

Participant for an amount equal to [REDACTED] of the fair market value of the Shares of the Recipient Participant (the "Buyout Option").

20.5 The Proposing Participant shall notify the Recipient Participant of the exercise of the Buyout Option, no later than 30 business days prior to the proposed exercise thereof, by delivering written notice to the Recipient Participant stating that the Buyout Option is exercised and the price at which the Proposing Participant is willing to purchase the Shares of the Recipient Participant.

20.6 In the event that the Participants do not agree upon a purchase price for the Shares within five Business Days following the receipt by the Recipient Participant of written notice from the Proposing Participant pursuant to Clause 20.5 above, the Proposing Participant may contact the American Arbitration Association ("AAA"), sitting in New York City and request that an independent US-based arbitrator who is expert in the pharmaceutical/biotechnology industry be appointed within 10 Business Days. The AAA shall endeavor to select an arbitrator who is technically knowledgeable in the pharmaceutical/biotechnology industry

(and who directly and through his affiliates, has no business relationship with, or shareholding in, either the Proposing Participant or the Recipient Participant). Promptly upon being notified of the arbitrator's appointment, the Proposing Participant and the Recipient Participant shall submit to the arbitrator details of their assessment of the fair market value for the Shares of the Recipient Participant together with such information as they think necessary to validate their assessment. The arbitrator shall notify the Recipient Participant of [REDACTED] of the fair market value assessed by the Proposing Participant (the "Proposing Participant Price") and shall notify the Proposing Participant of [REDACTED] of the fair market value assessed by the Recipient Participant (the "Recipient Participant Price"). The Proposing Participant and the Recipient Participant shall then be entitled to make further submissions to the arbitrator within five Business Days explaining why the Recipient Participant Price or the Proposing Participant Price, as the case may be, is unjustified. The arbitrator shall thereafter meet with the Proposing Participant and the Recipient Participant and shall thereafter choose either the Recipient Participant Price or the Proposing Participant Price (but not any other price) as the purchase price for the Shares (the "Purchase Price") on the basis of which price the Expert determines to be closer to [REDACTED] of the fair market value for the Shares of the Recipient Participant. The arbitrator shall use his best efforts to determine the Purchase Price within 30 Business Days of his appointment. The Proposing Participant and the Recipient Participant shall bear the costs of the arbitrator equally provided that the arbitrator may, in his discretion, allocate all or a portion of such costs to one Party. Any decision of the arbitrator shall be final and binding.

20.7 The Proposing Participant shall purchase the Shares of the Recipient Participant by delivery of the Purchase Price in cash no later than the 15th Business Day following determination of the Purchase Price by the

Expert.

20.8 The Shares of the Recipient Participant so transferred shall be sold by the transferor as beneficial owner with effect from the date of such transfer free from any lien, charge or encumbrance with all rights and restrictions attaching thereto. If the Proposing Participant elects to purchase the Shares of the Recipient Participant, the Shares of the Recipient Participant shall be sold by the Recipient Participant as beneficial owner for a price equal to [REDACTED] of the Purchase Price with effect from the date specified by the Proposing Participant in its notice of election free from any lien, charge or encumbrance together with all rights attaching thereto.

20.9 If the Proposing Participant exercises the Buyout Option, both parties will negotiate in good faith to agree to additional reasonable provisions and/or amendments to the License Agreements to protect the intellectual property rights of the Recipient Party.

20.10 If either Participant commits a Relevant Event, the other Stockholder shall have in addition to all other legal and equitable rights and remedies hereunder, the right to terminate this Agreement upon 30 days' written notice.

20.11 In the event of a termination of the Elan License Agreement and/or the Sheffield License Agreement, both parties will negotiate in good faith to determine whether this Agreement should be terminated and if so, which provisions should survive termination.

20.12 The provisions of Clauses 1.1, 18, 19, 20 and 22 shall survive the termination of this Agreement under this Clause 20.10 or by mutual consent pursuant to Clause 20.1 in accordance with their terms; all other terms and provisions of this Agreement shall cease to have effect and be null and void upon the termination of this Agreement under this Clause 20.10 or by mutual consent pursuant to Clause 20.1.

CLAUSE 21

SHARE RIGHTS

The following is a summary of the terms of the capital stock of Newco. This summary does not purport to be complete and is qualified in all respects by reference to the Newco By-laws, which are hereby incorporated by reference.

Each share of Common Stock is entitled to one vote on all matters on which the stockholders of Newco are entitled to vote. Subject to the Bermuda Companies Act of 1981 (or any successor legislation), shares of Preferred Stock shall not be entitled to vote on any matters brought before the shareholders of Newco. At any time after to the second anniversary of the date hereof each share of Preferred Stock may be converted into shares of Common Stock at a one-for-one ratio, subject to adjustment for stock splits, stock dividends and similar events. The Preferred Stock and the Common Stock rank pari passu with respect to

the payment of dividends, which shall be paid to the holders thereof on a pro rata basis. Upon any liquidation, dissolution or winding up of Newco or the sale of substantially all of the assets of Newco, or the merger of Newco with and into another Person, the Preferred Stock shall rank prior to the Common Stock and the holders of Preferred Stock shall be entitled to be paid, prior to any distribution to any holders of Common Stock, an amount in cash equal the aggregate purchase price paid by the Stockholders for the Preferred Stock, pursuant to Clause 4.41 hereof.

CLAUSE 22

CONFIDENTIALITY

22.1 The Parties and/or Newco acknowledge and agree that it may be necessary, from time to time, to disclose to each other confidential and/or proprietary information, including without limitation, inventions, works of authorship, trade secrets, specifications, designs, data, know-how and other information, relating to the Combined Fields, the Products, present or future products, the Newco Intellectual Property, the Elan Intellectual Property or the Sheffield Intellectual Property, as the case may be, methods, compounds, research

projects, work in process, services, sales suppliers, customers, employees and/or business of the disclosing Party, whether in oral, written, graphic or electronic form (collectively "Confidential Information").

22.2 Any Confidential Information revealed by a Party to another Party shall be maintained as confidential and shall be used by the receiving Party exclusively for the purposes of fulfilling the receiving Party's rights and obligations under this Agreement, and for no other purpose. Confidential Information shall not include:

22.2.1 information that is generally available to the public;

22.2.2 information that is made public by the disclosing Party;

22.2.3 information that is independently developed by the receiving Party, as evidenced by such Party's records, without the aid, application or use of the disclosing Party's Confidential Information;

22.2.4 information that is published or otherwise becomes part of the public domain without any disclosure by the receiving Party, or on the part of the receiving Party's directors, officers, agents, representatives or employees;

22.2.5 information that becomes available to the receiving Party on a non-confidential basis, whether directly or indirectly, from a

source other than the disclosing Party, which source did not acquire this information on a confidential basis; or

22.2.6 information which the receiving Party is required to disclose pursuant to:

(i) a valid order of a court or other governmental body or any political subdivision thereof or as otherwise required by law, rule or regulation; or

(ii) other requirement of law;

provided, however, that if the receiving Party becomes legally required to disclose any Confidential Information, the receiving Party shall give the disclosing Party prompt notice of such fact so that the disclosing Party may obtain a protective order or confidential treatment or other appropriate remedy concerning any such disclosure. The receiving Party shall fully co-operate with the disclosing Party in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving Party shall make such disclosure only to the extent that such disclosure is legally required; or

22.2.7 information which was already in the possession of the receiving Party at the time of receiving such information, as evidenced by its records, provided such information was not previously provided to the receiving party from a source which was under an obligation to keep such information confidential; or

22.2.8 information that is the subject of a written permission to disclose, without restriction or limitation, by the disclosing Party.

22.3 Each Party agrees to disclose Confidential Information of another Party only to those employees, representatives and agents requiring knowledge thereof in connection with their duties directly related to the fulfilling of the Party's obligations under this Agreement, so long as such persons are under an obligation of confidentiality no less stringent than as set forth herein. Each Party further agrees to inform all such employees, representatives and agents of the terms and provisions of this Agreement and their duties hereunder and to obtain their consent hereto as a condition of receiving Confidential Information. Each Party agrees that it will exercise a reasonable degree of care and protection to preserve the proprietary and confidential nature of the Confidential Information disclosed by a Party. Each Party agrees that it will, upon request of another Party, return all documents and any copies thereof containing Confidential Information belonging to or disclosed by such other Party. Each Party shall promptly notify the other Parties upon discovery of any unauthorized use or disclosure of the other Parties' Confidential Information.

22.4 Notwithstanding the above, each Party may use or disclose Confidential Information disclosed to it by another Party to the extent such use or disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, complying with patent applications, prosecuting or defending litigation, complying with applicable governmental regulations or otherwise submitting information to tax or other governmental authorities, conducting clinical trials, or granting a permitted sub-license or otherwise exercising its rights hereunder; provided, that if a Party is required to make any such disclosure of the other Party's Confidential Information, other than pursuant to a confidentiality agreement, such Party shall inform the third party recipient of the terms and provisions of this Agreement and their duties hereunder and shall obtain their commitment to abide by the confidentiality provisions of this Clause 22 as a condition of releasing to the third party recipient the Confidential Information.

22.5 Any breach of this Clause 22 by any employee, representative or agent of a Party is considered a breach by the Party itself.

22.6 The provisions relating to confidentiality in this Clause 22 shall remain in effect during the Term and for a period of seven years following the termination of this Agreement.

22.7 The Parties agree that the obligations of this Clause 22 are necessary and reasonable in order to protect the Parties' respective businesses, and each Party expressly agrees that monetary damages would be inadequate to compensate a Party for any breach by the other Party of its covenants and agreements set forth herein. Accordingly, the Parties agree and acknowledge that any such violation or threatened violation will cause irreparable injury to a Party and that, in addition to any other remedies that may be available, in law or in equity or otherwise, any Party shall be entitled to obtain injunctive relief against the threatened breach of the provisions of this Clause 22, or a continuation of any such breach by the other Party, specific performance and other equitable relief to redress such breach together with its damages and reasonable counsel fees and expenses to enforce its rights hereunder, without the necessity of proving actual or express damages.

CLAUSE 23

COSTS

22.1 Each Stockholder shall bear its own legal and other costs incurred in relation to preparing and concluding this Agreement and the Transaction Documents.

22.2 All other costs, legal fees, registration fees and other expenses relating to the transactions contemplated hereby, including the costs and expenses incurred in relation to the incorporation of Newco, shall be borne by Newco.

CLAUSE 24

GENERAL

24.1 Good Faith:

Each of the Parties hereto undertakes with the others to do all things reasonably within its power that are necessary or desirable to give effect to the spirit and intent of this Agreement.

24.2 Further Assurance:

At the request of any of the Parties, the other Party or Parties shall (and shall use reasonable efforts to procure that any other necessary parties shall) execute and perform all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting Party the full benefit of the terms hereof.

24.3 No Representation:

Each of the Parties hereto hereby acknowledges that in entering into this Agreement it has not relied on any representation or warranty except as expressly set forth herein or in any document referred to herein.

24.4 Force Majeure:

Neither Party to this Agreement shall be liable for delay in the performance of any of its obligations hereunder if such delay is caused by or results from causes beyond its reasonable control, including without limitation, acts of God, fires, strikes, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances or intervention of any relevant government authority, but any such delay or failure shall be remedied by such Party as soon as practicable.

24.5 Relationship of the Parties:

Nothing contained in this Agreement is intended or is to be construed to constitute Elan/EIS and Sheffield as partners, or Elan/EIS as an employee or agent of Sheffield, or Sheffield as an employee or agent of Elan/EIS.

No Party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of another Party or to bind another Party to any contract, agreement or undertaking with any third Party.

24.6 Counterparts:

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

24.7 Notices:

Any notice to be given under this Agreement shall be sent in writing by registered or recorded delivery post or reputable overnight courier such as Federal Express or telecopied to:

Elan/EIS at:

Lincoln House, Lincoln Place, Dublin 2, Ireland
Attention: Vice President & General Counsel
Elan Pharmaceutical Technologies,
a division of Elan Corporation, plc
Telephone: 353-1-709-4000
Fax: 353-1-709-4124

and

Elan International Services, Ltd.
102 St. James Court
Flatts, Smiths FL04
Bermuda
Attention: President
Telephone: 441-292-9169
Fax: 441-292-2224

Sheffield at:

Sheffield Pharmaceuticals Inc.
425 South Woodsmill Road
St. Louis, MO 63017
Attention: President
Telephone: 314-579-9899
Fax: 314-579-9799

and

3136 Winton Road, Suite 306
Rochester, NY 14623
Attention: Chairman
Telephone: 716-292-0310
Fax: 716-292-0522

with a copy to:

Daniel J. Gallagher, Esq.
Olshan, Grundman, Frome, Rosenzweig & Wolosky LLP
505 Park Avenue
New York, NY 10022
Telephone: 212-753-7200

Fax: 212-935-1787

Newco at:

102 St. James Court
Flatts, Smiths FL04
Bermuda
Attention: Secretary
Telephone: 441-292-9169
Fax: 441-292-2224

and to

Clarendon House
2 Church St.
Hamilton, Bermuda

or to such other address(es) as may from time to time be notified by any Party to the others hereunder.

Any notice sent by mail shall be deemed to have been delivered within three Business Days after dispatch or delivery to the relevant courier and any notice sent by telecopy shall be deemed to have been delivered upon confirmation of receipt. Notices of change of address shall be effective upon receipt. Notices by telecopy shall also be sent by another method permitted hereunder.

24.8 Governing Law; Arbitration

24.8.1. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

24.8.2. The Parties will attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between executives of the Parties. In the event that such negotiations do not result in a mutually acceptable resolution, the Parties agree to consider other dispute resolution mechanisms including mediation.

24.8.3 Any dispute under this Agreement which is not settled by mutual consent under Clause 24.8.2 shall be finally settled by binding arbitration, conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association by one arbitrator appointed in accordance with said rules. Such arbitrator shall be reasonably satisfactory to each of the Parties; provided, that if the Parties are unable to agree upon the identity of such arbitrator within 15 days of demand by either Party, then either Party shall have the right to petition a presiding justice of the Supreme Court of New York, New York County, to appoint an arbitrator.

The arbitration shall be held in New York, New York and the arbitrator shall be an independent expert in pharmaceutical product development and marketing (including clinical development and regulatory affairs).

The arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery; provided the arbitrator shall permit such discovery as they deem necessary to permit an equitable resolution of the dispute.

Any written evidence originally in a language other than English shall be submitted in English translation accompanied by the original or a true copy thereof.

The costs of the arbitration, including administrative and arbitrators' fees, shall be shared equally by the Parties and each Party shall bear its own costs and attorneys' and witness' fees incurred in connection with the arbitration.

In rendering judgement, the arbitrator shall be instructed by the Parties that he shall be permitted to select solely from between the proposals for resolution of the relevant issue presented by each Party, and not any other proposal.

A disputed performance or suspended performances pending the resolution of the arbitration must be completed within 30 days following the final decision of the arbitrators or such other reasonable period as the arbitrators determine in a written opinion.

Any arbitration under this Agreement shall be completed within one year from the filing of notice of a request for such arbitration.

The arbitration proceedings and the decision shall not be made public without the joint consent of the Parties and each Party shall maintain the confidentiality of such proceedings and decision unless otherwise permitted by the other Party.

The Parties agree that the decision shall be the sole, exclusive and binding remedy between them regarding any and all disputes, controversies, claims and counterclaims presented to the arbitrators. Application may be made to any court having jurisdiction over the Party (or its assets) against whom the decision is rendered for a judicial recognition of the decision and an order of enforcement.

24.9 Severability:

If any provision in this Agreement is agreed by the Parties to be, deemed to be or becomes invalid, illegal, void or unenforceable under

any law that is applicable hereto, such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the Parties, it will be deleted, with effect from the date of such agreement or such earlier date as the Parties may agree, and the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

24.10 Amendments:

No amendment, modification or addition hereto shall be effective or binding on any Party unless set forth in writing and executed by a duly authorized representative of all Parties.

24.11 Waiver:

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the Party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

24.12 Assignment:

None of the Parties shall be permitted to assign its rights or obligations hereunder without the prior written consent of the other Parties except as follows (in which case, written notice shall be delivered by the assigning Party to the other Parties):

24.12.1 Elan, EIS and/or Sheffield shall have the right to assign their rights and obligations hereunder to their Affiliates provided, however, that such assignment does not result in adverse tax consequences for any other Parties.

