

-----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, ChHi9Cmzg7kiV/1zcala8ocjce74nE5n9iFG1qBB/NTOuphNGFc9hSx7F6Ov3PWF xuucUbiawpzUKDBI58JR/w== 0000921895-98-000608.txt : 19980717 0000921895-98-000608.hdr.sgml : 19980717 ACCESSION NUMBER: 0000921895-98-000608 CONFORMED SUBMISSION TYPE: 8-K PUBLIC DOCUMENT COUNT: 7 CONFORMED PERIOD OF REPORT: 19980630 ITEM INFORMATION: ITEM INFORMATION: FILED AS OF DATE: 19980716 SROS: AMEX 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: 98667282 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): JUNE 30, 1998

SHEFFIELD PHARMACEUTICALS, INC.

-----  
(Exact name of Registrant as specified in its charter)

Delaware                      1-12584                      13-3808303

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(State or other jurisdiction      (Commission      (I.R.S. Employer

of incorporation)	File Number)	Identification
	Number)	
425 SOUTH WOODSMILL ROAD, ST. LOUIS, MISSOURI		63017

-----  
(Address of Principal executive offices) (Zip Code)

(314) 579-9899

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Registrant's telephone number, including area code

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

ITEM 5. OTHER EVENTS.

On June 30, 1998, 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 June 3, 1998 (the "Letter of Intent"). A copy of the press release disclosing information relating to the consummation of the transaction and certain related matters is attached as an exhibit to this report, and is incorporated herein by reference.

As part of the transaction, the Company has created a wholly owned subsidiary in Bermuda called Systemic Pulmonary Delivery, Ltd ("SPD") and entered into several agreements with Elan, including a Securities Purchase Agreement dated June 30, 1998 (the "Purchase Agreement") and a Joint Development and Operating Agreement dated June 30, 1998 (the "Operating Agreement"). Elan, the Company and SPD have also licensed certain of their intellectual property rights relating to pulmonary drug delivery systems pursuant to license agreements. Copies of the Purchase Agreement, the Operating 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

- (10.1) Securities Purchase Agreement, dated as of June 30, 1998, by and between Sheffield Pharmaceuticals, Inc. and Elan International Services, Ltd., which includes the Certificate of Designations of Series C Convertible Preferred Stock as Exhibit B.

The Company agrees to furnish the disclosure schedules as well as Exhibits A and C, which have been omitted from this filing, to the Commission upon request (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).

(10.2) Systemic Pulmonary Delivery, Ltd. Joint Development and Operating Agreement dated as of June 30, 1998 among Systemic Pulmonary Delivery, Ltd., Sheffield Pharmaceuticals, Inc. and Elan International Services, Ltd. (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).

(10.3) License and Development Agreement dated June 30, 1998 between Sheffield Pharmaceuticals, Inc. and Systemic Pulmonary Delivery, Ltd. and Elan Corporation, plc. (portions of this exhibit

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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).

(10.4) License and Development Agreement dated June 30, 1998 between Systemic Pulmonary Delivery, Ltd. and Sheffield Pharmaceuticals, Inc. and Elan Corporation, plc. (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).

(10.5) License and Development Agreement dated June 30, 1998 between Elan Corporation, plc and Systemic Pulmonary Delivery, Ltd. and Sheffield Pharmaceuticals, Inc. (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).

(99.1) Press Release of Sheffield Pharmaceuticals, Inc. dated July 1, 1998.

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#### 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: July 16, 1998

By: /s/ Judy Roeske Bullock

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Judy Roeske Bullock  
Vice President and Chief  
Financial Officer

EX-10.1

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SECURITIES PURCHASE AGREEMENT

CERTAIN PORTIONS HAVE BEEN OMITTED BASED ON  
A REQUEST FOR CONFIDENTIAL TREATMENT;  
OMITTED PORTIONS FILED SEPARATELY WITH THE  
SECURITIES AND EXCHANGE COMMISSION

SECURITIES PURCHASE AGREEMENT dated as of June 30, 1998, between ELAN INTERNATIONAL SERVICES, LTD., a Bermuda corporation ("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, as provided herein (i) 4,571,428 shares of the Company's common stock, par value \$ .01 per share (the "Common Stock"), and (ii) a warrant to acquire 990,000 shares (subject to adjustment) of Common Stock at an exercise price of \$2.00 per share, in the form attached hereto as EXHIBIT A (the "Warrant"), for aggregate consideration of \$6,000,000.

B. The Company desires to issue and sell to EIS, and EIS desires to purchase from the Company, all of the shares of a Series C Convertible Preferred Stock (the "Series C Preferred") which shall be issued to EIS pursuant to the Certificate of Designations in the form attached hereto as EXHIBIT B (the "Certificate of Designations"), for aggregate consideration of \$11,500,000 (the "Original Issue Price").

C. The Company may, in its discretion, issue a new series of convertible indebtedness, evidenced by a promissory note in the form attached hereto as EXHIBIT C (the "Convertible Note"; together with the Common Stock, the Warrant, and the Series C Preferred Stock, the "Securities"), and EIS hereby agrees to make purchases of the Convertible Note in accordance with the terms and conditions contained herein, in the event that such debt shall be issued.

D. The Company has previously caused to be formed Systemic Pulmonary Delivery, Ltd., a Bermuda corporation ("Newco"), and pursuant to the terms of a subscription agreement (the "Newco Subscription Agreement") has acquired 100% of the issued and outstanding shares of the common stock of Newco; and, as of the date hereof, Newco has entered into a license agreement with ELAN CORPORATION, PLC ("Elan"; the "Elan License Agreement"), and two license agreements with the Company (respectively, the "Sheffield License Agreement" and the "Newco License Agreement"; collectively with the Elan License Agreement, the "License Agreements") for the purpose of developing and commercializing products incorporating, INTER ALIA, the Enhancing Technology, the UPDASTM Technology, the Sheffield Technology and the ADDS Technology (as those terms are defined in each of the License Agreements) relating to the Systemic Pulmonary and Topical Pulmonary Fields (as those terms are defined in each of the license agreements).

E. The parties intend, as provided herein, that \$15,500,000 of the proceeds of the issuance of the sale of the Common Stock and the Series C Preferred shall be applied by the Company solely to fund the Company's initial investment in Newco and subsequent development funding required by Newco, as provided herein and as set forth in the Newco joint development and operating agreement dated as of the date hereof by and between Newco, EIS and the Company (the "Development Agreement"), and that \$2,000,000 of such proceeds shall be retained by the Company as working capital.

F. The Company and EIS are executing and delivering on the date hereof a Registration Rights Agreement in the form attached hereto as EXHIBIT D (the "Registration Rights Agreement"; together with this Agreement, the Securities, the Certificate of Designations, the Development Agreement and each other document or instrument executed and delivered in connection with the transactions contemplated hereby, the "Transaction Documents") in respect of the initial purchase of Common Stock and the Common Stock underlying the Securities and any other Common Stock that may at any time be acquired or owned by EIS or its affiliates.

## AGREEMENT:

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) 4,571,428 shares of Common Stock (the "Initial Common Stock") and (ii) the Warrant, for an aggregate purchase price of \$6,000,000, and (y) 11,500 shares of Series C Preferred for consideration of \$11,500,000.

(c) DELIVERY. At the Closing, EIS shall pay the purchase price for the Initial Common Stock, the Warrant and the Series C Preferred 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 the Initial Common Stock; (ii) the Warrant; (iii) a certificate or certificates for the shares of the Series C Preferred; (iv) certificates as to the incumbency of the officers executing this Agreement; and (vi) 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 attached hereto as EXHIBIT E.

(d) ADDITIONAL CLOSINGS. The Company shall be entitled from time to time, subject to the conditions herein, to require EIS to purchase all or part of the Convertible Note in accordance with Section 6 hereof.

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(e) EXEMPTION FROM REGISTRATION. The Securities will be issued under an exemption or exemptions from registration under the Securities Act of 1933, as amended; accordingly, the certificates evidencing the Initial Common Stock, and any shares of Common Stock issuable upon the exercise or exchange 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 AND MAY NOT UNDER ANY CIRCUMSTANCES BE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933 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 are each executing and delivering the Registration Rights Agreement, covering the resale by EIS of the Initial Common Stock issuable hereunder and any Common Stock issuable upon conversion, exercise or 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. 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. (i) The authorized capital stock of the Company consists of (i) 50,000,000 shares of Common Stock, par value \$.01 per share and (ii) 3,000,000 shares of Preferred Stock, par value \$.01 per share. As of June 25, 1998, 22,282,109 shares of Common Stock were issued and outstanding and 1,250 shares of Preferred Stock were issued and outstanding.

(ii) Except as listed in SCHEDULE 2(B), as of June 15, 1998 there were 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

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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, and, other than as set forth in SCHEDULE 2(B) or in the Registration Rights Agreement, there are no agreements to register any of the Company's outstanding securities under the U.S. federal securities acts relating to securities that have not already been registered under the Securities Act of 1933 as amended.

(iii) All of the outstanding shares of capital stock of the Company have been issued in accordance with applicable state and federal laws and regulations governing the sale and purchase of securities, all of such shares of have duly and validly issued and 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 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 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 Articles of Incorporation, as amended, its Certificate of Designations (in the form 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, by

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the Company. There is no approval of the Company's stockholders required under applicable laws in connection with the execution and delivery the Transaction Documents or the consummation of the transactions contemplated thereby, including the filing of the Certificate of Designations and the issuance of the Securities.

(f) FILINGS, TAXES AND FINANCIAL STATEMENTS. (i) The Company has filed its annual report on Form 10-K for the year ended December 31, 1997 (the "Annual Report"), its related proxy materials and the quarterly report on Form 10-Q for the quarter ended March 31, 1998 (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 acts. The audited financial statements of the Company for the fiscal year ended December 31, 1997 included in the Annual Report (the "Audited Financial Statements"), and the Company's unaudited balance sheet for the period ending March 31, 1998, together with the accompanying statements of operations and cash flows including the notes thereto included in the Quarterly Report (the "March 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 March 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 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, 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.

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(g) ABSENCE OF CHANGES. Except as set forth on SCHEDULE 2(G), since May 31, 1998, 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, 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) 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 \$50,000; 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 not, 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 ("Proprietary Rights"). The Proprietary Rights are adequate for the conduct of the Company's business. Except as set forth in the SEC Filings, the Sheffield License Agreement, or where the absence of which would not have a material Adverse Effect, (A) the Company is the sole and exclusive owner of all right, title and interest in and 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.

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(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, (ii) environmental matters, including the discharge of any hazardous or potentially hazardous materials into the environment, and (iii) 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. There is no legal, administrative, arbitration or other action or proceeding or governmental investigation pending or, to the best of the Company's 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 Annual Report and periodic reports subsequently filed under Section 13 of 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. (I) BROKERS OR FINDERS. The Company has not retained any investment banker, broker or finder in connection with the transactions contemplated by the Transaction Documents.

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

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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 purchase and accept the Note, and perform its obligations hereunder, which have been duly authorized by all requisite corporate action. This Agreement and the purchase of the Convertible Note 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 Convertible Note 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, written, injunction, order, judgment or decree of any court, arbitration, administrative agency of other governmental body applicable to EIS of 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 the Certificate of Incorporation or By-laws of EIS 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 or the Convertible Note (including the funding and acceptance thereof) by EIS.

(e) INVESTMENT REPRESENTATIONS. (i) EIS is an "accredited investor" as that term is 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, or for sale in connection with, any distribution of any part thereof; provided, that EIS shall be permitted to convert or exchange such Securities and/or transfer them as permitted herein and under applicable law. EIS has been afforded the opportunity to ask questions of and information about the Company and its business and prospects, from management and representatives of the Company, and have relied on its own independent judgment in making a judgment about an investment in the Securities.

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(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, the Company shall not 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 EIS (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; provided, that the Company shall provide EIS with a reasonable opportunity to review such releases or reports prior to release. This Section 4 shall not be construed to prohibit disclosure of any information which has not been previously determined to be confidential by EIS, or which shall have become publicly disclosed (other than by breach of the Company's obligations hereunder).

(b) BOARD OF DIRECTORS. Immediately following the Company's Annual Meeting of Stockholders scheduled to be held on July 15, 1998, the Company's board of directors shall be expanded by one member, and EIS shall be entitled to appoint a director to fill the vacancy so created (the "EIS Director"), who shall be reasonably satisfactory to the Company, and who shall be a duly elected director. The Company shall not enter into any agreement relating to a material acquisition or sale of assets or financing agreements from the date of this Agreement until July 15, 1998 without the prior approval of EIS or the prior election of the EIS Director to its Board of Directors. From and after the date hereof and for so long as EIS and/or its respective affiliates own Securities that represent ownership of at least 5% of the Common Stock, on a fully diluted basis, the Company shall use its best efforts to cause the EIS Director to be elected to the Company's board of directors, by including the EIS Director in the management slate of directors at each meeting of stockholders at which an

election of directors occurs.

(c) FULLY-DILUTED STOCK OWNERSHIP. 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 Common Stock (or securities or rights, options or warrants exercisable, exchangeable or convertible for or into Common Stock) representing in the aggregate in excess of 19.9% of the Company's outstanding Common Stock (assuming any such exercise, exchange or conversion, but not the exercise, exchange or conversion of any other similar securities), EIS shall have the right, in its sole discretion, rather than acquiring such securities from the Company, to exchange such number of securities, as are necessary to bring its holdings to below 19.9% of the voting securities of the Company, for non-

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voting, liquidation preferred stock of the Company (which shall be reasonably satisfactory to the Company and EIS), which equity securities shall be entitled to all of the other rights and benefits of the Common Stock. In the event that EIS shall undertake to exercise such right, EIS shall retain the additional right to exchange such new class of equity security for Common Stock, in its discretion on terms that are mutually agreeable to the Company and EIS.

(d) CERTAIN PREEMPTIVE RIGHTS. For a period of four years from and after the date hereof, EIS shall be entitled to participate in any convertible debt or equity financing (the "Preemptive Right") undertaken by the Company (each, a "Capital Raising"), in order that EIS may maintain its then current PRO RATA percentage ownership interest in equity securities (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 EIS's ownership interest in the Company's Common Stock 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; 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.

(e) USE OF PROCEEDS. The Company shall use \$15,500,000 of the aggregate proceeds of the sale of the Initial Common Stock and the Series C Preferred solely for the purpose of meeting its capitalization and funding requirements to Newco.

SECTION 5. MUTUAL COVENANTS OF THE PARTIES. (a) RIGHT OF CONVERSION. EIS may, pursuant to the Certificate of Designations, from and after the date hereof and until the term of the Series C Preferred shall expire, convert the Series C Preferred into Common Stock ("Conversion Right").

(b) RIGHTS OF EXCHANGE. (i) FIRST EXCHANGE RIGHT. (A) EIS may, in accordance with the Certificate of Designations, exchange the originally issued shares of the Series C Preferred for an aggregate of 50% of the common stock, par value \$1.00 per share of Newco (the "Newco Common Stock"), owned by the Company (the "First Exchange Right"). Thereafter, such shares of Series C

Preferred shall be of no further force or effect; provided, that all additional shares of Series C Preferred issued as a dividend thereon shall continue to carry all rights attributable thereto pursuant to the Certificate of Designations. Notwithstanding the foregoing, EIS, and any permitted transferees, will convert any Dividend Shares (as defined in the Certificate of Designations) within thirty months of the date of exercise of the First Exchange Right, in accordance with Article 7 of the Certificate of Designations.

(B) The First Exchange Right shall terminate upon the earlier of (X) exercise of the Conversion Right by EIS and (Y) termination of the Series C Preferred.

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(ii) SECOND EXCHANGE RIGHT. In the event that EIS shall consummate the exercise of the First Exchange Right, EIS shall be entitled to purchase from the Company, for consideration in the amount of \$[text omitted], a number of shares of Newco Common Stock sufficient to increase EIS's ownership interest therein to [text omitted] (the "Second Exchange Right").

(iii) THIRD EXCHANGE RIGHT. (A) In the event that EIS shall have consummated the exercise of each of the First Exchange Right and the Second Exchange Right, EIS shall be entitled, and the Company shall be required at EIS's request, to enter into good faith negotiations to arrange for the sale of the remaining [text omitted] of Newco Common Stock owned by the Company to EIS (the "Final Purchase"), for consideration of fair market value ("FMV"); such FMV to be determined without regard to EIS's [text omitted] ownership interest (i.e., as if such sale were to an unaffiliated third party and without effect to a premium for EIS's control position).

(B) In the event that EIS and the Company are unable to reach agreement on the FMV and other terms to be negotiated in connection with such sale, the parties shall mutually agree as to an arbitrator (or, failing mutual agreement, an arbitrator shall be appointed by the American Arbitration Association in accordance with its customary appointment provisions; each an "Arbitrator"), the expense of whom shall be borne equally by EIS and the Company, and the arbitrator shall establish FMV.

(C) FMV as determined by the Arbitrator shall be binding upon the Company, and the Company shall be obligated to enter into the Final Purchase at EIS's discretion; however, EIS shall be bound by the Arbitrator's determination of FMV and be required to enter into the Final Purchase only if such FMV shall be an amount which is less than EIS's most recent offer to the Company. In addition, in order to accommodate the Company's internal accounting requirements, the Company shall be entitled to request that the Arbitrator determine what portion of FMV is comprised of the value of rights to the MSI Technology (as defined in the Sheffield License Agreement), licensed by the Company to Newco; provided, that such determination shall be for information purposes only, and shall not create or add to EIS's obligations hereunder.

(D) In the event that EIS shall fail to enter into the Final Purchase within 30 days of receipt of notice of the Arbitrator's determination of FMV, the Company shall be free, for a period of [text omitted] months from and after the date of receipt of such notice, to consummate a sale of its remaining [text omitted] interest in Newco to an unaffiliated third party (notwithstanding Article IV of the Newco Subscription Agreement) without first offering such

interest to EIS.

(b) 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 the Transaction Documents or to better to assure and confirm unto each other their respective rights, powers and remedies hereunder and thereunder.

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SECTION 6. CONVERTIBLE NOTE. (a) ISSUANCE. (i) Beginning with the date which is 90 days from and after the date hereof, and until the date which is the 24-month anniversary of the date hereof, EIS shall be required, at the Company's discretion, to purchase up to \$[text omitted] of debt under the Convertible Note in minimum increments of \$[text omitted]; provided, that the maximum amount of debt under the Convertible Note which the Company may require EIS to purchase shall be \$[text omitted] in the event that the ADDS Technology (as described in the Newco License Agreement) is not acquired by Newco on or before December 31, 1998;

(ii) the maximum amount of debt under the Convertible Note which EIS shall be required to purchase in any calendar quarter shall be \$500,000.

(b) CONDITIONS TO THE PURCHASE OF CONVERTIBLE DEBT. It shall be a condition to EIS's obligation to purchase any debt under the Convertible Note that (A) each of the representations and warranties set forth in Section 2(a), (b)(iii), (c), (d), (f), (i) and (l) 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 Securities Exchange Act of 1934, as amended (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, (C) Newco shall continue to require funds, and the Company shall be continuing to provide services, in connection with the R&D Program (as defined in the Development Agreement), and (D) the Company shall have executed and delivered to EIS the promissory note attached hereto as EXHIBIT C.

(c) USE OF PROCEEDS. The Company shall use the proceeds of the Convertible Debt, if any, as follows: [text omitted]; provided, that in the event of a failure to acquire the ADDS Technology on or before December 31, 1998, the Company shall use [text omitted] of the proceeds of the Convertible Debt to meet its funding obligations to Newco in connection with Newco research and development.

SECTION 7. SURVIVAL AND INDEMNIFICATION. (a) SURVIVAL PERIOD. The representations and warranties of the Company 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

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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 or 5 of this Agreement.

(c) MAXIMUM RECOVERY. Notwithstanding anything to this Agreement to the contrary, in no event shall Sheffield be liable for indemnification under this Section 7, the Transaction Documents, or otherwise in an amount in excess of \$[text omitted], 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 Persons 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 Persons all amounts previously paid in full or partial satisfaction of such indemnity, together with all costs and expenses (including reasonable attorneys 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

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investigation, inquiry or examination made for or on behalf of, or any knowledge of the Indemnified Persons or the acceptance of any certificate or opinion.

(f) CONTRIBUTION. If the indemnity provided for the this Section 7 shall be, 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(h) 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 part 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 of 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 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 or by registered or certified airmail, return receipt requested and postage prepaid, addressed as follows:

(i) if to the Company, to:

Sheffield Pharmaceuticals, Inc.  
37 South Main Street  
Pittsford, New York 14534  
Attn: Chairman

and

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

with a copy to:

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

(ii) if to EIS, to:

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

with a copy to:

Brock Silverstein McAuliffe LLC  
153 East 53rd Street , 56th Floor  
New York, New York 10022  
Attention: David Robbins

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; such transmission shall be deemed a valid signature.

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 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. This Agreement, the other Transaction Documents, and the Securities may be transferred by EIS to affiliates and subsidiaries.

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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/ Thomas M. Fitzgerald

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Thomas M. Fitzgerald  
Chairman

ELAN INTERNATIONAL SERVICES, LTD.

By:/s/ Kevin Insley

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Name: Kevin Insley

Title: President

## EXHIBIT B

FORM OF

CERTIFICATE OF DESIGNATIONS,  
PREFERENCES AND RIGHTS

OF

SERIES C CUMULATIVE CONVERTIBLE PREFERRED STOCK

OF

SHEFFIELD PHARMACEUTICALS, INC.

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

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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 adopted by the Board of Directors of the Corporation by unanimous written consent dated June 26, 1998 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"), there hereby is created, 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"), a series of Preferred Stock consisting of 23,000 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 C Cumulative Convertible Preferred Stock" (the "Series C Preferred Stock") and the authorized number of shares constituting such series shall be 23,000 shares. The par value of the Series C Preferred Stock shall be \$.01 per share. The stated value of the Series C 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 C 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 PAYMENT DATE" has the meaning set forth in Section 4.1.

(j) "DIVIDEND PERIOD" has the meaning set forth in Section 4.1.

(k) "DIVIDEND SHARES" means the shares of Series C Preferred Stock issued as dividends on outstanding shares of Series C Preferred stock in accordance with Article 4 hereof.

(l) "DOLLARS" or "\$" means currency of the United States of America.

(m) "EXCHANGE DATE" has the meaning set forth in Article 7.

(n) "EXCHANGE NOTICE" has the meaning set forth in Article 7.

(o) "HOLDER" OR "HOLDERS" means Elan International Services, Ltd., a Bermuda corporation, any successor thereto, or any Person(s) to whom the Series C 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 C 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) "MANDATORY CONVERSION DATE" has the meaning set forth in Section 6.3.

(t) "PARI PASSU SECURITIES" has the meaning set forth in Article 3.

(u) "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.

(v) "RIGHTS" has the meaning set forth in Section 6.2(e).

(w) "SERIES C PREFERRED STOCK" means the Series C Cumulative Convertible Preferred Stock of the Corporation created by this Certificate of Designations.

(x) "SPD" Systemic Pulmonary Delivery, Ltd., a Bermuda corporation.

(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 C 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, "Junior Securities"); (iii) pari passu with the Corporation's Series B Cumulative Convertible Redeemable Preferred Stock (the "Series B Preferred Stock"); and (iv) pari passu with any class or series of capital stock of the Corporation hereafter created specifically ranking on parity with the Series C Preferred Stock (collectively, with the Series B Preferred Stock, "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 C Preferred Stock payable on and as of the most recent Dividend Payment Date with respect to each Dividend Period. Dividends on the Series C 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 C Preferred Stock by the Corporation.

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(ii) Dividend on the Series C Preferred Stock shall be payable in equal quarterly amounts on each March 31, June 30, September 30 and December 31 of each year (each, a "Dividend Payment Date"), commencing September 30, 1998, to the holders of record of shares of the Series C 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 C

Preferred Stock, shall mean (i) the period commencing on and including the Issue Date of such share and including September 30, 1998 and, thereafter, the quarterly 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 C Preferred Stock shall be paid through the issuance of duly and validly authorized and issued, fully paid and non-assessable additional shares of Series C Preferred Stock to be issued at the rate of one (1) share of Series C Preferred Stock for each \$1,000 of dividend due and payable. No fractional shares of the Series C Preferred Stock shall be issued as Dividend Shares. Instead of any fractional shares of Series C 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 C 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 C Preferred Stock that may be in arrears.

## 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

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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 C 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 C Preferred Stock shall mean an amount equal to (i) the Stated Value thereof, plus (ii) the aggregate of all accrued and unpaid stock dividends on such share of Series C 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 (iii) 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 C PREFERRED STOCK

### SECTION 6.1          CONVERSION.

(a) Holders of shares of the Series C Preferred Stock shall have the right, exercisable at any time and from time to time through the Mandatory Conversion Date, to convert all or any such shares of the Series C Preferred Stock into shares of the Common Stock (calculated as to each conversion to the nearest 1/100th of a share) at the conversion price of \$1.41 per share of the Common Stock (equivalent to a conversion rate of 709.22 shares of Common Stock for each share of the Series C Preferred Stock so converted), subject to adjustment as described below (the "Conversion Price"). Upon conversion, no adjustment or payment will be made for dividends, but if any holder surrenders a share of the Series C 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

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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 C 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 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 C Preferred Stock, all such shares of Series C 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 C Preferred Stock shall cease to accrue, and all rights of the Holders thereof as holders of Series C 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 C 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 C 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 C Preferred Stock. If more than one share of the Series C 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 C 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 C 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.

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(e) Each Conversion Notice under this Section 6.1 shall request the conversion of at least 500 shares of Series C Preferred Stock or the remaining balance of Series C 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 C Preferred Stock are subject to adjustment from time to time as follows:

(a) MERGER, SALE OF ASSETS, ETC. If at any time while the

Series C 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 C 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 C 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 C Preferred Stock.

(b) RECLASSIFICATION, ETC. If the Corporation, at any time while the Series C 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 C 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.

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(c) SPLIT, SUBDIVISION OR COMBINATION OF SHARES. If the Corporation at any time while the Series C 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 C 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 C 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 C 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 C 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 C 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 125% 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.

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(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.

SECTION 6.3 MANDATORY CONVERSION. On the tenth anniversary of the Issue Date (the "Mandatory Conversion Date"), all Series C Preferred Stock outstanding on such date shall be automatically converted at the Conversion Price in effect as of the Mandatory Conversion Date. For purposes of such conversion, each Holder shall be deemed to have delivered a Notice of Conversion to the Corporation in accordance with Section 6.1, with the applicable Conversion Date being the Mandatory Conversion Date.

## ARTICLE 7 EXCHANGE RIGHTS

Holders of at least a majority of the then outstanding shares of Series C 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 (the "Exchange Notice"), fully completed and duly executed by the requisite Holders, to require the Corporation to exchange all outstanding shares of Series C Preferred Stock as of any Dividend Payment Date (such date being the "Exchange Date") for fifty percent (50%) of the then outstanding capital stock of SPD owned by the Corporation 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 C 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.

From and after the delivery of the Exchange Notice, all shares of Series C Preferred Stock (other than Dividend Shares) shall be deemed to have been exchanged for fifty percent (50%) of the then outstanding capital stock of SPD (in the aggregate) as of Exchange Date, all stock dividends on such shares of the Series C Preferred Stock shall cease to accrue, and all rights of the Holders thereof as holders of Series C Preferred Stock, except the right to receive all accrued and unpaid stock dividends to the Exchange Date at the applicable rate for such shares of such shares of Series C Preferred Stock and the right to receive certificates representing the applicable shares of SPD capital stock issuable in respect of the exchange, shall cease and terminate, such shares of Series C 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.

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The Rights of Holders under this Article 7 shall terminate and such Holders shall not be entitled to exchange shares of Series C Preferred Stock under this Article 7 after a Conversion Notice has been delivered to the Corporation pursuant to this Section 6.1. Notwithstanding anything to the contrary in this Article 7, the delivery of the exchange notice shall not effect any Holder's rights to convert Dividend Shares held by such holder pursuant to Section 6.2 hereof, except that any conversion of Dividend Shares must occur within thirty months from the Exchange Date.

## ARTICLE 8

## VOTING RIGHTS

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

The Corporation shall provide each Holder of Series C 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 C 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 C 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 C 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 C Preferred Stock are entitled to vote on a matter with Holders of Common Stock, voting together as one class, each share of Series C Preferred Stock shall be entitled to a number of votes equal to the number of shares of Common Stock into which convertible the record date for the taking of such vote of shareholders as the date as of which the Conversion Price is calculated. Holders of the Series C 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

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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 C 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 C Preferred Stock:

(a) create any new class or series of capital stock having a

preference over the Series C 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 C 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 C Preferred Stock so as to affect the Series C Preferred Stock adversely.