24.12.2 Elan and EIS shall have the right to assign their rights and obligations hereunder to any Affiliate. Each assignee must comply with the representations and warranties in clause 3.5 hereof.

24.13 Whole Agreement/No Effect on Other Agreements:

This Agreement (including the Schedules attached hereto) and the Transaction Documents set forth all of the agreements and understandings between the Parties with respect to the subject matter hereof, and supersedes and terminates all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no agreements or understandings with respect to the subject matter hereof, either oral or written, between the Parties other than as set forth in this Agreement and the Transaction Documents.

In the event of any ambiguity or conflict arising between the terms of

this Agreement and those of the Newco Bye-Laws, the terms of this Agreement shall prevail, except with respect to Clause 21, in which case the terms of the Newco Bye-laws shall govern.

No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between any of the Parties unless specifically referred to, and solely to the extent provided herein. In the event of a conflict between the provisions of this Agreement and the provisions of the License Agreements, the terms of this Agreement shall prevail unless this Agreement specifically provide otherwise.

24.14 Successors:

This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their successors and permitted assigns.

SCHEDULE 1

ELAN LICENSE AGREEMENT

SCHEDULE 2

SHEFFIELD LICENSE AGREEMENT

SCHEDULE 3

TECHNOLOGICAL COMPETITORS OF ELAN

[REDACTED]

SCHEDULE 4

TECHNOLOGICAL COMPETITORS OF SHEFFIELD

[REDACTED]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the day first set forth above.

SIGNED

BY:/s/
---
for and on behalf of
ELAN PHARMA INTERNATIONAL LTD.
in the presence of:_____

SIGNED

BY:/s/
---

for and on behalf of
ELAN INTERNATIONAL SERVICES, LTD.
in the presence of:_____

SIGNED

BY:/s/
---

for and on behalf of
SHEFFIELD PHARMACEUTICALS, INC.
in the presence of:_____

SIGNED

BY:/s/
---

for and on behalf of
SHEFFIELD NEWCO, LTD.
in the presence of:_____

LICENSE AGREEMENT

BETWEEN

SHEFFIELD PHARMACEUTICALS, INC.

AND

SHEFFIELD NEWCO LIMITED

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THIS AGREEMENT made this 19 October 1999

between:

(1) Sheffield Pharmaceuticals, Inc., a corporation duly incorporated and validly existing under the laws of Delaware and having its principal place of business at 425 S. Woodsmill Road, Suite 270, St. Louis, MO 63017, USA("Sheffield");

(2) Newco Limited, a private limited company incorporated under the laws of Bermuda and having its registered office at Clarendon House, 2 Church Street, Hamilton, Bermuda ("Newco"); and

(3) Elan Pharma International Limited incorporated under the laws of Ireland, and having its registered office at WIL House, Shannon Business Park, Shannon, County Clare, Ireland ("EPIL").

RECITALS:

A. Simultaneously herewith, Sheffield, Elan, EIS, and Newco are entering into the JDOA for the purpose of recording the terms and conditions of the joint venture and of regulating their relationship with each other and certain aspects of the affairs of, and their dealings with Newco.

B. Newco desires to enter into this Agreement with Sheffield so as to permit Newco to utilize the Sheffield Intellectual Property in making, having made, importing, using, offering for sale and selling the Products in Field B and Formulations in Field C in the Territory in accordance with the terms of this Agreement.

C. Simultaneously herewith Newco and EPIL are entering into the Elan License Agreement relating to Newco's use of the Elan Intellectual Property.

1 DEFINITIONS

1.1 In this Agreement unless the context otherwise requires:

"Affiliate" shall mean any corporation or entity controlling, controlled or under the common control of Elan or Sheffield, as the case may be, excluding Systemic Pulmonary Delivery Ltd.. For the purpose of this definition, "control" shall mean direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors. Newco is not an Affiliate of Sheffield.

"Agreement" shall mean this license agreement (which expression shall be deemed to include the Recitals and Schedules hereto).

"Business Plan" shall have the meaning, as such term is defined in the JDOA.

"Combined Fields" shall mean Field A, Field B and Field C.

"Compounds" shall mean the Field A Compound, the Field B Compound and/or the Field C Compound.

"Confidential Information" shall have the meaning, as such term is defined in Clause 9.

"Definitive Documents" shall mean the definitive agreements relating to the transaction including finance, stock purchase, research and license agreements.

"Elan" shall mean EPIL and Affiliates and subsidiaries of Elan Corporation, Plc. within the division of Elan Corporation, Plc. carrying on business as Elan Pharmaceutical Technologies but shall not include Affiliates and subsidiaries (present or future) of Elan Corporation Plc within the division of Elan Corporation, Plc carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

"EIS" shall mean Elan International Services, Limited, a private limited company incorporated under the laws of Bermuda and having its registered office at St James Court, Flatts, Smiths, FL04 Bermuda.

"Effective Date" shall mean the date of this Agreement.

"Elan Intellectual Property" shall mean the Elan Know-How, the Elan Patents and the Elan Improvements, as such terms are defined in the Elan License Agreement.

"Elan Patents" shall have the meaning as such term is defined in the Elan License Agreement.

"Elan Improvements" shall have the meaning as such term is defined in the Elan License Agreement.

"Elan Licenses" shall have the meaning set forth in Clause 2.1 of the Elan License Agreement.

"Elan License Agreement" shall mean that certain license agreement, of even date herewith, entered into between Elan and Newco.

"Field A" shall mean the topical pulmonary delivery of Formulations of the Field A Compound by means of the Field A Device.

"Field B" shall mean the topical pulmonary delivery of Formulations of the Field B Compound by means of the Field B Device.

"Field C" shall mean the topical pulmonary delivery of Formulations of the Field C Compound by means of the Field C Device.

"Field A Device" shall mean a third party table top unit dose nebulizer having a reservoir capable of holding a unit dose (a device and the compressor to nebulize a unit dose shall be deemed a device), which is a device having any one the following characteristics:

(i) [REDACTED]

(ii) [REDACTED]

(iii) [REDACTED]

(iv) [REDACTED]

(v) [REDACTED]

For the avoidance of doubt, the Field A Device does not include [REDACTED].

"Field B Device" shall mean the Aerosol Drug Delivery System ("ADDS"), owned by Systemic Pulmonary Delivery Limited and exclusively licensed to Sheffield for topical pulmonary applications.

"Field C Device" shall mean the handheld multi-dose nebulizer ("MSI") which was licensed exclusively by Siemens to Sheffield pursuant to the Siemens Agreements and which was subsequently sub-licensed by Sheffield to Zambon (on an exclusive basis for delivery of various medicines for humans in treating respiratory disease and/or other lung diseases including, but not limited to, anti-infectives) provided that Newco, through the Management Committee, is successful in obtaining a sub-license from Zambon to Newco enabling the development and use of the Field C Compound for use with the Field C Device , as described in more detail in Clause 2.2.

"Field A Compound" shall mean [REDACTED].

"Field B Compound" shall mean [REDACTED] for therapeutic use to be nominated by the Management Committee pursuant to the JDOA and with reference to the JDOA, any Substitute Field B Compound.

"Field C Compound" shall mean [REDACTED] and with reference to the JDOA, any Substitute Field C Compound and/or any Additional Field C Compound.

"Financial Year" shall mean each year commencing on 1 January (or in the case of the first Financial Year, the Effective Date) and expiring on 31 December of each year.

"Formulations" shall mean Nanocrystal(TM) Technology formulations of Compounds for use in Field A, Field B or Field C, as applicable.

"JDOA" shall mean that certain joint development and operating agreement, of even date herewith, by and between Elan, Sheffield, EIS

and Newco.

"Licensed Technologies" shall mean the Elan Intellectual Property and the Sheffield Intellectual Property.

"Licenses" shall mean the Elan License and the Sheffield License.

"Management Committee" shall have the meaning, as such term is defined in the JDOA.

"Nanocrystal(TM) Technology" shall mean the Elan proprietary technology directed to nanoparticulate formulations of compounds used in the manufacturing and/or formulation process, and methods of making the same.

"Newco Intellectual Property" shall mean all rights to patents, know-how and other intellectual property arising out of the conduct of the Project by any person, including any technology acquired by Newco from a third party, that does not constitute Elan Intellectual Property or Sheffield Intellectual Property.

"Newco Patents" shall mean any and all patents now existing, currently pending or hereafter filed or obtained relating to the Newco Intellectual Property, and any foreign counterparts thereof and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"Party" shall mean Sheffield or Newco, as the case may be, and "Parties" shall mean Sheffield and Newco.

"Products" shall mean the Field A Products, the Field B Products and/or the Field C Products, as follows:

"Field A Products" shall mean Formulations of the Field A Compound delivered by means of any Field A Device in Field A.

"Field B Products" shall mean Formulations of the Field B Compound delivered by means of the Field B Device in Field B.

"Field C Products" shall mean Formulations of the Field C Compound delivered by means of the Field C Device in Field C.

"Project" shall mean all activities as undertaken by Elan, Sheffield and Newco in order to develop the Products.

"R&D Committee" shall have the meaning, as such term is defined in the JDOA.

"R&D Plan" shall have the meaning, as such term is defined in the JDOA.

"R&D Program" shall mean any research and development program commenced

by Newco pursuant to the Project.

"Sheffield" shall mean Sheffield Pharmaceuticals, Inc and its Affiliates, excluding Newco.

"Sheffield Devices" shall mean the Field B Device and the Field C Device.

"Sheffield Intellectual Property" shall mean the Sheffield Know-How, the Sheffield Patents and the Sheffield Improvements.

"Sheffield Know-How" shall mean any and all rights owned, licensed or controlled by Sheffield to any discovery, invention (whether patentable or not), know-how, substances, data, techniques, processes, systems, formulations and designs relating exclusively to the Sheffield Devices.

"Sheffield Licenses" shall have the meaning set forth in Clause 2.1.

"Sheffield Patents" shall mean any and all rights under any and all patents applications and/or patents, now existing, currently pending or hereafter filed or obtained by Sheffield relating to the Sheffield Devices and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"Sheffield Improvements" shall mean improvements relating to the Sheffield Patents and/or the Sheffield Know-How, developed (i) by Sheffield whether or not pursuant to the Project, (ii) by Newco or Elan or by a third party (under contract with Newco) whether or not pursuant to the Project, and/or (iii) jointly by any combination of Sheffield, Elan or Newco pursuant to the Project, except as limited by agreements with third Parties.

Subject to third party agreements, Sheffield Improvements shall constitute part of Sheffield Intellectual Property and be included in the license of the Sheffield Intellectual Property pursuant to Clause 2.1 solely for the purposes set forth therein. If the inclusion of a Sheffield Improvement in the license of Sheffield Intellectual Property is restricted or limited by a third party agreement, Sheffield shall use reasonable commercial efforts to minimize any such restriction or limitation.

"Siemens" shall mean Siemens Aktiengesellschaft.

"Siemens Agreements" shall mean the License Agreement dated 21 March 1997 and the Basic Supply Agreement dated 21 March 1997, both between Sheffield Medical Technologies Inc. and Siemens Aktiengesellschaft.

"Technological Competitor of Sheffield" shall mean a company, corporation or person listed in Schedule 1 and successors thereof or

any additional broad-based technological competitor of Sheffield added to such Schedule 1 from time to time upon mutual agreement of the Parties.

"Term" shall have the meaning set forth in Clause 8.

"Territory" shall mean all the countries of the world.

"United States Dollar" and "US$" shall mean the lawful currency for the time being of the United States of America.

"Zambon" shall mean Inpharzam International, S.A.

"Zambon Agreement" shall mean the agreement dated 15 June 1998 between Sheffield and Zambon.

1.2 In this Agreement:

1.2.1 The singular includes the plural and vice versa, and the masculine includes the feminine and vice versa and the neuter includes the masculine and the feminine.

1.2.2 Any reference to a Clause or Schedule shall, unless otherwise specifically provided, be to a Clause or Schedule of this Agreement.

1.2.3 The headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

2. SHEFFIELD LICENSE TO NEWCO

2.1. Sheffield hereby grants to Newco for the Term the following licenses:

2.1.1 a non-exclusive license (including the right to grant sublicenses subject to the limitations of Clause 2.7) of the Sheffield Intellectual Property solely to make, have made, import, use, offer for sale and sell the Field B Products in the Territory in Field B;

2.1.2 subject to the execution by Newco of a written sub-license with Zambon as more fully described in Clause 2.2 for the development by Newco of the Field C Formulations in accordance with Clause 2.2, a non-exclusive license (including the right to grant sublicenses subject to the limitations of Clause 2.7 and the Zambon Agreement) of the Sheffield Intellectual Property solely to make and have made, import, use, offer for sale and sell the Field C Products in the Territory in Field C

(the "Sheffield Licenses").

2.2 On the date which is [REDACTED] days following the Effective Date, or such extended date as may be agreed in writing by Elan and Newco pursuant to Clause 2.2 of the Elan License Agreement, Sheffield shall,

at its sole discretion, be entitled forthwith to terminate the license to Newco described in Clause 2.1.2, upon notice in writing to Newco, in the event that Newco has not, prior to such date, executed a written sub-license with Zambon for the development by Newco of the Field C Formulations in Field C.

Sheffield shall use reasonable commercial efforts to procure that Zambon executes such written sub-license with Newco in a timely manner and in any event within 180 days following the Effective Date, or such extended date as may be agreed in writing by Elan and Newco pursuant to Clause 2.2 of the Elan License Agreement.

Such written sub-license will be subject to the approval of the Management Committee and will include authority from Zambon to Newco to the extent necessary for Newco to develop, make, have made and use the Field C Formulations in the Territory, general financial terms, development schedule, and terms governing the funding by Zambon of any R&D Program(s) in Field C, together with such other substantive issues as the Management Committee shall deem appropriate and customary terms.

For the avoidance of doubt, to the extent royalty or other compensation obligations are payable to Zambon in respect of any license or sub-license from Zambon to Newco of intellectual property rights necessary for Newco to develop, make, have made and use the Field C Formulations in the Territory, Sheffield shall be responsible for same and shall indemnify Newco in respect of any such royalty or other compensation obligations payable to Zambon.

2.3 Sheffield shall be responsible for payments related to the financial provisions and obligations of any third party agreement with respect to the Sheffield Intellectual Property to which it is a party on the Effective Date (including amendments thereto) (the "Sheffield Effective Date Agreements"), including without limitation, any royalty or other compensation obligations triggered thereunder on the Effective Date, or triggered thereunder after the Effective Date.

For the avoidance of doubt, royalties, milestones or other payments which arise from the process of the commercialization or exploitation of products under the Sheffield Effective Date Agreements (for example, a milestone payment payable upon successful completion of Phase II clinical trials, the filing of an NDA application, obtaining NDA approval, or first commercial sale) shall be payments for which Sheffield will be responsible under this Clause 2.1.

2.4 Subject to Sheffield's obligations and indemnity set forth in Clause 2.2 to the extent royalty or other compensation obligations are payable to Zambon in respect of any license or sub-license from Zambon to Newco of intellectual property rights necessary for Newco to develop, make, have made and use the Field C Formulations in the Territory, to the extent royalty or other compensation obligations that are payable to third parties with respect to the Sheffield Intellectual Property would

be triggered after the Effective Date under any third party agreement

entered into by Sheffield after the Effective Date (the "Sheffield Post-Effective Date Agreements"), by a proposed use of such Sheffield Intellectual Property in connection with the Project, Sheffield will inform Newco of such royalty or compensation obligations. If Newco agrees to utilise such Sheffield Intellectual Property in connection with the Project, Newco will be responsible for the payment of such royalty or other compensation obligations relating thereto.

For the avoidance of doubt, royalties, milestones or other payments which arise from the process of the commercialization or exploitation of products under the Sheffield Post-Effective Date Agreements (for example, a milestone payment payable upon successful completion of Phase II clinical trials, the filing of an NDA application, obtaining NDA approval, or first commercial sale) shall be payments for which Newco will be responsible under this Clause 2.4.

2.5 Elan shall be a third party beneficiary under this Agreement and shall have the right to cause Newco to enforce Newco's rights under this Agreement against Sheffield.