In the event holders of at least a majority of the then outstanding shares of Series C Preferred Stock agree to allow the Corporation to amend or alter the preferences, rights or privileges of the shares of Series C Preferred Stock, pursuant to subsection (b) above, so as to affect adversely the Series C Preferred Stock, then the Corporation will deliver notice of such approved change to the Holders of the Series C Preferred Stock that did not agree to such amendment or change (the "Dissenting Holders") and Dissenting Holders shall have the right for a period of thirty (30) days to convert pursuant to Section 6.2 of this Certificate of Designations as they exist prior to such alteration or change or continue to hold their shares of Series C Preferred Stock.

## ARTICLE 10 MISCELLANEOUS

SECTION 10.1 LOSS, THEFT, DESTRUCTION OF PREFERRED STOCK. Upon receipt of evidence satisfactory to the Corporation of the loss, theft, destruction or mutilation of shares of Series C 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 C Preferred Stock, the Corporation shall make, issue and deliver, in lieu of such lost, stolen, destroyed or mutilated shares of Series C Preferred Stock, new shares of Series C Preferred Stock of like date and tenor.

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SECTION 10.2 WHO DEEMED ABSOLUTE OWNER. The Corporation may deem the Person in whose name the Series C 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 C Preferred Stock for the purpose of receiving payment of dividends on the Series C Preferred Stock, for the conversion of the Series C 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 C 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 C Preferred Stock. Upon any transfer of the Series C Preferred Stock in accordance with the provisions hereof, the Corporation shall register such

transfer on the Series C 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 C 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.

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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 Judy Roeske Bullock, its Secretary, on this 30th day of June, 1998.

SHEFFIELD PHARMACEUTICALS, INC.

By:

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Loren G. Peterson  
President and Chief Executive Officer

Attested:

By:

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Judy Roeske Bullock  
Secretary

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#### FORM OF CONVERSION NOTICE

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

The undersigned owner of shares of Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercises its option to convert \_\_\_\_\_ shares of the Series C 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 C Preferred Stock. The undersigned hereby instructs the Corporation to convert the



number of shares of the Series C 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 C 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:\_\_\_\_\_

\_\_\_\_\_  
Signature

Fill in for registration of Series C Preferred Stock:

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

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FORM OF EXCHANGE NOTICE

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

The undersigned owner(s) of shares of Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock") issued by Sheffield Pharmaceuticals, Inc. (the "Corporation") hereby irrevocably exercise its option to cause the Corporation to exchange 11,500 shares of Series C Preferred Stock for 50% of the outstanding capital stock Systemic Pulmonary Delivery, Ltd. ("SPD Stock") in accordance with the terms of the Certificate of Designations of the Series C Preferred Stock. The undersigned hereby instructs the Corporation to advise all other holders of Series C Preferred Stock, if any, of this exercise by the undersigned owner(s). The undersigned direct that the SPD 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:\_\_\_\_\_

\_\_\_\_\_  
Signature

Fill in for registration of SPD Stock:

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

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EX-10.2

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JOINT DEVELOPMENT AGREEMENT

CERTAIN PORTIONS HAVE BEEN OMITTED BASED ON  
A REQUEST FOR CONFIDENTIAL TREATMENT;  
OMITTED PORTIONS FILED SEPARATELY WITH THE  
SECURITIES AND EXCHANGE COMMISSION

SYSTEMIC PULMONARY DELIVERY, LTD.  
JOINT DEVELOPMENT AND OPERATING AGREEMENT

JOINT DEVELOPMENT AND OPERATING AGREEMENT, dated as of June 30, 1998,  
by and among SYSTEMIC PULMONARY DELIVERY, LTD., a Bermuda corporation (the  
"Company"), ELAN INTERNATIONAL SERVICES, LTD., a Bermuda corporation ("EIS"),  
and SHEFFIELD PHARMACEUTICALS INC., a Delaware corporation ("Sheffield").

#### R E C I T A L S:

A. Sheffield has subscribed for all of the issued and outstanding  
shares of the common stock of the Company pursuant to the terms of a  
subscription agreement between Sheffield and the Company dated as of the date  
hereof (the "SPD Subscription Agreement").

B. ELAN CORPORATION, PLC, an Irish public limited company ("Elan") and  
an Affiliate of EIS, has or has access to intellectual property, including  
patent rights and know-how relating to UPDASTM technology and the Enhancing  
Technology in the Systemic Pulmonary and Topical Pulmonary Fields, as those  
terms are defined in the Elan License Agreement (the "Elan Intellectual  
Property").

C. Sheffield has or has access to certain patent rights and know-how  
relating to the development of technology in the Systemic Pulmonary Field as  
defined in the Sheffield License Agreement (the "Sheffield Intellectual  
Property").

D. EIS, Sheffield and the Company desire to set forth herein certain  
provisions relating to the development of the Elan Intellectual Property and the

Sheffield Intellectual Property.

E. Elan and the Company have, as of the date hereof, entered into a license and supply agreement (the "Elan License Agreement") in connection with the Elan Intellectual Property. Sheffield and the Company have, as of the date hereof entered into (i) a sublicense and supply agreement (the "Sheffield License Agreement") in connection with the Sheffield Intellectual Property, and (ii) a license agreement in connection with patent rights related to certain technology in the Topical Pulmonary Field (the "SPD License Agreement"; together with the Elan License Agreement and the Sheffield License Agreement, the "License Agreements").

#### A G R E E M E N T:

The parties agree as follows:

#### DEFINITIONS

1.1 DEFINED TERMS. Capitalized terms used herein and not defined shall have the meaning assigned to them in each of the License Agreements. As used herein, the terms below shall have the following meanings:

"\$" means United States dollars.

"AFFILIATE" means any corporation or entity, other than the Company, controlling, controlled or under the common control of Elan or Sheffield, as the case may be. For the purposes of this definition, "Control" shall mean direct or indirect ownership of 25% or more of the issued stock or shares entitled to vote for the election of directors.

"BOARD" means the board of directors of the Company.

"COST" shall have the meaning as described in Section 6.1 hereof.

"EIS DIRECTOR" shall have the meaning described in Section 4.1 hereof.

"ELAN INTELLECTUAL PROPERTY" shall have the meaning as described in Recital B.

"ELAN LICENSE AGREEMENT" shall have the meaning described in Recital E above.

"FDA" means the United States Food and Drug Administration.

"INDEMNIFIED PERSON" shall have the meaning as described in Section 10.1 hereof.

"INDEMNIFYING PARTY" shall have the meaning as described in Section 10.1 hereof.

"INITIAL TERM" means the 24-month period from and after the Closing Date.

"LICENSE AGREEMENTS" means, collectively, the Elan License Agreement, the Sheffield License Agreement and the SPD License Agreement.

"LOSSES" shall have the meaning as described in Section 10.1 hereof.

"PARTY" means any party to this Development Agreement and "PARTIES" means all of them together.

"PATENT APPLICATION" means an application filed with the U.S. Patent and Trademark Office (or its foreign national equivalent) in order to acquire a patent on a product or process.

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"PERMITTED TRANSFEREE" means any Affiliate of EIS or Sheffield to whom this Agreement shall be assigned, pursuant to the terms hereof.

"PERSON" means an individual, partnership, joint venture, corporation, trust or unincorporated organization, a government or any department, agency or political subdivision thereof, or any other entity.

"PRODUCTS" shall have the meanings as described in the Elan License Agreement and the Sheffield License Agreement, respectively.

"R&D PROGRAM" means all research and development activity conducted in order to develop the Products.

"R&D SERVICES" means the services to be provided by Elan, Sheffield and/or a third party, to The Company in accordance with the R&D Program.

"SECURITIES PURCHASE AGREEMENT" means the securities purchase agreement by and between EIS and Sheffield, dated as of the date hereof.

"SHEFFIELD DIRECTORS" shall have the meaning as described in Section 4.1 hereof.

"SHEFFIELD INTELLECTUAL PROPERTY" shall have the meaning described in Recital C hereof.

"SHEFFIELD LICENSE AGREEMENT" shall have the meaning described in Recital E hereof.

"STEERING COMMITTEE" shall have the meaning as described in Section 5.1 hereof.

"SUBSCRIPTION AGREEMENT" means the SPD Subscription Agreement by and between Sheffield and The Company, dated as of the date hereof.

"TRANSACTION DOCUMENTS" shall mean, collectively, this Agreement, the Subscription Agreement, the Securities Purchase Agreement, the Elan License Agreement, the Sheffield License Agreement, the SPD License Agreement, and any other documents or certificates executed in connection with the transactions contemplated hereunder and thereunder.

ARTICLE II  
REPRESENTATIONS AND WARRANTIES

2.1 REPRESENTATIONS AND WARRANTIES OF THE COMPANY. The Company hereby

represents and warrants to each of EIS and Sheffield as follows, as of the date hereof:

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(a) ORGANIZATION. The Company was incorporated on June 30, 1998 and is 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 and to carry out the transaction contemplated hereby.

(b) AUTHORIZATION. The execution, delivery and performance by the Company of this Agreement, have been duly authorized by all requisite corporate actions; this Agreement has been duly executed and delivered by the Company and is the valid and binding obligation of the Company, enforceable against it in accordance with its terms.

(c) NO CONFLICTS. The execution, delivery and performance by the Company of this Agreement, and compliance with the provisions hereof by the Company, will not (a) 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 its properties or assets or (b) 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, or result in the creation of, any Encumbrance (as defined below) upon any of the properties or assets of the Company under, the charter or organizational documents of either 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 on the Company. As used herein, "Encumbrance" shall mean any liens, charges, encumbrances, equities, claims, options, proxies, pledges, security interests, or other similar rights of any nature.

(d) APPROVALS. No permit, authorization, consent or approval of or by, or any notification of or filing with, any person or entity (governmental or private) (collectively, "Approval"), which has not yet been obtained or given, as the case may be, is required in connection with the execution, delivery or performance of this Agreement by the Company.

(e) NO LIABILITIES. The Company has not conducted any business or activities since its incorporation, and has no liabilities as of the date hereof.

(f) LEGAL PROCEEDINGS, ETC. There is no legal, administrative, arbitration or other action or proceeding or governmental investigation pending or threatened against the Company. 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.

(g) 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 and therein not misleading. The Company 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 the Company not to be misleading in any material respect.

2.2 REPRESENTATIONS AND WARRANTIES OF SHEFFIELD. Sheffield hereby represents and warrants to each of EIS and the Company as follows:

(a) ORGANIZATION. Sheffield is a company duly incorporated and organized and validly existing under Delaware law 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 except where this failure to obtain such power and authority would not, individually or in the aggregate, have a Material Adverse Effect on Sheffield.

(b) AUTHORITY. Sheffield has full legal right, power and authority to enter into this Agreement and to perform its respective obligations hereunder, which have been duly authorized and by all requisite corporate action. This Agreement is the valid and binding obligation of Sheffield, enforceable against Sheffield in accordance with its terms.

(c) NO CONFLICTS. The execution, delivery and performance by Sheffield of this Agreement, and compliance with the provisions hereof by Sheffield will not (a) violate any provision of applicable law, statute, rule or regulation applicable to Sheffield, or any ruling, writ, injunction, order, judgment or decree of any court, arbitrator, administrative agency or other governmental body applicable to Sheffield or any of its respective properties or assets or (b) 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, or result in the creation of, any Encumbrance upon any of the properties or assets of Sheffield under its charter or organizational documents or any material contract to which Sheffield is a party, except where such violation, conflict or breach would not, individually or in the aggregate, have a material adverse effect on Sheffield.

(d) APPROVALS. No Approval is required in connection with the execution, delivery or performance of this Agreement by Sheffield; nor is any Approval required by Sheffield in order to fulfill its respective obligations hereunder.

(e) LEGAL PROCEEDINGS, ETC. There is no legal, administrative, arbitration or other legal action or proceeding or governmental investigation pending or threatened against Sheffield which would interfere with the performance of its obligations hereunder. Sheffield 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.

2.3 REPRESENTATIONS OF EIS. EIS hereby represents and warrants to each of the Sheffield and the Company as follows, as of the date hereof:

(a) ORGANIZATION. EIS is a company duly incorporated and organized and validly existing under Bermuda law 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.

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

(c) NO CONFLICTS. The execution, delivery and performance by EIS of this Agreement, and compliance with the provisions hereof by EIS will not (a) violate any provision of applicable law, statute, rule or regulation applicable to EIS, or any ruling, writ, injunction, order, judgment or decree of any court, arbitrator, administrative agency or other governmental body applicable to EIS or any of its respective properties or assets or (b) 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, or result in the creation of, any Encumbrance upon any of the properties or assets of EIS under its charter or organizational documents or any material contract to which EIS is a 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 Approval is required in connection with the execution, delivery or performance of this Agreement by EIS; nor is any Approval required by EIS in order to fulfill its respective obligations hereunder.

(e) LEGAL PROCEEDINGS, ETC. There is no legal, administrative, arbitration or other action or proceeding or governmental investigation pending or threatened against EIS which would interfere with the performance of its obligations hereunder. EIS 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.

### ARTICLE III DEVELOPMENT FUNDING

3.1 DEVELOPMENT FUNDING. During the Initial Term, Sheffield shall make such capital contributions to the Company as shall be necessary, up to \$[text omitted], for the development of the Product, as shall be reasonably and in good faith determined and certified by the Board, consistent with the R&D Program mutually and reasonably agreed to by Sheffield and Elan.

### ARTICLE IV EXCHANGES; TRANSFERS OF SECURITIES, GENERALLY

4.1 EXCHANGES. (a) EIS shall have the right, as fully described in Section 5(b)(i) of the Securities Purchase Agreement, to acquire 50% of the issued and outstanding number of shares of Common Stock of the Company, in exchange for the tender by EIS of all the shares of Series C Preferred Stock of Sheffield (the "First Exchange Right").

(b) EIS shall have the right, as fully described in Section 5(b)(ii) of the Securities Purchase Agreement, to purchase from Sheffield for consideration of \$[text omitted], an additional [text omitted] of the issued and outstanding shares of Common Stock of the Company; provided, that the exercise of the First Exchange Right shall have been consummated (the "Second Exchange Right").

(c) EIS shall have the right, as fully described in Section 5(b)(iii) of the Securities Purchase Agreement, to negotiate in good faith to acquire from Sheffield the remaining [text omitted] of the issued and outstanding shares of Common Stock of the Company; provided that the exercise of the Second Exchange Right has been consummated (the "Third Exchange Right").

4.2 TRANSFER, GENERALLY. (a) No shareholder of the Company (a "Shareholder") shall, directly or indirectly, sell, assign, pledge, encumber, hypothecate, grant a security interest in, or otherwise transfer (in each case, a "Transfer") any Company Securities except in accordance with this Agreement or the Securities Purchase Agreement. The Company shall not, and shall not permit any transfer agent or registrar for the Company Securities to transfer upon the books of the Company any Company Securities from any Shareholder to any transferee, in any manner, except in accordance with this Agreement or the Securities Purchase Agreement, and any purported transfer not in compliance with this Agreement or the Securities Purchase Agreement shall be void.

(b) Except as set forth in the Securities Purchase Agreement, no Shareholder shall be permitted to transfer Company Securities to an unaffiliated third party without the consent of the other Shareholders; except, that nothing herein shall be deemed to restrict transfer of such securities to an Affiliate.

4.3 TRANSFeree BOUND. No Shareholder shall effect a transfer of Company Securities unless such transferee shall agree to be bound by this Agreement, and shall further agree to permit the transferring shareholder to act on their behalf in accordance with the provisions of this Agreement. Notwithstanding anything contained herein to the contrary, no transferee who receives shares of the Common Stock of the Company pursuant to Section 5(b)(iii)(D) of the Securities Purchase Agreement shall be bound by the provisions of this Agreement.

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4.4 TERMINATION. In the event that EIS shall own 100% of the voting securities of the Company, the terms of this Article IV shall be of no further force or effect.

ARTICLE V  
BOARD OF DIRECTORS

5.1 BOARD OF DIRECTORS. (a) The Board of the Company shall consist of three directors, designated as follows: EIS shall be entitled to designate one director (the "EIS Director"), Sheffield shall be entitled to designate two directors (the "Sheffield Directors"). EIS and Sheffield hereby agree that the



initial EIS Director shall be Kevin Insley and the initial Sheffield Directors shall be Thomas Fitzgerald and Loren Peterson. The designation of future members to the Board shall be subject to the reasonable approval of Sheffield, in the case of a EIS Director, and EIS, in the case of a Sheffield Director. The Company's by-laws shall not provide for a Board that contains staggered terms. In the event that EIS shall consummate the exercise of the First Exchange Right, the number of directors on the Board shall increase by one, and the vacancy created thereby shall be filled by a nominee of EIS.

(b) Notwithstanding anything to the contrary herein, until the exercise of the Third Exchange Right is consummated, Sheffield (or any permitted transferee pursuant to Section 5(b) of the Securities Purchase Agreement) shall be entitled to designate at least one director of the Company who shall be entitled to attend all meetings of the Board of Directors and stockholders of the Company and shall be entitled to such notice of all Board and stockholders meetings of the Company.

5.2 VACANCIES. In the event that a vacancy is created on the Board at any time by the death, disability, retirement, resignation or removal of any director, or otherwise there shall exist or occur any vacancy on the Board: (a) EIS, in the case of a vacancy due to the absence of the EIS Director, and (b) Sheffield, in the case of vacancy due to the absence of a Sheffield Director, shall be entitled to appoint a replacement.

5.3 TERMINATION OF AGREEMENTS. Except as provided in Section 5.1(b) above or Section 5.5(b) below, the covenants and agreements contained in this Article V shall terminate upon the earlier of (i) termination of the Elan License Agreement, (ii) termination of the Sheffield License Agreement, and (iii) the date that either EIS or its Permitted Transferees shall have consummated the exercise of the Second Exchange Right.

5.4 CERTAIN ACTIONS REQUIRING APPROVALS. Until such time as the Company shall have consummated an initial public offering of equity securities under the Securities Act of 1933, as amended, or an investment of at least \$5,000,000 is made in the Company by an unaffiliated third party or parties, the following actions shall not be undertaken by the Company without the consent of the EIS Director: (a) filing an amendment to the Company's Articles of Incorporation or altering the by-laws of the Company; (b) altering the share capital of the Company; (c) altering the number of directors of the Company; (d) acquiring material assets (including

intellectual property and licenses), or selling all or substantially all of the assets of the Company, or granting an option for the same; (e) incurrence of debt or liens other than in the ordinary course of business; (f) declaring dividends or distributions to or purchasing share capital from any Shareholder; (g) disposition, licensing or sublicensing of any material asset; (h) entry into or ratification of a joint venture, contract or agreement not in the ordinary course of business of the Company; (i) granting, issuing or selling any shares of Common Stock, or options on the same, to any party, whether or not that party shall be a Shareholder at the time of the grant; (j) material changes to the business, products or material budgets of the Company; or (k) liquidating or winding up the Company. Notwithstanding the foregoing, the Company shall not be

required to obtain the consent of the EIS Director to purchase assets relating to the ADDS Technology from Aeroquip Corporation for an aggregate purchase price not to exceed \$1 million.

5.5 EIS ENFORCEMENT RIGHT. (a) In the event that EIS shall reasonably believe that Sheffield has materially breached the terms of the Sheffield License Agreement, and that the Board has failed to adequately protect or exercise the Company's rights and remedies thereunder, EIS shall have the right to (i) pursue such rights and remedies on behalf of the Company and/or (ii) require the Company to pursue such rights and remedies.

(b) Following the exercise of the Second Exchange Right, and only until such time, if any, that EIS shall own 100% of the outstanding equity securities of the Company, in the event that Sheffield shall reasonably believe EIS has materially breached the EIS License Agreement, and that the Board has failed to adequately protect or exercise the Company's rights and remedies thereunder, Sheffield shall have the right to (i) pursue such rights and remedies on behalf of the Company and/or (ii) require the Company to pursue such rights and remedies.

## ARTICLE VI DIRECTION OF RESEARCH AND DEVELOPMENT

6.1 STEERING COMMITTEE. (a) The Directors shall appoint a steering committee (the "Steering Committee") to perform certain advisory services, such delegation to be consistent with the Directors' right to delegate all powers pursuant to the Company's Certificate of Incorporation. The Steering Committee shall initially consist of four members, two of whom shall be appointed by the EIS Director and two of whom shall be appointed by the Sheffield Directors. EIS and Sheffield hereby agree that the initial members of the Steering Committee to be appointed by the EIS Director shall be Ena Prosser and Izzy Tsals and the initial members of the Steering Committee to be appointed by the Sheffield Directors shall be David Byron and Carl Siekman. Each of the EIS Director and the Sheffield Directors shall be entitled to remove any of their nominees to the Steering Committee and appoint a replacement in place of any nominees so removed, subject to reasonable approval of the other members of the Board.

(b) The Steering Committee shall be responsible for (i) assisting each of Elan and Sheffield with the transfer of know-how, Elan Intellectual Property and Sheffield Intellectual Property in accordance with each of the Elan License Agreement and Sheffield License

Agreement; (ii) providing access to Elan's external network of industry expertise; and (iii) advising the Company as to matters pertaining to developmental strategy.

(c) The Steering Committee shall report all significant developments to the Directors on the occurrence thereof and, in addition, shall report at quarterly intervals to the Directors.

(d) In the event that the Company shall become a wholly owned Subsidiary of EIS (or an Affiliate) the existence of the Steering Committee

shall terminate.

6.2 DIRECTION OF RESEARCH & DEVELOPMENT . The Steering Committee shall also provide advisory services in connection with the design and implementation of the R&D Program.

## ARTICLE VII CONDUCT OF RESEARCH AND DEVELOPMENT

7.1 RESEARCH AND DEVELOPMENT PROGRAM. (a) Sheffield shall provide (directly or through independent contractors) such research and development services as may reasonably be required by the Company and as described in the R&D Program, such services to be paid for by the Company at Sheffield's fully burdened costs plus [text omitted] (the "Cost"). The R&D Program shall be directed by the Steering Committee. Sheffield shall, in accordance with the terms and conditions set forth in this Agreement, undertake reasonably diligent efforts, as would be deemed commensurate with the achievement of its own business aims for a similar product of its own, to conduct the R&D Program; and further, shall maintain the facilities used by it for the performance of the R&D Program in compliance with the applicable requirements of the FDA and other regulatory authorities.

(b) The Company may evaluate the reports and other data furnished by Sheffield for the purpose of deciding whether or not to proceed with all or part of the applicable R&D Program.

(c) The Company shall make no filings with the FDA or equivalent foreign regulatory body without the approval of each of the EIS Director's and the Sheffield Directors' nominees to the Steering Committee.

7.2 RESEARCH BUDGET; RECORD KEEPING. (a) Sheffield, EIS, and the Company shall agree on a budget to be implemented in connection with the activities to be undertaken during the R&D Program for the Initial Term; thereafter the Parties shall agree on a budget in connection with the activities to be undertaken during the R&D Program subsequent to the Initial Term .

(b) Sheffield will keep accurate records, consistent with good business practices,

of the efforts expended by it under the R&D Program for which it is charging the Company, which will include estimates of time spent by each person working on the R&D Program.

(d) Sheffield shall permit the Company or its duly authorized representative, on reasonable notice and at any reasonable time during normal business hours, to have access to inspect and audit its accounts and records relating to the calculation of the Cost of the R&D Program or, where applicable, for the supply of the Products, and to the accuracy of the reports which accompanied them. Any such inspection of Sheffield's records shall be at the expense of the Company; except, that if any such inspection reveals an overpayment by the Company in the amount of the Costs allocated by Sheffield for the R&D Program in any calendar quarter of 5% or more of the amount of the Costs

actually incurred by Sheffield hereunder, then the expense of such inspection shall be borne solely by Sheffield instead of by the Company.

## ARTICLE VIII PATENTS; REGULATORY APPROVALS

8.1 REGULATORY APPROVALS. The rights and obligations of the Parties in respect of seeking regulatory approvals are governed by the applicable provisions of each of the Elan License Agreement and the Sheffield License Agreement, respectively.

## ARTICLE IX INTELLECTUAL PROPERTY RIGHTS

9.1 INTELLECTUAL PROPERTY RIGHTS. The rights and obligations of the Parties in respect of any intellectual property are governed by the applicable provisions of each of the Elan License Agreement and Sheffield License Agreement, respectively.

## ARTICLE X TECHNICAL SERVICES AND ASSISTANCE

10.1 OTHER SERVICES. Sheffield shall provide such other services as the Company may reasonably require, other than those specifically dealt with in the Sheffield License Agreement, such services to be paid for at Cost.

10.2 ADMINISTRATIVE SUPPORT. The Company shall, if appropriate, conclude an administrative support agreement with Sheffield on such terms as the parties thereto shall in good faith negotiate. The administrative services required include, but are not limited to, one or more of the following, which may be requested by the Company:

(i) accounting, financial and other services;

(ii) tax services;

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(iii) insurance services;

(iv) human resources services;

(v) legal and company secretarial services;

(vi) patent and related intellectual property services; and

(vii) 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.

## ARTICLE XI INDEMNIFICATION

11.1 INDEMNIFICATION. In addition to all rights and remedies available to the parties hereunder at law or in equity, each Party (each in such capacity, an "Indemnifying Party") shall indemnify each other Party and each other Party's stockholders, officers, directors, employees, agents, representatives,

successors and assigns (collectively, the "Indemnified Person"), and save and hold the 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:

(a) any material misrepresentation or breach of warranty on the part of the Indemnifying Party under Article 2 of this Agreement; or

(b) any material nonfulfillment, default or breach of any covenant or agreement on the part of the Indemnifying Party under Article V of this Agreement; or

(c) any material nonfulfillment, default or breach of any covenant or agreement under the other Transaction Documents.

11.2 RECOVERY LIMITATION. Notwithstanding anything in this Agreement to the contrary, in no event shall Sheffield be liable for indemnification under this Article XI, the Transaction Documents, or otherwise in an amount in excess of \$[text omitted], in the aggregate. An Indemnified Person shall not assert a claim hereunder unless the Losses, 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.

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11.3 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) or willful misconduct, 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 attorneys 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.

11.4 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 11.1 above, irrespective of any investigation, inquiry or examination made for or on behalf of, or any knowledge of the Indemnified Person or the acceptance of any

certificate or opinion.

11.5 CONTRIBUTION. If the indemnity provided for in this Article XI shall be, in whole or in part, unavailable to any Indemnified Person, as a result of Section 11.1 being declared unenforceable by a court of competent jurisdiction based upon reasons of public policy, so that Section 11.1 shall be insufficient to hold each such Indemnified Person harmless from Losses that 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. The indemnity, contribution and expense reimbursement obligations that the Indemnifying Party has under this Article XI shall survive the Closing. 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 part to any such lawsuit, claims or other proceedings.

11.6 CLAIM LIMITATION. No claim shall be brought by an Indemnified Person in respect of any misrepresentation or breach of warranty under this Agreement or the other Transaction Documents 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 of that such Indemnified Person became aware or should have become aware of the nonfulfillment, default or breach, unless written notice thereof shall have been provided prior to such one-year period, in which case such surviving claims shall be limited to those in such notice. Except as set forth in the previous sentence, this Article XI is not intended to limit the rights or remedies

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otherwise available to any party hereto with respect to this Agreement or the Transaction Documents.

## ARTICLE XII TERMINATION

12.1 GENERAL. The Company shall continue to operate and exist for so long as its shareholders shall determine, and this Agreement shall govern such operation and existence until this Agreement shall be terminated in accordance with this Article XII (the "Term"). Notwithstanding the foregoing, this Agreement may be terminated by either EIS or Sheffield in the case of a Relevant Event (as defined below) or a material breach, on the part of the other.

12.2 RELEVANT EVENT. For the purpose of this Article XII, a "Relevant Event" is committed by a Party if:

(a) it commits a material breach of its obligations under this Agreement and fails to remedy it within 60 days of being specifically required in writing to do so by the other Party; provided, however, that if the breaching party has proposed a course of action to rectify the breach and is acting in good faith to rectify same but has not cured the breach by the 60th day, such

rectifying period shall be extended by an amount of time as is reasonably necessary to permit the breach to be rectified;

(b) it ceases, wholly or substantially, to carry on its business, other than for the purpose of a reorganization;

(c) the voluntary appointment of a liquidator, receiver, administrator, examiner, trustee or similar officer over all or substantially all of its assets under the laws of such Party's country of incorporation;

(d) a petition for bankruptcy or seeking liquidation, corporate reorganization, administration, winding up or relief of debtors under any law relating to bankruptcy or insolvency or any other procedure similar to any of the foregoing under the laws of such Party's state or country of incorporation, is filed, and is not discharged within 90 days.

### ARTICLE XIII CONFIDENTIALITY

13.1 CONFIDENTIALITY. (a) Each of the Parties acknowledge that it may be necessary, from time to time, to disclose to one another confidential and proprietary information, including without limitation, inventions, the Elan Intellectual Property, the Sheffield Intellectual Property, works of authorship, trade secrets, specifications, designs, data, know-how and other information, relating to the intellectual property rights under the License Agreements, the terms of the various agreements between the Parties, the Products, processes, and services, of the disclosing Party ("Confidential Information").

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(b) Confidential Information shall be deemed not to include:

(i) information that is in the public domain;

(ii) information which is made public by the disclosing Party;

(iii) information which is independently developed by a Party without the aid or application of the Confidential Information;

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

(v) information that becomes available to a Party on a non-confidential basis, whether directly or indirectly, from a source other than another Party, which source, to the best of the receiving Party's knowledge, did not acquire this information on a confidential basis; or

(vi) information which will become public because the receiving Party is required to disclose pursuant to:

(A) a valid order of a court or other governmental body or any political subdivision thereof or otherwise required by law; or

(B) 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.

13.2 Any Confidential Information revealed by a Party to another Party shall be used by the receiving Party exclusively for the purpose of fulfilling the receiving Party's obligations under this Agreement and for no other purpose.

13.3 Each of the Parties 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. Each of the Parties 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 of the Parties agrees that it will exercise the same degree of care, but in no event less than a reasonable degree, and protection to preserve the proprietary and confidential nature of the Confidential Information disclosed by a Participant, as the

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receiving Party would exercise to preserve its own proprietary and confidential information. Each of the Parties agrees that it will, upon request of a Party, return all documents and any copies thereof containing Confidential Information belonging to or disclosed by, such Party; except, that one copy of any returned files may be retained in the legal files of the returning party.

13.4 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 regulations, 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 rights hereunder or under the License Agreement (including the right to develop jointly owned technology outside the Field); provided, that if a Party is required to make any such disclosure of another Party's confidential information, other than pursuant to a confidentiality agreement, such disclosing Party shall inform the other Party thereof, and allow such other Party to participate in the disclosure process for the purpose of generally limiting, to the extent possible, such disclosure.

13.5 The provisions relating to confidentiality in this Clause XIII shall remain in effect during the Initial Term, and for a period of three years following the expiration or earlier termination of this Agreement.



## MISCELLANEOUS

14.1 COSTS. Each Party shall bear its own legal and other costs incurred in relation to preparing and concluding this Agreement and the related agreements and other documents. All costs, legal fees, registration fees and other expenses, including the costs and expenses incurred in relation to the incorporation of the Company, shall be borne by the Company.

14.2 INJUNCTIVE RELIEF. With respect to Article XIII hereof, the Parties hereby agree and acknowledge that it will be impossible to measure in money the damages that would be suffered if any Party should breach any obligation, covenant or representation therein imposed or made, and that, in the event of such breach, a non-breaching Party will be irreparably damaged and will not have an adequate remedy at law. Any such non-breaching party shall, therefore, be entitled to injunctive relief, including specific performance, to enforce such obligations, and if any action should be brought in equity to enforce any of the provisions of Article XIII, none of the other Parties hereto shall raise the defense that there is an adequate remedy at law.

14.3 NOTICES. All notices, other communications or documents provided for or permitted to be given hereunder, shall be made in writing and shall be given either personally by hand-delivery, by mailing the same in a sealed envelope, certified first-class mail, postage prepaid, return receipt requested, or by an internationally recognized overnight delivery service:

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(i) if to the Company, to:

Systemic Pulmonary Delivery, Ltd.  
c/o Elan International Services, Ltd.  
102 St. James Court  
Flatts, Smiths Parish FL04  
Bermuda

and

Systemic Pulmonary Delivery, Ltd.  
c/o Sheffield Pharmaceuticals, Inc.  
37 South Main Street  
Pittsford, New York 14534  
Attn: Chairman

with a copy to Brock Silverstein McAuliffe LLC, and Olshan  
Grundman Frome & Rosenzweig LLP, at the respective addresses indicated below;

(ii) if to Sheffield, to:

Sheffield Pharmaceuticals, Inc.  
37 South Main Street  
Pittsford, New York 14534  
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 LLP  
505 Park Avenue  
New York, NY 10022  
Attention: Daniel J. Gallagher

(ii) if to EIS, to:

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Elan International Services, Ltd.  
Flatts Smiths SL04  
Bermuda  
Attention: Director

with a copy to:

Brock Silverstein McAuliffe LLC  
153 East 53rd Street , 56th Floor  
New York, New York 10022  
Attention: David Robbins

Each Party, by written notice given to the Company in accordance with this Section 14.3 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. Whenever pursuant to this Agreement any notice is required to be given by any Party to any other Party, such Party may request from the Company a list of addresses of all Parties, which list shall be promptly furnished to such Party.

14.4 ASSIGNMENT. EIS may assign this Agreement to an Affiliate at any time. Sheffield may assign this Agreement to an Affiliate with the written consent of EIS, which shall not be unreasonably withheld or delayed.

14.5 GOVERNING LAW. This Agreement shall be governed by and construed in accordance with the laws of the state of New York without regard to the principle of conflicts of laws thereof. 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 inconvenience forum for the maintenance of such an action.

14.6 HEADINGS. The headings in this Agreement are inserted for convenience of reference only and shall not constitute a part of this Agreement.

14.7 SEVERABILITY. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable, the validity, legality and enforceability of

any such provision in every other respect and of the remaining provisions contained herein shall not be affected or impaired thereby.

14.8 AMENDMENTS AND WAIVER. No provision of this Agreement may be amended, nor performance of any covenant or agreement waived, except by a written instrument executed by each of the Company, EIS and Sheffield. Neither a failure nor a delay in exercising any right, power or privilege of a Party hereunder shall operate as a waiver of, or a consent to the

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modification of, the terms hereof unless given by that Party in writing. The waiver by any Party hereto of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any preceding or succeeding breach.

14.9 COUNTERPARTS. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same Agreement.

14.10 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. 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, in any such other agreement. In the event of a conflict between the provisions of this Agreement and the provisions of the Elan License Agreement, the Sheffield License Agreement, or the SPD License Agreement, the terms of this Agreement shall prevail.

14.11 GOOD FAITH. Each of the Parties hereto undertakes with the others to do all things reasonably within its power which are necessary or desirable to give effect to the spirit and intent of this Agreement.

14.12 FURTHER ASSURANCE. The Parties hereto shall use their respective reasonable efforts to procure that any necessary third party shall do, execute and perform all such further deeds, documents, assurances, acts and things as any of the Parties hereto may reasonably require by notice in writing to the others to carry the provisions of this Agreement into full force and effect. In addition, each of EIS and Sheffield shall cooperate and make reasonably available to the Company (including its authorized agents and representatives) all assistance reasonably necessary or appropriate to enable the Company to prepare, file, prosecute and maintain Patents or other intellectual property related to the Elan Intellectual Property and Sheffield Intellectual Property. This Section 14.12 shall survive indefinitely beyond the termination of this Agreement; provided that following termination of this Agreement, Sheffield shall be entitled to reimbursement of expenses required for compliance with this section in excess of \$10,000 per annum.

IN WITNESS WHEREOF, the parties hereto have executed this Development Agreement as of the date first set forth above.

SYSTEMIC PULMONARY DELIVERY, LTD.

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald

Title: Chairman

ELAN INTERNATIONAL SERVICES, LTD.

By: /s/ Kevin Insley

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Name: Kevin Insley

Title: President

SHEFFIELD PHARMACEUTICALS, INC.

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald

Title: Chairman

EX-10.3

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AGREEMENT

CERTAIN PORTIONS HAVE BEEN OMITTED BASED ON  
A REQUEST FOR CONFIDENTIAL TREATMENT;  
OMITTED PORTIONS FILED SEPARATELY WITH THE  
SECURITIES AND EXCHANGE COMMISSION

LICENSE AND DEVELOPMENT AGREEMENT

BY AND BETWEEN

SHEFFIELD PHARMACEUTICAL, INC.

A Delaware Corporation

AND

SYSTEMIC PULMONARY DELIVERY, LTD.

A Bermuda Company

AND

ELAN CORPORATION, plc

An Irish Company

This Agreement is made the 30th day of June 1998

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LICENSE AND DEVELOPMENT Agreement, dated June 30, 1998, by and between Sheffield Pharmaceutical, Inc., a Delaware corporation ("Sheffield"), Systemic Pulmonary Delivery, Ltd., a Bermuda corporation ("Newco") and Elan Corporation plc., an Irish corporation ("Elan").

#### RECITALS

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A. Sheffield owns, controls and/or has rights in and to the Sheffield Intellectual Property (capitalized terms used herein are defined below), and

B. Elan is beneficially entitled to the use of various patents, including the Elan Patent Rights, which have been granted or are pending under the International Convention in relation to the development and production of drug delivery devices and processes, and

C. Elan has agreed to enter into the Elan License Agreement provided that Sheffield and Newco enter into this Agreement, and

D. Newco is entering into this Agreement with Sheffield pursuant to which Newco shall have the right to manufacture and to market the Products in the Territory, and

E. Sheffield is prepared to license the Sheffield Intellectual Property in the Territory to Newco.

NOW THEREFORE, The Parties agree as follows:

#### 1. ARTICLE I: DEFINITIONS

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1.1. In the present Agreement and any further agreements based thereon between the Parties hereto, the following definitions shall apply:

"Affiliate" shall mean any corporation or entity controlling, controlled by or under the common control of Sheffield, Newco or Elan, as the case may be. For the purpose of this Agreement, "control" shall mean the direct or indirect ownership of at least twenty-five (25%) percent of the outstanding shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

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

"cGCP", "cGLP" and "cGMP" shall mean current Good Clinical Practices, current Good Laboratory Practices and current Good Manufacturing Practices respectively.

"Confidential Information" shall have the meaning set forth in Article 5.1 below.

"Definitive Documents" shall mean this Agreement, the Elan License Agreement, the Newco/Sheffield License Agreement, and any other documents or agreements executed in connection with the transactions contemplated hereunder and thereunder.

"Effective Date" shall mean June 30, 1998.

"Elan" shall mean Elan Corporation, plc and any of its Affiliates.

"Elan License Agreement" shall mean the License and Development Agreement, dated even date herewith, among Elan, Newco and Sheffield pursuant to which, among other things, Elan is licensing to Newco the Elan Know-How and the Elan Patent Rights in accordance with the terms and conditions of said agreement.

"FDA" shall mean the United States Food and Drug Administration or any other successor agency, whose approval is necessary to market the Products in the United States of America.

"Field" shall mean the Systemic Pulmonary Field.

"Joint Intellectual Property" shall mean the Joint Know-How and/or the Joint Patent Rights.

"Joint Know-How" shall mean all knowledge, information and expertise developed by at least two of the three Parties during the Term relating to the Field and in accordance with the Project whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

"Joint Patent Rights" shall mean any patent and patent applications created, developed, conceived or otherwise invented by at least two of the three Parties pursuant to the Agreement, relating to the Field, and in accordance with the Project. Joint Patent Rights shall also include extensions, continuations, continuations-in-part, divisionals, patents of additions, reexaminations, re-issues supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder.

"Marketing Authorization" shall mean the procurement of registrations and permits required by applicable government authorities in a country in the Territory for the marketing, sale, and distribution of a Product in such country.

"MSI Delivery System" shall mean Sheffield's multi dose nebulizer comprising a device and dosator that generally conforms to the specifications in Annex 2 to the Siemens Supply Agreement for use with medicines for the systemic treatment of diseases, and improvements thereto, excluding the use of medicines for humans in treating respiratory disease and/or other lung disease, which exclusion includes, but is not limited to, the use of anti-infectives.

"Newco" shall mean Systemic Pulmonary Delivery, Ltd. and any of its Affiliates.

"Newco Intellectual Property" shall mean the Newco Know-How and/or the Newco Patent Rights.

"Newco Know-How" shall mean all knowledge, information, trade secrets, data and expertise, or from time to time, developed, invented or otherwise acquired by or on behalf of Newco during the Term, including without limitation, the ADDS Technology, the Trademark, Newco Project Know-How, and clinical data and test results, whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

"Newco/Sheffield License Agreement" shall mean the License Agreement, dated even date herewith, among Newco, Sheffield and Elan pursuant to, among other things, Newco is sublicensing certain intellectual property rights and know-how to Sheffield in accordance with the terms and conditions of said agreement.

"Newco Patent Rights" shall mean all patents and patent applications owned or to be owned by, or licensed or to be licensed by Newco. Newco Patent Rights shall also include all extensions, continuations, continuations-in-part, divisionals, patents in addition, reexaminations, re-issues, supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder. Newco Patent Rights shall further include any patents or patent applications covering any improved Products or improved methods of making or using the Products invented or acquired by Newco during the Term (and shall for the avoidance of doubt include the Newco Project Patent Rights and such patent and patent applications relating to the ADDS Technology).



"Newco Project Know-How" shall mean all knowledge, information, trade secrets, data and expertise which is owned or to be developed by or on behalf of Newco in connection with the Project relating to the Products, including clinical data, whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

"Newco Project Patent Rights" shall mean any patents or patent applications covering any improved Products or methods of making or using the Products, invented or acquired by or on behalf of Newco in connection with the Project.

"Party" shall mean Newco, Sheffield or Elan as the case may be. "Parties" shall mean any two of Newco, Sheffield and Elan.

"Plan" shall mean the business plan and program of development agreed to by the Parties and attached to the Elan License Agreement as Appendix B, with respect to the research, development, prosecution and commercialization of the Products.

"Products" shall mean all devices and products or any parts or components thereof (including, without limitation, any and all compounds and/or drug products delivered with, by and/or via the Products) that are used, developed, manufactured, offered for sale and/or sold by or on behalf of Newco and/or its permitted sublicensees, and that utilize, incorporate, apply and/or are based on the Sheffield Intellectual Property, the Newco Intellectual Property, and/or the Elan Intellectual Property.

"Project" shall mean all activity as undertaken by Elan, Sheffield and Newco in order to develop the Products in accordance with the Plan.

"Sheffield" shall mean Sheffield Pharmaceutical, Inc., a Delaware corporation.

"Sheffield Intellectual Property" shall mean the Sheffield Know-How and/or the Sheffield Patent Rights.

"Sheffield Know-How" shall mean all knowledge, information, trade secrets, data and expertise relating to the Systemic Pulmonary Field, other than compounds, that is possessed by Sheffield, or from time to time, developed or invented (but not acquired) by or on behalf of Sheffield during the Term relating to the Systemic Pulmonary Field for use with medicines for the systemic treatment of diseases (but excluding the use of medicines for humans in treating respiratory disease and/or other lung disease, including, but not limited to, the use of anti-infectives), including,

without limitation, clinical data, the MSI Delivery System and the Sheffield Project Know-How, whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

"Sheffield Patent Rights" shall mean all patents and patent applications related to the Systemic Pulmonary Field, other than compounds, owned by or licensed by or on behalf, of Sheffield, which patents as of the Effective Date are set forth on Appendix A, attached hereto. Sheffield Patent Rights shall also include all extensions, continuations, continuations-in-part, divisionals, patents of addition, re-issues, re-examinations supplementary protection certificates and foreign

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counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder (and shall for the avoidance of doubt include patents and patent applications relating to the MSI Delivery System and the Sheffield Patent Project Rights).

"Sheffield Project Know-How" shall mean all knowledge, information, trade secrets, data and expertise which is possessed or developed by or on behalf of Sheffield in connection with the Project relating to the Field for use with medicines for the systemic treatment of diseases (but excluding the use of medicines for humans in treating respiratory disease and/or other lung disease including, but not limited to, the use of anti-infectives), including, but not limited to, clinical data, whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

"Sheffield Project Patent Rights" shall mean any patents or patent applications covering any improved Products or methods of making or using the Products, invented or acquired by or on behalf of Sheffield in connection with the Project during the Term.

"Siemens" shall mean Siemens Aktiengesellschaft, a company organized under the laws of Germany.

"Siemens License Agreement" shall mean the License Agreement, dated February 21, 1997, between Sheffield and Siemens.

"Siemens Supply Agreement" shall mean the Basic Supply Agreement dated March 21, 1997, between Sheffield and Siemens.

"Steering Committee" shall have the meaning set forth in the Newco Development Agreement, dated even date herewith, between Sheffield and EIS.

"Systemic Pulmonary Field" shall mean the practice of delivering therapeutic entities via the lung, with the primary intention of making them systemically available.

"Term" shall have the meaning set forth in Article 5.5 below.

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

"Topical Pulmonary Field" shall mean the practice of delivering respiratory therapeutic entities via the lung with the primary intention of making them available for local respiratory therapeutic effect on the lung.

"Trademark" shall mean the trademark(s) as may be selected by Newco which has been or may be registered by Newco in one or more countries in the Territory.

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"\$" shall mean United States Dollars.

The following terms shall have the meanings set forth in the Elan License Agreement: Elan Improvements, Elan Intellectual Property, Elan Know-How, and Elan Patent Rights.

1.2. Interpretation. In this Agreement, the following shall apply:

1.2.1. the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa;

1.2.2. any reference to an Article or Appendix shall, unless otherwise specifically provided, be to a Article or Appendix of this Agreement; and

1.2.3. the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

## 2. ARTICLE II : THE LICENSE

2.1. Subject to the terms and conditions of this Agreement and the rights of Elan under the Definitive Documents, Sheffield hereby grants to Newco for the Term, and Newco hereby accepts, an exclusive, royalty free, sublicense of the Sheffield Intellectual Property for the Territory to develop, make, have made, manufacture, have manufactured, package, use, import, export, promote, distribute, market, offer for sale, and sell the Products in the Field in the Territory. Elan shall have the right to cause Newco to enforce Newco's rights against Sheffield hereunder.

2.1.1. Except for an assignment or sublicense to Elan in accordance with this Agreement and the Definitive Documents, Newco may not assign or sublicense the licenses and rights granted to it herein without the

prior written approval of Sheffield and Elan, which approval may be withheld for any reason whatsoever. Subject to Elan's rights under the Definitive Documents, Sheffield shall be entitled to use the Sheffield Intellectual Property and all technical and clinical data or improvements thereto in connection with (i) Sheffield's commercial arrangements for the Products in any country that ceases to be a part of the Territory, or in relation to the Products in a country in the Territory in the event of the expiration or sooner termination of this Agreement, or (ii) Sheffield's commercial arrangements for products outside of the Field. Such commercial arrangements referred to in the immediately preceding sentence shall include the right to research, develop, manufacture, sell, license or otherwise market the Products. Notwithstanding anything contained herein to the contrary, during the Term (and for a period of two (2) years thereafter if Elan acquires 100% of Newco's Common Stock within five (5) years from the Effective Date), Sheffield shall not directly or indirectly compete with Newco in the Field, and Sheffield shall not participate in the ownership, management, operation or control of, or act in any advisory, expert or other capacity for, any entity or individual that competes with Newco

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in the Field; provided, however, that upon Elan's acquisition of at least 100% of Newco's Common Stock, Sheffield shall have the right to compete with Newco in the Field with products that are not based on or utilize the Elan Intellectual Property, the Newco Intellectual Property, the Sheffield Intellectual Property, and/or the Joint Intellectual Property.

2.2. Notwithstanding anything contained in this Agreement to the contrary, Newco may without the prior approval of Sheffield, enter into an agreement with Elan to manufacture, package, use, import, export, promote, distribute, market, offer for sale, and sell all Products (including products that utilize, incorporate, apply and/or are based on the Sheffield Intellectual Property) on such terms as Newco and Elan shall mutually agree.

2.3. Newco shall market the Products in the Territory under a Trademark, which Trademark will be owned by Newco subject to the terms and conditions of this Agreement. 2.4. Sheffield hereby grants to Newco during the Term a non-exclusive royalty free license in the Territory, solely for use in connection with the sale of the Products, to use Sheffield's trademark or trademarks, on the following terms:

2.4.1. Newco shall as soon as it becomes aware of any infringement give to Sheffield in writing full particulars of any use or proposed use by any other person, firm or company of a trade name or trademark or promotional or advertising activity which may constitute infringement.

2.4.2. If Newco becomes aware that any other person, firm or company alleges that such trademark is invalid or that the use of such trademark infringes any rights of another party or that the trademark is otherwise attacked, Newco shall immediately give to Sheffield full particulars in writing thereof and shall make no comment or admission to any third party in respect thereof.

2.4.3. Sheffield shall have the right to conduct all proceedings relating to such trademark and shall in its sole discretion decide

what action, if any, to take in respect of any infringement or alleged infringement of such trademark or any other claim or counter-claim brought or threatened in respect of the use or registration of such trademark. Any such proceedings shall be conducted at Sheffield's expense and for its own benefit.

2.4.4. Nothing contained in this Agreement shall grant to Newco any right, title, or interest in or to such trademark, whether or not specifically recognized or perfected under applicable laws. At no time during or after the Term shall Newco challenge or assist others to challenge any such trademark or the registration thereof or attempt to register any trademarks, marks, or trade names confusingly similar to any such trademark. All displays of any such trademark that Newco intends to adopt shall first be submitted to Sheffield for approval (which shall not be unreasonably withheld) of design, color, and other details, or shall be exact copies of those used by Sheffield. In addition, Newco shall fully comply with all reasonable guidelines, if any, communicated by Sheffield concerning the use of any such trademark as well as all rules and regulations of such use throughout the Territory.

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2.5. When packaged, and to the extent permitted by law, a product label shall include an acknowledgement that the Product is made under license from Sheffield. Such acknowledgement shall take into consideration regulatory requirements and Newco's reasonable commercial requirements. Newco shall wherever possible give due acknowledgement and recognition to Sheffield in all printed promotional and other material regarding the Product such as stating that the Product is under license from Sheffield and that the applicable Sheffield technology has been applied to the Products. Newco shall consult with and obtain the written approval of Sheffield as to the format and content of the promotional and other material insofar as it relates to a description of, or other reference to, the application of the Sheffield Intellectual Property, such approval not to be unreasonably withheld or delayed. The further consent of Sheffield shall not be required where the format and content of such materials is substantively similar as the materials previously furnished to and approved in writing by Sheffield.

2.6. Newco shall cause the Products that relate to the MSI Delivery System to be labeled in accordance with any obligation by Sheffield in the Siemens License Agreement and in accordance with applicable laws and regulations, including without limitation, 35 United States Code Section 287, as the same may be amended from time to time.

### 3. ARTICLE III: WARRANTY AND INDEMNITY.

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3.1. Sheffield represents, warrants and covenants to Newco and Elan as follows:

3.1.1. Sheffield is duly and validly existing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse affect on the business and assets of Sheffield), and is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

3.1.2. Sheffield has full corporate authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby; this Agreement has been duly executed and delivered by Sheffield and constitutes the legal and valid obligations of Sheffield and is enforceable against Sheffield in accordance with its terms; and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under Sheffield's memorandum and articles of association or any material agreement or instrument binding upon or affecting Sheffield or its properties or assets or any applicable laws, rules, regulations or orders affecting Sheffield or its properties or assets;

3.1.3. Sheffield is not in material default of its memorandum and articles of association, any applicable material laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not result in any such violation;

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3.1.4. As of the Effective Date, Sheffield is the sole and exclusive owner or licensee of, or controls all right, title and interest to the Sheffield Patent Rights; and to Sheffield's knowledge and belief, Sheffield is the sole owner or licensee of the Sheffield Know-How. Sheffield has the right to grant the licenses and sublicenses granted herein. The Sheffield Patent Rights, and to Sheffield's knowledge and belief, the Sheffield Know-How, are free and clear of any lien, encumbrances, security interest or restriction on the license granted herein. Sheffield will not grant during the Term, any right, license or interest in and to the Sheffield Intellectual Property, or any portion thereof, inconsistent with the license and sublicense granted herein; and to the best of Sheffield's knowledge there are no pending or threatened adverse actions, suits, investigations, claims or proceedings brought by one or more third parties related to the Sheffield Intellectual Property as of Effective Date;

3.1.5. The Products that are developed, manufactured, transported, stored, handled, packaged, marketed, promoted, distributed, offered for sale and/or sold by Sheffield shall be in accordance with all applicable regulations and requirements of the FDA and foreign regulatory authorities including, without limitation, cGCP, cGLP, cGMP regulations with respect thereto. The Products shall not be adulterated or misbranded as defined by the Federal Food, Drug and Cosmetic Act (or applicable foreign law) and shall not be a product which would violate any section of such Act if introduced in interstate commerce;

3.1.6. Sheffield is fully cognizant of all applicable statutes, ordinances and regulations of the United States of America and countries in the Territory with respect to the manufacture of the Products including, but not limited to, the U.S. Federal Food, Drug and Cosmetic Act and regulations thereunder and similar statutes in countries outside of the United States, and cGMPs. To the extent that Sheffield manufactures or procures the manufacture of the Products, such manufacture or procurement shall be in conformity with the Marketing Authorizations and in a manner which fully

complies with all United States of America and foreign statutes, ordinances, regulations and practices;

3.1.7. Sheffield represents and warrants that the execution of this Agreement will not breach or in any way be inconsistent with the terms and conditions of any license, contract, understanding or agreement, whether express, implied, written or oral between Sheffield and any third party, including without limitation, the Siemens License Agreement;

3.1.8. Sheffield and Siemens are parties to the Siemens License Agreement pursuant to which, among other things, Siemens is licensing to Sheffield, with the right to sublicense, a license for the manufacture, distribution and sale the MSI Delivery System. The Siemens License Agreement is valid and in full force and effect and will continue to be valid and in full force and effect upon completion of the transactions contemplated by the Definitive Documents without any modifications. There are no existing or claimed defaults by any party under the Siemens License Agreement 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 License Agreement. Sheffield shall comply with all of its obligations under the Siemens License Agreement and shall promptly notify Elan and Newco of any breach or event of default thereunder; and

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3.1.9. EXCEPT AS SET FORTH IN THIS ARTICLE 3.1, SHEFFIELD IS GRANTING THE SUBLICENSES HEREUNDER ON AN "AS IS" BASIS WITHOUT RECOURSE, 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.

3.2. Newco represents and warrants to Elan and Sheffield the following:

3.2.1. Newco is duly and validly existing in good standing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse affect on the business and assets of Newco), and Newco is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

3.2.2. Newco has full corporate authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby; this Agreement has been duly executed and delivered and constitutes the legal and valid obligations of Newco and is enforceable against Newco in accordance with its terms; and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under Newco's certificate of incorporation, by-laws or other organic documents, any material agreement or instrument binding upon or affecting Newco, or its properties or assets or any applicable laws, rules, regulations or orders affecting Newco, or its properties or assets;

3.2.3. Newco is not in default of its charter or by-laws, any applicable laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not result in any such violation;

3.2.4. Newco has not granted any option, license, right or interest to any third party which would conflict with the terms of this Agreement;

3.2.5. The Products that are to be developed, manufactured, transported, stored, handled, packaged, marketed, promoted, distributed, offered for sale and/or sold by Newco shall be in accordance with all applicable regulations and requirements of the FDA and foreign regulatory authorities including, without limitation, cGCP, cGLP, cGMP regulations relating thereto. The Products shall not be adulterated or misbranded as defined by the Federal Food, Drug and Cosmetic Act (or applicable foreign law) and shall not be a product which would violate any section of such Act if introduced in interstate commerce; and

3.2.6. Newco is fully cognizant of all applicable statutes, ordinances and regulations of the United States of America and countries in the Territory with respect to the manufacture of the Products including, but not limited to, the U.S. Federal Food, Drug and

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Cosmetic Act and regulations thereunder and similar statutes in countries outside of the United States, and cGMPs. To the extent that Newco manufactures or procures the manufacture of the Products, such manufacture or procurement shall be in conformity with the Marketing Authorizations and in a manner which fully complies with all United States of America and foreign statutes, ordinances, regulations and practices.

3.3. Elan represents and warrants to Newco and Sheffield the following:

3.3.1. Elan is duly and validly existing in good standing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse effect on the business and assets of Elan), and Elan is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

3.3.2. Elan has full corporate authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby; this Agreement has been duly executed and delivered and constitutes the legal and valid obligations of Elan and is enforceable against Elan in accordance with its terms; and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under Elan's certificate of incorporation, by-laws or other organic documents, any material agreement or instrument binding



upon or affecting Elan, or its properties or assets or any applicable laws, rules, regulations or orders affecting Elan, or its properties or assets;

3.3.3. Elan is not in default of its charter or by-laws, any applicable laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not result in any such violation.

3.4. Sheffield shall indemnify, defend and hold harmless Newco, Elan and their respective officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to third party claims to which Newco or Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Sheffield of any of its obligations under this Agreement, (ii) any breach of a representation or warranty of Sheffield made in this Agreement, and (iii) any activities conducted by Sheffield in connection with the Project, except to the extent due to the negligence or willful misconduct of Newco or Elan.

3.5. Newco shall indemnify, defend and hold harmless Sheffield and Elan and their respective officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to third party claims to which Sheffield or Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Newco of any of its obligations under this Agreement, (ii) any breach of any representation or warranty of Newco made in this Agreement, (iii) any activities conducted by Newco in connection with the Project, except to the extent due to the

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negligence or willful misconduct of Sheffield or Elan (which negligence or willful misconduct of Sheffield or Elan, as the case may be, shall not affect the obligations of Newco to the other party hereunder), and (iv) third party claims to which Sheffield or Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of the development, manufacture, transport, packaging, storage, handling, distribution, promotion, marketing, offer for sale or sale of the Products, including any product liability claim or any claim relating to any recall of a Product.