2.6 Notwithstanding anything contained in this Agreement to the contrary, Sheffield shall have the right outside the Field B and Field C and subject to the non-competition provisions of Clause 4 to exploit and grant licenses and sublicenses of the Sheffield Intellectual Property.

For the avoidance of doubt, Newco shall have no right to use the Sheffield Intellectual Property outside Field B or Field C.

2.7 Newco shall not be permitted to assign or sublicense any of its rights under the Sheffield Intellectual Property without the prior written consent of Sheffield, which consent shall not be unreasonably withheld or delayed provided that Sheffield shall in all cases, in its sole discretion, be entitled to withhold its consent in the case of a proposed sublicense to any Technological Competitor to Sheffield.

2.8 Any agreement between Newco and any permitted third party for the development or exploitation of the Sheffield Intellectual Property shall require such third party to maintain the confidentiality of all information concerning the Sheffield Intellectual Property.

Insofar as the obligations owed by Newco to Sheffield are concerned, Newco shall remain responsible for all acts and omissions of any permitted sub-licensee, including Elan, as if they were acts and omissions by Newco.

3 INTELLECTUAL PROPERTY

3.1 Ownership of Intellectual Property:

3.1.1 Newco shall own the Newco Intellectual Property.

3.1.2 Sheffield shall own the Sheffield Intellectual Property.

3.2 Trademarks:

3.2.1 Sheffield hereby grants to Newco for the Term a non-exclusive, royalty free license in the Territory to use and display the Sheffield Trademarks to promote, offer for sale and sell the Products in Field B in the Territory and the following provisions shall apply as regards the use of the Sheffield Trademarks by Newco hereunder:

(1) Newco shall ensure that each reference to and use of an Sheffield Trademark by Newco is in a manner approved by Sheffield and accompanied by an acknowledgement, in a form approved by Sheffield, that the same is a trademark (or registered trademark) of Sheffield.

From time to time, upon the reasonable request of Sheffield, Newco shall submit samples of the Product to Sheffield or its duly appointed agent to ensure compliance with quality standards and specifications. Sheffield, or its duly appointed agent, shall have the right to inspect the premises of Newco where the Products are manufactured, held or stored, and Newco shall permit such inspection, upon advance notice at any reasonable time, of the methods and procedures used in the manufacture, storage and sale of the Product. Newco shall not sell or otherwise dispose of any Product under the Sheffield Trademarks that fails to comply with the quality standards and specifications referred to in this Clause 3.2, as determined by Sheffield.

(2) Newco shall not use an Sheffield Trademark in any way which might materially prejudice its distinctiveness or validity or the goodwill of Sheffield therein.

(3) The parties recognize that the Sheffield Trademarks have considerable goodwill associated therewith. Newco shall not use in relation to the Products any trademarks other than the Sheffield Trademarks (except the Elan Trademarks (as defined in the Elan License Agreement) licensed to Newco under the Elan License Agreement) without obtaining the prior consent in writing of Sheffield, which consent may not be unreasonably withheld. However, such use must not conflict with the use and display of the Sheffield Trademark and such use and display must be approved by Sheffield.

(4) Newco shall not use in the Territory any trademarks or trade names so resembling the Sheffield Trademark as to be likely to cause confusion or deception.

(5) Newco shall promptly notify Sheffield in writing of any alleged infringement or unauthorised use of which it

becomes aware by a third party of the Sheffield Trademarks and provide Sheffield with any applicable evidence of infringement or unauthorised use.

(6) Newco shall not be permitted to assign or sublicense any of its rights under the Sheffield Trademarks without the prior written consent of Sheffield, which consent shall not be unreasonably withheld or delayed.

3.2.2 Sheffield shall, at its expense and sole discretion, file and prosecute applications to register and maintain registrations of the Sheffield Trademarks in the Territory. Newco shall reasonably co-operate with Sheffield in such efforts. In the event Sheffield decides not to file or prosecute such Sheffield Trademark, Newco may request Sheffield to do the same at Newco's expense, and Sheffield shall file or prosecute such Sheffield Trademark at Newco's request and expense unless Sheffield believes such action is without merit.

3.2.3 Sheffield will be entitled to conduct all enforcement proceedings relating to the Sheffield Trademarks and shall at its sole discretion decide what action, if any, to take in respect to any enforcement proceedings of the Sheffield Trademarks or any other claim or counter-claim brought in respect to the use or registration of the Sheffield Trademarks. Any such proceedings shall be conducted at Sheffield's expense and for its own benefit. Newco and Sheffield shall reasonably cooperate with Sheffield in such efforts. In the event Sheffield decides not to engage in enforcement proceedings of the Sheffield Trademarks, Newco may request Sheffield to do the same at Newco's expense unless Sheffield believes the basis for such enforcement proceedings is without merit. In such a case, Sheffield shall have the sole discretion not to engage in any such enforcement proceedings

3.2.4 Save where Newco adopts its own mark under Clause 3.2.4, in the event Newco becomes aware that any Sheffield Trademark has been challenged by a third party in a judicial or administrative proceeding in a country in the Territory as infringing on the rights of a third party Newco shall promptly notify Sheffield in writing and Sheffield shall have the first right to decide whether or not to defend such allegations, or to adopt an alternative mark, or allow Newco to adopt an alternative mark. If Sheffield decides not defend the Sheffield Trademark, then Newco may request Sheffield to defend the Sheffield Trademark, at Newco's expense, unless such requested defense is reasonably believed by Sheffield to be unsubstantiated and without merit. In such a case, Sheffield may elect not to initiate defence proceedings.

3.2.5 Newco will have no ownership rights in respect of the Sheffield Trademarks or of the goodwill associated therewith, and Newco hereby acknowledges that, except as expressly provided in this Agreement, it shall not acquire any rights in

respect thereof and that all such rights and goodwill are, and will remain, vested in Sheffield.

3.2.6 Nothing in this Agreement shall be construed as a warranty on the part of Sheffield regarding the Sheffield Trademarks,

including without limitation, that use of the Sheffield Trademarks in the Territory will not infringe the rights of any third parties. Accordingly, Newco acknowledges and agrees that Sheffield makes no such warranty.

3.2.7 Sheffield assumes no liability to Newco or to any third parties with respect to the quality, performance or characteristics of any of the goods manufactured or sold by Newco under the Sheffield Trademarks pursuant to this Agreement.

4 NON-COMPETITION/AFTER ACQUIRED TECHNOLOGY

4.1 Subject to Clause 4.2 and Clause 8.6, during the period during which the license described in Clause 2.1.1 of the Elan License Agreement has not been terminated, Sheffield shall not, alone or in conjunction with a third party, develop or commercialize any unit dose steroid listed in Schedule 2 for topical pulmonary delivery using a Field A Device, subject to written agreements between Sheffield and unaffiliated third parties in effect on the Effective Date.

Sheffield hereby confirms that no such agreements are in effect on the date hereof between Sheffield and an unaffiliated third party.

4.2 If, after the Effective Date, Sheffield acquires know-how or patent rights relating to the Field A, Field B or Field C (in the case of Field C, subject to the Zambon Agreement), or acquires or merges with a third party entity that has know-how or patent rights relating to the Field A, Field B or Field C (in the case of Field C, subject to the Zambon Agreement), Sheffield shall offer to license such know-how and patent rights to Newco (subject to existing contractual obligations), on commercially reasonable terms on an arm's length basis for a reasonable period under the prevailing circumstances.

If Newco determines that Newco should not acquire such license, Sheffield shall be free to fully exploit such know-how and patent rights with the Sheffield Intellectual Property then licensed to Newco, whether inside or outside the Field A, Field B or Field C, as applicable, and to grant to third parties licenses and sublicenses with respect thereto.

5 FINANCIAL PROVISIONS

5.1 Royalties:

Prior to the commercialization of the Products, the Management Committee shall consider and if appropriate, determine reasonable royalties with respect to the commercialization of the Products by Newco that shall be payable by Newco to Elan and Sheffield, and shared by Elan and Sheffield equally.

At such time, the Management Committee will agree an appropriate definition of "Net Sales" as such term is used in this Agreement.

5.2 Payment of any royalties pursuant to Clause 5.1 shall be made quarterly in arrears during each Financial Year within 30 days after the expiry of the calendar quarter. The method of payment shall be by wire transfer to an account specified by Sheffield. Each payment made to Sheffield shall be accompanied by a true accounting of all Products sold by Newco's permitted sublicensees, if any, during such quarter.

Such accounting shall show, on a country-by-country and Product-by-Product basis, Net Sales (and the calculation thereof) and each calculation of royalties with respect thereto, including the calculation of all adjustments and currency conversions.

5.3 Newco shall maintain and keep clear, detailed, complete, accurate and separate records for a period of 3 years:

5.3.1 to enable any royalties on Net Sales that shall have accrued hereunder to be determined; and

5.3.2 to enable any deductions made in the Net Sales calculation to be determined.

5.4 All payments due hereunder shall be made in United States Dollars. Payments due on Net Sales of any Product for each calendar quarter made in a currency other than United States Dollars shall first be calculated in the foreign currency and then converted to United States Dollars on the basis of the exchange rate in effect on the last working day for such quarter for the purchase of United States Dollars with such foreign currency quoted in the Wall Street Journal (or comparable publication if not quoted in the Wall Street Journal) with respect to the currency of the country of origin of such payment, determined by averaging the rates so quoted on each business day of such quarter.

5.5 If, at any time, legal restrictions in the Territory prevent the prompt payment when due of royalties or any portion thereof, the Parties shall meet to discuss suitable and reasonable alternative methods of paying Sheffield the amount of such royalties. In the event that Newco is prevented from making any payment under this Agreement by virtue of the statutes, laws, codes or government regulations of the country from which the payment is to be made, then such payments may be paid by depositing them in the currency in which they accrue to Sheffield's account in a bank acceptable to Sheffield in the country the currency of which is involved or as otherwise agreed by the Parties.

5.6 Sheffield and Newco agree to co-operate in all respects necessary to take advantage of any double taxation agreements or similar agreements as may, from time to time, be available.

5.7 Any taxes payable by Sheffield on any payment made to Sheffield pursuant to this Agreement shall be for the account of Sheffield. If so required by applicable law, any payment made pursuant to this Agreement shall be made by Newco after deduction of the appropriate withholding tax, in which event the Parties shall co-operate to obtain the appropriate tax clearance as soon as is practicable. On receipt of such clearance, Newco shall forthwith arrange payment to Sheffield of the amount so withheld.

6 RIGHT OF INSPECTION AND AUDIT

6.1 Once during each Financial Year, or more often not to exceed quarterly as reasonably requested by Sheffield, Newco shall permit Sheffield or its duly authorised representatives, upon reasonable notice and at any reasonable time during normal business hours, to have access to inspect and audit the accounts and records of Newco and any other book, record, voucher, receipt or invoice relating to the calculation of the royalty payments on Net Sales submitted to Sheffield.

Any such inspection of Newco's records shall be at the expense of Sheffield, except that if any such inspection reveals a deficiency in the amount of the royalty actually paid to Sheffield hereunder in any Financial Year quarter of [REDACTED] or more of the amount of any royalty actually due to Sheffield hereunder, then the expense of such inspection shall be borne solely by Newco. Any amount of deficiency shall be paid promptly to Sheffield by Newco.

If such inspection reveals a surplus in the amount of royalties actually paid to Sheffield by Newco, Sheffield shall reimburse Newco the surplus within 15 days after determination.

6.2 In the event of any unresolved dispute regarding any alleged deficiency or overpayment of royalty payments hereunder, the matter will be referred to an independent firm of chartered accountants chosen by agreement of Sheffield and Elan for a resolution of such dispute. Any decision by the said firm of chartered accountants shall be binding on the Parties.

7 REPRESENTATIONS AND WARRANTIES

7.1 Sheffield represents and warrants to Newco and Elan, as of the Effective Date, as follows:

7.1.1 Sheffield has the right to grant the Sheffield Licenses subject to the Zambon Agreement in the case of the license described in Clause 2.1.2;

7.1.2 there are no agreements with any third parties that conflict with the Sheffield Licenses.

7.2 Sheffield further agrees and represents and warrants to Newco and Elan as follows:

7.2.1 as of the Effective Date, each of the Siemens Agreements is valid and in full force and effect;

7.2.2 as of the Effective Date, there are no existing or claimed defaults by Sheffield, and to Sheffield's best knowledge by

any other party, under any of the Siemens Agreements and no event, act or omission has occurred which (with or without notice, lapse of time or the happening or occurrence of any other event) would result in a default under the Siemens Agreements by Sheffield, or to Sheffield's best knowledge by any other party;

7.2.3 during the Term, Sheffield will fully comply with all of the terms and conditions of the Siemens Agreements. Sheffield will enforce its rights under the Siemens Agreements and save with the prior approval in writing of the Management Committee which shall not unreasonably be withheld, Sheffield will not assign its rights under the Siemens Agreements; and

7.2.4 during the Term, Sheffield will keep Newco and Elan fully informed with respect to Sheffield's transactions, arrangements and business under the Siemens Agreements that relate to Newco and/or the transactions contemplated hereunder, and Sheffield shall provide Newco and Elan with any written notices delivered by any party thereunder that relate to Newco and/or the transactions contemplated hereunder, or that may affect Newco.

7.3 During the Term, Sheffield shall not terminate, amend, modify, or waive any of its rights under the Siemens Agreements without the prior written consent of the Management Committee (by the unanimous vote of its members) provided, however, that such consent will not be required if such termination, amendment, modification, or waiver would not have a material adverse effect, individually or in the aggregate, on the financial condition, results of operation, business and/or assets of Newco.

7.4 Sheffield shall indemnify Newco and Elan against all costs claims and liabilities which may arise in any way in relation to or in connection with the Siemens Agreements and/or any sub-license agreement or agreements entered into by Newco pursuant to Clause 2.2.

7.5 In addition to any other indemnities provided for herein, Sheffield shall indemnify and hold harmless Newco and its Affiliates and their respective employees, agents, officers and directors from and against

any claims, losses, liabilities or damages (including reasonable attorney's fees and expenses) incurred or sustained by Newco arising out of or in connection with any:

7.5.1 breach of any representation, covenant, warranty or obligation by Sheffield hereunder; or

7.5.2 act or omission on the part of Sheffield or any of its respective employees, agents, officers and directors in the performance of this Agreement.

7.6 In addition to any other indemnities provided for herein, Newco shall indemnify and hold harmless Sheffield and its Affiliates and their respective employees, agents, officers and directors from and against any claims, losses, liabilities or damages (including reasonable attorney's fees and expenses) incurred or sustained by Sheffield arising out of or in connection with any:

7.6.1 breach of any representation, covenant, warranty or obligation by Newco hereunder; or

7.6.2 act or omission on the part of Newco or any of its agents or employees in the performance of this Agreement.

7.7 The Party seeking an indemnity shall:

7.7.1 fully and promptly notify the other Party of any claim or proceeding, or threatened claim or proceeding;

7.7.2 permit the indemnifying Party to take full care and control of such claim or proceeding;

7.7.3 co-operate in the investigation and defence of such claim or proceeding;

7.7.4 not compromise or otherwise settle any such claim or proceeding without the prior written consent of the other Party, which consent shall not be unreasonably withheld conditioned or delayed; and

7.7.5 take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceeding.

7.8 EXCEPT AS SET FORTH IN THIS CLAUSE 7, SHEFFIELD IS GRANTING THE LICENSES HEREUNDER ON AN "AS IS" BASIS WITHOUT REPRESENTATION OR WARRANTY WHETHER EXPRESS OR IMPLIED INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF THIRD PARTY RIGHTS, AND ALL SUCH WARRANTIES ARE EXPRESSLY DISCLAIMED.

7.9 EXCEPT AS SET FORTH IN CLAUSE 7.4, NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, SHEFFIELD AND NEWCO SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF

THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF PROFITS OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

8. TERM AND TERMINATION

8.1 The term of this Agreement shall commence as of the Effective Date and shall, subject to the rights of termination outlined in this Clauses 8, expire on a Product-by-Product basis and on a country-by-country basis on the last to occur of:

8.1.1 [REDACTED] years starting from the date of the first commercial sale of the Product in the country concerned; or

8.1.2 the date of expiration of the last to expire of the patents included in the Elan Patents and/or the Elan Improvements and/or the Sheffield Patents and/or the Elan Improvements that relate to the Product.