3.6. As a condition of obtaining an indemnity in the circumstances set out above or elsewhere in the Agreement, the Party seeking an indemnity shall:

3.6.1. fully and promptly notify the other Party of any claim or proceeding, or threatened claim or proceeding;

3.6.2. permit the indemnifying Party to take full care and control of such claim or proceeding;

3.6.3. reasonably assist in the investigation and defense of such claim or proceeding;

3.6.4. 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; and take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceeding.

3.7. Notwithstanding anything to the contrary in this Agreement, Elan, Sheffield and Newco shall not be liable to the other for any punitive, consequential or incidental loss or damage (whether for loss of profit or otherwise) by reason of any representation or warranty, condition or other term or any duty of common law, or under the express or implied terms of this Agreement, and whether occasioned by the negligence of the respective Parties, their employees or agents or otherwise.

#### 4. ARTICLE IV: PATENTS

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4.1. Title: Subject to the terms and conditions of this Agreement, title to the various inventions and intellectual property are set forth below as follows:

(i) title to all inventions and other intellectual property made solely by employees of Elan in connection with the Project shall be owned by Elan;

(ii) title to all inventions and other intellectual property made solely by Newco in connection with the Project shall be owned by Newco;

(iii) title to all inventions and other intellectual property made solely by Sheffield in connection with the Project, other than set forth in Article 7.1(v) below, shall be

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owned by Newco including, without limitation, any such inventions or intellectual property relating to the ADDS Technology;

(iv) title to all inventions and other intellectual property made jointly by Elan and Newco in connection with the Project shall be owned by Newco;

(v) title to all inventions and other intellectual property made solely by Sheffield employees or jointly by Newco and Sheffield employees relating to the MSI Delivery System shall be owned by Sheffield; and

(vi) all other inventions and other intellectual property made between Sheffield and Newco employees in connection with the Project shall be owned by Newco, including, without limitation, any such inventions or intellectual property relating to the ADDS Technology.

#### 4.2. Filing and Prosecution of Patents

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4.2.1. Each Party shall timely inform the other in writing of any improvement or development made by such Party relating, respectively, to

the Elan Intellectual Property, the Sheffield Intellectual Property, and/or the Newco Intellectual Property so that any patent protection that may be available for any such improvement or development is not compromised.

4.2.2. Newco shall prepare, prosecute and maintain all patents applications and issued patents relating to the inventions, improvements and other intellectual property set forth in paragraphs (ii), (iii), (iv) and (vi) in Article 7.1. With respect to such preparation, prosecution and maintenance activities, Newco shall timely inform Sheffield of the status of such activity if such inventions have application in the Topical Pulmonary Field. In the event Newco shall decide not to seek patent protection for any such intellectual property, Elan shall have the option to take control of such prosecution. In the event that Elan shall determine, in good faith, that any patents applications and issued patents relating to the inventions, improvements and other intellectual property set forth in paragraphs (ii), (iii), (iv) and (vi) in Article 7.1 predominantly relates to an area other than the Field, Elan shall have the option to take control of the preparation, prosecution and maintenance of patent protection directed to such intellectual property. In the event that Elan does not exercise such right, Newco shall have the option to take responsibility for the preparation, prosecution and maintenance of patent protection directed to such intellectual property.

4.2.3. Sheffield shall prepare, prosecute and maintain all patents applications and issued patents relating to paragraph (v) in section 7.1 with respect to such preparation, prosecution and maintenance activities.

#### 4.3. Enforcement of Intellectual Property Rights; Third party infringement

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4.3.1. Newco and Sheffield 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 Sheffield Intellectual Property, Newco Intellectual Property, the Elan Intellectual Property and/or Joint Intellectual Property and provide such other with any available evidence of such unauthorized activity.

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4.3.2. During the Term, Newco shall have the right to pursue at its own expense any enforcement activities of the Sheffield Intellectual Property and/or the Newco Intellectual Property and/or the Joint Intellectual Property within the Field. Sheffield shall agree to be named as a necessary party in an action brought by and fully financed by Newco and will reasonably co-operate with such action. Newco shall reimburse any out of pocket expenses borne by Sheffield. Should Newco decide not to enforce the Sheffield Intellectual Property and/or the Newco Intellectual Property and/or the Joint Intellectual Property within the Field, Sheffield may do so at its expense and for its own benefit, and Newco will reasonably co-operate with such action. Any actual out of pocket expenses borne by Newco in cooperating with such action shall be reimbursed by Sheffield.

4.3.3. Notwithstanding anything contained in Article 4.3.2 to the contrary, in the event that a third party is believed to be infringing

any intellectual property right relating to the MSI Delivery System, then at the request of Newco, Sheffield shall, at Sheffield's discretion, take such reasonable and necessary actions to remove such infringing activity or, in the alternative, Sheffield shall promptly grant to Newco the right to pursue any enforcement activities of the intellectual property relating to the MSI Delivery System.

#### 4.4. Infringement of third party patents

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

4.4.2. Newco shall indemnify, defend and hold Sheffield and Elan 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 referred to in this Article 4.4; provided that Sheffield or Elan 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.

#### 5A. ARTICLE V(A): REGARDING THE SHEFFIELD INTELLECTUAL PROPERTY

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##### 5A.1 Conformance With Siemens Agreements

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The Parties acknowledge that those Sheffield rights in and to the Sheffield Intellectual Property which are derived from the Siemens Supply Agreement and the Siemens License Agreement, are therefore subject to all the terms and conditions thereof. It is the Parties' express intent that the grant by Sheffield of any such rights be consistent with the terms and conditions thereof and Sheffield's obligations thereunder.

##### 5A.2 After Acquired Know How

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If Sheffield acquires the rights to additional know how or patents in the Systemic Pulmonary Field after the execution of this Agreement, it agrees to negotiate in good faith with Elan and Newco a license or sublicense, as appropriate, of such know how and patents to Newco for use in the Systemic Pulmonary Field.

#### 5. ARTICLE V: MISCELLANEOUS CLAUSES

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##### 5.1. Secrecy

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5.1.1. Any information, whether written or oral (provided that oral information shall be reduced to writing within one month by the party giving the oral information and the written form shall be furnished to the other party) pertaining to the Product that has been or will be communicated or delivered by any Party to the other, including, without limitation, trade secrets, business methods, and cost, supplier, manufacturing and customer information (collectively, "Confidential Information"), shall be treated by Newco, Sheffield and Elan, respectively, as confidential information, and shall not be disclosed or revealed to any third party whatsoever or used in any manner except as expressly provided for herein; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this Article to the extent that such Confidential Information:

- (A) is available to the public in public literature or otherwise, or after disclosure by one Party to the other becomes public knowledge through no default of the Party receiving such Confidential Information; or
- (B) was known to the Party receiving such Confidential Information prior to the receipt of such Confidential Information by such Party, whether received before or after the Effective Date; or
- (C) is obtained by the Party receiving such Confidential Information from a third party not subject to a requirement of confidentiality with respect to such Confidential Information; or
- (D) is required to be disclosed pursuant to: (A) any order of a court having jurisdiction and power to order such information to be released or made public; or (B) any lawful action of a governmental or regulatory agency.

5.1.2. Each Party shall take all such precautions with Confidential Information disclosed to it by the other Party as it normally takes with its own confidential information to prevent any improper disclosure of the Confidential Information disclosed to it by the other

Party to any third party; provided, however, that such Confidential Information may be disclosed within the limits required to obtain any authorization from the

FDA or any other United States of America or foreign governmental or regulatory agency or, with the prior written consent of the other Party, which shall not be unreasonably withheld, or as may otherwise be required in connection with the purposes of this Agreement.

5.1.3. Notwithstanding the above, each Party hereto may use or disclose Confidential Information disclosed to it by the other Party to the extent such use or disclosure is reasonably necessary in filing or prosecuting 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 making 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, it will give reasonable advance notice to the latter Party of such disclosure and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise).

5.1.4. Each Party agrees that it will not use, directly or indirectly, any Confidential Information disclosed by the other Party pursuant to this Agreement, other than as expressly provided herein.

5.1.5. Newco and Sheffield will not publicize the existence of this Agreement in any way without the prior written consent of the other subject to the disclosure requirements of applicable laws and regulations. The Parties agree that promptly following the execution of this Agreement they shall issue an agreed press release which will not disclose the terms of this Agreement. In the event that one of the Parties wishes to make an announcement concerning the Agreement, that Party will seek the consent of the other Parties. The terms of any such announcement shall be agreed in good faith.

5.2. Conflict. IN THE EVENT OF ANY INCONSISTENCY OR CONFLICT BETWEEN THE PROVISIONS OF THE ELAN LICENCE AGREEMENT ON THE ONE HAND, AND THE PROVISIONS OF THIS AGREEMENT AND THE NEWCO/SHEFFIELD LICENSE AGREEMENT ON THE OTHER HAND, THE TERMS OF THE ELAN LICENSE AGREEMENT SHALL GOVERN AND CONTROL IN ALL RESPECTS.

5.3. Parties bound. This Agreement shall be binding upon and inure for the benefit of Parties hereto, their successors and permitted assigns.

5.4. 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, (i) 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 (ii) the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

## 5.5. Duration and Termination

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5.5.1. Subject to the other provisions of Article 5.5, this Agreement shall remain in full force and effect on a Product by Product and country by country basis, for a period commencing as of the Effective Date and expiring [text omitted] years from the date of the first commercial sale of such Product in such country in the Territory, or [text omitted], whichever is longer (the "Term"). Promptly following the signing of this Agreement, Sheffield will use its best and diligent efforts to extend the term of the Siemens License Agreement and its rights thereunder, including, without limitation, the exclusive license granted to Sheffield in and to the Sheffield Intellectual Property, for an initial period of at least fifteen years from the date thereof. Upon Sheffield's obtaining such extension, it promptly shall so notify Newco and Elan in writing, specifying the period and territories covered by such extension. The Term shall be automatically extended for a period equal to any such extension of such rights of Sheffield under the Siemens License Agreement at no additional cost to Newco and Elan.

5.5.2. In addition to the rights of early or premature termination provided for elsewhere in this Agreement, the term of this Agreement may be terminated immediately upon written notice of termination given by:

- (A) the non-defaulting party in the event that the other party shall: (1) commit a material breach or default under a Definitive Document, which breach or default shall not be remedied within sixty (60) days after the receipt of written notice thereof by the party in breach or default; or (2) have made a material misrepresentation of any representation or warranty contained herein or any Definitive Document; or
- (B) Elan on the one hand, and Sheffield and Newco on the other hand, if Elan, Sheffield or Newco (on an individual basis), as the case may be, shall at any time be Insolvent, dissolved, liquidated, discontinued, or when any proceeding is filed or commenced by either Party under bankruptcy, insolvency or debtor relief laws. For purposes of this Agreement, "Insolvent" shall mean (1) the sum of a Party's debts exceeds its assets, (2) a Party is unable, or has reason to believe it is unable, to pay its debts as such debts mature, or (3) a Party does not have sufficient capital with which to conduct its business.

5.5.3. Upon exercise of those rights of termination as set forth in this Agreement with respect to any country or countries or the entire

Agreement as the case may be, this Agreement shall, subject to the other provisions of the Agreement, automatically terminate forthwith in the applicable country or countries or the entire Agreement as the case may be, and be of no further legal force or effect.

5.5.4. Upon termination of this Agreement:

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- (A) all confidentiality provisions set out herein shall remain in full force and effect for a period of five (5) years;
- (B) all representations, warranties, and indemnities shall survive the termination of this agreement and shall remain in full force and effect;
- (C) termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement;
- (D) except as is necessary to enable Elan to exercise the licenses to be granted by Newco and/or Sheffield to Elan under this Agreement, upon any termination of this Agreement, Newco, Sheffield and Elan shall promptly return to the other Party all Confidential Information received from the other Party (except one copy of which may be retained for archival purposes);
- (E) in the event this Agreement is terminated for any reason, Newco shall have the right for a period of six (6) months from termination to sell or otherwise dispose of the stock of any Product then on hand, which such sale shall be subject to applicable terms of this Agreement;
- (F) At Elan's option, except for the termination of this Agreement due to the Insolvency of Elan, or unless the Elan License Agreement is terminated



due to the breach by Elan beyond any cure or grace period in accordance with the terms thereof, the Sheffield Intellectual Property and all of the rights granted to Newco hereunder shall immediately be deemed to have been assigned and transferred to Elan, and Sheffield shall take such actions, without cost to Elan, to sublicense to Elan Sheffield's rights under the Siemens License Agreement to secure for Elan the benefits of such agreement.

- (G) The following Articles shall survive the termination or expiration of this Agreement for any reason: Article 1, Article 2.1.1, Article 3, Article 4 and Article 5.

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5.6. Force Majeure. Neither Party to this Agreement 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, or intervention of a Government Authority, non availability of raw materials, but any such delay or failure shall be remedied by such Party as soon as practicable.

5.7. Relationship of the Parties. Nothing contained in this Agreement is intended or is to be construed to constitute Elan, Newco and Sheffield as partners or joint venturers or either Party as an employee of the other. 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.

5.8. 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.

5.9. 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.

5.10. No effect on other agreements. 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, in any such other agreement.

5.11. Applicable Law. This Agreement is construed under and ruled by the laws of the State of New York. For the purpose of this Agreement the Parties submit to the personal jurisdiction of the United States District Court for the State of New York. The Parties each further irrevocably consent to the

service of any complaint, summons, notice or other process by delivery thereof to it by any manner in which notices may be given pursuant to this Agreement.

5.12. Notices. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or faxed to:

- ELAN at

Elan Corporation plc.  
Lincoln House,  
Lincoln Place,  
Dublin 2, Ireland.

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Attention: President, Elan Pharmaceutical Technologies,  
a division of Elan Corporation plc  
Telefax : 353 1 662 4960

- Newco at

Systemic Pulmonary Delivery, Ltd.  
c/o Elan International Services, Ltd.  
102 St. James Street  
Flatts, Smith Parish FL04  
Bermuda

Attention: Chief Executive Officer

- Sheffield at

Sheffield Pharmaceuticals, Inc.  
37 South Main Street  
Pittsford, New York 14534

Attention: Chairman

and

Sheffield Pharmaceutical, Inc.  
425 South Woodsmill Road  
St. Louis, Missouri 63017

Attention: Chief Executive Officer  
Telefax: (314) 579-9799

with a copy to

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

and

Fitzpatrick, Cella, Harper & Scinto  
30 Rockefeller Plaza  
New York, NY 10112

Attention: Michael P. Sandonato, Esq.  
Telefax: (212) 218-2200

or to such other address(es) and telefax numbers as may from time to time be notified by either Party to the other hereunder.

If a notice is sent by Sheffield to Newco or Newco to Sheffield pursuant to any agreements relating to the transactions contemplated hereunder, then Sheffield or Newco, as the case may be, shall send a copy of such notice to Elan in accordance with the provisions of this Article.

Any notice sent by registered air-mail shall be deemed to have been delivered within seven (7) working days after dispatch and any notice sent by telefax (with confirmed answer back) shall be deemed to have been delivered within twenty four (24) hours of the time of the dispatch. Notice of change of address shall be effective upon receipt.

5.13. No Implied Rights. No rights or licenses are granted or deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement.

5.14. Further Assurances. At any time or from time to time on and after Effective Date, each party shall at the request of the other (i) deliver such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as the other Party may reasonably deem necessary or desirable in order for it to obtain the full benefits of this Agreement and the transactions contemplated hereby.

5.15. Entire Agreement. This Agreement including its Appendices, together with the Definitive Documents, sets forth the entire agreement and understanding of the Parties with respect to the subject matter hereof, and supersedes all prior discussions, agreements and writings in relating thereto, including the letter of agreement of June 3, 1998.

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5.16. Counterparts. This Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS THEREOF the Parties hereto have executed this Agreement in duplicate.

By: /s/ Thomas M. Fitzgerald

-----  
Name: Thomas M. Fitzgerald  
Title: Chairman

SHEFFIELD PHARMACEUTICAL, INC.

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald  
Title: Chairman

ELAN CORPORATION, PLC

By: /s/ Thomas Lynch

-----  
Name: Thomas Lynch  
Title: Chief Financial Officer

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#### APPENDIX A

##### SHEFFIELD PATENT RIGHTS

[TEXT OMITTED]

#### APPENDIX B

##### PLAN

[TEXT OMITTED]

EX-10.4  
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AGREEMENT

CERTAIN PORTIONS HAVE BEEN OMITTED BASED ON  
A REQUEST FOR CONFIDENTIAL TREATMENT;  
OMITTED PORTIONS FILED SEPARATELY WITH THE

SECURITIES AND EXCHANGE COMMISSION

LICENSE AND DEVELOPMENT AGREEMENT

BY AND BETWEEN

SYSTEMIC PULMONARY DELIVERY, LTD.  
A BERMUDA COMPANY

AND

SHEFFIELD PHARMACEUTICAL, INC.  
A DELAWARE CORPORATION

AND

ELAN CORPORATION, PLC  
AN IRISH COMPANY

THIS AGREEMENT IS MADE THE 30TH DAY OF JUNE 1998

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LICENSE AND DEVELOPMENT Agreement, dated June 30, 1998, by and between Systemic Pulmonary Delivery, Ltd., a Bermuda corporation ("Newco"), Sheffield Pharmaceutical, Inc., a Delaware corporation ("Sheffield"), and Elan Corporation plc., an Irish corporation ("Elan").

#### RECITALS

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A. Newco owns, controls and/or has rights in and to the Newco Intellectual Property (capitalized terms used herein are defined below), and

B. Elan is beneficially entitled to the use of various patents, including the Elan Patent Rights, which have been granted or are pending under the International Convention in relation to the development and production of drug delivery devices and processes, and

C. Elan has agreed to enter into the Elan License Agreement provided that Sheffield and Newco enter into this Agreement, and

D. Newco is entering into this Agreement with Sheffield pursuant to which Sheffield shall have the right to manufacture and to market the Products in the Territory.

NOW THEREFORE, The Parties agree as follows:

## 1. ARTICLE I : DEFINITIONS

-----

1.1. In the present Agreement and any further agreements based thereon between the Parties hereto, the following definitions shall apply:

"ADDs Technology" shall mean all of the MDI-Aeroquip technology for all pharmaceutical, medicinal and therapeutic applications acquired or to be acquired by Newco upon terms and conditions approved in advance by EIS.

"Affiliate" shall mean any corporation or entity controlling, controlled by or under the common control of Sheffield, Newco or Elan, as the case may be. For the purpose of this Agreement, "control" shall mean the direct or indirect ownership of at least twenty-five (25%) percent of the outstanding shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

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

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"cGCP", "cGLP" and "cGMP" shall mean current Good Clinical Practices, current Good Laboratory Practices and current Good Manufacturing Practices respectively.

"Confidential Information" shall have the meaning set forth in Article 8.1 below.

"Definitive Documents" shall mean this Agreement, the Elan License Agreement, the Sheffield/Newco License Agreement, and any other documents or agreements executed in connection with the transactions contemplated hereunder and thereunder.

"EIS" shall mean Elan International Services, Ltd.

"Effective Date" shall mean June 30, 1998.

"Elan" shall mean Elan Corporation, plc and any of its Affiliates.

"Elan Intellectual Property" shall mean the Elan Patent Rights and/or the Elan Know-How.

"Elan Know-How" shall mean all knowledge, information, trade secrets, data and expertise relating to the UPDAS Technology and the Enhancing Technology (only as defined in subparagraph "(ii)" of the definition of Enhancing Technology), where the therapeutic mechanism of action is

local to the lung, solely and specifically for asthma, cystic fibrosis, chronic obstructive pulmonary disease and the use of anti-infectives for the treatment of respiratory infection, that is owned or licensed by Elan (other than the Excluded Technology) as of the Effective Date, including, but not limited to, clinical data and test results, and for the avoidance of doubt shall include the Elan Project Know-How, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights, but all subject to any contractual obligations to unaffiliated third parties that Elan has as of the Effective Date.

"Elan License Agreement" shall mean the License and Development Agreement, dated even date herewith, among Elan, Newco and Sheffield pursuant to which, among other things, Elan is licensing to Newco the Elan Know-How and the Elan Patent Rights in accordance with the terms and conditions of said agreement.

"Elan Patent Rights" shall mean all patents and patent applications related to the UPDAS Technology and Enhancing Technology (only as defined in subparagraph "(ii)" of the definition of Enhancing Technology), where the therapeutic mechanism of action is local to the lung, solely and specifically for asthma, cystic fibrosis, chronic obstructive pulmonary disease and the use of anti-infectives for the treatment of respiratory infection, that are owned or licensed by or on behalf of Elan, including the Elan Project Patent Rights, (but excluding the Excluded

Technology), as of the Effective Date, which patents as of the Effective Date are set forth on Appendix A attached hereto; all subject, however, to any contractual obligations to unaffiliated third parties that Elan has as of the Effective Date. Elan Patent Rights shall also include Elan Improvements and all extensions, continuations, continuations-in-part, divisionals, patents of additions, reexaminations, re-issues, supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder.

"Elan Project Know-How" shall mean all knowledge, information, trade secrets, data and expertise relating to the UPDAS Technology and Enhancing Technology that is owned or developed by or on behalf of Elan (other than with respect to the Excluded Technology) pursuant to the Project, including clinical data, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.



"Elan Project Patent Rights" shall mean any patents or patent applications related to the UPDAS Technology and/or the Enhancing Technology that are owned or developed by or on behalf of Elan (other than the Excluded Technology), under this Agreement and pursuant to the Project.

"Enhancing Technology" shall mean (i) the use of [text omitted] that is intended to facilitate or enhance systemic delivery of a drug for therapeutic purposes, when co-administered via inhalation with said drug via the pulmonary route, and/or (ii) the use if any, of [text omitted] that is intended to facilitate or enhance topical delivery to the lung of a drug for therapeutic purposes when co-administered via inhalation with said drug via the pulmonary route.

"Excluded Technology" shall mean all knowledge, information, trade secrets, data, discoveries, inventions, improvements, ideas, techniques, processes, formulations, systems, designs and/or expertise, and any and all other intellectual property (including patents and patent applications that are issued or that may be issued), relating to motor driven dry powder inhalers and related powdered storage systems, and any and all other transactions contemplated under the License Agreement, and the Protein and Peptide Development Agreement, each dated September 5, 1994, between [text omitted] and Elan, as the same may be amended from time to time.

"FDA" shall mean the United States Food and Drug Administration or any other successor agency, whose approval is necessary to market the Products in the United States of America.

"Field" shall mean the Topical Pulmonary Field.

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"In Market" shall mean the sale of the Products, whether by Sheffield or its Affiliates, or where applicable by a permitted sublicensee, to a third party such as a wholesaler, distributor, managed care organization, hospital, pharmacy and/or the like.

"Joint Intellectual Property" shall mean the Joint Know-How and/or the Joint Patent Rights.

"Joint Know-How" shall mean all knowledge, information and expertise developed by at least two of the three Parties during the Term relating to the Field and in accordance with the Project whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights..

"Joint Patent Rights" shall mean any patent and patent applications created, developed, conceived or otherwise

invented by at least two of the three Parties pursuant to the Agreement, relating to the Field, and in accordance with the Project. Joint Patent Rights shall also include all extensions, continuations, continuations-in-part, divisionals, patents of additions, re-examinations, re-issues, supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder.

"Marketing Authorization" shall mean the procurement of registrations and permits required by applicable government authorities in a country in the Territory for the marketing, sale, and distribution of a Product in such country.

"MSI Delivery System" shall mean Sheffield's Multi Dose Nebulizer comprising a device and dosator that generally conforms to the specifications in Annex 2 to the Siemens Supply Agreement for use with medicines for the systemic treatment of diseases, and improvements thereto, excluding the use of medicines for humans in treating respiratory disease and/or other lung disease, which exclusion includes, but is not limited to, the use of anti-infectives.

"Newco" shall mean Systemic Pulmonary Delivery, Ltd. and any of its Affiliates.

"Newco Improvements" shall mean any and all improvements conceived, created, developed, and/or otherwise invented by or on behalf of Newco relating to the Field that are made pursuant to the Agreement only during the Project.

"Newco Intellectual Property" shall mean the Newco Know-How and/or the Newco Patent Rights.

"Newco Know-How" shall mean all knowledge, information, trade secrets, data and expertise relating to the UPDAS Technology, the Enhancing Technology (only as defined in subparagraph "(ii)" of the definition of the Enhancing

Technology) and ADDS Technology, where the therapeutic mechanism of action is local to the lung, solely and specifically for [text omitted] that is owned or licensed by Newco as of the Effective Date, including, but not limited to, the Newco Improvements and clinical data and test results, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights, but subject to any contractual obligations to unaffiliated third parties that Elan has as of the Effective Date or in the future as developed pursuant to the Project.

"Newco Patent Rights" shall mean all patents and patent

applications related to ADDS Technology, where the therapeutic mechanism of action is local to the lung, solely and specifically for [text omitted] that is owned or licensed by Newco as of the Effective Date, including the Newco Improvements, which patents as of the Effective Date are set forth on Appendix B attached hereto. Newco Patent Rights shall also include all extensions, continuations, continuations-in-part, divisionals, patents of addition, reexaminations, re-issues, supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder.

"NSP" shall mean that sum determined by deducting from the gross amount billed for the Products (including, without limitation, any and all sums billed for the compound and/or drug product delivered with, by and/or via the Products; sums billed for the supply of the Products; and royalties receivable for the sale of the Products) sold In Market, the following:

(a) transportation charges or allowances, including freight pick-up allowances, and packaging costs, if any;

(b) trade, quantity or cash discounts, service allowances and independent broker's or agent's commissions, if any, allowed or paid;

(c) credits or allowances, if any, given or made on account of price adjustments, returns up to ten per cent (10%) of gross sales, off-invoice promotional discounts, rebates, any and all national, federal, state or local government rebates, whether in existence now, or enacted at any time during the term of this Agreement; and

(d) any tax (other than income or corporation tax), excise or governmental charge upon or measured by the production, import, export, sale, transportation, delivery, or use of the Products.

If Sheffield or its permitted sublicensees shall sell any of the Products together with other products to third parties in a particular country and the price attributable to the Products is less than the average price of "arms length" sales of the Products alone in the particular country for the reporting period in which such sales occur (such sales to be excluded from the calculation of the average price of "arms length" sales), NSP for any such sales shall be the average price of "arms length" sales by Sheffield or its Affiliates of the Products alone and in the country during the reporting period in which such sales occur.

"Party" shall mean Newco, Sheffield or Elan as the case may be. "Parties" shall mean any two of Newco, Sheffield and Elan.

"Plan" shall mean the business plan and program of development agreed to by the Parties and attached to the Elan License Agreement as Appendix C, with respect to the research, development, prosecution and commercialization of the Products.

"Products" shall mean all devices and products or any parts or components thereof (including, without limitation, any and all compounds and/or drug products delivered with, by and/or via the Products) that are used, developed, manufactured, offered for sale and/or sold by or on behalf of Sheffield and/or its permitted sublicensees, and that utilize, incorporate, apply and/or are based on the Newco Intellectual Property, the Sheffield Intellectual Property, and/or the Elan Intellectual Property.

"Project" shall mean all activity as undertaken by Elan, Sheffield and Newco in order to develop the Products in accordance with the Plan.

"Sheffield" shall mean Sheffield Pharmaceutical, Inc., a Delaware corporation.

"Sheffield Intellectual Property" shall mean the Sheffield Know-How and/or the Sheffield Patent Rights.

"Sheffield Know-How" shall mean all knowledge, information, trade secrets, data and expertise relating to the Systemic Pulmonary Field, other than compounds, that is possessed by Sheffield, or from time to time, developed or invented (but not acquired) by or on behalf of Sheffield during the Term, including without limitation, the Trademark, Sheffield Project Know-How, and clinical data and test results, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.

"Sheffield Patent Rights" shall mean all patents and patent applications related to the Systemic Pulmonary Field, other than compounds, that are owned by or licensed by Sheffield. Sheffield Patent Rights shall also include all extensions, continuations, continuations-in-part, divisionals, patents of addition, reexaminations, re-issues, supplementary protection certificates and foreign

counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder (and shall for the avoidance of doubt include the Sheffield Project Patent Rights and such patent

and patent applications relating to the MSI Delivery System).

"Sheffield/Newco License Agreement" shall mean the License Agreement, dated even date herewith, among Sheffield, Newco and Elan pursuant to, among other things, Sheffield is sublicensing certain intellectual property rights and know-how to Newco in accordance with the terms and conditions of said agreement.

"Sheffield Project Know-How" shall mean all knowledge, information, trade secrets, data and expertise which is not generally known to the public owned or to be developed by or on behalf of Sheffield in connection with the Project, including clinical data, whether or not covered by any patent, copyright, design, trademark, trade secret, or other industrial or intellectual property rights.

"Sheffield Project Patent Rights" shall mean any patents or patent applications related to the Systemic Pulmonary Field that are owned or developed by or on behalf of Sheffield under this Agreement and pursuant to the Project.