("the Term")

8.2 If either Party commits a Relevant Event, the other Party shall have, in addition to all other legal and equitable rights and remedies hereunder, the right to terminate this Agreement upon 30 days' prior written notice to the defaulting Party.

8.3 For the purpose of this Clause 8, a "Relevant Event" is committed or suffered by a Party if:

8.3.1 [REDACTED]

8.3.2 [REDACTED]

8.3.3 [REDACTED]

8.3.4 [REDACTED]

8.3.5 [REDACTED]

8.3.6 [REDACTED]

8.4 Sheffield shall be entitled to forthwith terminate this Agreement if Elan elects to terminate the Elan License Agreement under Clause 8.4 of the Elan License Agreement.

8.5 Upon expiration or termination of the Agreement:

8.5.1. any sums that were due from Newco to Sheffield on Net Sales in

the Territory or in such particular country or countries in the Territory (as the case may be) prior to the expiration or termination of this Agreement as set forth herein shall be paid in full within 60 days after the expiration or termination of this Agreement for the Territory or for such particular country or countries in the Territory (as the case may be);

8.5.2 any provisions that expressly survive termination or expiration of this Agreement, including without limitation this Clause 8, shall remain in full force and effect;

8.5.3 all representations, warranties and indemnities shall insofar as are appropriate remain in full force and effect;

8.5.4 the rights of inspection and audit set out in Clause 6 shall continue in force for a period of one year; and

8.5.5 all rights and licenses granted pursuant to this Agreement and to the Sheffield Intellectual Property pursuant to the JDOA (including the rights of Newco pursuant to Clause 11 of the JDOA) shall cease for the Territory or for such particular country or countries in the Territory (as the case may be) and shall revert to or be transferred to Sheffield, and Newco shall not thereafter use in the Territory or in such particular country or countries in the Territory (as the case may be) any rights covered by this Agreement;

8.5.6 subject to Clause 8.5.7 and to such license, if any, granted by Newco to Sheffield pursuant to the provisions of Clause 12 of the JDOA, all rights to Newco Intellectual Property shall be transferred to and jointly owned by Sheffield and Elan and may only be exploited by either Elan or Sheffield with the consent of the other Party pursuant to a written agreement to be negotiated in good faith;

8.5.7 the rights of permitted third party sub-licensees in and to the Sheffield Intellectual Property shall survive the termination of the license and sublicense agreements granting said intellectual property rights to Newco; and Newco, Elan and Sheffield shall in good faith agree upon the form most advantageous to Elan and Sheffield in which the rights of Newco under any such licenses and sublicenses are to be held (which form may include continuation of Newco solely as the holder of such licenses or assignment of such rights to a third party or parties, including an assignment to both Elan and Sheffield).

Any sublicense agreement between Newco and such permitted sublicensee shall permit an assignment of rights by Newco and shall contain appropriate confidentiality provisions.

8.6 In the event that the Parties and Elan mutually agree to terminate the portion of the Project (as defined in the JDOA) which relates to Field A, the provisions of Clause 4.1 and the provisions of Clause 4.2 (insofar as the provisions of Clause 4.2 relate to Field A) shall automatically terminate.

9 CONFIDENTIAL INFORMATION

9.1 The Parties agree that it will be necessary, from time to time, to disclose to each other confidential and proprietary information, including without limitation, inventions, works of authorship, trade secrets, specifications, designs, data, know-how and other proprietary information relating to the Combined Fields, the Products, processes, services and business of the disclosing Party.

The foregoing shall be referred to collectively as "Confidential Information".

9.2 Any Confidential Information disclosed by one Party to another Party shall be used by the receiving Party exclusively for the purposes of fulfilling the receiving Party's obligations under this Agreement and the JDOA and for no other purpose.

9.3 Each Party shall disclose Confidential Information of the other Party only to those employees, representatives and agents requiring knowledge thereof in connection with fulfilling the Party's obligations under this Agreement. Each Party further agrees to inform all such employees, representatives and agents of the terms and provisions of this Agreement and their duties hereunder and to obtain their agreement hereto as a condition of receiving Confidential Information. Each Party shall exercise the same standard of care as it would itself exercise in relation to its own confidential information (but in no event less than a reasonable standard of care) to protect and preserve the proprietary and confidential nature of the Confidential Information disclosed to it by the other Party. Each Party shall, upon request of the other Party, return all documents and any copies thereof containing Confidential Information belonging to, or disclosed by, such other Party.

9.4 Any breach of this Clause 9 by any person informed by one of the Parties is considered a breach by the Party itself.

9.5 Confidential Information shall not be deemed to include:

9.5.1 information that is in the public domain;

9.5.2 information which is made public through no breach of this Agreement;

9.5.3 information which is independently developed by a Party as evidenced by such Party's records;

9.5.4 information that becomes available to a Party on a non-confidential basis, whether directly or indirectly, from a source other than a Party, which source did not acquire this information on a confidential basis; or

9.5.5 information which the receiving Party is required to disclose pursuant to:

(i) a valid order of a court or other governmental body; or

(ii) any other requirement of law;

provided that if the receiving Party becomes legally required to disclose any Confidential Information, the receiving Party shall give the disclosing Party prompt notice of such fact so that the disclosing Party may obtain a protective order or other appropriate remedy concerning any such disclosure. The receiving Party shall fully co-operate with the disclosing Party in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving Party shall make such disclosure only to the extent that such disclosure is legally required.

9.6 The provisions relating to confidentiality in this Clause 9 shall remain in effect during the term of this Agreement, and for a period of 7 years following the expiration or earlier termination of this Agreement.

9.7 The Parties agree that the obligations of this Clause 9 are necessary and reasonable in order to protect the Parties' respective businesses, and each Party agrees that monetary damages would be inadequate to compensate a Party for any breach by the other Party of its covenants and agreements set forth herein.

Accordingly, the Parties agree that any such violation or threatened violation shall cause irreparable injury to a Party and that, in addition to any other remedies that may be available, in law and equity or otherwise, each Party shall be entitled to obtain injunctive relief against the threatened breach of the provisions of this Clause 9, or a continuation of any such breach by the other Party, specific performance and other equitable relief to redress such breach together with its damages and reasonable counsel fees and expenses to enforce its rights hereunder, without the necessity of proving actual or express damages.

10 GOVERNING LAW AND JURISDICTION

10.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

10.2 The Parties will attempt in good faith to resolve any dispute arising

out of or relating to this Agreement promptly by negotiation between executives of the Parties. In the event that such negotiations do not result in a mutually acceptable resolution, the Parties agree to consider other dispute resolution mechanisms including mediation.

In the event that the Parties fail to agree on a mutually acceptable dispute resolution mechanism, any such dispute shall be finally settled by the courts of competent jurisdiction. For the purposes of this Agreement the parties submit to the non-exclusive jurisdiction of the courts of the State of New York.

11 IMPOSSIBILITY OF PERFORMANCE - FORCE MAJEURE

Neither Sheffield nor Newco shall be liable for delay in the performance of any of its obligations hereunder if such delay results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, intervention of a government authority, but any such delay or failure shall be remedied by such Party as soon as practicable.

12 ASSIGNMENT

This Agreement may not be assigned by either Party without the prior written consent of the other, save that either Party may assign this Agreement to its Affiliates or subsidiaries without such prior written consent provided that such assignment does not have any adverse tax consequences on the other Party.

13 NOTICES

13.1 Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or telefaxed to the following addresses:

If to Newco at:

102 St. James Court
Flatts,
Smiths FL04
Bermuda
Attention: Secretary
Telephone: 441 292 9169
Fax: 441 292 2224

with a copy to Elan and Sheffield at the addresses listed below:

If to Sheffield at:
Sheffield Pharmaceuticals, Inc.
425 S. Woodsmill Road
Suite 270
St Louis
MO 63017

USA.

Attn: Chief Executive Officer
Telephone 001 314 579 9899
Fax: 001 314 579 9799

with a copy to:

Daniel Gallagher, Esq.
Olshan, Grundman, Trome
Rosenzeig, LLP
505 Park Avenue
New York, NY 10022

Telephone 002 212 753 7200
Fax: 001 212 935 1787

If to Elan at:

Elan Corporation, plc
Lincoln House,
Lincoln Place,
Dublin 2,
Ireland.

Attention: Vice President, General Counsel,
Elan Pharmaceutical Technologies,
a division of Elan Corporation, plc
Telephone: + 353 1 709 4000
Telefax: + 353 1 709 4124

or to such other address(es) and telefax numbers as may from time to time be notified by either Party to the other hereunder.

13.2 Any notice sent by mail shall be deemed to have been delivered within seven 7 working days after dispatch and any notice sent by telex or telefax shall be deemed to have been delivered within twenty 24 hours of the time of the dispatch. Notice of change of address shall be effective upon receipt.

14 MISCELLANEOUS

14.1 Waiver:

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the Party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any other breach or failure to perform or of any other right arising under this Agreement.

14.2 Severability:

If any provision in this Agreement is agreed by the Parties to be, or

is deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto:

14.2.1 such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable; or

14.2.2 if it cannot be so amended without materially altering the intention of the Parties, it will be deleted, with effect from the date the Parties may agree, and the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

14.3 Further Assurances:

At the request of any of the Parties, the other Party or Parties shall (and shall use reasonable efforts to procure that any other necessary parties shall) execute and perform all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting Party the full benefit of the terms hereof.

14.4 Successors:

This Agreement shall be binding upon and enure to the benefit of the Parties hereto, their successors and permitted assigns.

14.5 No Effect on Other Agreements/Conflict:

No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the Parties unless specifically referred to, and solely to the extent provided herein.

In the event of a conflict between the provisions of this Agreement and the provisions of the JDOA, the terms of the JDOA shall prevail unless this Agreement specifically provides otherwise.

14.6 Amendments:

No amendment, modification or addition hereto shall be effective or binding on any Party unless set forth in writing and executed by a duly authorised representative of each Party.

14.7 Counterparts:

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

14.8 Good Faith:

Each Party undertakes to do all things reasonably within its power

which are necessary or desirable to give effect to the spirit and intent of this Agreement.

14.9 No Reliance:

Each Party hereby acknowledges that in entering into this Agreement it has not relied on any representation or warranty save as expressly set out herein or in any document referred to herein.

14.10 Relationship of the Parties:

Nothing contained in this Agreement is intended or is to be construed to constitute Sheffield and Newco as partners, or Sheffield as an employee of Newco, or Newco as an employee of Sheffield.

Neither Party hereto shall 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 contract, agreement or undertaking with any third party.

SCHEDULE 1

TECHNOLOGICAL COMPETITIORS OF SHEFFIELD

[REDACTED]

SCHEDULE 2

List of Steroids for Clause 4.1

[REDACTED]

IN WITNESS WHEREOF the Parties hereto have executed this Agreement.

/s/
SIGNED BY
for and on behalf of
SHEFFIELD PHARMACEUTICALS, INC.

/s/
SIGNED BY
For and on behalf of
SHEFFIELD NEWCO LIMITED

/s/
AGREED TO AND ACCEPTED BY
ELAN PHARMA INTERNATIONAL LIMITED

EX-10.28
8
ELAN LICENSE AGREEMENT

LICENSE AGREEMENT

BETWEEN

ELAN PHARMA INTERNATIONAL LIMITED

AND

SHEFFIELD NEWCO LIMITED

TABLE OF CONTENTS

THIS AGREEMENT made this 20 October 1999

between:

(1) Elan Pharma International Limited incorporated under the laws of Ireland, and having its registered office at WIL House, Shannon Business Park, Shannon, County Clare, Ireland ("EPIL");

(2) Newco Limited, a private limited company incorporated under the laws of Bermuda and having its registered office at Clarendon House, 2 Church Street, Hamilton, Bermuda ("Newco"); and

(3) Sheffield Pharmaceuticals, Inc., a corporation duly incorporated and validly existing under the laws of Delaware and having its principal place of business at 425 S. Woodsmill Road, Suite 270, St. Louis, MO 63017, USA("Sheffield").

RECITALS:

A. Simultaneously herewith, Sheffield, Elan, EIS, and Newco are entering into the JDOA for the purpose of recording the terms and conditions of the joint venture and of regulating their relationship with each other and certain aspects of the affairs of, and their dealings with Newco.

B. Newco desires to enter into this Agreement with Elan so as to permit Newco to utilize the Elan Intellectual Property in making, having made,

importing, using, offering for sale and selling the Products in Field A and Field B and Formulations in Field C in the Territory in accordance with the terms of this Agreement.

C. Simultaneously herewith Newco and Sheffield are entering into the Sheffield License Agreement relating to Newco's use of the Sheffield Intellectual Property.

1 DEFINITIONS

1.1 In this Agreement unless the context otherwise requires:

"Affiliate" shall mean any corporation or entity controlling, controlled or under the common control of Elan or Sheffield, as the case may be, excluding Systemic Pulmonary Delivery Ltd.. For the purpose of this definition, "control" shall mean direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors. Newco is not an Affiliate of Sheffield.

"Agreement" shall mean this license agreement (which expression shall be deemed to include the Recitals and Schedules hereto).

"Business Plan" shall have the meaning, as such term is defined in the JDOA.

"Change of Control of Sheffield/Newco" shall mean circumstances where:

(i) a Technological Competitor of Elan shall, directly or indirectly, acquire [REDACTED] or more of the voting stock of Sheffield or Newco, or otherwise control or influence in any material respect their management or business or otherwise have entered into any joint venture, collaboration, license or other arrangement with Sheffield or Newco, as the case may be, to such an extent that such a Technological Competitor of Elan is materially engaged or involved with the business or development of Sheffield or Newco, as the case may be; or

(ii) any person other than a Technological Competitor of Elan shall, directly or indirectly, acquire [REDACTED] or more of the then voting stock of Sheffield or Newco, or otherwise merge, consolidate or enter into any similar transaction (or binding agreement in respect thereof) with Sheffield or Newco.

"Combined Fields" shall mean Field A, Field B and Field C.

"Compounds" shall mean the Field A Compound, the Field B Compound and/or the Field C Compound.

"Confidential Information" shall have the meaning, as such term is defined in Clause 9.

"Definitive Documents" shall mean the definitive agreements relating to the transaction including finance, stock purchase, research and license agreements.

"Elan" shall mean EPIL and Affiliates and subsidiaries of Elan Corporation, Plc. within the division of Elan Corporation, Plc. carrying on business as Elan Pharmaceutical Technologies but shall not include Affiliates and subsidiaries (present or future) of Elan Corporation Plc within the division of Elan Corporation, Plc carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

"EIS" shall mean Elan International Services, Limited, a private limited company incorporated under the laws of Bermuda and having its registered office at Clarendon House, 2 Church Street, Hamilton, Bermuda.

"Effective Date" shall mean the date of this Agreement.

"Elan Intellectual Property" shall mean the Elan Know-How, the Elan Patents and the Elan Improvements.

For the avoidance of doubt, Elan Intellectual Property shall exclude (i) Elan's patent rights and know-how relating to protein or peptide agents or peptodomimetics, derivatives or analogs thereof, designed to

target a pharmaceutically active agent to a certain site or sites in the body (targeting technology) and (ii) inventions, patents and know-how owned, licensed or controlled by Axogen Limited and Neuralab Limited, and by all Affiliates and subsidiaries (present or future) of Elan Corporation, Plc. carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

"Elan Know-How" shall mean any and all rights owned, licensed or controlled by Elan to any discovery, invention (whether patentable or not), know-how, substances, data, techniques, processes, systems, formulations and designs relating to Nanocrystal(TM) Technology.

"Elan Licenses" shall have the meaning set forth in Clause 2.1.

"Elan Patents" shall mean any and all rights under any and all patents applications and/or patents, now existing, currently pending or hereafter filed or obtained by Elan relating to Nanocrystal(TM) Technology as set forth in Schedule 1, and any foreign counterparts thereof and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"EPIL Patents" shall mean the Elan Patents owned by EPIL.