"Siemens" shall mean Siemens Aktiengesellschaft, a company organized under the laws of Germany.

"Siemens License Agreement" shall mean the license Agreement dated February 21, 1997 between Sheffield and Siemens.

"Siemens Supply Agreement" shall mean the Basic Supply Agreement dated March 21, 1997, between Sheffield and Siemens.

"Steering Committee" shall have the meaning set forth in the Newco Development Agreement, dated even date herewith, between Sheffield and EIS.

"Systemic Pulmonary Field" shall mean the practice of delivering therapeutic entities via the lung, with the primary intention of making them systemically available.

"Technological Competitor" shall mean any entity (including, if applicable, Zambon Group S.p.A) that substantially engages or proposes to substantially engage directly or indirectly in the areas of drug delivery, neurological therapies, pain therapies, acute care, and/or oncology in the pharmaceutical industry.

"Term" shall have the meaning set forth in Article 8.5 below.

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

"Topical Pulmonary Field" shall mean the practice of

delivering respiratory therapeutic entities via the lung with the primary intention of making them available for local respiratory therapeutic effect on the lung.

"Trademark" shall mean the trademark(s) as may be selected by Sheffield which has been or may be registered by Newco in one or more countries in the Territory.

"UPDAS Technology" (Ultrasonic Pulmonary Drug Absorption System) shall mean a system intended to enhance pulmonary delivery via inhalation by applying [text omitted].

"\$" shall mean United States Dollars.

1.2. INTERPRETATION. In this Agreement, the following shall apply:

1.2.1. the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa;

1.2.2. any reference to an Article or Appendix shall, unless otherwise specifically provided, be to a Article or Appendix of this Agreement; and

1.2.3. the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

2. ARTICLE II : THE LICENSE

2.1. Subject to the terms and conditions of this Agreement and the rights of Elan under the Definitive Documents, Newco hereby grants to Sheffield for the Term, and Sheffield hereby accepts, an exclusive, sublicense of the Newco Intellectual Property (and a license for the ADDS Technology component of the Newco Intellectual Property) in the Field for the Territory to develop, make, have made, manufacture, have manufactured, package, use, import, export, promote, distribute, market, offer for sale, and sell the Products in the Territory.

Except for an assignment or sublicense to Elan in accordance with this Agreement and the Definitive Documents, Sheffield may not (i) assign the licenses, sublicenses and rights granted to it herein without the prior written approval of Newco and Elan, which approval may be withheld for any reason whatsoever, and/or (ii) sublicense the licenses, sublicenses and rights granted to it herein without the prior written approval of Newco and Elan, which approval shall not be unreasonably withheld. Sheffield shall remain responsible for all of the acts and omissions of its permitted sublicensees. Subject to Elan's rights under the Definitive Documents, Newco shall be entitled to use the Newco Intellectual Property and all technical and clinical data or improvements thereto in connection with (i) Newco's commercial arrangements for the Products in any country

that ceases to be a part of the Territory, or any country in the Territory in the event of the expiration or sooner termination of this Agreement, or (ii) Newco's commercial arrangements for products outside of the Field. Such commercial arrangements referred to in the immediately preceding sentence shall include the right to research, develop, manufacture, offer for sale, sell, license or otherwise market the Products.

2.2. Elan shall have the right to cause Newco to enforce Newco's rights against Sheffield hereunder. This Agreement shall either terminate or survive the termination of the Elan License Agreement as follows: (i) if Sheffield is in default or breach of any of its obligations, representations or warranties under the Definitive Documents beyond any applicable cure period, or if Elan terminates the Elan License Agreement under Section 8.6.2 thereof, or if Elan terminates this Agreement pursuant to Article 8.5.2 (B) or (C) of this Agreement, then Elan shall have a right to immediately terminate the licenses, sublicenses and any other rights whatsoever granted to Sheffield hereunder, provided, however, that Elan agrees to enter into licenses with all sublicensees of Sheffield on terms no less favorable to the sublicensees than the terms contained in the sublicensees' agreements with Sheffield; provided such sublicense agreements have been approved by Elan in accordance with this Agreement (ii) if Elan acquires 100% of Newco's Common Stock, or if Elan and Sheffield mutually agree in accordance with an orderly windup of Newco, then Elan shall not have the right to terminate the licenses, sublicenses and any other rights whatsoever granted to Sheffield hereunder (except as otherwise set forth herein), and (iii) upon the occurrence of any other event not set forth in subsections (i) and (ii) above, Sheffield and Elan shall negotiate in good faith with respect to the survival or termination of the licenses and sublicenses granted to Sheffield hereunder. If this Agreement shall survive the termination of the Elan License Agreement in accordance with this Article 2.2, then Sheffield and Elan shall enter into a License Agreement upon the same terms and conditions as this Agreement.

2.3. Notwithstanding anything contained in this Agreement to the contrary, Elan shall have the right of first negotiation to manufacture, package, use, import, export, promote, distribute, market, offer for sale, and sell all Products in the Field (including products that utilize, incorporate, apply and/or are based on the Newco Intellectual Property and/or the Sheffield Intellectual Property) outside of the United States. Such right of first negotiation shall be exercised as follows:

2.3.1. (A) If Sheffield intends to develop a Product that is subject to Elan's right of first negotiation, then Sheffield immediately shall notify Elan in writing that Elan may elect to enter into negotiations referred to in this Article 2.3, or (B) if Sheffield, on its own behalf (and/or together with Newco), has developed a Product that is subject to Elan's right of first negotiation, then at such time that Sheffield determines in good faith that it wishes to commercialize the Product itself, with a third party or otherwise, then, Sheffield shall notify Elan in writing that Elan may elect to enter into negotiations referred to in this Article 2.3, subject to Elan satisfying the reasonable requirements of Sheffield's strategic commercial plan with respect to such Product in terms of formulation, manufacturing and marketing. Elan shall indicate its desire to enter into such negotiations pursuant to this Article 2.3 by delivering written notice to Sheffield within forty-five (45) days of Elan's receipt of the written notification from Sheffield to Elan. If Elan elects to enter into such negotiations, the Parties shall negotiate in good faith the terms of an applicable agreement.

2.3.2. If, despite such good faith negotiations, Elan and Sheffield do not reach agreement on the terms of such an agreement within six (6) months from the notification in writing by Sheffield to Elan, then Sheffield shall be free to offer a third party (other than a Technological Competitor unless consented to by Elan which consent shall not be unreasonably withheld, and otherwise subject to the terms and conditions of this Agreement) terms to develop and commercialize, as applicable, such Product in the Territory, which terms when taken as a whole, are more favorable to Sheffield than the principal terms of the last written proposal offered to Sheffield by Elan, or by Sheffield to Elan, as the case may be. Prior to entering into such an agreement with a third party, Sheffield shall promptly notify Elan, in writing and in confidence, of the principal terms of such agreement and the identity of the third party with whom Sheffield intends to contract. Elan shall have the right, to be exercised within ten (10) days of receipt of such notice, to elect by written notice to Sheffield, to enter into an agreement with Sheffield upon the same terms and conditions contained in Sheffield's notice to Elan. In the event Elan does not elect to enter into such agreement, Sheffield shall have the right, for a period of sixty (60) days from the expiration of the ten (10) day period set forth above, to enter into an agreement with the third party specified in Sheffield's notice upon the same terms and conditions as contained in such notice.

2.4. Sheffield shall market the Products in the Territory under a Trademark, which Trademark will be owned by Sheffield subject to the terms and conditions of this Agreement.

2.5. Newco hereby grants to Sheffield during the Term a non-exclusive royalty free license in the Territory, solely for use in connection with the sale of the Products, to use Newco's trademark or trademarks, on the following terms: 2.5.1. Sheffield shall as soon as it becomes aware of any infringement give to Newco in writing full particulars of any use or proposed use by any other person, firm or company of a trade name or trademark or promotional or advertising activity which may constitute infringement.

2.5.2. If Sheffield becomes aware that any other person, firm or company alleges that such trademark is invalid or that the use of such trademark infringes any rights of another party or that the trademark is otherwise attacked, Sheffield shall immediately give to Newco full particulars in writing thereof and shall make no comment or admission to any third party in respect thereof.

2.5.3. Newco shall have the right to conduct all proceedings relating to such trademark and shall in its sole discretion decide what action, if any, to take in respect of any infringement or alleged infringement of such trademark or any other claim or counter-claim brought or threatened in respect of the use or registration of such trademark. Any such proceedings shall be conducted at Newco's expense and for its own benefit.

2.5.4. Nothing contained in this Agreement shall grant to Sheffield any right, title, or interest in or to such trademark, whether or not specifically recognized or perfected under applicable laws. At no time during or after the Term shall Sheffield challenge or assist others to



challenge any such trademark or the registration thereof or attempt to register any trademarks, marks, or trade names confusingly similar to any such trademark. All displays of any such trademark that Sheffield intends to adopt shall first be submitted to Newco for approval (which shall not be unreasonably withheld) of design, color, and other details, or shall be exact copies of those used by Newco. In addition, Sheffield shall fully comply with all reasonable guidelines, if any, communicated by Newco concerning the use of any such trademark as well as all rules and regulations of such use throughout the Territory.

2.6. When packaged, and to the extent permitted by law, a product label shall include an acknowledgement that the Product is made under license from Newco. Such acknowledgement shall take into consideration regulatory requirements and Sheffield's reasonable commercial requirements. Sheffield shall wherever possible give due acknowledgement and recognition to Newco in all printed promotional and other material regarding the Product such as stating that the Product is under license from Newco and that the applicable Newco technology has been applied to the Products. Sheffield shall consult with and obtain the written approval of Newco as to the format and content of the promotional and other material insofar as it relates to a description of, or other reference to, the application of the Newco Intellectual Property, such approval not to be unreasonably withheld or delayed. The further consent of Newco shall not be required where the format and content of such materials is substantively similar as the materials previously furnished to and approved in writing by Newco.

2.7. Sheffield will use reasonable best efforts to file and obtain Marketing Authorizations in a country in the Major Markets as soon as possible. If (i) Sheffield fails to obtain Marketing Authorization to commercialize a Product in a country in the Major Markets within a commercially reasonable time, in accordance with the Plan and as determined by the Steering Committee, or (ii) Sheffield fails to effect a national commercial launch of a Product in a country in the Major Markets within the period specified in Article 2.10 below then, in such event, Newco and Sheffield shall, at the option of Elan, make available and transfer to Elan all of Newco's and Sheffield's respective data, information, applications, approvals, filings and the like to permit Elan to commercialize such Product in the applicable country or countries in the Major Markets. In such event Elan shall be entitled to an irrevocable, exclusive, perpetual, royalty free, license from Newco and Sheffield to the Newco Intellectual Property, the Sheffield Intellectual Property, and the Trademark to commercialize such Product in the applicable country in the Field on the terms set forth in this Article 2.7. Elan may sublicense the rights granted to it pursuant to this Article 2.7 to one or more sublicensees without the prior consent of Newco or Sheffield. Insofar as Newco or Sheffield has licensed or acquired third party technology, Newco and Sheffield shall use all commercially reasonable efforts to exclude or where applicable to minimize the extent of any limitations or restrictions on its use for such purposes, and it is understood that no such limitations or restrictions shall be permitted as between Sheffield and Newco. In the event that Elan acquires such a license, the Parties shall enter into a further written license and other applicable agreement which shall include customary and reasonable terms in accordance with this Article 2.7, and at Elan's option, Sheffield and Newco shall use their best efforts to assign to Elan their respective rights under any third party supply

or other agreement relating to such Product, or if Sheffield or Newco are supplying the Product or

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components thereof, Sheffield and Newco shall enter into good faith negotiations with Elan to continue such supply.

2.8. Sheffield will use its reasonable best efforts to obtain Marketing Authorizations to commercialize the Products in the other countries of the Territory (I.E., other than the Major Markets) that it selects, having regard to the effort and expenditure required to obtain Marketing Authorizations for the Products and the commercial opportunities for the Products in such other countries of the Territory.

2.9. In general, Sheffield shall employ diligent efforts to research, develop, register, market, promote and sell and maintain sales of the Products in the Territory and Sheffield shall employ a level of advertising, sales, marketing, and promotion efforts in each country in the Territory where Marketing Authorization for Product has been obtained which is: (i) commensurate with that put forth by other pharmaceutical manufacturers for products of similar market potential in that country in the Territory, and (ii) sufficient with respect to the potential for that country to fully exploit the market potential for the Product as depicted in the Plan and as determined by the Steering Committee. Such Plan shall be reviewed and mutually agreed to by the Parties on an annual basis.

2.10. Sheffield shall effect a national commercial launch of a Product in a country in the Major Markets within one hundred and eighty (180) days of Marketing Authorization thereof in such country in the Major Markets. If Sheffield does not make a national commercial launch of such Product in one or more countries of the Major Markets within the one hundred and eighty (180) day period, the licenses granted to Sheffield hereunder shall with thirty (30) days written notice from Elan terminate in the applicable country and Elan shall be entitled to commercialize such Product in the Field and to receive a license to the Newco Intellectual Property, the Sheffield Intellectual Property and the Trademark in the applicable country on the terms set forth in Article 2.10.

2.11. If Sheffield indicates to Newco and Elan that it does not intend to obtain Marketing Authorization and commercialize the Products in a particular country or countries of the Territory, or fails to commence commercialization in any country within one hundred and (180) days after receiving the required Marketing Authorization therefor, Elan shall be entitled to license from Sheffield and Newco the Newco Intellectual Property the Sheffield Intellectual Property, and the Trademark to commercialize the Products in such countries on the terms set forth in Article 2.7.

### 3. ARTICLE III: DEVELOPMENT OF THE PRODUCT

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3.1. Sheffield shall be responsible for the cost of the development, registration, manufacture and marketing of the Products, and Sheffield shall use its reasonable best efforts to conduct the Project, as would be deemed commensurate with the achievement by Sheffield of the business aims for a similar product of its own.

3.2. Sheffield shall mark or have marked the patent number(s) on all Products or otherwise reasonably communicate to the trade concerning the existence of any Elan Patent

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Rights, Sheffield Patent Rights, Newco Patent Rights or Joint Patent Rights for the countries within the Territory in such a manner as to ensure compliance with, and enforceability under, all applicable laws, including, without limitation, 35 United States Code Section 287, as the same may be amended from time to time.

#### 4. ARTICLE IV: FINANCIAL PROVISIONS

4.1. Newco hereby irrevocably assigns and transfers to Elan or Elan's designee Newco's rights to receive any payments or compensation in whatever form under this Agreement and, at Elan's option, Sheffield shall make such payments directly to Elan or Elan's designee.

##### 4.2. Royalty Payments.

4.2.1. In consideration of the rights and licenses granted to Sheffield to the Elan Patent Rights by virtue of this Agreement, Sheffield shall pay to Elan or Elan's designee a single payment of \$[text omitted] of a product in the Field utilizing or based on the Elan Intellectual Property first receives Marketing Authorization in a country in the Major Markets. Sheffield shall immediately notify Newco and Elan in writing upon Sheffield's receipt of such Marketing Authorization; and

4.2.2. In consideration of the rights and licenses granted to Sheffield to the Elan Patent Rights by virtue of this Agreement, Sheffield shall pay to EIS or EIS's designee a single payment of \$[text omitted] in cash plus a milestone payment accrued thereon at the rate of [text omitted] per annum through the date of payment shall be payable by Sheffield upon [text omitted].

4.2.3. In consideration of the rights and licenses granted to Sheffield to the Elan Patent Rights by virtue of this Agreement, Sheffield shall pay to Elan or Elan's designee a royalty based on NSP generated by Sheffield or its sublicensees, [text omitted] percent of NSP for Products that utilize, incorporate, apply and/or are based on the UPDAS Technology in the Field and/or the Enhancing Technology in the Field.

##### 4.3. ROYALTIES, PAYMENTS, REPORTS AND RECORDS

4.3.1. Within forty five (45) days of the end of each quarter, Sheffield shall notify Newco and Elan of the NSP of Products sold in that preceding quarter. Payments shown by each calendar quarter report to have accrued shall be due on the date such report is due and shall be payable to the designated bank account of Elan or its designee as instructed by Elan. All payments due under this Agreement shall be made in United States Dollars and shall be non-refundable to Sheffield.

4.3.2. Sheffield shall keep and shall cause its Affiliates and sublicensees to keep true and accurate records of gross sales of the Product, the items deducted from the gross amount in calculating the NSP, the NSP and the royalties payable to Elan under this Article 4. Sheffield shall deliver to Elan a written statement thereof within forty-five (45) days following the end of each calendar quarter (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The said written statements shall set forth for each Product on country-by-country basis, the calculation of the NSP from gross revenues during that calendar quarter, the applicable percentage rate, a computation of the sums due to Elan, and such details of the transactions that are relevant to the calculations of NSP ("the Statement"). The Parties' financial officers shall agree upon the precise format of the Statement.

4.3.3. Payments due on NSP of the Product based on sales amounts 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 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 sale of currency of the country of origin of such payment for the day prior to the date on which the payment by Sheffield is being made.

4.3.4. Any income or other taxes which Sheffield is required by law to pay or withhold on behalf of Elan with respect to royalties and any other monies payable to Elan under this Agreement shall be deducted from the amount of such NSP payments, royalties and other monies due. Sheffield shall furnish Elan with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by Elan. Sheffield shall promptly provide Elan with a certificate or other documentary evidence to enable Elan to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by Sheffield. The Parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable Sheffield to make such payments to Elan without any deduction or withholding.

4.3.5. For the twenty four (24) month period following the close of each calendar year during the Term, Sheffield and its sublicensees will provide Elan's independent certified accountants (reasonably acceptable to Sheffield) with access, during regular business hours and upon reasonable prior request and subject to the confidentiality provisions as contained in this Agreement, to the books and records relating to the Products, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended, including the sums payable by Sheffield to Elan pursuant to Article 4.

4.3.6. Any adjustment required by such inspection shall be made within thirty (30) days of the agreement of the Parties or, if not agreed, upon the determination of an arbitrator to whom any dispute under this Article shall be submitted to arbitration. If the adjustment payable to Elan is greater

than [text omitted] of the amount paid for the relevant period, then the cost to Elan for the inspection, and if applicable the arbitration, shall be paid by Sheffield provided that the costs of the inspection shall not exceed [text omitted]. In

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addition, Sheffield shall pay interest to Elan at the rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office as its prime rate plus one per cent (1%) (applicable as of the date on which payment should have been made pursuant to Article 4), from the date on which the payment should have been made pursuant to Article 4.3.1 until the date of payment.

4.3.7. Sheffield shall pay interest to Elan at the rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office as its prime rate plus one per cent (applicable as of the date on which payment should have been made pursuant to the applicable provisions of this Agreement) from the date on which payment should have been made pursuant to the applicable provision of this Agreement until the date of payment.

4.4 If Sheffield claims in good faith that one or more of its devices, products, parts or components thereof, compounds and/or drug products does not utilize, incorporate, apply or is not based on the Elan Intellectual Property, the Sheffield Intellectual Property and/or Newco Intellectual Property, then Sheffield shall immediately notify Newco and Elan in writing. If Newco or Elan disputes Sheffield's claim, the Parties shall discuss such matter in good faith and determine a mutually agreeable resolution.

## 5. ARTICLE V: REGISTRATION OF THE PRODUCT

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5.1. Sheffield shall at its sole cost file, and Sheffield shall use its reasonable best efforts to prosecute to approval, the Marketing Authorizations for the Products in the Territory in accordance with the Plan and subject to the direction of the Steering Committee.

5.2. Sheffield shall maintain at its own cost the Marketing Authorizations during the period that Sheffield is marketing the Products. Sheffield shall continue to maintain the Marketing Authorizations in the applicable countries at Elan's request and expense, if Elan acquires the right to a license pursuant to Article 2.7 for such term thereafter during which Elan and/or its designees is marketing the Products, and Sheffield hereby agrees to provide to Elan, or at Elan's option to transfer and assign to Elan, the Marketing Authorizations (and applications for regulatory approvals) within thirty (30) days of the submission thereof to the applicable authority. Sheffield shall furnish to Elan all regulatory filings and other material correspondence with the FDA and other regulatory authorities within thirty (30) days of submission.

5.3. During the registration procedure for Marketing Authorizations, Sheffield shall keep Newco and Elan promptly and fully advised of Sheffield's registration activities, progress and procedures. Sheffield shall notify Newco and Elan immediately of any inspection by the FDA or any other regulatory authority of the manufacturing or other facilities used in the clinical research, manufacturing, packaging, storage or handling of the

Products. Copies of all correspondence with the regulatory authority will be provided to Newco and Elan.

5.4. Sheffield shall indemnify and hold harmless Newco and Elan, their respective agents and employees from and against all claims, damages, losses, liabilities and expenses to which Newco or Elan, their respective agents, and employees may become subject related to or

arising out of Sheffield's bad faith, negligence or intentional misconduct in connection with the filing or maintenance of the Marketing Authorizations.

## 6. ARTICLE VI: WARRANTY AND INDEMNITY.

6.1. Newco represents and warrants to Sheffield and Elan as follows:

6.1.1. Newco is duly and validly existing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse affect on the business and assets of Newco), and is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

6.1.2. Newco has full corporate authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby; this Agreement has been duly executed and delivered by Newco and constitutes the legal and valid obligations of Newco and is enforceable against Newco in accordance with its terms; and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under Newco's memorandum and articles of association or any material agreement or instrument binding upon or affecting Newco or its properties or assets or any applicable laws, rules, regulations or orders affecting Newco or its properties or assets;

6.1.3. Newco is not in material default of its memorandum and articles of association, any applicable material laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not result in any such violation;

6.1.4. Newco is the sole and exclusive owner or licensee of, or controls all right, title and interest to the Newco Patent Rights except those developed under Section 7.1(v) hereof; and to Newco's knowledge and belief, Newco is the sole owner or licensee of the Newco Know-How. Newco has the right to grant the licenses and sublicenses granted herein. The Newco Patent Rights, and to Newco's knowledge and belief, the Newco Know-How, are free and clear of any lien, encumbrances, security interest or restriction on the license granted herein. Newco will not grant during the Term, any right, license or interest in and to the Newco Intellectual Property, or any portion thereof,

inconsistent with the license and sublicense granted herein; and to the best of Newco's knowledge there are no pending or threatened adverse actions, suits, investigations, claims or proceedings brought by one or more third parties related to the Newco Intellectual Property as of Effective Date;

6.1.5. Newco represents and warrants that the execution of this Agreement will not breach or in any way be inconsistent with the terms and conditions of any license, contract,

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understanding or agreement, whether express, implied, written or oral between Sheffield and any third party;

6.1.6. EXCEPT AS SET FORTH IN THIS ARTICLE 6.1, NEWCO IS GRANTING THE LICENSES AND SUBLICENSES HEREUNDER ON AN "AS IS" BASIS WITHOUT RECOURSE, 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.

6.2. Sheffield represents and warrants to Newco and Elan the following:

6.2.1. Sheffield is duly and validly existing in good standing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse effect on the business and assets of Sheffield), and Sheffield is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

6.2.2. Sheffield has full corporate authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby; this Agreement has been duly executed and delivered and constitutes the legal and valid obligations of Sheffield and is enforceable against Sheffield in accordance with its terms; and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under Sheffield's certificate of incorporation, by-laws or other organic documents, any material agreement or instrument binding upon or affecting Sheffield, or its properties or assets or any applicable laws, rules, regulations or orders affecting Sheffield, or its properties or assets;

6.2.3. Sheffield is not in default of its charter or by-laws, any applicable laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not result in any such violation;

6.2.4. Sheffield has not granted any option, license, right or interest to any third party which would conflict with the terms of this Agreement.

6.2.5. The Products shall be developed, manufactured, transported, stored, handled, packaged, marketed, promoted, distributed, offered for sale and/or sold in accordance with all applicable regulations and requirements of the FDA and foreign regulatory authorities including, without limitation, cGCP, cGLP, cGMP regulations relating thereto. The Products shall not be adulterated or misbranded as defined by the Federal Food, Drug and Cosmetic Act (or applicable foreign law) and shall not be a product which would violate any section of such Act if introduced in interstate commerce.

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6.2.6. Sheffield is fully cognizant of all applicable statutes, ordinances and regulations of the United States of America and countries in the Territory with respect to the manufacture of the Products including, but not limited to, the U.S. Federal Food, Drug and Cosmetic Act and regulations thereunder and similar statutes in countries outside of the United States, and cGMPs. Sheffield shall manufacture or procure the manufacture of the Products in conformity with the Marketing Authorizations and in a manner which fully complies with all United States of America and foreign statutes, ordinances, regulations and practices.

6.3. Elan represents and warrants to Newco and Sheffield the following:

6.3.1. Elan is duly and validly existing in good standing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse affect on the business and assets of Elan), and Elan is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

6.3.2. Elan has full corporate authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby; this Agreement has been duly executed and delivered and constitutes the legal and valid obligations of Elan and is enforceable against Elan in accordance with its terms; and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under Elan's certificate of incorporation, by-laws or other organic documents, any material agreement or instrument binding upon or affecting Elan, or its properties or assets or any applicable laws, rules, regulations or orders affecting Elan, or its properties or assets;

6.3.3. Elan is not in default of its charter or by-laws, any applicable laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this Agreement and the transactions contemplated hereby will not result in any such violation.

6.4. Newco shall indemnify, defend and hold harmless Sheffield, Elan and their respective officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to third party claims to which Newco or Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Newco of any of its obligations under this



Agreement, (ii) any breach of a representation or warranty of Newco made in this Agreement, and (iii) any activities conducted by Newco in connection with the Project, except to the extent due to the negligence or willful misconduct of Sheffield or Elan.

6.5. Sheffield shall indemnify, defend and hold harmless Newco and Elan and their respective officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to third party claims to which Newco or Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Sheffield of any of its obligations under this Agreement,

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(ii) any breach of any representation or warranty of Sheffield made in this Agreement, (iii) any activities conducted by Sheffield in connection with the Project, except to the extent due to the negligence or willful misconduct of Newco or Elan (which negligence or willful misconduct of Newco or Elan, as the case may be, shall not affect the obligations of Sheffield to the other party hereunder), and (iv) third party claims to which Newco or Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of the development, manufacture, transport, packaging, storage, handling, distribution, promotion, marketing, offer for sale or sale of the Products, including any product liability claim or any claim relating to any recall of a Product.

6.6. As a condition of obtaining an indemnity in the circumstances set out above or elsewhere in the Agreement, the Party seeking an indemnity shall:

6.6.1. fully and promptly notify the other Party of any claim or proceeding, or threatened claim or proceeding;

6.6.2. permit the indemnifying Party to take full care and control of such claim or proceeding;

6.6.3. reasonably assist in the investigation and defense of such claim or proceeding;

6.6.4. 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; and take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceeding.

6.7. Notwithstanding anything to the contrary in this Agreement, Elan, Sheffield and Newco shall not be liable to the other for any punitive, consequential or incidental loss or damage (whether for loss of profit or otherwise) by reason of any representation or warranty, condition or other term or any duty of common law, or under the express or implied terms of this Agreement, and whether occasioned by the negligence of the respective Parties, their employees or agents or otherwise.

## 7. ARTICLE VII: PATENTS

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7.1. TITLE: Subject to the terms and conditions of this Agreement, title to the various inventions and intellectual property are set forth below as follows:

(i) title to all inventions and other intellectual property made solely by employees of Elan in connection with the Project shall be owned by Elan;

(ii) title to all inventions and other intellectual property made solely by employees of Newco in connection with the Project shall be owned by Newco;

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(iii) title to all inventions and other intellectual property made solely by employees of Sheffield in connection with the Project, other than set forth in Article 7.1(v) below, shall be owned by Newco including, without limitation, any such inventions or intellectual property relating to the ADDS Technology;

(iv) title to all inventions and other intellectual property made jointly by Elan and Newco in connection with the Project shall be owned by Newco;

(v) title to all inventions and other intellectual property made solely by Sheffield employees or jointly by Newco and Sheffield employees relating to the MSI Delivery System shall be owned by Sheffield; and

(vi) all other inventions and other intellectual property made between Sheffield and Newco employees in connection with the Project shall be owned by Newco, including, without limitation, any such inventions or intellectual property relating to the ADDS Technology.

## 7.2. FILING AND PROSECUTION OF PATENTS

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7.2.1. Each Party shall timely inform the other in writing of any improvement or development made by such Party relating, respectively, to the Sheffield Intellectual Property, and/or Newco Intellectual Property so that any patent protection that may be available for any such improvement or development is not compromised.