"Elan Improvements" shall mean improvements relating to the Elan Patents and/or the Elan Know-How, developed (i) by Elan whether or not pursuant to the Project, (ii) by Newco or Sheffield or by a third party (under contract with Newco) whether or not pursuant to the Project, and/or (iii) jointly by any combination of Elan, Sheffield or Newco pursuant to the Project, except as limited by agreements with third Parties.

Subject to third party agreements, Elan Improvements shall constitute part of Elan Intellectual Property and be included in the license of the Elan Intellectual Property pursuant to Clause 2.1 solely for the purposes set forth therein. If the inclusion of an Elan Improvement in the license of Elan Intellectual Property is restricted or limited by a third party agreement, Elan shall use reasonable commercial efforts to minimize any such restriction or limitation.

"Elan Trademark(s)" shall mean one or more trademarks, trade names, or service marks that are owned or licensed by or on behalf of Elan which Elan may nominate and approve in writing from time to time for use in connection with the sale or promotion of the Products by Newco.

"Field A" shall mean the topical pulmonary delivery of Formulations of the Field A Compound by means of the Field A Device.

"Field B" shall mean the topical pulmonary delivery of a Formulations of the Field B Compound by means of the Field B Device.

"Field C" shall mean the topical pulmonary delivery of a Formulations of the Field C Compound by means of the Field C Device.

"Field A Device" shall mean a third party table top unit dose nebulizer having a reservoir capable of holding a unit dose (a device and the compressor to nebulize a unit dose shall be deemed a device), which is a device having any one the following characteristics:

(i) [REDACTED]

(ii) [REDACTED]

(iii) [REDACTED]

(iv) [REDACTED]

(v) [REDACTED]

For the avoidance of doubt, the Field A Device does not include [REDACTED]

"Field B Device" shall mean the Aerosol Drug Delivery System ("ADDS"), owned by Systemic Pulmonary Delivery Limited and exclusively licensed to Sheffield for topical pulmonary applications.

"Field C Device" shall mean the handheld multi-dose nebulizer ("MSI")

which was licensed exclusively by Siemens to Sheffield pursuant to the Siemens Agreements and which was subsequently sub-licensed by Sheffield to Zambon (on an exclusive basis for delivery of various medicines for humans in treating respiratory disease and/or other lung diseases including, but not limited to, anti-infectives) provided that Newco, through the Management Committee, is successful in obtaining a sub-license from Zambon to Newco enabling the development of the Field C Compound for use with the Field C Device, as described in more detail in Clause 2.2.

"Field A Compound" shall mean [REDACTED]

"Field B Compound" shall mean [REDACTED] for therapeutic use to be nominated by the Management Committee pursuant to the JDOA and with reference to the JDOA, any Substitute Field B Compound.

"Field C Compound" shall mean [REDACTED] and with reference to the JDOA, any Substitute Field C Compound and/or any Additional Field C Compound.

"Financial Year" shall mean each year commencing on 1 January (or in the case of the first Financial Year, the Effective Date) and expiring on 31 December of each year.

"Formulations" shall mean Nanocrystal(TM) Technology formulations of Compounds for use in Field A, Field B or Field C, as applicable.

"JDOA" shall mean that certain joint development and operating agreement, of even date herewith, by and between Elan, Sheffield, EIS and Newco.

"Licensed Technologies" shall mean the Elan Intellectual Property and the Sheffield Intellectual Property.

"Licenses" shall mean the Elan License and the Sheffield License.

"Management Committee" shall have the meaning, as such term is defined in the JDOA.

"Nanocrystal(TM) Technology" shall mean the Elan proprietary technology directed to nanoparticulate formulations of compounds used in the manufacturing and/or formulation process, and methods of making the same.

"Newco Intellectual Property" shall mean all rights to patents, know-how and other intellectual property arising out of the conduct of the Project by any person, including any technology acquired by Newco from a third party, that does not constitute Elan Intellectual Property or Sheffield Intellectual Property.

"Newco Patents" shall mean any and all patents now existing, currently pending or hereafter filed or obtained relating to the Newco Intellectual Property, and any foreign counterparts thereof and all

divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on, any of the foregoing, together with all registrations, reissues, re-examinations or extensions thereof.

"Party" shall mean Elan or Newco, as the case may be, and "Parties" shall mean Elan and Newco.

"Products" shall mean the Field A Products, the Field B Products and/or the Field C Products, as follows:

"Field A Products" shall mean Formulations of the Field A Compound delivered by means of any Field A Device in Field A.

"Field B Products" shall mean Formulations of the Field B Compound delivered by means of the Field B Device in Field B.

"Field C Products" shall mean Formulations of the Field C Compound delivered by means of the Field C Device in Field C.

"Project" shall mean all activities as undertaken by Elan, Sheffield and Newco in order to develop the Products.

"R&D Committee" shall have the meaning, as such term is defined in the JDOA.

"R&D Plan" shall have the meaning, as such term is defined in the JDOA.

"R&D Program" shall mean any research and development program commenced by Newco pursuant to the Project.

"Sheffield" shall mean Sheffield Pharmaceuticals, Inc and its Affiliates, excluding Newco.

"Sheffield Intellectual Property" shall mean the Sheffield Know-How, the Sheffield Patents and the Sheffield Improvements, as such terms are defined in the Sheffield License Agreement.

"Sheffield License" shall have the meaning set forth in Clause 2.1 of the Sheffield License Agreement.

"Sheffield License Agreement" shall mean that certain license agreement, of even date herewith, entered into between Sheffield and Newco.

"Sheffield Patents" shall have the meaning as such term is defined in the Sheffield License Agreement.

"Sheffield Improvements" shall have the meaning as such term is defined in the Sheffield License Agreement.

"Siemens" shall mean Siemens Aktiengesellschaft.

"Siemens Agreements" shall mean the License Agreement dated 21 March

1997 and the Basic Supply Agreement dated 21 March 1997, both between Sheffield Medical Technologies Inc. and Siemens Aktiengesellschaft.

"Technological Competitor of Elan" shall mean a company, corporation or person listed in Schedule 2 and successors thereof or any additional broad-based technological competitor of Elan added to such Schedule from time to time upon mutual agreement of the Parties.

"Term" shall have the meaning set forth in Clause 8.

"Territory" shall mean all the countries of the world.

"United States Dollar" and "US$" shall mean the lawful currency for the time being of the United States of America.

"Zambon" shall mean Inpharzam International, S.A.

1.2 In this Agreement:

1.2.1 The singular includes the plural and vice versa, and the masculine includes the feminine and vice versa and the neuter includes the masculine and the feminine.

1.2.2 Any reference to a Clause or Schedule shall, unless otherwise specifically provided, be to a Clause or Schedule of this Agreement.

1.2.3 The headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

2. ELAN LICENSE TO NEWCO

2.1. Elan hereby grants to Newco for the Term the following licenses subject to any contractual obligations that Elan has as of the Effective Date, including but not limited to [REDACTED]

2.1.1 an exclusive license (including the right to grant sublicenses subject to the limitations of Clause 2.7) of the Elan Intellectual Property solely to make, have made, import, use, offer for sale and sell the Field A Products in the Territory in Field A;

2.1.2 a non-exclusive license (including the right to grant sublicenses subject to the limitations of Clause 2.7) of the Elan Intellectual Property solely to make, have made, import, use, offer for sale and sell the Field B Products in the Territory in Field B;

2.1.3 subject to the execution by Newco of a written sub-license with Zambon as more fully described in Clause 2.2 for the development by Newco of the Field C Formulations in accordance with Clause 2.2, a non-exclusive license (including the right to grant sublicenses subject to the limitations of Clause 2.7)

of the Elan Intellectual Property solely to make, have made, import, use, offer for sale and sell the Field C Formulations in the Territory in Field C;

(the "Elan Licenses").

2.2 On the date which is [REDACTED] days following the Effective Date, or such extended date as may be agreed in writing by Elan and Newco, Elan shall, at its sole discretion, be entitled forthwith to terminate the license to Newco described in Clause 2.1.3, upon notice in writing to Newco, in the event that Newco has not, prior to such date, executed a written sub-license with Zambon for the development by Newco of the Field C Formulations in Field C.

Such written sub-license will be subject to the approval of the Management Committee and will include authority from Zambon to Newco to

the extent necessary for Newco to develop, make, have made and use the Field C Formulations in the Territory, general financial terms, development schedule, and terms governing the funding by Zambon of any R&D Program(s) in Field C, together with such other substantive issues as the Management Committee shall deem appropriate and customary terms.

For the avoidance of doubt, to the extent royalty or other compensation obligations are payable to Zambon in respect of any license or sub-license from Zambon to Newco of intellectual property rights necessary for Newco to develop, make, have made the Field C Formulations in the Territory, Sheffield shall be responsible for same and shall indemnify Newco in respect of any such royalty or other compensation obligations payable to Zambon.

2.3 Elan shall be responsible for payments related to the financial provisions and obligations of any third party agreement with respect to the Elan Intellectual Property to which it is a party on the Effective Date (including amendments thereto) (the "Elan Effective Date Agreements"), including without limitation, any royalty or other compensation obligations triggered thereunder on the Effective Date, or triggered thereunder after the Effective Date.

For the avoidance of doubt, royalties, milestones or other payments which arise from the process of the commercialization or exploitation of products under the Elan Effective Date Agreements (for example, a milestone payment payable upon successful completion of Phase II clinical trials, the filing of an NDA application, obtaining NDA approval, or first commercial sale) shall be payments for which Elan will be responsible under this Clause 2.1.

2.4 To the extent royalty or other compensation obligations that are payable to third parties with respect to the Elan Intellectual Property would be triggered after the Effective Date under any third party agreement entered into by Elan after the Effective Date (the "Elan Post-Effective Date Agreements"), by a proposed use of such Elan Intellectual Property in connection with the Project, Elan will inform

Newco of such royalty or compensation obligations. If Newco agrees to utilise such Elan Intellectual Property in connection with the Project, Newco will be responsible for the payment of such royalty or other compensation obligations relating thereto.

For the avoidance of doubt, royalties, milestones or other payments which arise from the process of the commercialization or exploitation of products under the Elan Post-Effective Date Agreements (for example, a milestone payment payable upon successful completion of Phase II clinical trials, the filing of an NDA application, obtaining NDA approval, or first commercial sale) shall be payments for which Newco will be responsible under this Clause 2.2.

2.5 Sheffield shall be a third party beneficiary under this Agreement and shall have the right to cause Newco to enforce Newco's rights under this Agreement against Elan.

2.6 Notwithstanding anything contained in this Agreement to the contrary, Elan shall have the right outside the Field A, Field B and Field C and

subject to the non-competition provisions of Clause 4 to exploit and grant licenses and sublicenses of the Elan Intellectual Property.

For the avoidance of doubt, Newco shall have no right to use the Elan Intellectual Property outside Field A, Field B or Field C.

2.7 Newco shall not be permitted to assign or sublicense any of its rights under the Elan Intellectual Property without the prior written consent of Elan, which consent shall not be unreasonably withheld or delayed provided that Elan shall in all cases, in its sole discretion, be entitled to withhold its consent in the case of a proposed sublicense to any Technological Competitor to Elan.

2.8 Any agreement between Newco and any permitted third party for the development or exploitation of the Elan Intellectual Property shall require such third party to maintain the confidentiality of all information concerning the Elan Intellectual Property.

Insofar as the obligations owed by Newco to Elan are concerned, Newco shall remain responsible for all acts and omissions of any permitted sub-licensee, including Sheffield, as if they were acts and omissions by Newco.

3 INTELLECTUAL PROPERTY

3.1 Ownership of Intellectual Property:

3.1.1 Newco shall own the Newco Intellectual Property.

3.1.2 Elan shall own the Elan Intellectual Property.

3.2 Trademarks:

3.2.1 Elan hereby grants to Newco for the Term a non-exclusive, royalty free license in the Territory to use and display the Elan Trademarks to promote, offer for sale and sell the Products in Field A, Field B and the Formulations in Field C in the Territory and the following provisions shall apply as regards the use of the Elan Trademarks by Newco hereunder:

(1) Newco shall ensure that each reference to and use of an Elan Trademark by Newco is in a manner approved by Elan and accompanied by an acknowledgement, in a form approved by Elan, that the same is a trademark (or registered trademark) of Elan.

From time to time, upon the reasonable request of Elan, Newco shall submit samples of the Product to Elan or its duly appointed agent to ensure compliance with quality standards and specifications. Elan, or its duly appointed agent, shall have the right to inspect the premises of Newco where the Products are manufactured, held or stored, and Newco shall permit such inspection,

upon advance notice at any reasonable time, of the methods and procedures used in the manufacture, storage and sale of the Product. Newco shall not sell or otherwise dispose of any Product under the Elan Trademarks that fails to comply with the quality standards and specifications referred to in this Clause 3.2, as determined by Elan.

(2) Newco shall not use an Elan Trademark in any way which might materially prejudice its distinctiveness or validity or the goodwill of Elan therein.

(3) The parties recognize that the Elan Trademarks have considerable goodwill associated therewith. Newco shall not use in relation to the Products any trademarks other than the Elan Trademarks (except the Sheffield Trademarks (as defined in the Sheffield License Agreement) licensed to Newco under the Sheffield License Agreement) without obtaining the prior consent in writing of Elan, which consent may not be unreasonably withheld. However, such use must not conflict with the use and display of the Elan Trademark and such use and display must be approved by Elan.

(4) Newco shall not use in the Territory any trademarks or trade names so resembling the Elan Trademark as to be likely to cause confusion or deception.

(5) Newco shall promptly notify Elan in writing of any alleged infringement or unauthorised use of which it becomes aware by a third party of the Elan Trademarks

and provide Elan with any applicable evidence of infringement or unauthorised use.

(6) Newco shall not be permitted to assign or sublicense any of its rights under the Elan Trademarks without the prior written consent of Elan, which consent shall not be unreasonably withheld or delayed.

3.2.2 Elan shall, at its expense and sole discretion, file and prosecute applications to register and maintain registrations of the Elan Trademarks in the Territory. Newco shall reasonably co-operate with Elan in such efforts. In the event Elan decides not to file or prosecute such Elan Trademark, Newco may request Elan to do the same at Newco's expense, and Elan shall file or prosecute such Elan Trademark at Newco's request and expense unless Elan believes such action is without merit.

3.2.3 Elan will be entitled to conduct all enforcement proceedings relating to the Elan Trademarks and shall at its sole discretion decide what action, if any, to take in respect to any enforcement proceedings of the Elan Trademarks or any other claim or counter-claim brought in respect to the use or registration of the Elan Trademarks. Any such proceedings shall be conducted at Elan's expense and for its own benefit. Newco and Sheffield shall reasonably cooperate with Elan in

such efforts. In the event Elan decides not to engage in enforcement proceedings of the Elan Trademarks, Newco may request Elan to do the same at Newco's expense unless Elan believes the basis for such enforcement proceedings is without merit. In such a case, Elan shall have the sole discretion not to engage in any such enforcement proceedings

3.2.4 Save where Newco adopts its own mark under Clause 3.2.4, in the event Newco becomes aware that any Elan Trademark has been challenged by a third party in a judicial or administrative proceeding in a country in the Territory as infringing on the rights of a third party Newco shall promptly notify Elan in writing and Elan shall have the first right to decide whether or not to defend such allegations, or to adopt an alternative mark, or allow Newco to adopt an alternative mark. If Elan decides not defend the Elan Trademark, then Newco may request Elan to defend the Elan Trademark, at Newco's expense, unless such requested defense is reasonably believed by Elan to be unsubstantiated and without merit. In such a case, Elan may elect not to initiate defence proceedings.

3.2.5 Newco will have no ownership rights in respect of the Elan Trademarks or of the goodwill associated therewith, and Newco hereby acknowledges that, except as expressly provided in

this Agreement, it shall not acquire any rights in respect thereof and that all such rights and goodwill are, and will remain, vested in Elan.

3.2.6 Nothing in this Agreement shall be construed as a warranty on the part of Elan regarding the Elan Trademarks, including without limitation, that use of the Elan Trademarks in the Territory will not infringe the rights of any third parties. Accordingly, Newco acknowledges and agrees that Elan makes no such warranty.

3.2.7 Elan assumes no liability to Newco or to any third parties with respect to the quality, performance or characteristics of any of the goods manufactured or sold by Newco under the Elan Trademarks pursuant to this Agreement.