7.2.2. Newco shall prepare, prosecute and maintain all patents applications and issued patents relating to the inventions, improvements and other intellectual property set forth in paragraphs (ii), (iii), (vi) and (vi) in section 7.1. With respect to such preparation, prosecution and maintenance activities, Newco shall timely apprise Sheffield and Elan of the status of any such activity and shall inform Sheffield and Elan of the status of such activity if such inventions have application in the Topical Pulmonary Field. In the event Newco shall decide not to seek patent protection for any Newco Intellectual Property or Sheffield Intellectual Property, Elan shall have the option to take control of such prosecution. In the event that Elan shall

determine, in good faith, that patents applications and issued patents relating to the inventions, improvements and other intellectual property set forth in paragraphs (ii), (iii), (vi) and (vi) in section 7.1. predominantly relates to an area other than the Field, Elan shall have the option to take control of the preparation, prosecution and maintenance of patent protection directed to such intellectual property. In the event that Elan does not exercise such right, Newco shall have the option to take responsibility for the preparation, prosecution and maintenance of patent protection directed to such Joint Patent Rights.

7.2.3. Sheffield shall prepare, prosecute and maintain all patents applications and issued patents relating to paragraph (v) in section 7.1 with respect to such preparation, prosecution and maintenance activities.

### 7.3. ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS; THIRD PARTY INFRINGEMENT

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

7.3.2. During the Term, Sheffield shall have the right to pursue at its own expense any enforcement activities of the Sheffield Intellectual Property and/or the Newco Intellectual Property and/or the Joint Intellectual Property within the Field. Newco shall agree to be named as a necessary party in an action brought by and fully financed by Sheffield and will reasonably co-operate with such action. Sheffield shall reimburse any out of pocket expenses borne by Newco. Should Sheffield decide not to enforce the Sheffield Intellectual Property and/or the Newco Intellectual Property and/or the Joint Intellectual Property within the Field, Newco may do so at its expense and for its own benefit, and Sheffield will reasonably co-operate with such action. Any actual out of pocket expenses borne by Sheffield in cooperating with such action shall be reimbursed by Newco.

### 7.4. INFRINGEMENT OF THIRD PARTY PATENTS

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

7.4.2. Sheffield shall indemnify, defend and hold Newco and Elan 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 referred to in this Article 7.4;

provided that Newco or Elan 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 Sheffield, not to be unreasonably withheld or delayed.

8A. ARTICLE VIII(A): REGARDING THE SHEFFIELD INTELLECTUAL PROPERTY

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8A.1 CONFORMANCE WITH SIEMENS AGREEMENTS

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The Parties acknowledge that those Sheffield rights in and to the Sheffield Intellectual Property which are derived from the Siemens Supply Agreement and the Siemens License Agreement, are therefore subject to all the terms and conditions thereof. It is the Parties' express intent that the grant by Sheffield of any such rights be consistent with the terms and conditions thereof and Sheffield's obligations thereunder.

8A.2 AFTER ACQUIRED KNOW HOW

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If Sheffield acquires the rights to additional know how or patents in the Systemic Pulmonary Field after the execution of this Agreement, it agrees to negotiate in good faith with Elan and Newco a license or sublicense, as appropriate, of such know how and patents to Newco for use in the Systemic Pulmonary Field.

8. ARTICLE VIII: MISCELLANEOUS CLAUSES

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8.1. SECRECY

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8.1.1. Any information, whether written or oral (provided that oral information shall be reduced to writing within one month by the party giving the oral information and the written form shall be furnished to the other party) pertaining to the Product that has been or will be communicated or delivered by any Party to the other, including, without limitation, trade secrets, business methods, and cost, supplier, manufacturing and customer information (collectively, "Confidential Information"), shall be treated by Newco, Sheffield and Elan, respectively, as confidential information, and shall not be disclosed or revealed to any third party whatsoever or used in any manner except as expressly provided for herein; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this Article to the extent that such Confidential Information:

- (A) is available to the public in public literature or otherwise, or after disclosure by one Party to the other

becomes public knowledge through no default of the Party receiving such Confidential Information; or

- (B) was known to the Party receiving such Confidential Information prior to the receipt of such Confidential Information by such Party, whether received before or after the Effective Date; or
- (C) is obtained by the Party receiving such Confidential Information from a third party not subject to a requirement of confidentiality with respect to such Confidential Information; or
- (D) is required to be disclosed pursuant to:
  - (A) any order of a court having jurisdiction and power to order such information to be released or made public; or (B) any lawful action of a governmental or regulatory agency.

8.1.2. Each Party shall take all such precautions with Confidential Information disclosed to it by the other Party as it normally takes with its own confidential information to prevent any improper disclosure of the Confidential Information disclosed to it by the other

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Party to any third party; PROVIDED, HOWEVER, that such Confidential Information may be disclosed within the limits required to obtain any authorization from the FDA or any other United States of America or foreign governmental or regulatory agency or, with the prior written consent of the other Party, which shall not be unreasonably withheld, or as may otherwise be required in connection with the purposes of this Agreement.

8.1.3. Notwithstanding the above, each Party hereto may use or disclose Confidential Information disclosed to it by the other Party to the extent such use or disclosure is reasonably necessary in filing or prosecuting 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 making 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, it will give reasonable advance notice to the latter Party of such disclosure and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise).

8.1.4. Each Party agrees that it will not use, directly or indirectly, any Confidential Information disclosed by the other Party pursuant to this Agreement, other than as expressly provided herein.

8.1.5. Newco and Sheffield will not publicize the existence of this Agreement in any way without the prior written consent of the other subject to the disclosure requirements of applicable laws and regulations. The Parties agree that promptly following the execution of this Agreement they shall issue an agreed press release which will not disclose the terms of this Agreement. In the event that one of the Parties wishes to make an announcement concerning the Agreement, that Party will seek the consent of the other Parties. The terms of any such announcement shall be agreed in good faith.

8.2. CONFLICT. IN THE EVENT OF ANY INCONSISTENCY OR CONFLICT BETWEEN THE PROVISIONS OF THE ELAN LICENCE AGREEMENT ON THE ONE HAND, AND THE PROVISIONS OF THIS AGREEMENT AND THE SHEFFIELD/NEWCO LICENSE AGREEMENT ON THE OTHER HAND, THE TERMS OF THE ELAN LICENSE AGREEMENT SHALL GOVERN AND CONTROL IN ALL RESPECTS.

8.3. PARTIES BOUND. This Agreement shall be binding upon and inure for the benefit of Parties hereto, their successors and permitted assigns.

8.4. 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, (i) 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 (ii) the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

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#### 8.5. DURATION AND TERMINATION

8.5.1. Subject to the other provisions of Article 8.5, this Agreement shall remain in full force and effect on a Product by Product and country by country basis, for a period commencing as of the Effective Date and expiring [text omitted] years from the date of the first commercial sale of such Product in such country in the Territory, or [text omitted], whichever is longer (the "Term").

8.5.2. In addition to the rights of early or premature termination provided for elsewhere in this Agreement, the term of this Agreement may be terminated immediately upon written notice of termination given by:

(A) the non-defaulting party in the event that the other party shall: (1) commit a material breach or default under a Definitive Document, which breach or default shall not be remedied within sixty (60) days after the receipt of written notice thereof by the party in breach or default; or (2) have made a material misrepresentation of any representation or warranty contained herein or any Definitive Document; or

(B) Elan, in the event that (1) a change of "control" of Newco or Sheffield shall occur (the term "control" shall have the

meaning set forth in the definition of "Affiliate"), or (2) a Technological Competitor acquires directly or indirectly voting stock or equivalent securities in Sheffield or Newco representing [text omitted] or more of the stock which carries entitlement to vote, or where [text omitted] or more of such Technological Competitor's stock or equivalent securities is acquired by Sheffield or Newco; provided, however, that in the case of [text omitted] (should [text omitted] become a Technological Competitor), the [text omitted] threshold set forth in this sentence shall be deemed to be [text omitted], or (3) if such Technological Competitor otherwise controls Sheffield's or Newco's respective board of directors, or either Sheffield or Newco otherwise controls such Technological Competitor's board of directors or similar governing body.

(C) Elan on the one hand, and Sheffield and Newco on the other hand, if Elan, Sheffield or Newco (on an individual basis), as the case may be, shall at any time be Insolvent, dissolved, liquidated, discontinued, or when any proceeding is filed or commenced by either Party under bankruptcy, insolvency or debtor relief laws. For purposes of this Agreement, "Insolvent" shall mean (1) the sum of a Party's debts exceeds its assets, (2) a Party is unable, or has reason to believe it is unable, to pay its debts as such debts mature, or (3) a Party does not have sufficient capital with which to conduct its business.

8.5.3. Upon exercise of those rights of termination as set forth in this Agreement with respect to any country or countries or the entire Agreement as the case may be, this Agreement shall, subject to the other provisions of the Agreement, automatically terminate forthwith in the applicable country or countries or the entire Agreement as the case may be, and be of no further legal force or effect.

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8.5.4. Upon termination of this Agreement:

- (A) all confidentiality provisions set out herein shall remain in full force and effect for a period of five (5) years;
- (B) all representations, warranties, and indemnities shall survive the termination of this agreement and shall remain in full force and effect;
- (C) termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement;
- (D) except as is necessary to enable Elan to

exercise the licenses to be granted by Newco and/or Sheffield to Elan under this Agreement, upon any termination of this Agreement, Newco, Sheffield and Elan shall promptly return to the other Party all Confidential Information received from the other Party (except one copy of which may be retained for archival purposes);

- (E) in the event this Agreement is terminated for any reason, Sheffield shall have the right for a period of six (6) months from termination to sell or otherwise dispose of the stock of any Product then on hand, which such sale shall be subject to applicable terms of this Agreement;
- (F) any sums that were due from Sheffield to Newco and Elan prior to the exercise of the right to terminate this Agreement shall be paid in full within sixty (60) days of termination of this Agreement;
- (G) the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement;
- (H) At Elan's option, except for the termination of this Agreement due to the Insolvency of Elan, or unless the Elan License Agreement is terminated due to the breach by Elan beyond any cure or grace period in accordance with the terms thereof, the Newco Intellectual Property, the

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Newco Improvements, all improvements developed or invented by or on behalf of Sheffield during the Project and all of the rights whatsoever granted to Sheffield hereunder shall immediately be deemed to have been reverted, assigned and transferred to Elan, including rights in and to the Joint Intellectual Property.

- (H) The following Articles shall survive the termination or expiration of this Agreement for any reason: Article 1;



Articles 2.2., 2.7, 2.10 and 2.11;  
Articles 4.3.5 and 4.3.6 and 4.3.7;  
Article 5.4; Article 6; Article 7 and  
Article 8.

8.6. FORCE MAJEURE. Neither Party to this Agreement 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, or intervention of a Government Authority, non availability of raw materials, but any such delay or failure shall be remedied by such Party as soon as practicable.

8.7. RELATIONSHIP OF THE PARTIES. Nothing contained in this Agreement is intended or is to be construed to constitute Elan, Newco and Sheffield as partners or joint venturers or either Party as an employee of the other. 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.

8.8. 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.

8.9. 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.

8.10. NO EFFECT ON OTHER AGREEMENTS. 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, in any such other agreement.

8.11. APPLICABLE LAW. This Agreement is construed under and ruled by the laws of the State of New York. For the purpose of this Agreement the Parties submit to the personal jurisdiction of the United States District Court for the State of New York. The Parties each further irrevocably consent to the service of any complaint, summons, notice or other process by delivery thereof to it by any manner in which notices may be given pursuant to this Agreement.

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8.12. NOTICES. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or faxed to:

- Elan at

Elan Corporation plc.  
Lincoln House,  
Lincoln Place,  
Dublin 2, Ireland.

Attention: President, Elan Pharmaceutical Technologies,  
a division of Elan Corporation plc  
Telefax : 353 1 662 4960

- Newco at

Systemic Pulmonary Delivery, Ltd.  
c/o Elan International Services, Ltd.  
102 St. James Street  
Flatts, Smith Parish FL04  
Bermuda

Attention: Chief Executive Officer

- If to Sheffield, at

Sheffield Pharmaceutical, Inc.  
425 South Woodsmill Road  
St. Louis, Missouri 63017

Attention: Chief Executive Officer  
Telefax : (314) 579-9799

with a copy to  
Fitzpatrick, Cella, Harper & Scinto  
30 Rockefeller Plaza  
New York, NY 10112

Attention: Michael P. Sandonato, Esq.  
Telefax: (212) 218-2200

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or to such other address(es) and telefax numbers as may  
from time to time be notified by either Party to the  
other hereunder.

If a notice is sent by Sheffield to Newco or Newco to Sheffield  
pursuant to any agreements relating to the transactions contemplated hereunder,  
then Sheffield or Newco, as the case may be, shall send a copy of such notice to  
Elan in accordance with the provisions of this Article.

Any notice sent by registered air-mail shall be deemed to have been  
delivered within seven (7) working days after dispatch and any notice sent by  
telefax (with confirmed answer back) shall be deemed to have been delivered  
within twenty four (24) hours of the time of the dispatch. Notice of change of  
address shall be effective upon receipt.

8.13. NO IMPLIED RIGHTS. No rights or licenses are granted or deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement.

8.14. FURTHER ASSURANCES. At any time or from time to time on and after Effective Date, each party shall at the request of the other (i) deliver such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as the other Party may reasonably deem necessary or desirable in order for it to obtain the full benefits of this Agreement and the transactions contemplated hereby.

8.15. ENTIRE AGREEMENT. This Agreement including its Appendices, together with the Definitive Documents, sets forth the entire agreement and understanding of the Parties with respect to the subject matter hereof, and supersedes all prior discussions, agreements and writings in relating thereto, including the letter of agreement of June 3, 1998.

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8.16. COUNTERPARTS. This Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS THEREOF the Parties hereto have executed this Agreement in duplicate.

SYSTEMIC PULMONARY DELIVERY, LTD

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald

Title: Chairman

SHEFFIELD PHARMACEUTICAL, INC.

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald

Title: Chairman

ELAN CORPORATION, PLC

By: /s/ Thomas Lynch

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Name: Thomas Lynch

Title: Chief Financial Officer

#### APPENDIX A

ELAN PATENT RIGHTS

NONE AT PRESENT

#### APPENDIX B

ELAN PATENT RIGHTS

[text omitted]

#### APPENDIX C

THE PLAN

[text omitted]

EX-10.5

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AGREEMENT

CERTAIN PORTIONS HAVE BEEN OMITTED BASED ON  
A REQUEST FOR CONFIDENTIAL TREATMENT;  
OMITTED PORTIONS FILED SEPARATELY WITH THE  
SECURITIES AND EXCHANGE COMMISSION

LICENSE AND DEVELOPMENT AGREEMENT

BY AND BETWEEN

ELAN CORPORATION, PLC  
AN IRISH COMPANY

AND

SYSTEMIC PULMONARY DELIVERY, LTD.  
A BERMUDA COMPANY

AND

SHEFFIELD PHARMACEUTICAL, INC.  
A DELAWARE CORPORATION

THIS AGREEMENT IS MADE THE 30TH DAY OF JUNE 1998

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LICENSE AND DEVELOPMENT AGREEMENT, dated June 30, 1998, by and between Elan Corporation, plc., an Ireland corporation ("Elan"); Systemic Pulmonary Delivery, Ltd., a Bermuda corporation ("Newco") and Sheffield Pharmaceutical, Inc., a Delaware corporation.

#### RECITALS

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A. ELAN is beneficially entitled to the use of various patents, including the ELAN PATENT RIGHTS (capitalized terms used herein are defined below), which have been granted or are pending under the International Convention in relation to the development and production of drug delivery devices and processes, and

B. ELAN is knowledgeable in the development of devices and has developed a unique range of delivery systems designed to provide newer and better formulations of medicaments, and

C. SHEFFIELD possesses proprietary information, including patented and patent applications, relating to certain technologies in the Systemic Pulmonary Field, and

D. NEWCO desires to enter into a licensing agreement with ELAN pursuant to which NEWCO shall have the right to manufacture and to market the PRODUCTS in the TERRITORY, and

E. ELAN is prepared to license the ELAN PATENT RIGHTS and the ELAN KNOW HOW in the TERRITORY to NEWCO. The PARTIES entered into a letter of agreement dated June 3, 1998 (the "LETTER AGREEMENT") pursuant to which the PARTIES agreed to enter into definitive documents, including this Agreement, and

F. As of the date of this Agreement, NEWCO, ELAN, EIS and SHEFFIELD are entering into several agreements with respect to the transactions contemplated hereunder.

The PARTIES agree as follows:

#### 1. ARTICLE I: DEFINITIONS

-----

1.1. In the present Agreement and any further agreements based thereon between the PARTIES hereto, the following definitions shall apply:

"ADDS TECHNOLOGY" shall mean all of the MDI-Aeroquip technology for all pharmaceutical, medicinal and therapeutic applications, acquired or to be acquired by NEWCO upon terms and conditions approved in advance by EIS.

"AFFILIATE" shall mean any corporation or entity controlling, controlled by or under the common control of ELAN or NEWCO as the case may be. For the

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purpose of this Agreement, "control" shall mean the direct or indirect ownership of at least twenty-five (25%) percent of the outstanding shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

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

"cGCP", "cGLP" and "cGMP" shall mean current Good Clinical Practices, current Good Laboratory Practices and current Good Manufacturing Practices respectively.

"COMPETING PRODUCT" shall mean a product in the FIELDS which is not a PRODUCT but which would compete with one or more of the PRODUCTS in the TERRITORY such that sales of the COMPETING PRODUCT would significantly reduce the sales of a PRODUCT.

"CONFIDENTIAL INFORMATION" shall have the meaning set forth in Article 8.1 below.

"DEFINITIVE DOCUMENTS" shall mean this AGREEMENT; the Security Agreement from Newco to Elan, the Pledge Agreement from Sheffield to Elan, the Subscription Agreement, the Securities Purchase Agreement, Registration Rights Agreement, the Newco Development Agreement, all as contemplated under the LETTER AGREEMENT (as defined in the Recitals); the NEWCO/SHEFFIELD LICENSE AGREEMENT, the SHEFFIELD/NEWCO LICENSE AGREEMENT, and any other documents or agreements executed in connection with the transactions contemplated hereunder and thereunder.

"EFFECTIVE DATE" shall mean June 30, 1998.

"ELAN" shall mean Elan Corporation, plc and any of its AFFILIATES.

"EIS" shall mean Elan International Services, Ltd.

"ELAN INTELLECTUAL PROPERTY" shall mean the ELAN PATENT RIGHTS and/or the ELAN KNOW-HOW.

"ELAN KNOW-HOW" shall mean all knowledge, information, trade secrets, data and expertise relating to the UPDAS TECHNOLOGY and ENHANCING TECHNOLOGY and that is owned or licensed by ELAN (other than the EXCLUDED TECHNOLOGY) as of the EFFECTIVE DATE, including, but not limited to, clinical data and test results, and for the avoidance of doubt shall

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include the ELAN PROJECT KNOW-HOW, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights, but all subject to any contractual obligations to unaffiliated third parties that relates to specific pharmaceuticals that may be formulated for delivery by the UPDAS TECHNOLOGY or ENHANCING TECHNOLOGY that ELAN has as of the EFFECTIVE DATE.

"ELAN PATENT RIGHTS" shall mean all patents and patent applications related to the UPDAS TECHNOLOGY and/or the ENHANCING TECHNOLOGY that are owned or licensed by or on behalf of Elan, including the ELAN PROJECT PATENT RIGHTS, (but excluding the EXCLUDED TECHNOLOGY), which patents as of the EFFECTIVE DATE are set forth on Appendix A attached hereto; subject, however, to any contractual obligations to unaffiliated third parties that relates to specific pharmaceuticals that may be formulated for delivery by the UPDAS TECHNOLOGY or ENHANCING TECHNOLOGY that ELAN has as of the EFFECTIVE DATE. ELAN PATENT RIGHTS shall also include all extensions, continuations, continuations-in-part, divisionals, patents-of-additions reexaminations, re-issues, supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder.

"ELAN PROJECT KNOW-HOW" shall mean all knowledge, information, trade secrets, data and expertise relating to the UPDAS TECHNOLOGY and ENHANCING TECHNOLOGY that is owned or developed by or on behalf of ELAN (other than with respect to the EXCLUDED TECHNOLOGY) pursuant to the PROJECT, including but not limited to clinical data, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.

"ELAN PROJECT PATENT RIGHTS" shall mean any patents or patent applications related to the UPDAS TECHNOLOGY and/or the ENHANCING TECHNOLOGY that are owned or developed by or on behalf of Elan (other than the EXCLUDED TECHNOLOGY), under this AGREEMENT and pursuant to the PROJECT.

"ENHANCING TECHNOLOGY" shall mean (i) the use of [text omitted] that is intended to facilitate or enhance systemic delivery of a drug for therapeutic purposes, when co-administered via inhalation with said drug via the pulmonary route, and/or (ii)



the use, if any, of [text omitted] that is intended to facilitate or enhance topical delivery to the lung of a drug for therapeutic purposes when co-administered via inhalation with said drug via the pulmonary route.

"EXCLUDED TECHNOLOGY" shall mean all knowledge, information, trade secrets, data, discoveries, inventions, improvements, ideas, techniques, processes, formulations, systems, designs and/or expertise, and any and all other intellectual

property (including patents and patent applications that are issued or that may be issued), relating to motor driven dry powder inhalers and related powdered storage systems, and any and all other transactions contemplated under the License Agreement, and the Protein and Peptide Development Agreement, each dated September 5, 1994, between [text omitted] and ELAN, as the same may be amended from time to time.

"FDA" shall mean the United States Food and Drug Administration or any other successor agency, whose approval is necessary to market the PRODUCTS in the United States of America.

"FIELDS" shall mean the SYSTEMIC PULMONARY FIELD and/or the TOPICAL PULMONARY FIELD.

"IN MARKET" shall mean the sale of the PRODUCTS, whether by NEWCO or its AFFILIATES, or where applicable by a permitted sublicensee, to a third party such as a wholesaler, distributor, managed care organization, hospital, pharmacy and/or the like.

"JOINT INTELLECTUAL PROPERTY" shall mean the JOINT KNOW-HOW and/or the JOINT PATENT RIGHTS.

"JOINT KNOW-HOW" shall mean all knowledge, information and expertise developed by at least two of the three PARTIES during the TERM relating to the FIELD and in accordance with the PROJECT whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

"JOINT PATENT RIGHTS" shall mean any patent and patent applications created, developed, conceived or otherwise invented by at least two of the three PARTIES pursuant to the AGREEMENT, relating to the FIELDS, and in accordance with the PROJECT. JOINT PATENT RIGHTS shall also include all extensions, continuations, continuations-in-part, divisionals, patents of additions, reexaminations, re-issues supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder.

"MAJOR MARKETS" shall mean the United States of America, the United Kingdom of Great Britain and Northern Ireland, Italy,

France, Germany, Japan and/or Korea.

"MARKETING AUTHORIZATION" shall mean the procurement of registrations and permits required by applicable government authorities in a country in the TERRITORY for the marketing, sale, and distribution of a PRODUCT in such country.

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"MSI DELIVERY SYSTEM" shall mean SHEFFIELD'S Multi Dose Nebulizer comprising a device and dosator that generally conforms to the specifications in Annex 2 to the SIEMENS SUPPLY AGREEMENT for use with medicines for the systemic treatment of diseases, and improvements thereto, excluding the use of medicines for humans in treating respiratory disease and/or other lung disease, which exclusion includes, but is not limited to, the use of anti-infectives.

"NEWCO" shall mean Systemic Pulmonary Delivery, Ltd. and any of its AFFILIATES.

"NEWCO INTELLECTUAL PROPERTY" shall mean the NEWCO KNOW-HOW and/or the NEWCO PATENT RIGHTS.

"NEWCO KNOW-HOW" shall mean all knowledge, information, trade secrets, data and expertise that is possessed by NEWCO, or from time to time, developed, invented or otherwise acquired by or on behalf of NEWCO during the TERM, including without limitation, the ADDS TECHNOLOGY, NEWCO PROJECT KNOW-HOW, and clinical data and test results, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.

"NEWCO/SHEFFIELD LICENSE AGREEMENT" shall mean the License Agreement, dated as of the date hereof, entered into between NEWCO and SHEFFIELD with respect to, among other things, the sublicense of certain rights in accordance with Article 2.2 below.

"NEWCO PATENT RIGHTS" shall mean all patents and patent applications owned or to be owned by, or licensed or to be licensed by NEWCO. NEWCO PATENT RIGHTS shall also include all extensions, continuations, continuations-in-part, divisionals, patents of additions, reexaminations, re-issues, supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder. NEWCO PATENT RIGHTS shall further include any patents or patent applications covering any improved PRODUCTS or improved methods of making or using the PRODUCTS invented or acquired by NEWCO during the TERM (and shall for the avoidance of doubt include the NEWCO PROJECT PATENT RIGHTS and such patent and patent applications relating to the ADDS TECHNOLOGY).

"NEWCO PROJECT KNOW-HOW" shall mean all knowledge, information,

trade secrets, data and expertise owned or to be developed by or on behalf of NEWCO in connection with the PROJECT, including clinical data, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.

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"NEWCO PROJECT PATENT RIGHTS" shall mean any patents or patent applications covering any improved PRODUCTS or methods of making or using the PRODUCTS, invented or acquired by or on behalf of NEWCO in connection with the PROJECT.

"NSP" shall mean that sum determined by deducting from the gross amount billed for the PRODUCTS (including, without limitation, any and all sums billed for the compound and/or drug product delivered with, by and/or via the PRODUCTS; sums billed for the supply of the PRODUCTS; and royalties receivable for the sale of the PRODUCTS) sold IN MARKET, the following:

(a) transportation charges or allowances, including freight pick-up allowances, and packaging costs, if any;

(b) trade, quantity or cash discounts, service allowances and independent broker's or agent's commissions, if any, allowed or paid;

(c) credits or allowances, if any, given or made on account of price adjustments, returns up to ten per cent (10%) of gross sales, off-invoice promotional discounts, rebates, any and all national, federal, state or local government rebates, whether in existence now, or enacted at any time during the term of this Agreement; and

(d) any tax (other than income or corporation tax), excise or governmental charge upon or measured by the production, import, export, sale, transportation, delivery, or use of the PRODUCTS.

If NEWCO or its permitted sublicensees shall sell any of the PRODUCTS together with other products to third parties in a particular country and the price attributable to the PRODUCTS is less than the average price of "arms length" sales of the PRODUCTS alone in the particular country for the reporting period in which such sales occur (such sales to be excluded from the calculation of the average price of "arms length" sales), NSP for any such sales shall be the average price of "arms length" sales by NEWCO or its AFFILIATES of the PRODUCTS alone and in the country during the reporting period in which such sales occur.

"PARTY" shall mean NEWCO, SHEFFIELD or ELAN as the case may be.

"PARTIES" shall mean NEWCO, SHEFFIELD and ELAN.

"PLAN" shall mean the business plan and program of development

agreed to by the PARTIES and attached hereto as Appendix B, with respect to the research, development, prosecution and commercialization of the PRODUCTS, which PLAN shall be reviewed and mutually agreed to by the PARTIES on an annual basis.

"PRODUCTS" shall mean all devices and products or any parts or components thereof (including, without limitation, any and all compounds and/or drug products delivered with, by and/or via the PRODUCTS) that are used, developed, manufactured, offered for sale and/or sold by or on behalf of NEWCO and/or its permitted sublicensees, and that utilize, incorporate, apply and/or are based on the ELAN INTELLECTUAL PROPERTY, the SHEFFIELD INTELLECTUAL PROPERTY and/or the NEWCO INTELLECTUAL PROPERTY.

"PROJECT" shall mean all activity as undertaken by ELAN, SHEFFIELD and NEWCO in order to develop the PRODUCTS in accordance with the PLAN.

"SHEFFIELD" shall mean Sheffield Pharmaceutical, Inc., a Delaware corporation.

"SHEFFIELD INTELLECTUAL PROPERTY" shall mean the SHEFFIELD KNOW-HOW and/or the SHEFFIELD PATENT RIGHTS.

"SHEFFIELD KNOW-HOW" shall mean all knowledge, information, trade secrets, data and expertise related to the SYSTEMIC PULMONARY FIELD, other than compounds, that is possessed by SHEFFIELD, or from time to time, developed or invented (but not acquired) by or on behalf of SHEFFIELD during the TERM related to the SYSTEMIC PULMONARY FIELD, including clinical data, and shall for the avoidance of doubt include the MSI DELIVERY SYSTEM and the SHEFFIELD PROJECT KNOW-HOW, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.

"SHEFFIELD/NEWCO LICENSE AGREEMENT" shall mean the Sublicense Agreement, dated even date herewith, between SHEFFIELD and NEWCO, pursuant to which, among other things, SHEFFIELD is licensing to NEWCO certain intellectual property rights.

"SHEFFIELD PATENT RIGHTS" shall mean all patents and patent applications related to the SYSTEMIC PULMONARY FIELD, other than compounds, that are owned or licensed by SHEFFIELD, which patents as of the EFFECTIVE DATE are set forth on Appendix C attached hereto. SHEFFIELD PATENT RIGHTS shall also include all extensions, continuations, continuations-in-part, divisionals, patents of addition, re-issues, reexaminations supplementary protection certificates and foreign counterparts of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder (and shall for the avoidance of doubt include patent and patent applications relating to the MSI DELIVERY SYSTEM and the SHEFFIELD PROJECT PATENT RIGHTS).

"SHEFFIELD PROJECT KNOW-HOW" shall mean all knowledge, information, trade secrets, data and expertise relating to the SYSTEMIC PULMONARY FIELD that is owned or developed by or on behalf of SHEFFIELD in connection with the PROJECT, including, but not limited to, clinical data, whether or not covered by any patent, copyright, design, trademark, trade secret or other industrial or intellectual property rights.

"SHEFFIELD PROJECT PATENT RIGHTS" shall mean any patents or patent applications related to the SYSTEMIC PULMONARY FIELD that are owned or developed by or on behalf of SHEFFIELD in connection with the PROJECT during the TERM.

"SIEMENS" shall mean Siemens Aktiengesellschaft, a company organized under the laws of Germany.

"SIEMENS LICENSE AGREEMENT" shall mean the license Agreement dated February 21, 1997 between SHEFFIELD and SIEMENS.

"SIEMENS SUPPLY AGREEMENT" shall mean the Basic Supply Agreement dated March 21, 1997, between SHEFFIELD and SIEMENS.

"STEERING COMMITTEE" shall have the meaning set forth in the Newco Development Agreement, dated even date herewith, between SHEFFIELD and EIS.

"SYSTEMIC PULMONARY FIELD" shall mean the practice of delivering therapeutic entities via the lung, with the primary intention of making them systemically available.

"TECHNOLOGICAL COMPETITOR" shall mean any entity (including, if applicable, Zambon Group S.p.A) that substantially engages or proposes to substantially engage directly or indirectly in the areas of drug delivery, neurological therapies, pain therapies, acute care, and/or oncology in the pharmaceutical industry.

"TERM" shall have the meaning set forth in Article 8.6 below.

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

"TOPICAL PULMONARY FIELD" shall mean the practice of delivering respiratory therapeutic entities via the lung with the primary intention of making them available for local respiratory therapeutic effect on the lung.

"TRADEMARK" shall mean the trademark(s) as may be selected by NEWCO which has been or may be registered by NEWCO in one or more countries in the TERRITORY.

"UPDAS TECHNOLOGY" (Ultrasonic Pulmonary Drug Absorption System) shall mean a system intended to enhance pulmonary delivery via inhalation by [text omitted]

"\$" shall mean United States Dollars.

1.2. INTERPRETATION. In this Agreement, the following shall apply:

1.2.1. the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa;

1.2.2. any reference to an Article or Appendix shall, unless otherwise specifically provided, be to a Article or Appendix of this Agreement; and

1.2.3. the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

2. ARTICLE II : THE LICENSE

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2.1. Subject to the terms and conditions of this Agreement, ELAN hereby grants to NEWCO for the TERM, and NEWCO hereby accepts, an exclusive license of the ELAN INTELLECTUAL PROPERTY, only in the FIELDS, for the TERRITORY to develop, make, have made, manufacture, have manufactured, package, use, import, export, promote, distribute, market, offer for sale, and sell the PRODUCTS in the TERRITORY.

2.2. NEWCO may not assign or sublicense the licenses and rights granted to it herein without the prior written approval of ELAN, which approval may be withheld for any reason whatsoever, provided, however, that Elan will not unreasonably withhold its consent to any sublicense, PROVIDED, FURTHER HOWEVER, that simultaneously with the execution and delivery of this Agreement, NEWCO and SHEFFIELD are entering into the NEWCO/SHEFFIELD LICENSE AGREEMENT pursuant to which NEWCO shall grant to SHEFFIELD an exclusive license or sublicense, as the case may be, to the intellectual property rights, including patent rights, in and to the NEWCO INTELLECTUAL PROPERTY and ELAN INTELLECTUAL PROPERTY and only in the TOPICAL PULMONARY FIELD, where the therapeutic mechanism of action is local to the lung, solely and specifically for asthma, cystic fibrosis, chronic obstructive pulmonary disease and the use of anti-infectives for the treatment of respiratory infection. ELAN hereby consents to the license and sublicense granted by NEWCO to SHEFFIELD as set forth in this Article 2.2, subject to the terms and conditions of the NEWCO/SHEFFIELD LICENSE AGREEMENT. Subject to Article 2.2 of the NEWCO/SHEFFIELD LICENSE AGREEMENT with respect to SHEFFIELD, any sublicense or other agreement permitted by this Article 2.2 shall survive the termination of this Agreement

as follows: upon termination of this AGREEMENT, ELAN shall, with NEWCO'S

assistance, notify each permitted sublicensee of the termination of this AGREEMENT. If a sublicensee elects to notify ELAN that it requires the continuation of the permitted sublicense granted to it by NEWCO pursuant to this AGREEMENT, ELAN shall promptly negotiate with such sublicensee in good faith with a view to entering into a direct contractual relationship with such sublicensee. Such agreement between ELAN and such sublicensee shall, in ELAN'S reasonable discretion be on commercially reasonable terms and shall be, to the extent practicable, on terms no less favorable to the sublicensee than the terms of such sublicensee's agreement with NEWCO, and shall provide that such sublicensee shall take over the applicable obligations owed by NEWCO to ELAN. Sales of PRODUCTS payable to such a sublicensee in relation to the PRODUCTS shall constitute NSP for the purpose of calculating the sums payable by the sublicensee to ELAN. If NEWCO does not continue, or procure the continuance, of the supply of the relevant PRODUCT to the said sublicensee, then NEWCO shall use its reasonable endeavors to ensure that ELAN or the sublicensee can enter into the appropriate supply arrangements with NEWCO or NEWCO'S suppliers of the PRODUCTS and the components thereof and grant ELAN a licence on the terms set forth in Article 2.9 below.

2.3. ELAN shall be entitled to use the ELAN INTELLECTUAL PROPERTY and all technical and clinical data or improvements thereto in connection with (i) ELAN's commercial arrangements for the PRODUCTS in any country that ceases to be a part of the TERRITORY, or in any country in the TERRITORY in the event of the expiration or sooner termination of this Agreement, or (ii) ELAN'S commercial arrangements for products outside of the FIELDS. Such commercial arrangements referred to in the immediately preceding sentence shall include the right to research, develop, manufacture, offer for sale, sell, license or otherwise market the PRODUCTS.

2.4. NEWCO and SHEFFIELD will not market, develop for market, offer for sale or sell a COMPETING PRODUCT during the TERM and for a period of one year thereafter. Should NEWCO or SHEFFIELD market, develop for market, offer for sale or sell a COMPETING PRODUCT in the TERRITORY, ELAN reserves the right to terminate the licenses granted to NEWCO hereunder.

2.5. Notwithstanding anything contained in this Agreement to the contrary, ELAN shall have the right of first negotiation to manufacture, package, use, import, export, promote, distribute, market, offer for sale, and sell all PRODUCTS (including products that utilize, incorporate, apply and/or are based on the NEWCO INTELLECTUAL PROPERTY and/or SHEFFIELD INTELLECTUAL PROPERTY) in the SYSTEMIC PULMONARY FIELD that relate to the areas of pain, neurology, oncology and acute care. Such right of first negotiation shall be exercised as follows:

2.5.1. (A) If NEWCO intends to develop a PRODUCT that is subject to ELAN'S right of first negotiation, then NEWCO immediately shall notify ELAN in writing that ELAN may elect to enter into negotiations referred to in this Article 2.5, or (B) if NEWCO, on its own behalf (and/or together with SHEFFIELD), has developed a PRODUCT that is subject to ELAN'S right of first negotiation, then at such time that NEWCO determines in good faith that it wishes to commercialize the PRODUCT itself, whether with a third party or otherwise, then

NEWCO shall notify ELAN in writing that ELAN may elect to enter into negotiations referred to in this Article 2.5. ELAN shall indicate its desire to enter into such negotiations pursuant to this Article 2.5 by delivering written notice to NEWCO within forty-five (45) days of ELAN's receipt of the written notification from NEWCO to ELAN. If ELAN elects to enter into such negotiations, the Parties shall negotiate in good faith the terms of an applicable agreement.

2.5.2. If, despite such good faith negotiations, ELAN and NEWCO do not reach agreement on the terms of such an agreement within six (6) months from the notification in writing by NEWCO to ELAN, then NEWCO shall be free to offer a third party (other than a TECHNOLOGICAL COMPETITOR unless consented to by ELAN which consent shall not be unreasonably withheld, and otherwise subject to the terms and conditions of this Agreement) terms to develop and commercialize, as applicable, such PRODUCT in the TERRITORY, which terms when taken as a whole, are more favorable to NEWCO than the principal terms of the last written proposal offered to NEWCO by ELAN, or by NEWCO to ELAN, as the case may be. Prior to entering into such an agreement with a third party, NEWCO shall promptly notify ELAN, in writing and in confidence, of the principal terms of such agreement and the identity of the third party with whom NEWCO intends to contract. ELAN shall have the right, to be exercised within ten (10) days of receipt of such notice, to elect by written notice to NEWCO, to enter into an agreement with NEWCO upon the same terms and conditions contained in NEWCO'S notice to ELAN. In the event ELAN does not elect to enter into such agreement, NEWCO shall have the right, for a period of sixty (60) days from the expiration of the ten (10) day period set forth above, to enter into an agreement with the third party specified in NEWCO'S notice upon the same terms and conditions as contained in such notice.

2.6 NEWCO shall market the PRODUCTS in the TERRITORY under a TRADEMARK, which TRADEMARK will be owned by NEWCO subject to the terms and conditions of this Agreement.

2.7 ELAN hereby grants to NEWCO during the TERM a non-exclusive royalty free license in the TERRITORY, solely for use in connection with the sale of the PRODUCTS, to use the "UPDAS"(TM)trademark, on the following terms:

2.7.1 NEWCO shall as soon as it becomes aware of any infringement give to ELAN in writing full particulars of any use or proposed use by any other person, firm or company of a trade name or trademark or promotional or advertising activity which may constitute infringement.

2.7.2 If NEWCO becomes aware that any other person, firm or company alleges that such trademark is invalid or that the use of such trademark infringes any rights of another party or that the trademark is otherwise attacked or attackable, NEWCO shall immediately give to ELAN full particulars in writing thereof and shall make no comment or admission to any third



party in respect thereof.

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2.7.3 ELAN shall have the right to conduct all proceedings relating to such trademark and shall in its sole discretion decide what action, if any, to take in respect of any infringement or alleged infringement of such trademark or any other claim or counter-claim brought or threatened in respect of the use or registration of such trademark. Any such proceedings shall be conducted at ELAN'S expense and for its own benefit.

2.7.4 Nothing contained in this Agreement shall grant to NEWCO any right, title, or interest in or to such trademark, whether or not specifically recognized or perfected under applicable laws. At no time during or after the term of this Agreement shall NEWCO challenge or assist others to challenge any such trademark or the registration thereof or attempt to register any trademarks, marks, or trade names confusingly similar to any such trademark. All displays of any such trademark that NEWCO intends to adopt shall first be submitted to ELAN for approval (which shall not be unreasonably withheld) of design, color, and other details, or shall be exact copies of those used by ELAN. In addition, NEWCO shall fully comply with all reasonable guidelines, if any, communicated by ELAN concerning the use of any such trademark as well as all rules and regulations of such use throughout the Territory.

2.7.5 The rights granted to NEWCO under this Article 2.7 shall automatically terminate on termination or expiration of this Agreement with respect to a PRODUCT in a country in the TERRITORY.

2.8 When packaged, and to the extent permitted by law, a product label shall include an acknowledgement that the PRODUCT is made under license from ELAN. Such acknowledgement shall take into consideration regulatory requirements and NEWCO's reasonable commercial requirements. NEWCO shall wherever possible give due acknowledgement and recognition to ELAN in all printed promotional and other material regarding the PRODUCT such as stating that the PRODUCT is under license from ELAN and that the applicable ELAN technology has been applied to the PRODUCTS. NEWCO shall consult with and obtain the written approval of ELAN as to the format and content of the promotional and other material insofar as it relates to a description of, or other reference to, the application of the ELAN INTELLECTUAL PROPERTY, such approval not to be unreasonably withheld or delayed. The further consent of ELAN shall not be required where the format and content of such materials is substantively similar as the materials previously furnished to and approved in writing by ELAN.

2.9 NEWCO will use reasonable best efforts to file and obtain MARKETING AUTHORIZATIONS in the MAJOR MARKETS as soon as possible. If (i) NEWCO fails to obtain MARKETING AUTHORIZATION to commercialize a PRODUCT in a country in the MAJOR MARKETS within a commercially reasonable time, in accordance with the PLAN and as determined by the STEERING COMMITTEE, or (ii) NEWCO fails to effect a national commercial launch of a PRODUCT in a country in the MAJOR MARKETS within the period specified in Article 2.12 below then, in such event,

NEWCO and SHEFFIELD shall, at the option of ELAN, make available and transfer to ELAN all of NEWCO'S and SHEFFIELD'S respective data, information, applications, approvals, filings and the like to permit ELAN to

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commercialize such PRODUCT in the applicable country or countries in the MAJOR MARKETS. In such event ELAN shall be entitled to an irrevocable, exclusive, perpetual, royalty free, license from NEWCO and SHEFFIELD to the NEWCO INTELLECTUAL PROPERTY, the SHEFFIELD INTELLECTUAL PROPERTY and the TRADEMARK to commercialize such PRODUCT in the applicable country in the FIELDS on the terms set out in this Article 2.9. ELAN may sublicense the rights granted to it pursuant to this Article 2.9 to one or more sublicensees without the prior consent of NEWCO or SHEFFIELD. Insofar as NEWCO or SHEFFIELD has licensed or acquired third party technology, NEWCO and SHEFFIELD shall use all commercially reasonable efforts to exclude or where applicable to minimize the extent of any limitations or restrictions on its use for such purposes, and it is understood that no such limitations or restrictions shall be permitted as between SHEFFIELD and NEWCO. In the event that ELAN acquires such a license, the PARTIES shall enter into a further written license and other applicable agreement which shall include customary and reasonable terms in accordance with this Article 2.9, and at ELAN'S option, SHEFFIELD and NEWCO shall use their best efforts to assign to ELAN their respective rights under any third party supply or other agreement relating to such PRODUCT.

2.10 NEWCO will use its reasonable best efforts to obtain MARKETING AUTHORIZATIONS to commercialize the PRODUCTS in the other countries of the TERRITORY (I.E., other than the MAJOR MARKETS) that it selects, having regard to the effort and expenditure required to obtain MARKETING AUTHORIZATIONS for the PRODUCTS and the commercial opportunities for the PRODUCTS in such other countries of the TERRITORY.

2.11 In general, NEWCO and SHEFFIELD shall employ diligent efforts to research, develop, register, market, promote and sell and maintain sales of the PRODUCTS in the TERRITORY and NEWCO shall employ a level of advertising, sales, marketing, and promotion efforts in each country in the TERRITORY where MARKETING AUTHORIZATION for PRODUCT has been obtained which is: (i) commensurate with that used by other pharmaceutical manufacturers for products of similar market potential in that country in the TERRITORY, and (ii) sufficient with respect to the potential for that country to fully exploit the market potential for the PRODUCT as depicted in the PLAN and as determined by the STEERING COMMITTEE. Such PLAN shall be reviewed and mutually agreed to by the PARTIES on an annual basis.

2.12 NEWCO shall effect a national commercial launch of a PRODUCT in a country in the MAJOR MARKETS within one hundred and eighty (180) days of MARKETING AUTHORIZATION thereof in such country in the MAJOR MARKETS. If NEWCO does not make a national commercial launch of such PRODUCT in one or more countries of the MAJOR MARKETS within the one hundred and eighty (180) day period, the licenses granted to NEWCO hereunder shall with thirty (30) days written notice from ELAN terminate in the applicable country and ELAN shall be entitled to commercialize such PRODUCT in the FIELDS and to receive a license in the FIELDS to the NEWCO INTELLECTUAL PROPERTY, SHEFFIELD

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INTELLECTUAL PROPERTY and TRADEMARK in the applicable country on the terms set forth in Article 2.9.

2.13 If NEWCO indicates to ELAN that it does not intend to obtain MARKETING AUTHORIZATION and commercialize the PRODUCTS in a particular country or countries of the TERRITORY, or fails to commence commercialization in any country within one hundred and (180) days after receiving the required MARKETING AUTHORIZATION therefor, ELAN shall be entitled to license from NEWCO the NEWCO INTELLECTUAL PROPERTY, SHEFFIELD INTELLECTUAL PROPERTY and TRADEMARK to commercialize the PRODUCTS in the FIELDS and to receive licenses in the FIELDS in such countries on the terms set forth in Article 2.9.

### 3. ARTICLE III: DEVELOPMENT OF THE PRODUCT

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3.1 NEWCO shall be responsible for the cost of the development, registration, manufacture and marketing of the PRODUCTS, in accordance with the PLAN and subject to the direction of the STEERING COMMITTEE, and NEWCO and SHEFFIELD shall each use its reasonable best efforts, as would be deemed commensurate with the achievement by SHEFFIELD of the business aims for a similar product of its own, to conduct the PROJECT. Subject to the provisions of this Article 3, ELAN shall use its reasonable best efforts, as would be deemed commensurate with the achievement of its own business aims for a similar product of its own, to conduct such part of the PROJECT as the Parties mutually agree that shall be conducted by ELAN in accordance with the PLAN.

3.2 Each Party hereby confirms that it shall undertake its respective part of the PROJECT as a collaborative effort and that the provisions of this Agreement requires that each Party diligently carries out those tasks assigned to it under the PROJECT and as otherwise agreed during the course of the PROJECT. Each Party shall co-operate with the other in good faith particularly with respect to unknown problems or contingencies and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner. Each Party will update the other Party on the progress of the PROJECT.

3.3 For the avoidance of doubt, the Parties hereby confirm that a primary objective of the PROJECT is to procure MARKETING AUTHORIZATIONS in the MAJOR MARKETS for the PRODUCTS. As of the EFFECTIVE DATE, it is the Parties' expectation that the body of data so generated in the PROJECT will also support such applications for regulatory approval that NEWCO shall make in the other countries of the TERRITORY. In the event however that such expectation proves incorrect and further data is required to obtain such other approvals as are pursued by NEWCO in the other countries of the TERRITORY, NEWCO shall determine the viability of proceeding further with the regulatory application and generation of the further data requirements. In the event that NEWCO elects to continue, the Parties shall agree on the program of work to be undertaken to generate such additional data and the apportioning of tasks therefor in accordance with the other provisions of Article 3.

3.4 NEWCO shall mark or have marked the patent number(s) on all PRODUCTS or otherwise reasonably communicate to the trade concerning the existence of any ELAN PATENT RIGHTS, SHEFFIELD PATENT RIGHTS, NEWCO PATENT RIGHTS or JOINT PATENT RIGHTS for the countries within the TERRITORY in such a manner as to ensure compliance with, and enforceability under, all applicable laws, including, without limitation, 35 United States Code Section 287, as the same may be amended from time to time.

#### 4. ARTICLE IV: FINANCIAL PROVISIONS

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4.1 In consideration of the rights and licenses granted to NEWCO to the ELAN PATENT RIGHTS by virtue of this Agreement, NEWCO shall pay to ELAN or ELAN'S designee the following:

4.1.1 [text omitted]

4.1.2 a single payment of [text omitted] within [text omitted] days of NEWCO'S receipt of Marketing Authorization in a country in the MAJOR MARKETS for the first PRODUCT. NEWCO shall immediately notify ELAN in writing upon NEWCO'S receipt of such MARKETING AUTHORIZATION.

4.1.3 a royalty based on NSP generated by NEWCO or its sublicensees, as follows:

(A) [text omitted] percent of NSP for PRODUCTS due and payable to ELAN that utilize, incorporate, apply and/or are based on the UPDAS TECHNOLOGY in the SYSTEMIC PULMONARY FIELD and/or the ENHANCING TECHNOLOGY in the SYSTEMIC PULMONARY FIELD,

(B) [text omitted] percent of NSP due and payable to EIS for PRODUCTS that utilize, incorporate, apply and/or are based solely on the ADDS TECHNOLOGY; and

(C) [text omitted] percent of NSP for PRODUCTS due and payable to ELAN that utilize, incorporate, apply and/or are based on any combination of UPDAS TECHNOLOGY, ENHANCING TECHNOLOGY, and/or ADDS TECHNOLOGY.

4.1.4 If NEWCO claims in good faith that one or more of its devices, products, parts or components thereof, compounds and/or drug products does not utilize, incorporate, apply or is not based on the ELAN INTELLECTUAL PROPERTY, the SHEFFIELD

INTELLECTUAL PROPERTY and/or NEWCO INTELLECTUAL PROPERTY, then NEWCO shall immediately notify ELAN in writing. If ELAN disputes NEWCO's claim, the PARTIES shall discuss such matter in good faith and determine a mutually agreeable resolution.

#### 4.2 ROYALTIES, PAYMENTS, REPORTS AND RECORDS

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4.2.1 Within forty five (45) days of the end of each quarter, NEWCO shall notify ELAN of the NSP of PRODUCTS sold in that preceding quarter. Payments shown by each calendar quarter report to have accrued shall be due on the date such report is due and shall be payable to the designated bank account of ELAN or its designee as instructed by ELAN. All payments due under this Agreement shall be made in United States Dollars and shall be non-refundable to NEWCO.

4.2.2 NEWCO shall keep and shall cause its AFFILIATES and sublicensees to keep true and accurate records of gross sales of the PRODUCT, the items deducted from the gross amount in calculating the NSP, the NSP and the royalties payable to ELAN under this Article 4. NEWCO shall deliver to ELAN a written statement thereof within forty-five (45) days following the end of each calendar quarter (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The said written statements shall set forth for each PRODUCT on country-by-country basis, the calculation of the NSP from gross revenues during that calendar quarter, the applicable percentage rate, a computation of the sums due to ELAN, and such details of the transactions that are relevant to the calculations of NSP ("the Statement"). The Parties' financial officers shall agree upon the precise format of the Statement.

4.2.3 Payments due on NSP of the PRODUCT based on sales amounts 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 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 sale of currency of the country of origin of such payment for the day prior to the date on which the payment by NEWCO is being made.

4.2.4 Any income or other taxes which NEWCO is required by law to pay or withhold on behalf of ELAN with respect to royalties and any other monies payable to ELAN under this Agreement shall be deducted from the amount of such NSP payments, royalties and other monies due. NEWCO shall furnish ELAN with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by ELAN. NEWCO shall promptly provide ELAN with a certificate or

other documentary evidence to enable ELAN to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by NEWCO. The Parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable NEWCO to make such payments to ELAN without any deduction or withholding.

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4.2.5 For the twenty four (24) month period following the close of each calendar year during the TERM, NEWCO and its sublicensees will provide ELAN's independent certified accountants (reasonably acceptable to NEWCO) with access, during regular business hours and upon reasonable prior request and subject to the confidentiality provisions as contained in this Agreement, to the books and records relating to the PRODUCTS, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended, including the sums payable by NEWCO to ELAN pursuant to Article 4.

4.2.6 Any adjustment required by such inspection shall be made within thirty (30) days of the agreement of the Parties or, if not agreed, upon the determination of an arbitrator to whom any dispute under this Article shall be submitted to arbitration. If the adjustment payable to ELAN is greater than [text omitted] of the amount paid for the relevant period, then the cost to ELAN for the inspection, and if applicable the arbitration, shall be paid by NEWCO provided that the costs of the inspection shall not exceed the adjustment payable to ELAN. In addition, NEWCO shall pay interest to ELAN at the rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office as its prime rate plus one per cent (1%) (applicable as of the date on which payment should have been made pursuant to Article 4), from the date on which the payment should have been made pursuant to Article 4.2.1 until the date of payment.

4.2.7 NEWCO shall pay interest to ELAN at the rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office as its prime rate plus one per cent (applicable as of the date on which payment should have been made pursuant to the applicable provisions of this AGREEMENT) from the date on which payment should have been made pursuant to the applicable provision of this AGREEMENT until the date of payment.

## 5. ARTICLE V: REGISTRATION OF THE PRODUCT

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5.1 NEWCO shall at its sole cost file, and NEWCO and SHEFFIELD shall use their reasonable best efforts to prosecute to approval, the MARKETING AUTHORIZATIONS for the PRODUCTS in the TERRITORY in accordance with the Plan and

subject to the direction of the STEERING COMMITTEE.

5.2 NEWCO shall maintain at its own cost the MARKETING AUTHORIZATIONS during the period that NEWCO is marketing the PRODUCTS. NEWCO shall continue to maintain the MARKETING AUTHORIZATIONS in the applicable countries at ELAN'S request and expense, if ELAN acquires the right to a license pursuant to Article 2.9 for such term thereafter during which ELAN and/or its designees is marketing the PRODUCTS, and NEWCO hereby agrees to provide to ELAN, or at ELAN'S option to transfer and assign to ELAN, the MARKETING AUTHORIZATIONS and any applications for regulatory approval within thirty (30) days of the submission thereof to the applicable authority. NEWCO shall furnish to ELAN all regulatory filings and other material correspondence with the FDA and other regulatory authorities within thirty (30) days of submission.

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5.3 During the registration procedure for MARKETING AUTHORIZATIONS, NEWCO shall keep ELAN promptly and fully advised of NEWCO's registration activities, progress and procedures. NEWCO shall notify ELAN immediately of any inspection by the FDA or any other regulatory authority of the manufacturing or other facilities used in the clinical research, manufacturing, packaging, storage or handling of the PRODUCTS. Copies of all correspondence with the regulatory authority will be provided to ELAN.

5.4 NEWCO shall indemnify and hold harmless ELAN, its agents and employees from and against all claims, damages, losses, liabilities and expenses to which ELAN, its agents, and employees may become subject related to or arising out of NEWCO's and SHEFFIELD'S bad faith, negligence or intentional misconduct in connection with the filing or maintenance of the MARKETING AUTHORIZATIONS.

## 6, ARTICLE VI: WARRANTY AND INDEMNITY.

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6.1 ELAN represents and warrants to NEWCO and SHEFFIELD as follows:

6.1.1 ELAN is duly and validly existing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such failure to so qualify shall not have a material adverse affect on the business and assets of ELAN), and is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

6.1.2. ELAN has full corporate authority to execute and deliver this AGREEMENT and to consummate the transactions contemplated hereby; this AGREEMENT has been duly executed and delivered by ELAN and constitutes the legal and valid obligations of ELAN and is enforceable against ELAN in accordance with its terms and the execution, delivery and performance of this AGREEMENT and the transactions contemplated hereby and will not violate or result in a default under or

creation of lien or encumbrance under ELAN's memorandum and articles of association or any material agreement or instrument binding upon or affecting ELAN or its properties or assets or any applicable laws, rules, regulations or orders affecting ELAN or its properties or assets;

6.1.3. ELAN is not in material default of its memorandum and articles of association, any applicable material laws or regulations or any material contract or agreement binding upon or affecting it or its properties or assets and the execution, delivery and performance of this AGREEMENT and the transactions contemplated hereby will not result in any such violation;

6.1.4. As of the EFFECTIVE DATE, ELAN is the sole and exclusive owner or licensee of, or controls all right, title and interest to the ELAN PATENT RIGHTS; and to ELAN'S knowledge and belief without independent investigation, ELAN is the sole owner or licensee of the ELAN KNOW-HOW. ELAN has the right to grant the licenses granted herein.

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The ELAN PATENT RIGHTS, and to ELAN'S knowledge and belief, the ELAN KNOW-HOW, are free and clear of any lien, encumbrances, security interest or restriction granted by ELAN. ELAN will not grant during the TERM, any right, license or interest in and to the ELAN INTELLECTUAL PROPERTY, or any portion thereof, inconsistent with the license granted herein; and to the best of ELAN's knowledge there are no pending or threatened adverse actions, suits, investigations, claims or proceedings brought by one or more third parties related to the ELAN INTELLECTUAL PROPERTY as of the EFFECTIVE DATE;

6.1.5 ELAN represents and warrants that the execution of this AGREEMENT will not breach or in any way be inconsistent with the terms and conditions of any license, contract, understanding or agreement, whether express, implied, written or oral between ELAN and any third party; and

6.1.6 EXCEPT AS SET FORTH IN THIS ARTICLE 6.1, ELAN IS GRANTING THE LICENSES HEREUNDER ON AN "AS IS" BASIS WITHOUT RECOURSE, 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.