4 NON-COMPETITION/AFTER ACQUIRED TECHNOLOGY

4.1 Subject to Clause 4.2 and Clause 4.3 and Clause 8.6, during the period during which the license described in Clause 2.1.1 has not been terminated, Elan shall not, alone or in conjunction with a third party, develop or commercialize any of the unit dose steroids listed in Schedule 3 for topical pulmonary delivery using a Field A Device and utilizing the Nanocrystal(TM)Technology, subject to written agreements between Elan and unaffiliated third parties on the Effective Date, including but not limited to the Development License and Supply Agreement dated 26 July 1999 between EPIL and Merck Corporation.

For the avoidance of doubt, the non-compete obligation set forth in this Clause 4 shall not prevent or restrict EPIL (as the owner of intellectual property related to Nanocrystal(TM) Technology) from entering into any agreement with any third party to license the Nanocrystal(TM) Technology, such license being limited to compounds

owned, acquired, in-licensed or otherwise proprietary to such third party but not including any of the unit dose steroids listed in Schedule 3 for topical pulmonary delivery using a Field A Device and utilizing the Nanocrystal(TM) Technology.

The provisions of this Clause 4.1 shall only act as a restriction upon Affiliates and subsidiaries of Elan Corporation, Plc. within the division of Elan Corporation, Plc. carrying on business as Elan Pharmaceutical Technologies and shall not act as a restriction upon, nor in any way affect, Affiliates and subsidiaries (present or future) of Elan Corporation Plc within the division of Elan Corporation, Plc carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

4.2 Notwithstanding the provisions of Clause 4.1, the non-competition

obligations of Elan set forth in Clause 4.1 shall not restrict Elan from entering into an agreement with [REDACTED] during the period of [REDACTED] following the Effective Date, or such longer period as may be agreed by Elan and Newco, for the development of a unit dose of [REDACTED], for topical pulmonary delivery using a Field A Device and utilizing the Nanocrystal(TM)Technology subject to the following conditions:

4.2.1 if such agreement is not executed by Elan and [REDACTED] within the period of [REDACTED] following the Effective Date, or such longer period as may be agreed by Elan and Newco, this exception to the non-competition obligations of Elan set forth in Clause 4.1 shall expire and be of no further force or effect;

4.2.2 if such agreement is agreed for execution by Elan and [REDATED] within the period of [REDACTED] following the Effective Date, or such longer period as may be agreed by Elan and Newco, Newco and Sheffield shall forthwith sign an amendment to this License Agreement (and any of the other Definitive Documents, if necessary) terminating the non-competition obligations of Elan set forth in Clause 4.1 insofar as such obligations relate to [REDACTED] and the Parties shall agree in good faith and on reasonable commercial and customary terms what portion of the royalties payable by [REDACTED] to Elan under the agreement proposed for execution should be payable to Newco in return for such amendment to this License Agreement (and any of the other Definitive Documents, if necessary).

4.3 If, after the Effective Date, Elan acquires know-how or patent rights relating to the Field A, Field B or Field C, or acquires or merges with a third party entity that has know-how or patent rights relating to the Field A, Field B or Field C, Elan shall offer to license such know-how and patent rights to Newco (subject to existing contractual obligations), on commercially reasonable terms on an arm's length basis for a reasonable period under the prevailing circumstances.

If Newco determines that Newco should not acquire such license, Elan shall be free to fully exploit such know-how and patent rights with the Elan Intellectual Property then licensed to Newco, whether inside or outside the Field A, Field B or Field C, as applicable, and to grant to third parties licenses and sublicenses with respect thereto.

5 FINANCIAL PROVISIONS

5.1 License Fee:

In consideration of the license by EPIL to Newco of the EPIL Patents under Clause 2, Newco shall pay to EPIL a non-refundable license fee of [REDACTED] in cash (the "License Fee"), the receipt of which is hereby acknowledged by EPIL.

The License Fee shall not be subject to future performance obligations

of Elan to Newco or Sheffield and shall not be applicable against future services provided by Elan to Newco or Sheffield.

For the avoidance of doubt, in the event that Elan terminates the license to Newco described in Clause 2.1.3 pursuant to the provisions of Clause 2.2, no part of the License Fee described in this Clause 5.1 shall become refundable to Sheffield.

5.2 Royalties:

Prior to the commercialization of the Products, the Management Committee shall consider and if appropriate, determine reasonable royalties with respect to the commercialization of the Products by Newco that shall be payable by Newco to Elan and Sheffield, and shared by Elan and Sheffield equally.

At such time, the Management Committee will agree an appropriate definition of "Net Sales" as such term is used in this Agreement.

5.3 Payment of any royalties pursuant to Clause 5.2 shall be made quarterly in arrears during each Financial Year within 30 days after the expiry of the calendar quarter. The method of payment shall be by wire transfer to an account specified by Elan. Each payment made to Elan shall be accompanied by a true accounting of all Products sold by Newco's permitted sublicensees, if any, during such quarter.

Such accounting shall show, on a country-by-country and Product-by-Product basis, Net Sales (and the calculation thereof) and each calculation of royalties with respect thereto, including the calculation of all adjustments and currency conversions.

5.4 Newco shall maintain and keep clear, detailed, complete, accurate and separate records for a period of 3 years:

5.4.1 to enable any royalties on Net Sales that shall have accrued hereunder to be determined; and

5.4.2 to enable any deductions made in the Net Sales calculation to be determined.

5.5 All payments due hereunder shall be made in United States Dollars. Payments due on Net Sales of any Product for each calendar quarter made in a currency other than United States Dollars shall first be calculated in the foreign currency and then converted to United States Dollars on the basis of the exchange rate in effect on the last working day for such quarter for the purchase of United States Dollars with such foreign currency quoted in the Wall Street Journal (or comparable publication if not quoted in the Wall Street Journal) with respect to the currency of the country of origin of such payment, determined by averaging the rates so quoted on each business day of such quarter.

5.6 If, at any time, legal restrictions in the Territory prevent the prompt payment when due of royalties or any portion thereof, the Parties shall

meet to discuss suitable and reasonable alternative methods of paying Elan the amount of such royalties. In the event that Newco is prevented from making any payment under this Agreement by virtue of the statutes, laws, codes or government regulations of the country from which the payment is to be made, then such payments may be paid by depositing them in the currency in which they accrue to Elan's account in a bank acceptable to Elan in the country the currency of which is involved or as otherwise agreed by the Parties.

5.7 Elan and Newco agree to co-operate in all respects necessary to take advantage of any double taxation agreements or similar agreements as may, from time to time, be available.

5.8 Any taxes payable by Elan on any payment made to Elan pursuant to this Agreement shall be for the account of Elan. If so required by applicable law, any payment made pursuant to this Agreement shall be made by Newco after deduction of the appropriate withholding tax, in which event the Parties shall co-operate to obtain the appropriate tax clearance as soon as is practicable. On receipt of such clearance, Newco shall forthwith arrange payment to Elan of the amount so withheld.

6 RIGHT OF INSPECTION AND AUDIT

6.1 Once during each Financial Year, or more often not to exceed quarterly as reasonably requested by Elan, Newco shall permit Elan or its duly authorised representatives, upon reasonable notice and at any reasonable time during normal business hours, to have access to inspect and audit the accounts and records of Newco and any other book, record, voucher, receipt or invoice relating to the calculation of the royalty payments on Net Sales submitted to Elan.

Any such inspection of Newco's records shall be at the expense of Elan, except that if any such inspection reveals a deficiency in the amount of the royalty actually paid to Elan hereunder in any Financial Year quarter of [REDACTED] or more of the amount of any royalty actually due to Elan hereunder, then the expense of such inspection shall be borne solely by Newco. Any amount of deficiency shall be paid promptly to Elan by Newco.

If such inspection reveals a surplus in the amount of royalties actually paid to Elan by Newco, Elan shall reimburse Newco the surplus within 15 days after determination.

6.2 In the event of any unresolved dispute regarding any alleged deficiency or overpayment of royalty payments hereunder, the matter will be referred to an independent firm of chartered accountants chosen by agreement of Sheffield and Elan for a resolution of such dispute. Any decision by the said firm of chartered accountants shall be binding on the Parties.

7 REPRESENTATIONS AND WARRANTIES

7.1 Elan represents and warrants to Newco and Sheffield, as of the Effective Date, as follows:

7.1.1 Elan has the right to grant the Elan Licenses;

7.1.2 there are no agreements with any third parties that conflict with the Elan Licenses.

7.2 In addition to any other indemnities provided for herein, Elan shall indemnify and hold harmless Newco and its Affiliates and their respective employees, agents, officers and directors from and against any claims, losses, liabilities or damages (including reasonable attorney's fees and expenses) incurred or sustained by Newco arising out of or in connection with any:

7.2.1 breach of any representation, covenant, warranty or obligation by Elan hereunder; or

7.2.2 act or omission on the part of Elan or any of its respective employees, agents, officers and directors in the performance of this Agreement.

7.3 In addition to any other indemnities provided for herein, Newco shall indemnify and hold harmless Elan and its Affiliates and their respective employees, agents, officers and directors from and against any claims, losses, liabilities or damages (including reasonable attorney's fees and expenses) incurred or sustained by Elan arising out of or in connection with any:

7.3.1 breach of any representation, covenant, warranty or obligation by Newco hereunder; or

7.3.2 act or omission on the part of Newco or any of its agents or employees in the performance of this Agreement.

7.4 The Party seeking an indemnity shall:

7.4.1 fully and promptly notify the other Party of any claim or proceeding, or threatened claim or proceeding;

7.4.2 permit the indemnifying Party to take full care and control of such claim or proceeding;

7.4.3 co-operate in the investigation and defence of such claim or proceeding;

7.4.4 not compromise or otherwise settle any such claim or proceeding without the prior written consent of the other Party, which consent shall not be unreasonably withheld conditioned or delayed; and

7.4.5 take all reasonable steps to mitigate any loss or liability in

respect of any such claim or proceeding.

7.5 EXCEPT AS SET FORTH IN THIS CLAUSE 7, ELAN IS GRANTING THE LICENSES HEREUNDER ON AN "AS IS" BASIS WITHOUT REPRESENTATION OR WARRANTY WHETHER EXPRESS OR IMPLIED INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF THIRD PARTY RIGHTS, AND ALL SUCH WARRANTIES ARE EXPRESSLY DISCLAIMED.

7.6 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, ELAN AND NEWCO SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF PROFITS OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

8. TERM AND TERMINATION

8.1 The term of this Agreement shall commence as of the Effective Date and shall, subject to the rights of termination outlined in this Clauses 8, expire on a Product-by-Product basis and on a country-by-country basis on the last to occur of:

8.1.1 [REDACTED] years starting from the date of the first commercial sale of the Product in the country concerned; or

8.1.2 the date of expiration of the last to expire of the patents included in the Elan Patents and/or the Elan Improvements and/or the Sheffield Patents and/or the Elan Improvements that relate to the Product.

("the Term")

8.2 If either Party commits a Relevant Event, the other Party shall have, in addition to all other legal and equitable rights and remedies hereunder, the right to terminate this Agreement upon 30 days' prior written notice to the defaulting Party.

8.3 For the purpose of this Clause 8, a "Relevant Event" is committed or suffered by a Party if:

8.3.1 [REDACTED]

8.3.2 [REDACTED]

8.3.3 [REDACTED]

8.3.4 [REDACTED]

8.3.5 [REDACTED]

8.3.6 [REDACTED]

8.4 Elan shall be entitled to forthwith terminate this Agreement in the event of a Change of Control of Sheffield/Newco.

As provided in Clause 8.4 of the Sheffield License Agreement, Sheffield shall be entitled to terminate the Sheffield License Agreement if Elan elects to terminate the Elan Licenses hereunder.

8.5 Upon expiration or termination of the Agreement:

8.5.1. any sums that were due from Newco to Elan on Net Sales in the Territory or in such particular country or countries in the Territory (as the case may be) prior to the expiration or termination of this Agreement as set forth herein shall be paid in full within 60 days after the expiration or

termination of this Agreement for the Territory or for such particular country or countries in the Territory (as the case may be);

8.5.2 any provisions that expressly survive termination or expiration of this Agreement, including without limitation this Clause 8, shall remain in full force and effect;

8.5.3 all representations, warranties and indemnities shall insofar as are appropriate remain in full force and effect;

8.5.4 the rights of inspection and audit set out in Clause 6 shall continue in force for a period of one year; and

8.5.5 all rights and licenses granted pursuant to this Agreement and to the Elan Intellectual Property pursuant to the JDOA (including the rights of Newco pursuant to Clause 11 of the JDOA) shall cease for the Territory or for such particular country or countries in the Territory (as the case may be) and shall revert to or be transferred to Elan, and Newco shall not thereafter use in the Territory or in such particular country or countries in the Territory (as the case may be) any rights covered by this Agreement;

8.5.6 subject to Clause 8.5.7 and to such license, if any, granted by Newco to Elan pursuant to the provisions of Clause 12 of the JDOA, all rights to Newco Intellectual Property shall be transferred to and jointly owned by Sheffield and Elan and may only be exploited by either Elan or Sheffield with the consent of the other Party pursuant to a written agreement to be negotiated in good faith;

8.5.7 the rights of permitted third party sub-licensees in and to the Elan Intellectual Property shall survive the termination of the license and sublicense agreements granting said intellectual property rights to Newco; and Newco, Elan and

Sheffield shall in good faith agree upon the form most advantageous to Elan and Sheffield in which the rights of Newco under any such licenses and sublicenses are to be held (which form may include continuation of Newco solely as the holder of such licenses or assignment of such rights to a third party or parties, including an assignment to both Elan and Sheffield).

Any sublicense agreement between Newco and such permitted sublicensee shall permit an assignment of rights by Newco and shall contain appropriate confidentiality provisions.

8.6 In the event that the Parties and Sheffield mutually agree to terminate the portion of the Project (as defined in the JDOA) which relates to Field A, the license described in Clause 2.1.1, the provisions of Clause 4.1 and the provisions of Clause 4.3 (insofar as the provisions of Clause 4.3 relate to Field A) shall automatically terminate.

9 CONFIDENTIAL INFORMATION

9.1 The Parties agree that it will be necessary, from time to time, to disclose to each other confidential and proprietary information, including without limitation, inventions, works of authorship, trade secrets, specifications, designs, data, know-how and other proprietary information relating to the Combined Fields, the Products, processes, services and business of the disclosing Party.

The foregoing shall be referred to collectively as "Confidential Information".

9.2 Any Confidential Information disclosed by one Party to another Party shall be used by the receiving Party exclusively for the purposes of fulfilling the receiving Party's obligations under this Agreement and the JDOA and for no other purpose.

9.3 Each Party shall disclose Confidential Information of the other Party only to those employees, representatives and agents requiring knowledge thereof in connection with fulfilling the Party's obligations under this Agreement. Each Party further agrees to inform all such employees, representatives and agents of the terms and provisions of this Agreement and their duties hereunder and to obtain their agreement hereto as a condition of receiving Confidential Information. Each Party shall exercise the same standard of care as it would itself exercise in relation to its own confidential information (but in no event less than a reasonable standard of care) to protect and preserve the proprietary and confidential nature of the Confidential Information disclosed to it by the other Party. Each Party shall, upon request of the other Party, return all documents and any copies thereof containing Confidential Information belonging to, or disclosed by, such other Party.

9.4 Any breach of this Clause 9 by any person informed by one of the Parties is considered a breach by the Party itself.

9.5 Confidential Information shall not be deemed to include:

9.5.1 information that is in the public domain;

9.5.2 information which is made public through no breach of this Agreement;

9.5.3 information which is independently developed by a Party as evidenced by such Party's records;

9.5.4 information that becomes available to a Party on a non-confidential basis, whether directly or indirectly, from a source other than a Party, which source did not acquire this information on a confidential basis; or

9.5.5 information which the receiving Party is required to disclose pursuant to:

(i) a valid order of a court or other governmental body; or

(ii) any other requirement of law;

provided that if the receiving Party becomes legally required to disclose any Confidential Information, the receiving Party shall give the disclosing Party prompt notice of such fact so that the disclosing Party may obtain a protective order or other appropriate remedy concerning any such disclosure. The receiving Party shall fully co-operate with the disclosing Party in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving Party shall make such disclosure only to the extent that such disclosure is legally required.

9.6 The provisions relating to confidentiality in this Clause 9 shall remain in effect during the term of this Agreement, and for a period of 7 years following the expiration or earlier termination of this Agreement.

9.7 The Parties agree that the obligations of this Clause 9 are necessary and reasonable in order to protect the Parties' respective businesses, and each Party agrees that monetary damages would be inadequate to compensate a Party for any breach by the other Party of its covenants and agreements set forth herein.

Accordingly, the Parties agree that any such violation or threatened violation shall cause irreparable injury to a Party and that, in addition to any other remedies that may be available, in law and equity or otherwise, each Party shall be entitled to obtain injunctive relief against the threatened breach of the provisions of this Clause 9, or a continuation of any such breach by the other Party, specific performance and other equitable relief to redress such breach together

with its damages and reasonable counsel fees and expenses to enforce its rights hereunder, without the necessity of proving actual or express damages.

9.8 For the avoidance of doubt, all Confidential Information of Newco received by Elan hereunder shall not be disclosed by Elan to Affiliates and/or subsidiaries (present or future) of Elan Corporation, Plc. within the division of Elan Corporation, Plc. carrying on business as Elan Pharmaceuticals which incorporates, inter alia, Targon Corporation, Athena Neurosciences, Inc., Elan Pharmaceuticals, Inc., Elan Diagnostics, Carnrick Laboratories, and Elan Europe Limited.

10 GOVERNING LAW AND JURISDICTION

10.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

10.2 The Parties will attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between executives of the Parties. In the event that such negotiations do not result in a mutually acceptable resolution, the Parties agree to consider other dispute resolution mechanisms including mediation.

In the event that the Parties fail to agree on a mutually acceptable

dispute resolution mechanism, any such dispute shall be finally settled by the courts of competent jurisdiction. For the purposes of this Agreement the parties submit to the non-exclusive jurisdiction of the courts of the State of New York.

11 IMPOSSIBILITY OF PERFORMANCE - FORCE MAJEURE

Neither Elan nor Newco shall be liable for delay in the performance of any of its obligations hereunder if such delay results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, intervention of a government authority, but any such delay or failure shall be remedied by such Party as soon as practicable.

12 ASSIGNMENT

This Agreement may not be assigned by either Party without the prior written consent of the other, save that either Party may assign this Agreement to its Affiliates or subsidiaries without such prior written consent provided that such assignment does not have any adverse tax consequences on the other Party.

13 NOTICES

13.1 Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or telefaxed to the following addresses:

If to Newco at:

Clarendon House,
2 Church Street,
Hamilton,
Bermuda
Attention: Secretary
Telephone: 441 292 9169
Fax: 441 292 2224

with a copy to Elan and Sheffield at the addresses listed below:

If to Sheffield at:
Sheffield Pharmaceuticals, Inc.
425 S. Woodsmill Road
Suite 270
St Louis
MO 63017
USA.

Attn: Chief Executive Officer
Telephone 001 314 579 9899
Fax: 001 314 579 9799

with a copy to:

Daniel Gallagher, Esq.
Olshan, Grundman, Trome
Rosenzeig, LLP
505 Park Avenue
New York, NY 10022
Telephone 002 212 753 7200
Fax: 001 212 935 1787

If to Elan at:

Elan Corporation, plc
Lincoln House,
Lincoln Place,
Dublin 2,
Ireland.
Attention: Vice President, General Counsel,
Elan Pharmaceutical Technologies,
a division of Elan Corporation, plc
Telephone: + 353 1 709 4000
Telefax: + 353 1 709 4124

or to such other address(es) and telefax numbers as may from time to time be notified by either Party to the other hereunder.

13.2 Any notice sent by mail shall be deemed to have been delivered within

seven 7 working days after dispatch and any notice sent by telex or telefax shall be deemed to have been delivered within twenty 24 hours of the time of the dispatch. Notice of change of address shall be effective upon receipt.

14 MISCELLANEOUS

14.1 Waiver:

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the Party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any other breach or failure to perform or of any other right arising under this Agreement.

14.2 Severability:

If any provision in this Agreement is agreed by the Parties to be, or is deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto:

14.2.1 such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable; or

14.2.2 if it cannot be so amended without materially altering the intention of the Parties, it will be deleted, with effect from the date the Parties may agree, and the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

14.3 Further Assurances:

At the request of any of the Parties, the other Party or Parties shall (and shall use reasonable efforts to procure that any other necessary parties shall) execute and perform all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting Party the full benefit of the terms hereof.

14.4 Successors:

This Agreement shall be binding upon and enure to the benefit of the Parties hereto, their successors and permitted assigns.

14.5 No Effect on Other Agreements/Conflict:

No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the Parties unless specifically referred to, and solely to the extent provided herein.

In the event of a conflict between the provisions of this Agreement and

the provisions of the JDOA, the terms of the JDOA shall prevail unless this Agreement specifically provides otherwise.

14.6 Amendments:

No amendment, modification or addition hereto shall be effective or binding on any Party unless set forth in writing and executed by a duly authorised representative of each Party.

14.7 Counterparts:

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

14.8 Good Faith:

Each Party undertakes to do all things reasonably within its power which are necessary or desirable to give effect to the spirit and intent of this Agreement.

14.9 No Reliance:

Each Party hereby acknowledges that in entering into this Agreement it has not relied on any representation or warranty save as expressly set out herein or in any document referred to herein.

14.10 Relationship of the Parties:

Nothing contained in this Agreement is intended or is to be construed to constitute Elan and Newco as partners, or Elan as an employee of Newco, or Newco as an employee of Elan.

Neither Party hereto shall 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 contract, agreement or undertaking with any third party.

SCHEDULE 1

ELAN PATENTS

[REDACTED]

SCHEDULE 2

TECHNOLOGICAL COMPETITORS OF ELAN

[REDACTED]

SCHEDULE 3

List of Steroids for Clause 4.1

[REDACTED]

IN WITNESS WHEREOF the Parties hereto have executed this Agreement.

/S/
SIGNED BY
for and on behalf of
ELAN PHARMA INTERNATIONAL LIMITED

/S/
SIGNED BY
For and on behalf of
SHEFFIELD NEWCO LIMITED

/S/
AGREED TO AND ACCEPTED BY
SHEFFIELD PHARMACEUTICALS, INC.

EX-10.29
9
REGISTRATION RIGHTS AGREEMENT

REGISTRATION RIGHTS AGREEMENT

THIS REGISTRATION RIGHTS AGREEMENT (the "Agreement") is made as of October 18, 1999 by and between Sheffield Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Elan International Services, Ltd., a Bermuda exempted limited liability company incorporated under the laws of Bermuda ("EIS").

R E C I T A L S:

A. Pursuant to a Securities Purchase Agreement (the "Purchase Agreement") by and between EIS and the Company, dated as of the date hereof, the Company has issued to EIS (i) shares of Series D Preferred Stock; (ii) shares of Series F Preferred Stock; and (iii) a Warrant to acquire up to 150,000 shares of the Common Stock.

B. In addition, pursuant to the Purchase Agreement, the Company may require that EIS purchase shares of Series E Preferred Stock with an aggregate stated value of up to $4,005,000.

C. The closings under the Purchase Agreement have occurred on the date hereof; it being a condition to such closings that the parties execute and deliver this Agreement.

D. The parties desire to set forth herein their agreement relating to the granting of certain resale registration rights to the Holders (as defined below) of the Common Stock issuable upon conversion, exercise or exchange of any of the other Securities. All capitalized terms used in this Agreement and not otherwise defined herein shall have the meaning ascribed to such terms in the Purchase Agreement.

A G R E E M E N T:

The parties hereto agree as follows:

1. CERTAIN DEFINITIONS. As used in this Agreement, the following terms shall have the following respective meanings:

"Affiliate" of any Person shall mean any other Person controlling, controlled by or under common control with such particular Person. In the case of a natural Person, his Affiliates include

members of such Person's immediate family, natural lineal descendants of such Person or a trust for the exclusive benefit of such Person and his immediate family and natural lineal descendants.

"Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.

"Common Stock" shall mean the common stock, par value $0.01 per share of the Company.

"Holder", "Holders" or "Holders of Registrable Securities" shall mean EIS and any Person who shall have acquired Registrable Securities from EIS as permitted herein, either individually or jointly as the case may be.

"Person" shall mean an individual, a partnership, a company, an association, a joint stock company, a trust, a joint venture, an unincorporated organization and a governmental or quasi-governmental entity or any department, agency or political subdivision thereof.

"Preferred Stock" shall mean, collectively, the Series D Preferred Stock, the Series E Preferred Stock and the Series F Preferred Stock.

"Registrable Securities" means (i) any Common Stock issued or issuable upon conversion, exchange or exercise of the Securities held or otherwise acquired by any Holders, and (ii) any Common Stock issued or issuable in respect of the securities referred to in clause (i) above upon any stock split, stock dividend, recapitalization or similar event; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction (including a transaction pursuant to a registration statement under this Agreement and a transaction pursuant to Rule 144 promulgated under the Securities Act) in which registration rights are not transferred pursuant to Section 9 hereof.

"Register," "Registered" and "Registration" shall refer to a resale registration effected by preparing and filing a registration statement in compliance with the Securities Act, and the declaration or ordering of the effectiveness of such registration statement.

"Registration Expenses" shall mean all expenses, other than Selling Expenses, incurred by the Company in complying with Sections 2 or 3 hereof, including without limitation, all registration, qualification and filing fees, exchange listing fees, printing expenses, escrow fees, fees and disbursements of counsel for the Company, blue sky fees and expenses, the expense of any special audits incident to or required by any such registration and the reasonable fees and disbursements, of one counsel for the Holders, such counsel to be selected by Holders holding a majority of the Registrable Securities held by the Holders and included in such registration.

"Requisite Holders" shall mean Holders holding at least 50% of the authorized and outstanding Preferred Stock.

"Securities" shall mean shares of Series D Preferred Stock, Series E Preferred Stock, Series F Preferred Stock and the Warrant, in each case issued to EIS pursuant to the Purchase Agreement.

"Securities Act" shall mean the Securities Act of 1933, as amended, or any similar federal statute and the rules and regulations of the Commission

thereunder, all as the same shall be in effect at the time.

"Selling Expenses" shall mean all underwriting discounts, selling commissions and stock transfer taxes applicable to the securities registered by the Holders and the costs of any accountants, counsel or other experts retained by the Holders.

"1934 Act" shall mean the Securities Exchange Act of 1934, as amended, or any similar federal statute and the rules and regulations of the Commission thereunder, all as the same shall be in effect at the time.

2. Demand Registration. (a) Request or exercise for Registration. Requisite Holders shall have the right at any time and on one occasion to request registration under the Securities Act of all or part of the Registrable Securities held by such Holder on Form S-3, or if such form is unavailable for such a registration, such other form as is available for such a registration (the "Demand Registration"). A Demand Registration shall specify the approximate number of Registrable Securities requested to be registered. Within 10 days after receipt of any such request, the Company will give written notice of such requested registration to all other Holders of Registrable Securities and, if they request to be included in such registration, the Company shall include the Registrable Securities held by such Holders in such offering if they have responded affirmatively within 15 days after the receipt of the Company's notice. The Holders in aggregate will be entitled to request one Demand Registration. A registration will not count as the permitted Demand Registration until it has become effective (unless the Demand Registration has not become effective due solely to the fault of the Holders requesting such registration, including a request by such Holders that such registration be withdrawn). The Company will pay all Registration Expenses in connection with the Demand Registration whether or not it has become effective.

(b) Priority on Demand Registration. If the Demand Registration is an underwritten offering and the managing underwriter or underwriters advise the Company in writing that in their opinion the number of Registrable Securities and, if permitted hereunder, other securities requested to be included in such offering, exceeds the number of Registrable Securities and other securities, if any, which can be sold in such offering without adversely affecting the marketability of the offering, the Company will include in such registration:

(i) first, the Registrable Securities requested to be included in such registration by the Holders (or, if necessary, such Registrable Securities pro rata among the Holders thereof based upon the number of Registrable Securities owned by each such Holder); and

(ii) thereafter, other securities requested to be included in such registration.

(c) Restrictions on Demand Registration. The Company may postpone for up to three months in any 12 month period, the filing or the effectiveness of a registration statement for the Demand Registration if the Company

determines in good faith that such Demand Registration would reasonably be expected to have a material adverse effect on any proposal or plan by the Company to engage in any acquisition of assets (other than in the ordinary course of business) or any merger, consolidation, tender offer or similar transaction; provided, that in such event, the Holders initially requesting such Demand Registration will be entitled to withdraw such request and, if such request is withdrawn, such Demand Registration will not count as the Demand Registration hereunder and the Company will pay all Registration Expenses in connection with such registration.

(d) Selection of Underwriters. The Holders will have the right to select the investment banker(s) and manager(s) to administer an offering pursuant to the Demand Registration, subject to the Company's approval, which will not be unreasonably withheld.

(e) Other Registration Rights. Except as provided in this Agreement, so long as any Holder owns any Registrable Securities, the Company will not grant to any Persons the right to request the Company to register any equity securities of the Company, or any securities convertible, exchangeable or exercisable for such securities, which is superior to or in conflict with the rights granted to the Holders hereunder, without the prior written consent of the Requisite Holders; it being understood, however, that the Company may grant rights to other Persons to (i) participate in Piggyback Registrations (as defined below) so long as such rights are subordinate or pari passu to the rights of the Holders of Registrable Securities with respect to such Piggyback Registrations and (ii) request registrations so long as the Holders of Registrable Securities are entitled to participate in any such registrations with such Persons pro rata on the basis of the number of shares owned by each such Holder.

3. Piggyback Registrations. (a) Right to Piggyback. Whenever the Company proposes to register any of its securities under the Securities Act (each, a "Piggyback Registration"), the Company will give prompt written notice to all Holders of Registrable Securities of its intention to effect such a registration and, subject to Section 3(b) and the other terms of this Agreement, will include in such registration all Registrable Securities with respect to which the Company has received written requests for inclusion therein within 15 days after the receipt of the Company's

notice. Notwithstanding the foregoing, a Piggyback Registration shall not include any registration statement (i) on Form S-8 or any successor form to such form, (ii) on Form S-4 or any successor form to such form, (iii) filed in connection with an exchange offer or an offering of Common Stock or of securities convertible or exchangeable into Common Stock made solely to its existing stockholders in connection with a rights offering or solely to the Company's employees, or a post-effective amendment to any then effective registration statement.

(b) Priority on Piggyback Registrations. If a Piggyback Registration is an underwritten registration on behalf of the Company, and the managing underwriter(s) advise the Company in writing that in their opinion the

number of securities requested to be included in such registration exceeds the number which can be sold in such offering without adversely affecting the marketability of the offering, the Company will include in such registration:

(i) first, the securities the Company proposes to sell;

(ii) second, the Registrable Securities requested to be included in such registration by the Holders and any securities requested to be included in such registration by any other Person that is entitled to registration rights that are not subordinate to the rights of the Holders, pro rata among the Holders of such Registrable Securities and such other Persons, on the basis of the number of shares owned by each of such Holders; and

(iii) thereafter, other securities requested to be included in such registration.

(c) Right to Terminate Registration. If, at any time after giving written notice of its intention to register any of its securities as set forth in Section 3(a) and prior to the effective date of the registration statement filed in connection with such registration, the Company shall determine for any reason not to register such securities, the Company may, at its election, give written notice of such determination to each Holder of Registrable Securities and thereupon be relieved of its obligation to register any Registrable Securities in connection with such registration (but not from its obligation to pay the Registration Expenses in connection therewith as provided herein).

(d) Selection of Underwriters. The Company will have the right to select the investment banker(s) and manager(s) to administer an offering pursuant to a Piggyback Registration.

4. Expenses of Registration. Except as otherwise provided herein, all Registration Expenses incurred in connection with all registrations pursuant to Sections 2 and 3 shall be borne by the Company. Unless otherwise stated, all Selling Expenses relating to securities registered on behalf of the Holders of Registrable Securities shall be borne by such holders.