6.2 NEWCO and SHEFFIELD, jointly and severally, represent and warrant to ELAN the following:

6.2.1 Each of NEWCO and SHEFFIELD is duly and validly existing in good standing in the jurisdiction of its incorporation and each other jurisdiction in which the conduct of its business requires such qualification (except where such



failure to so qualify shall not have a material adverse affect on the business and assets of NEWCO or SHEFFIELD, respectively), and each of NEWCO and SHEFFIELD is in compliance with all applicable laws, rules, regulations or orders relating to its business and assets;

6.2.2 Each of NEWCO and SHEFFIELD has full corporate authority to execute and deliver this AGREEMENT and to consummate the transactions contemplated hereby; this AGREEMENT has been duly executed and delivered and constitutes the legal and valid obligations of NEWCO and SHEFFIELD and is enforceable against NEWCO and SHEFFIELD in accordance with its terms; and the execution, delivery and performance of this AGREEMENT and the transactions contemplated hereby will not violate or result in a default under or creation of lien or encumbrance under NEWCO's and SHEFFIELD'S respective certificate of incorporation, by-laws or other organic documents, any material agreement or instrument binding upon or affecting NEWCO or SHEFFIELD, or their respective properties or assets or any applicable laws, rules, regulations or orders affecting NEWCO, SHEFFIELD or their respective properties or assets;

6.2.3 Each of NEWCO and SHEFFIELD is not in default of its charter or by-laws, any applicable laws or regulations or any material contract or agreement binding upon or

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affecting it or its properties or assets and the execution, delivery and performance of this AGREEMENT and the transactions contemplated hereby will not result in any such violation; and

6.2.4 As of the EFFECTIVE DATE, each of NEWCO and SHEFFIELD is the sole and exclusive owner or licensee of, or controls all right, title and interest to the NEWCO INTELLECTUAL PROPERTY and the SHEFFIELD INTELLECTUAL PROPERTY, respectively; and

6.2.5 Each of NEWCO and SHEFFIELD has not granted any option, license, right or interest to any third party which would conflict with the terms of this AGREEMENT.

6.2.6 The PRODUCTS shall be developed, manufactured, transported, stored, handled, packaged, marketed, promoted, distributed, offered for sale and sold in accordance with all regulations and requirements of the FDA and foreign regulatory authorities including, without limitation, cGCP, cGLP, cGMP regulations. The PRODUCTS shall not be adulterated or misbranded as defined by the Federal Food, Drug and Cosmetic Act (or applicable foreign law) and shall not be a product which would violate any section of such Act if introduced in interstate commerce.

6.2.7 NEWCO is fully cognizant of all applicable

statutes, ordinances and regulations of the United States of America and countries in the TERRITORY with respect to the manufacture of the PRODUCTS including, but not limited to, the U.S. Federal Food, Drug and Cosmetic Act and regulations thereunder and similar statutes in countries outside of the United States, and cGMPs. NEWCO shall manufacture or procure the manufacture of the PRODUCTS in conformity with the MARKETING AUTHORIZATIONS and in a manner which fully complies with all United States of America and foreign statutes, ordinances, regulations and practices.

6.3 ELAN shall indemnify, defend and hold harmless NEWCO, SHEFFIELD and their respective officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to third party claims to which NEWCO or SHEFFIELD is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by ELAN of any of its obligations under this AGREEMENT, (ii) any breach of a representation or warranty of ELAN made in this AGREEMENT, and (iii) any activities conducted by ELAN in connection with the PROJECT, except to the extent due to the negligence or willful misconduct of NEWCO or SHEFFIELD.

6.4 NEWCO and SHEFFIELD, jointly and severally, shall indemnify, defend and hold harmless ELAN and its officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to third party claims to which ELAN is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by NEWCO or SHEFFIELD of any of its obligations under the AGREEMENT, (ii) any breach of any representation or warranty of NEWCO or SHEFFIELD made in this AGREEMENT, (iii) any activities conducted by NEWCO

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or SHEFFIELD in connection with the PROJECT, except to the extent due to the negligence or willful misconduct of ELAN, and (iv) third party claims to which ELAN is or may become subject insofar as they arise out of or are alleged or claimed to arise out of the development, manufacture, transport, packaging, storage, handling, distribution, promotion, marketing, offer for sale or sale of the PRODUCTS, including any product liability claim or any claim relating to any recall of a PRODUCT.

6.5 As a condition of obtaining an indemnity in the circumstances set out above or elsewhere in the AGREEMENT, the Party seeking an indemnity shall:

6.5.1 fully and promptly notify the other Party of any claim or proceeding, or threatened claim or proceeding;

6.5.2 permit the indemnifying Party to take full care and control of such claim or proceeding;

6.5.3 reasonably assist in the investigation and defense of such claim or proceeding; and

6.5.4 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; and take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceeding.

6.6 Notwithstanding anything to the contrary in this AGREEMENT, ELAN, SHEFFIELD and NEWCO shall not be liable to the other for any punitive, consequential or incidental loss or damage (whether for loss of profit or otherwise) by reason of any representation or warranty, condition or other term or any duty of common law, or under the express or implied terms of this AGREEMENT, and whether occasioned by the negligence of the respective PARTIES, their employees or agents or otherwise.

## 7. ARTICLE VII: PATENTS

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7.1 TITLE: Subject to the terms and conditions of this Agreement, title to the various inventions and intellectual property are set forth below as follows:

(i) title to all inventions and other intellectual property made solely by employees of ELAN in connection with the PROJECT shall be owned by ELAN;

(ii) title to all inventions and other intellectual property made solely by NEWCO in connection with the PROJECT shall be owned by NEWCO;

(iii) title to all inventions and other intellectual property made solely by SHEFFIELD in connection with the PROJECT, other than set forth in Article 7.1(v) below, shall be owned by NEWCO including, without limitation, any such inventions or intellectual property relating to the ADDS TECHNOLOGY;

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(iv) title to all inventions and other intellectual property made jointly by ELAN and NEWCO in connection with the PROJECT shall be owned by NEWCO;

(v) title to all inventions and other intellectual property made solely by SHEFFIELD employees or jointly by NEWCO and SHEFFIELD employees relating to the MSI DELIVERY SYSTEM shall be owned by SHEFFIELD; and

(vi) all other inventions and other intellectual property made between SHEFFIELD and NEWCO employees in connection with the PROJECT shall be owned by NEWCO, including, without limitation, any such inventions or intellectual property relating to the ADDS TECHNOLOGY.

## 7.2 FILING AND PROSECUTION OF PATENTS

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7.2.1 Each Party shall timely inform the other in writing of any improvement or development made by such Party relating, respectively, to the ELAN INTELLECTUAL PROPERTY, the

SHEFFIELD INTELLECTUAL PROPERTY, and/or the NEWCO INTELLECTUAL PROPERTY so that any patent protection that may be available for any such improvement or development is not compromised.

7.2.2 NEWCO shall prepare, prosecute and maintain all patents applications and issued patents relating to the inventions, improvements and other intellectual property set forth in paragraphs (ii), (iii), (iv) and (vi) in Article 7.1. With respect to such preparation, prosecution and maintenance activities, NEWCO shall timely apprise ELAN of the status of any such activity and shall inform SHEFFIELD of the status of such activity if such inventions have application in the TOPICAL PULMONARY FIELD. In the event NEWCO shall decide not to seek patent protection for any such intellectual property, ELAN shall have the option to take control of such prosecution. In the event that ELAN shall determine, in good faith, that any patents applications and issued patents relating to the inventions, improvements and other intellectual property set forth in paragraphs (ii), (iii), (iv) and (vi) in Article 7.1 predominantly relates to an area other than the FIELDS, ELAN shall have the option to take control of the preparation, prosecution and maintenance of patent protection directed to such intellectual property. In the event that ELAN does not exercise such right, NEWCO shall have the option to take responsibility for the preparation, prosecution and maintenance of patent protection directed to such intellectual property.

7.2.3 SHEFFIELD shall prepare, prosecute and maintain all patents applications and issued patents relating to paragraph (v) in section 7.1 with respect to such preparation, prosecution and maintenance activities.

### 7.3 ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS; THIRD PARTY INFRINGEMENT

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7.3.1 NEWCO and ELAN shall promptly inform the other in writing of any alleged infringement or unauthorized use of which it shall become aware

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by a third party of ELAN INTELLECTUAL PROPERTY, NEWCO INTELLECTUAL PROPERTY, SHEFFIELD INTELLECTUAL PROPERTY and/or JOINT INTELLECTUAL PROPERTY and provide such other with any available evidence of such unauthorized activity.

7.3.2 During the TERM, NEWCO shall have the right to pursue at its own expense any enforcement activities of the ELAN INTELLECTUAL PROPERTY the NEWCO INTELLECTUAL PROPERTY, the SHEFFIELD INTELLECTUAL PROPERTY and/or the JOINT INTELLECTUAL PROPERTY within the FIELDS. ELAN shall agree to be named as a necessary party in an action brought by and fully financed by NEWCO and will reasonably co-operate with such action. Any expenses borne by ELAN shall be reimbursed by NEWCO. Any

recovery remaining after the deduction by NEWCO of the reasonable expenses (including attorney's fees) incurred in relation to such action shall be treated as NSP for all the purposes of this AGREEMENT. Should NEWCO decide not to enforce the ELAN INTELLECTUAL PROPERTY, the SHEFFIELD INTELLECTUAL PROPERTY and/or the NEWCO INTELLECTUAL PROPERTY and/or the JOINT INTELLECTUAL PROPERTY within the FIELD, ELAN may do so at its expense and for its own benefit, and NEWCO will reasonably co-operate with such action. Any actual out of pocket expenses borne by NEWCO in cooperating with such action shall be reimbursed by ELAN.

7.3.3 Notwithstanding anything contained in Article 7.3.2 to the contrary, in the event that a third party is believed to be infringing any intellectual property right relating to the MSI DELIVERY SYSTEM, then at the request of NEWCO, SHEFFIELD shall, at SHEFFIELD'S discretion, take such reasonable and necessary actions to remove such infringing activity or, in the alternative, SHEFFIELD shall promptly grant to NEWCO the right to pursue any enforcement activities of the intellectual property relating to the MSI DELIVERY SYSTEM.

#### 7.4 INFRINGEMENT OF THIRD PARTY PATENTS

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7.4.1 In the event that a claim or proceedings are brought against NEWCO by a third party alleging that the manufacture, use, offer for sale, sale or other activity relating to 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 of such threat or suit.

7.4.2 NEWCO shall indemnify, defend and hold ELAN 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 referred to in this Article 7.4; provided that ELAN shall not acknowledge to the third party or to any other person the validity of any claims

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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, ELAN 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 ELAN; and ELAN shall not compromise or settle any such claim or proceeding without the prior written consent of NEWCO, not to be unreasonably withheld or delayed.

7.4.3 ELAN shall have no liability to NEWCO or SHEFFIELD whatsoever or howsoever arising for any losses

incurred by NEWCO as a result of having to cease selling PRODUCTS or having to defer the launch of selling PRODUCTS, whether as a result of a court order or otherwise.

## 8A ARTICLE VIII(A): REGARDING THE SHEFFIELD INTELLECTUAL PROPERTY

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### 8A.1 CONFORMANCE WITH SIEMENS AGREEMENTS

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The PARTIES acknowledge that those SHEFFIELD rights in and to the SHEFFIELD INTELLECTUAL PROPERTY which are derived from the SIEMENS SUPPLY AGREEMENT and the SIEMENS LICENSE AGREEMENT, are subject to all the terms and conditions thereof. It is the PARTIES' express intent that the grant by SHEFFIELD of any such rights be consistent with the terms and conditions thereof and SHEFFIELD's obligations thereunder.

### 8A.2 AFTER ACQUIRED KNOW HOW

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If SHEFFIELD acquires the rights to additional know how or patents in the SYSTEMIC PULMONARY FIELD after the execution of this Agreement, it agrees to negotiate in good faith with ELAN and NEWCO a license or sublicense, as appropriate, of such know how and patents to NEWCO for use in the Systemic Pulmonary Field.

## 8. ARTICLE VIII: MISCELLANEOUS CLAUSES

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### 8.1 SECRECY

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8.1.1 Any information, whether written or oral (provided that oral information shall be reduced to writing within one month by the party giving the oral information and the written form shall be furnished to the other party) pertaining to the PRODUCT that has been or will be communicated or delivered by ELAN to NEWCO and/or SHEFFIELD, or by NEWCO and/or SHEFFIELD to ELAN, including, without limitation, trade secrets, business methods, and cost, supplier, manufacturing and customer information

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(collectively, "Confidential Information"), shall be treated by NEWCO, SHEFFIELD and ELAN, respectively, as confidential information, and shall not be disclosed or revealed to any third party whatsoever or used in any manner except as expressly provided for herein; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this Article to the extent that such CONFIDENTIAL INFORMATION:

- (A) is available to the public in public literature or otherwise, or after

disclosure by one Party to the other becomes public knowledge through no default of the Party receiving such CONFIDENTIAL INFORMATION; or

- (B) was known to the Party receiving such CONFIDENTIAL INFORMATION prior to the receipt of such CONFIDENTIAL INFORMATION by such Party, whether received before or after the EFFECTIVE DATE; or
- (C) is obtained by the Party receiving such CONFIDENTIAL INFORMATION from a third party not subject to a requirement of confidentiality with respect to such CONFIDENTIAL INFORMATION; or
- (D) is required to be disclosed pursuant to:
  - (A) any order of a court having jurisdiction and power to order such information to be released or made public;
  - or (B) any lawful action of a governmental or regulatory agency.

8.1.2 Each Party shall take all such precautions with CONFIDENTIAL INFORMATION disclosed to it by the other Party as it normally takes with its own confidential information to prevent any improper disclosure of the CONFIDENTIAL INFORMATION disclosed to it by the other Party to any third party; PROVIDED, HOWEVER, that such CONFIDENTIAL INFORMATION may be disclosed within the limits required to obtain any authorization from the FDA or any other United States of America or foreign governmental or regulatory agency or, with the prior written consent of the other Party, which shall not be unreasonably withheld, or as may otherwise be required in connection with the purposes of this Agreement.

8.1.3 Notwithstanding the above, each Party hereto may use or disclose CONFIDENTIAL INFORMATION disclosed to it by the other Party to the extent such use or disclosure is reasonably necessary in filing or prosecuting 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 making 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, it will give reasonable advance notice to the latter Party of such disclosure and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information prior to its disclosure (whether

through protective orders or otherwise).

8.1.4 Each Party agrees that it will not use, directly or indirectly, any CONFIDENTIAL INFORMATION disclosed by the other Party pursuant to this Agreement, other than as expressly provided herein.

8.1.5 NEWCO and ELAN will not publicize the existence of this Agreement in any way without the prior written consent of the other subject to the disclosure requirements of applicable laws and regulations. The PARTIES agree that promptly following the execution of this Agreement they shall issue an agreed press release which will not disclose the terms of this Agreement. In the event that one of the PARTIES wishes to make an announcement concerning the Agreement, that Party will seek the consent of the other PARTIES. The terms of any such announcement shall be agreed in good faith.

8.2 CONFLICT. IN THE EVENT OF ANY INCONSISTENCY OR CONFLICT BETWEEN THE PROVISIONS OF THIS AGREEMENT ON THE ONE HAND, AND THE PROVISIONS OF THE SHEFFIELD/NEWCO LICENSE AGREEMENT OR THE NEWCO/SHEFFIELD LICENSE AGREEMENT ON THE OTHER HAND, THE TERMS OF THIS AGREEMENT SHALL GOVERN AND CONTROL IN ALL RESPECTS.

8.3 ASSIGNMENTS/ SUBCONTRACTING. This Agreement shall not be assignable by ELAN, SHEFFIELD or NEWCO to any third party without the prior written consent of the other Party hereto. Notwithstanding the above and subject to the following sentence, ELAN may assign this Agreement, without the consent of NEWCO or SHEFFIELD, to an AFFILIATE or to an entity that acquires all or substantially all of the business or assets of ELAN to which this Agreement pertains, whether by merger, reorganization, acquisition, sale, or otherwise. Notwithstanding the foregoing, NEWCO, SHEFFIELD and ELAN will, subject to any confidentiality obligations to third parties, discuss any assignment prior to its implementation in order to consider how to avoid or reduce any additional tax liability to either Party resulting solely from different tax law provisions applying after such assignment. For the purpose hereof, an additional tax liability to either Party means that such Party would be subject to a higher net tax on payments made hereunder after taking into account any applicable tax treaty and available tax credits, than the said Party was subject to before the proposed assignment.

8.4 PARTIES BOUND. This Agreement shall be binding upon and inure for the benefit of PARTIES hereto, their successors and permitted assigns.

8.5 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, (i) 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 (ii) the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.



## 8.6 DURATION AND TERMINATION

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8.6.1 Subject to the other provisions of Article 8.6, this Agreement shall remain in full force and effect on a PRODUCT by PRODUCT and country by country basis, for a period commencing as of the EFFECTIVE DATE and expiring [text omitted] years from the date of the first commercial sale of such PRODUCT in such country in the TERRITORY, or [text omitted], whichever is longer (the "TERM").

8.6.2 In addition to the rights of early or premature termination provided for elsewhere in this Agreement, the term of this Agreement may be terminated immediately upon written notice of termination given by:

- (A) the non-defaulting party in the event that the other party shall: (1) commit a material breach or default under a DEFINITIVE DOCUMENT, which breach or default shall not be remedied within sixty (60) days after the receipt of written notice thereof by the party in breach or default; or (2) have made a material misrepresentation of any representation or warranty contained herein or any DEFINITIVE DOCUMENT; or
- (B) ELAN, in the event that (1) a change of "control" of NEWCO or SHEFFIELD shall occur (the term "control" shall have the meaning set forth in the definition of "Affiliate"), or (2) a TECHNOLOGICAL COMPETITOR acquires directly or indirectly voting stock or equivalent securities in SHEFFIELD or NEWCO representing [text omitted] percent or more of the stock which carries entitlement to vote, or where [text omitted] or more of such TECHNOLOGICAL COMPETITOR'S stock or equivalent securities is acquired by SHEFFIELD or NEWCO; provided, however, that in the case of [text omitted] (should [text omitted] become a Technological Competitor), the [text omitted] percent threshold set forth in this sentence shall be deemed to be [text omitted] percent, or (3) if such TECHNOLOGICAL COMPETITOR otherwise controls SHEFFIELD'S or NEWCO'S respective board of directors, or either SHEFFIELD or NEWCO otherwise controls such TECHNOLOGICAL COMPETITOR's board of directors or similar governing body.
- (C) ELAN on the one hand, and SHEFFIELD and

NEWCO on the other hand, if ELAN, SHEFFIELD or NEWCO (on an individual basis), as the case may be, shall at any time be Insolvent, dissolved, liquidated, discontinued, or when any proceeding is filed or commenced by either Party under bankruptcy, insolvency or debtor relief laws. For

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purposes of this Agreement, "Insolvent" shall mean (1) the sum of a PARTY'S debts exceeds its assets, (2) a PARTY is unable, or has reason to believe it is unable, to pay its debts as such debts mature, or (3) a PARTY does not have sufficient capital with which to conduct its business.

8.6.3 Upon exercise of those rights of termination as set forth in this Agreement with respect to any country or countries or the entire Agreement as the case may be, this Agreement shall, subject to the other provisions of the Agreement, automatically terminate forthwith in the applicable country or countries or the entire Agreement as the case may be, and be of no further legal force or effect.

8.6.4 Upon termination of this Agreement:

- (A) any sums that were due from NEWCO to ELAN prior to the exercise of the right to terminate this Agreement shall be paid in full within sixty (60) days of termination of this Agreement;
- (B) all confidentiality provisions set out herein shall remain in full force and effect for a period of five (5) years;
- (C) all representations, warranties, and indemnities shall survive the termination of this agreement and shall remain in full force and effect;
- (D) the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement;
- (E) termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any

breach of this Agreement;

- (F) except as is necessary to enable ELAN to exercise the licenses granted by NEWCO and/or SHEFFIELD to ELAN under this Agreement, upon any termination of this Agreement, NEWCO, SHEFFIELD and ELAN shall promptly return to the other Party all CONFIDENTIAL INFORMATION received from the other Party (except one copy of which may be retained for archival purposes);

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- (G) in the event this Agreement is terminated for any reason, NEWCO shall have the right for a period of six (6) months from termination to sell or otherwise dispose of the stock of any PRODUCT then on hand, which such sale shall be subject to Article 4 and Article 5 and the other applicable terms of this Agreement;
- (H) The ELAN INTELLECTUAL PROPERTY and all of the rights granted to NEWCO hereunder shall immediately revert to ELAN and, unless this Agreement is terminated due to the breach by ELAN beyond any cure or grace period in accordance with the terms of this Agreement, NEWCO and SHEFFIELD shall immediately be deemed to have assigned and transferred to ELAN the MARKETING AUTHORIZATIONS (together with all applications for regulatory approvals), the TRADEMARK, the SHEFFIELD INTELLECTUAL PROPERTY, the NEWCO INTELLECTUAL PROPERTY, the JOINT INTELLECTUAL PROPERTY, all rights under the purchase agreement for the ADDS TECHNOLOGY (including any employment and other agreements contemplated thereunder), all rights under supply or other agreements relating to the PRODUCTS, and all other transactions and documents relating to the foregoing and/or contemplated thereby.
- (I) All sublicenses of the ELAN INTELLECTUAL PROPERTY shall terminate, provided, however, that ELAN agrees to enter into licenses with all sublicensees of NEWCO on terms no less favorable to the sublicensees than those contained in the sublicense agreements with NEWCO; provided such sublicense agreements have been approved by ELAN in accordance with this AGREEMENT.

- (j) The following Articles shall survive the termination or expiration of this Agreement for any reason: Article 1; Articles 2.2, 2.4, 2.9, 2.12, and 2.13; Articles 4.2.5; 4.2.6; and 4.2.7; Article 5.4; Article 6; Article 7, and Article 8.

8.7 FORCE MAJEURE. Neither Party to this Agreement 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, or intervention of a Government Authority, non availability of raw materials, but any such delay or failure shall be remedied by such Party as soon as practicable.

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8.8 RELATIONSHIP OF THE PARTIES. Nothing contained in this Agreement is intended or is to be construed to constitute ELAN, NEWCO and SHEFFIELD as partners or joint venturers or either Party as an employee of the other. 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.

8.9 AMENDMENTS. No amendment, modification or addition hereto shall be effective or binding on either Party unless set forth in writing and executed by a duly authorized representative of both PARTIES.

8.10 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.

8.11 NO EFFECT ON OTHER AGREEMENTS. 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, in any such other agreement.

8.12 APPLICABLE LAW. This Agreement is construed under and ruled by the laws of the State of New York. For the purpose of this Agreement the PARTIES submit to the personal jurisdiction of the United States District Court for the State of New York. The PARTIES each further irrevocably consent to the service of any complaint, summons, notice or other process by delivery thereof to it by any manner in which notices may be given pursuant to this Agreement.

8.13 NOTICES. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or faxed to:

- If to ELAN, at

Elan Corporation plc.  
Lincoln House,  
Lincoln Place,  
Dublin 2, Ireland.

Attention: President, Elan Pharmaceutical Technologies,  
a division of Elan Corporation plc  
Telefax: 353 1 662 4960

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- If to NEWCO, at

Systemic Pulmonary Delivery, Ltd.  
c/o Elan International Services, Ltd.  
102 St. James Street  
Flatts, Smith Parish FL04  
Bermuda

Attention: Chief Executive Officer

- If to SHEFFIELD, at

Sheffield Pharmaceutical, Inc.  
425 South Woodsmill Road  
St. Louis, Missouri 63017

Attention: Chief Executive Officer  
Telefax : (314) 579-9799

with a copy to  
Fitzpatrick, Cella, Harper & Scinto  
30 Rockefeller Plaza  
New York, NY 10112

Attention: Michael P. Sandonato, Esq.  
Telefax: (212) 218-2200

or to such other address(es) and telefax numbers as may  
from time to time be notified by either Party to the  
other hereunder.

If a notice is sent by SHEFFIELD to NEWCO OR NEWCO to SHEFFIELD  
pursuant to any agreements relating to the transactions contemplated hereunder,  
then SHEFFIELD or NEWCO, as the case may be, shall send a copy of such notice to  
ELAN in accordance with the provisions of this Article.

Any notice sent by registered air-mail shall be deemed to have been  
delivered within seven (7) working days after dispatch and any notice sent by  
telefax (with confirmed answer back) shall be deemed to have been delivered  
within twenty four (24) hours of the time of the dispatch. Notice of change of  
address shall be effective upon receipt.

8.14 NO IMPLIED RIGHTS. No rights or licenses are granted or deemed

granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement.

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8.15 FURTHER ASSURANCES. At any time or from time to time on and after EFFECTIVE DATE, each party shall at the request of the other (i) deliver such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as the other Party may reasonably deem necessary or desirable in order for it to obtain the full benefits of this Agreement and the transactions contemplated hereby.

8.16 ENTIRE AGREEMENT. This Agreement including its Appendices, together with the DEFINITIVE DOCUMENTS, sets forth the entire agreement and understanding of the PARTIES with respect to the subject matter hereof, and supersedes all prior discussions, agreements and writings in relating thereto, including the letter of agreement of June 3, 1998.

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8.17 COUNTERPARTS. This Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS THEREOF the Parties hereto have executed this Agreement in duplicate.

SYSTEMIC PULMONARY DELIVERY, LTD

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald

Title: Chairman

SHEFFIELD PHARMACEUTICAL, INC.

By: /s/ Thomas M. Fitzgerald

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Name: Thomas M. Fitzgerald

Title: Chairman

ELAN CORPORATION, PLC

By: /s/ Thomas Lynch

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Name: Thomas Lynch  
Title: Chief Financial Officer

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APPENDIX A

ELAN PATENT RIGHTS

NONE AT PRESENT

APPENDIX B

PLAN

[text omitted]

APPENDIX C

SHEFFIELD PATENT RIGHTS

[text omitted]

EX-99.1

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PRESS RELEASE

For further information:

Sheffield Pharmaceuticals, Inc.	John Muir Associates
425 South Woodsmill Road, Suite 270	5400 Kincheloe Drive
St. Louis, MO 63017	Los Angeles, CA 90041
(314) 579-9899	

Contact: Thomas Fitzgerald	Contact: John Muir
(716) 385-0810	(213) 257-4701

FOR IMMEDIATE RELEASE

## SHEFFIELD PHARMACEUTICALS AND ELAN COMPLETE FORMATION OF PULMONARY DRUGS DELIVERY COLLABORATION

ST. LOUIS, JULY 1, 1998 - Sheffield Pharmaceuticals, Inc. (AMEX:SHM) announced today that it has entered into a definitive agreement with Elan Corporation, plc (NYSE:ELN) to create a wholly owned subsidiary of Sheffield responsible for a worldwide collaboration to develop systematic therapies delivered by a range of pulmonary drug delivery systems.

Terms of the agreement include a \$17.5 million equity investment in Sheffield by Elan consisting of \$6.0 million of common stock, that will result in ownership of approximately 17% of Sheffield's outstanding common shares, and \$11.5 million of 7% convertible preferred stock. In addition to providing operating funds for Sheffield, a substantial portion of the funding will be contributed to the subsidiary to pay license fees to Elan for certain of the technologies acquired as well as future development costs. Elan, which will be represented on Sheffield's Board of Directors, will also provide funding for the acquisition of additional, value-adding, pulmonary delivery technologies. Products resulting from the collaboration will be available for marketing by either Elan or Sheffield. Elan has the right to convert the preferred stock into either an ownership interest in Sheffield or the new subsidiary.

The first technologies to be developed by the collaborative venture are Sheffield's Metered Solution Inhaler (MSI) system for systemic disease applications and Elan's proprietary UPDAS(TM) delivery system, a unit-dose pulmonary delivery system. Outside of the collaboration, Sheffield will hold licenses to any rights relating to the respiratory disease applications of the UPDAS(TM) technology and other new technologies the subsidiary may acquire.

Thomas Fitzgerald, Chairman of Sheffield said, "We are very excited about our collaboration with Elan. This venture brings together a broad-based platform of pulmonary drug delivery technologies - each with its own particular strengths - which can be developed into a wide array of specialized applications. For example, we see significant commercial opportunity in applying these pulmonary delivery platforms to the systemic delivery of large and small molecules." Added Fitzgerald, "Elan is a world leader in drug delivery with a great deal of experience in collaborating with a wide range of companies. Through this collaboration, we can fully maximize the potential of our MSI delivery system and add depth and breadth to our pulmonary delivery platform."

Seamus Mulligan, President, Elan Pharmaceutical Technologies, a division of Elan, commented, "We are pleased to expand our portfolio of technology-based drug delivery collaborations. The Sheffield team has demonstrated a high degree of insight and expertise in the area of pulmonary drug delivery as evidenced by their novel MSI system. The combined capabilities of Sheffield and Elan provide an excellent platform to pursue the development of specific pulmonary drug delivery technologies."

Sheffield Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of later stage, lower risk pharmaceutical opportunities, particularly those utilizing unique pulmonary delivery technologies over a range of therapeutic areas.

This press release contains certain forward-looking statements within the



meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbors created hereby. Investors are cautioned that all forward-looking statements involve risks and uncertainty, including without limitation, the ability of the Company to successfully develop and commercialize their technologies. Although the Company believes that the assumptions underlying the forward-looking statements contained herein are reasonable, any assumptions could be inaccurate, and therefore, there can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the objectives and plans of the Company will be achieved.

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-----END PRIVACY-ENHANCED MESSAGE-----