5. Holdback Agreements. (a) The Company agrees (i) not to effect any public sale or distribution for its own account of its equity securities, or any securities convertible into or exchangeable or exercisable for such securities, during the seven days prior to and during the 90-day period beginning on the effective date of the underwritten Demand Registration or any underwritten Piggyback Registration (except as part of such underwritten registration or pursuant to registrations on Form S-8 or any successor form), unless the underwriter(s) managing the registered public offering otherwise agree, and (ii) to use reasonable efforts to cause each Holder of at least 5% (on a fully-diluted basis) of its Common Stock, or any securities convertible into or exchangeable or exercisable for Common Stock, purchased from the Company at any time after the date of this Agreement (other than in a registered public offering) to agree not to effect any public sale or distribution (including

sales pursuant to Rule 144) of any such securities during such periods (except as part of such underwritten registration, if otherwise permitted), unless the underwriter(s) managing the registered public offering otherwise agree.

(b) Each Holder of Registrable Securities whose Registrable Securities are eligible for inclusion in a Registration Statement filed pursuant to Section 2 hereof agrees, if requested by the managing underwriter(s) in an underwritten offering of any Registrable Securities, not to effect any public sale or distribution of Registrable Securities, including a sale pursuant to Rule 144 (or any similar provision then effect) under the Securities Act (except as part of such underwritten registration), during the seven-day period prior to, and during the 90-day period or such shorter period as may be agreed to by the parties hereto) following the effective date of such Registration Statement to the extent timely notified in writing by the Company or the managing underwriter or underwriters.

6. Registration Procedures. Whenever the Holders of Registrable Securities have requested that any Registrable Securities be registered pursuant to this Agreement, the Company will use its best efforts to effect the registration and the sale of such Registrable Securities in accordance with the intended method of distribution thereof, and pursuant thereto the Company will as expeditiously as possible:

(a) prepare and file with the Commission a registration statement on any form for which the Company qualifies with respect to such Registrable Securities and use its best efforts to cause such registration statement to become effective (provided that before filing a registration statement or prospectus or any amendments or supplements thereto, the Company will (i) furnish to the counsel selected by the Holders copies of all such documents proposed to be filed, which documents will be subject to the review of such counsel, and (ii) notify each holder of Registrable Securities covered by such registration of any stop order issued or threatened by the Commission);

(b) prepare and file with the Commission such amendments and supplements to such registration statement and the prospectus used in connection therewith as may be necessary to keep such registration statement effective for a period of not less than nine months and comply with the

provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement during such period in accordance with the intended methods of disposition by the sellers thereof set forth in such registration statement;

(c) furnish to each seller of Registrable Securities such number of copies of such registration statement, each amendment and supplement thereto, the prospectus included in such registration statement (including each preliminary prospectus) and such other documents as such seller may reasonably request in order to facilitate the disposition of the Registrable Securities owned by such seller;

(d) use its best efforts to register or qualify such Registrable

Securities under such other securities or blue sky laws of such jurisdiction as any seller reasonably requests and do any and all other acts and things which may be reasonably necessary or advisable to enable such seller to consummate the disposition in such jurisdictions of the Registrable Securities owned by such seller (provided that the Company will not be required to (i) qualify generally to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 6(d), (ii) subject itself to taxation in any jurisdiction or (iii) consent to general service of process in any such jurisdiction);

(e) notify each seller of such Registrable Securities, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event as a result of which the prospectus included in such registration statement contains an untrue statement of a material fact or omits any fact necessary to make the statements therein not misleading, and, at the request of any such seller, the Company will prepare a supplement of amendment to such prospectus so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus will not contain an untrue statement of a material fact or omit to state any fact necessary to make the statements therein not misleading;

(f) Use its best efforts to cause all such Registrable Securities to be listed on each securities exchange on which similar securities issued by the Company are then listed and, if not so listed, to be listed on the NASD automated quotation system and, if listed on the NASD automated quotation system, use its best efforts to secure designation of all such Registrable Securities covered by such registration statement as a NASDAQ National market system security within the meaning of Rule 11Aa2-1 of the Commission or, failing that, to secure NASDAQ authorization for such Registrable Securities and, without limiting the generality of the foregoing, to arrange for at least two market makers to register as such with respect to such Registrable Securities with the NASD;

(g) provide a transfer agent and registrar for all such Registrable Securities not later than the effective date of such registration statement;

(h) enter into such customary agreements (including underwriting agreements in customary form) and take all such other actions as the holders of a majority of the Registrable Securities being sold or the underwriter(s), if any, reasonably request in order to expedite or facilitate the disposition of such Registrable Securities;

(i) make available for inspection by a representative of the Holders of Registrable Securities included in the registration statement, any underwriter(s) participating in any disposition pursuant to such registration statement and any attorney, accountant or other agent retained by any such seller or underwriter, subject to a confidentiality agreement in customary form, all pertinent financial and other records, pertinent corporate documents and properties of the Company, and cause the Company's officers, directors, employees and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant or agent in

connection with such registration statement;

(j) otherwise use its reasonable efforts to comply with all applicable rules and regulations of the Commission, and make available to its security holders, as soon as reasonably practicable, an earnings statement covering the period of at least 12 months beginning with the first day of the Company's first full calendar quarter after the effective date of the registration statement, which earnings statement shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 thereunder.

(k) in the event of the issuance of any stop order suspending the effectiveness of a registration statement, or of any order suspending or preventing the use of any related prospectus or suspending the qualification of Common Stock included in such registration statement for sale in any jurisdiction, the Company will use its reasonable best efforts promptly to obtain the withdrawal of such order;

(l) obtain a so-called "cold comfort" letter from the Company's independent public accountants in customary form and covering such matters of the type customarily covered by such letters; and

(m) undertake such other actions and do all other things which the Holders shall reasonably request and which shall be customary at the time for such registrations.

7. Indemnification. (a) The Company agrees to indemnify, to the fullest extent permitted by applicable law, each Holder of Registrable Securities, its officers and directors and each Person who controls such Holder (within the meaning of the Securities Act) against all losses, claims, damages, liabilities, expenses or any amounts paid in settlement of any litigation, investigation or proceeding commenced or threatened (collectively, the "Claims") to which each such indemnified party may become subject under the Securities Act insofar as such Claim(s) arose out of (i) any untrue or alleged untrue statement of material fact contained, on the effective date thereof, in any registration

statement, prospectus or preliminary prospectus or any amendment thereof or supplement thereto, (ii) any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violations by the Company of any federal, state or common law rule or regulation applicable to the Company and relating to action required of or inaction by the Company in connection with any such registration, except insofar as the same are caused by or contained in any information furnished in writing to the Company by such Holder expressly for use therein or by such Holder's failure to deliver a copy of the registration statement or prospectus or any amendments or supplements thereto after the Company has furnished such Holder with a sufficient number of copies of the same. In connection with an underwritten offering, the Company will indemnify such underwriter(s), their officers and directors and each Person who controls such underwriter(s) (within the meaning of the Securities Act) to the same extent as provided above with respect to the indemnification of the holders of Registrable Securities.

(b) In connection with any registration statements in which a Holder of Registrable Securities is participating, each such Holder will furnish

to the Company in writing such customary information and affidavits as the Company reasonably requests for use in connection with any such registration statement or prospectus (the "Seller's Information") and, to the fullest extent permitted by applicable law will indemnify the Company, its directors and officers and each Person who controls the Company (within the meaning of the Securities Act) against any and all Claims to which each such indemnified party may become subject under the Securities Act insofar as such Claim(s) arose out of (i) any untrue or alleged untrue statement of material fact contained, on the effective date thereof, in any registration statement, prospectus or preliminary prospectus or any amendment thereof or supplement thereto, (ii) any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or (iii) any violations by such Person of any federal, state or common law rule or regulation applicable to such Person and relating to action required of or inaction by such Person in connection with any such registration; provided that with respect to Claim(s) arising pursuant to clause (i) or (ii) above, the material misstatement or omission is contained in such Seller's Information; provided, further, that the obligation to indemnify will be individual to each Holder and will be limited to the net amount of proceeds received by such Holder from the sale of Registrable Securities pursuant to such registration statement.

(c) Any Person entitled to indemnification hereunder will (i) give prompt written notice to the indemnifying party of any claim with respect to which it seeks indemnification (but the failure to provide such notice shall not release the indemnifying party of its obligation under paragraphs (a) and (b), unless and then only to the extent that the indemnifying party has been prejudiced by such failure to provide such notice) and (ii) unless in such indemnified party's reasonable judgment a conflict of interest between such indemnified and indemnifying parties may exist with respect to such claim, permit such indemnifying party to assume the defense of such claim with counsel reasonably satisfactory to the indemnified party. An indemnifying party who is

not entitled to, or elects not to, assume the defense of a claim will not be obligated to pay the fees and expenses of more than one counsel for all parties indemnified by such indemnifying party with respect to such claim, unless in the reasonable judgment of any indemnified party a conflict of interest may exist between such indemnified party and any other of such indemnified parties with respect to such claim.

(d) The indemnifying party shall not be liable to indemnify an indemnified party for any settlement, or consent to judgment of any such action effected without the indemnifying party's consent (but such consent will not be unreasonably withheld). Furthermore, the indemnifying party shall not, except with the approval of each indemnified party, consent to the entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to each indemnified party of a release from all liability in respect to such claim or litigation without any payment or consideration provided by each such indemnified party.

(e) If the indemnification provided for in this Section 7 is unavailable to an indemnified party under clauses (a) and (b) above in respect of any losses, claims, damages or liabilities referred to therein, then each indemnifying party, in lieu of indemnifying such indemnified party, shall

contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities in such proportion as is appropriate to reflect not only the relative benefits received by the Company, the underwriter(s), the sellers of Registrable Securities and any other sellers participating in the registration statement from the sale of shares pursuant to the registered offering of securities to which indemnity is sought but also the relative fault of the Company, the underwriter(s), the sellers of Registrable Securities and any other sellers participating in the registration statement in connection with the statement or omissions which resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company, the underwriter(s), the sellers of Registrable Securities and any other sellers participating in the registration statement shall be deemed to be based on the relative relationship of the total net proceeds from the offering (before deducting expenses) to the Company, the total underwriting commissions and fees from the offering (before deducting expenses) to the underwriter(s) and the total net proceeds from the offering (before deducting expenses) to the sellers of Registrable Securities and any other sellers participating in the registration statement. The relative fault of the Company, the underwriter(s), the sellers of Registrable Securities and any other sellers participating in the registration statement shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by registration statement and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

(f) The indemnification provided for under this Agreement will remain in full force and effect regardless of any investigation made by or on behalf of the indemnified party or any

officer, director or controlling person of such indemnified party and will survive the transfer of securities.

8. Participation in Underwritten Registrations. No Person may participate in any registration hereunder which is underwritten unless such Person (a) agrees to sell such Person's securities on the basis provided in any underwriting arrangements approved by the Person or Persons entitled hereunder to approve such arrangements, (b) as expeditiously as possible notifies the Company of the occurrence of any event as a result of which such prospectus contains an untrue statement of material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading and (c) completes and executes all questionnaires, powers of attorney, indemnities, underwriting agreements and other documents reasonably required under the terms of such underwriting arrangements.

9. Transfer of Registration Rights. The rights granted to any Person under this Agreement may be assigned to a transferee or assignee in connection with any transfer or assignment of Registrable Securities by a Holder; provided, that: (a) such transfer may otherwise be effected in accordance with applicable securities laws, (b) if not already a party hereto, the assignee or transferee agrees in writing prior to such transfer to be bound by the provisions of this

Agreement applicable to the transferor, (c) such transferee shall own Registrable Securities representing at least 250,000 shares of Common Stock (subject to the anti-dilution adjustments contained in the Purchase Agreement), and (d) EIS shall act as agent and representative for such Holder for the giving and receiving of notices hereunder. In the event that such assignment occurs subsequent to the date of effectiveness of a Registration Statement filed pursuant to this Agreement, the transferee agrees to pay all reasonable expenses necessary to amend or supplement such Registration Statement to reflect such assignment.

10. Information by Holder. Each Holder shall furnish the Company such written information regarding such Holder and any distribution proposed by such Holder as the Company may reasonably request in writing and as shall be reasonably required in connection with any registration qualification or compliance referred to in this Agreement.

11. Exchange Act Compliance. The Company shall comply with all of the reporting requirements of the 1934 Act applicable to it and shall comply with all other public information reporting requirements of the Commission which are conditions to the availability of Rule 144 for the sale of the Registrable Securities. The Company shall cooperate with each Purchaser in supplying such information as may be necessary for such Purchaser to complete and file any information reporting forms presently or hereafter required by the Commission as a condition to the availability of Rule 144.

12. Limitation on Registration. Notwithstanding anything to the contrary in this Agreement, the Company shall not be obligated to effect a registration of any Holder's Registrable Securities pursuant to Sections 2 or 3 hereof if all of the Registrable Securities have been sold under Rule 144, Regulation S or similar provision under the Securities Act so that there is no further restriction on the transfer by the transferee or if the Holders may sell the Registrable Securities without restriction pursuant to Rule 144(k) under the Securities Act (or any successor statute thereto).

13. Miscellaneous. (a) No Inconsistent Agreements. The Company will not hereafter enter into any agreement with respect to its securities which is inconsistent with or violates the rights granted to the Holders of Registrable Securities in this Agreement.

(b) Remedies. Any Person having rights under any provision of this Agreement will be entitled to enforce such rights specifically to recover damages caused by reason of any breach of any provision of this Agreement and to exercise all other rights granted by law. The parties hereto agree and acknowledge that money damages may not be an adequate remedy for any breach of the provisions of this Agreement and that any party may in its sole discretion apply to any court of law or equity of competent jurisdiction (without posting any bond or other security) for specific performance and for other injunctive relief in order to enforce or prevent violation of the provisions of this Agreement.

(c) Amendments and Waivers. Except as otherwise provided herein, the provisions of this Agreement may be amended or waived only upon the prior

written consent of the Company and Holders of at least 50% of the Registrable Securities; provided, that without the prior written consent of all the Holders, no such amendment or waiver shall reduce the foregoing percentage.

(d) Successors and Assigns. All covenants and agreements in this Agreement by or on behalf of any of the parties hereto will bind and inure to the benefit of the respective successors and assigns of the parties hereto whether so expressed or not. In addition, whether or not any express assignment has been made, the provisions of this Agreement which are for the benefit of Holders of Registrable Securities are also for the benefit of, and enforceable by, any subsequent holder of Registrable Securities.

(e) Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.

(f) Counterparts. This Agreement may be executed simultaneously in two or more counterparts, any one of which need not contain the signatures of more than one party, but all such counterparts taken together will constitute one and the same Agreement.

(g) Descriptive Headings. The descriptive headings of this Agreement are inserted for convenience only and do not constitute a part of this Agreement.

(h) Governing Law. All questions concerning the construction, validity and interpretation of this Agreement and the exhibits and schedules hereto will be governed by the internal law, and not the law of conflicts, of New York. Each of the Parties hereby irrevocably submits to the jurisdiction of any New York State or United States Federal court sitting in the county, city and state of New York over any action or proceeding arising out of or relating to this Agreement or the Transaction Documents; and each hereby waives the defense of an inconvenient forum for the maintenance of such an action.

(i) Notices. All notices, demands or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given when delivered personally or by hand to the recipient, one day after being sent to the recipient by an internationally recognized overnight delivery service (charges prepaid) or three days after being mailed to the recipient by certified or registered mail, return receipt requested and postage prepaid. Such notices, demands and other communications will be sent to the parties hereto at the addresses indicated on the signature page hereto and to the Company at the address indicated below:

Sheffield Pharmaceuticals, Inc.
South Winton Court
3136 Winton Road South
Suite 306
Rochester, New York 14623

Attention: Chairman

and

Sheffield Pharmaceuticals, Inc.
425 South Woodsmill Road
St. Louis, Missouri 63017-3441
Attention: Chief Executive Officer

(j) Termination. This Agreement shall terminate on the date as of which each Holder has sold all remaining Registrable Securities in a transaction or transactions of the type described in Section 12 hereof.

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

Sheffield Pharmaceuticals, Inc.

By:/s/

Name:
Title:

Elan International Services, Ltd.

By:/s/

Name:
Title:

102 St. James Court
Flatts, Smiths Parish
Bermuda, FL04
Attention: Director
Facsimile: (441) 292-2224

-----END PRIVACY-ENHANCED MESSAGE-----