

SECURITIES AND EXCHANGE COMMISSION

FORM 10-K/A

Annual report pursuant to section 13 and 15(d) [amend]

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FILER

CELL PATHWAYS INC /DE

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SIC: **2834** Pharmaceutical preparations

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HORSHAM PA 19044

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2157063800

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A
AMENDMENT NO. 1

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

COMMISSION FILE NUMBER 00024889

CELL PATHWAYS, INC.

(Exact name of Registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

702 ELECTRONIC DRIVE
HORSHAM, PA 19044
(Address of principal
executive offices)

23-2969600
(I.R.S. Employer
Identification No.)

(215) 706-3800
(Registrant's telephone number,
including area code)

Securities registered pursuant to section 12(b) of the Act:

NONE

Securities registered pursuant to section 12(g) of the Act:

COMMON STOCK, \$.01 PAR VALUE PER SHARE
PREFERRED STOCK PURCHASE RIGHTS
(TITLE OF CLASS)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10. [X]

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of March 7, 2002 was approximately \$135,375,000 based upon the last reported sales price of the Registrant's Common Stock on the Nasdaq National Market.

As of March 7, 2002 there were 31,170,166 shares of the Registrant's Common Stock outstanding, not including 1,700,000 shares committed to be issued in settlement of litigation.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement relating to the Annual Meeting of Stockholders to be held on May 29, 2002, are incorporated by reference into Part III of this report. Other documents incorporated by reference are listed in the Exhibit Index.

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Explanatory Note

This Amendment No. 1 to the Registrant's 2001 Annual Report on Form 10-K is being filed for the sole purpose of amending Part IV, Item 14 (a) (3) and in particular to file Exhibit 10.4 for which confidential treatment was requested with this Amendment No. 1.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a)

1. LIST OF FINANCIAL STATEMENTS

See page F-1 of this report, which includes an index to consolidated financial statements.

2. LIST OF FINANCIAL STATEMENT SCHEDULES

None.

3. LIST OF EXHIBITS

- 3.1 Certificate of Incorporation as amended November 2, 1998 (incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 10-K for 1998 filed with the Securities and Exchange Commission (the "1998 10-K")).
- 3.2 Amendment to Certificate of Incorporation by way of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.2 to the 1998 10-K).
- 3.3 Amendment to Certificate of Incorporation increasing the number of authorized shares of Common Stock and Preferred Stock (incorporated by reference to Exhibit 3.3 to Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2000).
- 3.4 Bylaws of Cell Pathways, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-4 (No. 333-59557) filed with the Securities and Exchange Commission on July 22, 1998 (the "July 1998 S4")).
- 4.1 Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
- 4.2 Specimen certificate of Registrant (incorporated by reference to Exhibit 4.2 to the July 1998 S-4).
- 4.3 Rights Agreement dated as of December 3, 1998 between Registrant and Registrar and Transfer Company (incorporated by reference to Exhibit 4 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 1998).
- 4.4 Form of Warrant issued in Private Placement, November 9, 2000 (incorporated by reference to Exhibit 4 to Registrant's Registration Statement on Form S-3 (No. 333-50514), filed with the Securities and Exchange Commission on November 22, 2000 (the "November 2000 S-3")).
- 10.1 Lease, dated June 25, 1998, between Cell Pathways, Inc. and ARE-702 Electronic Drive, L.P. (incorporated by reference to Exhibit 10.2 to the July 1998 S-4).

- 10.2 Research and License Agreement, dated June 26, 1991, between Cell Pathways, Inc. and the University of Arizona, as amended (incorporated by reference to Exhibit 10.23 to Registrant's Registration Statement on Form S-1 (No. 333-37557), filed October 9, 1997, or amendments thereto (the "October 1997 S-1")).
- 10.3 Form of Purchase Agreement in Private Placement, November 9, 2000 (incorporated by reference to Exhibit 10.1 to the November 2000 S-3).
- 10.4* Distribution Agreement, dated January 22, 2002, between Cell Pathways, Inc. and Sinclair Pharmaceuticals Ltd.

EXECUTIVE COMPENSATION PLANS AND ARRANGEMENTS

- 10.5 1997 Equity Incentive Plan of Cell Pathways, Inc, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Report on Form 10-K for 2000 filed with the Securities and Exchange Commission (the "2000 10-K")).
- 10.6 Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 to the 2000 10-K).
- 10.7 Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.8 to the 2000 10-K).
- 10.8 1997 Non-Employee Director Stock Option Plan of Cell Pathways, Inc. (incorporated by reference to Exhibit 10.5 to the July 1998 S-4).
- 10.9 Form of Stock Option Agreement (incorporated by reference to Exhibit 10.6 to the July 1998 S-4).
- 10.10 1997 Employee Stock Purchase Plan of Cell Pathways, Inc. (incorporated by reference to Exhibit 10.28 to the October 1997 S-1).
- 10.11 1995 Stock Award Plan of Cell Pathways, Inc. (incorporated by reference to Exhibit 10.6 to the October 1997 S-1).
- 10.12 Employment Agreement, dated October 12, 1996, between Cell Pathways, Inc. and Robert J. Towarnicki (incorporated by reference to Exhibit 10.13 to the October 1997 S-1).
- 10.13 Change in Control Agreement, dated as of November 30, 2000, between Cell Pathways, Inc. and Robert J. Towarnicki (incorporated by reference to Exhibit 10.14 to the 2000 10-K).
- 10.14 Employment Agreement, dated February 1, 1993, between Cell Pathways, Inc. and Rifat Pamukcu (incorporated by reference to Exhibit 10.17 to the October 1997 S-1).

- 10.15 Change in Control Agreement, dated as of November 30, 2000, between Cell Pathways, Inc. and Rifat Pamukcu (incorporated by reference to Exhibit 10.16 to the 2000 10-K).
- 10.16 Employment Agreement, dated as of October 12, 2000, between Cell Pathways, Inc. and Martha E. Manning (incorporated by reference to Exhibit 10.17 to the 2000 10-K).
- 10.17 Change in Control Agreement, dated as of November 30, 2000, between Cell Pathways, Inc. and Martha E. Manning (incorporated by reference to Exhibit 10.18 to the 2000 10-K).
- 10.18 Employment Agreement, dated as of July 12 2000, between Cell Pathways, Inc. and Robert E. Bellet, M.D. (incorporated by reference to Exhibit 10.19 to the 2000 10-K).
- 10.19 Change in Control Agreement, dated as of November 30, 2000, between Cell Pathways, Inc. and Robert E. Bellet, M.D. (incorporated by reference to Exhibit 10.20 to the 2000 10-K)

- 10.20 Employment Agreement, dated as of November 6, 1997, between Cell Pathways, Inc. and Brian J. Hayden (incorporated by reference to Exhibit 10.21 to the 2000 10-K).
- 10.21 Change in Control Agreement, dated as of November 30, 2000, between Cell Pathways, Inc. and Brian J. Hayden (incorporated by reference to Exhibit 10.22 to the 2000 10-K).
- 10.22 Employment Agreement, dated as of November 29, 2000, between Cell Pathways, Inc. and Lloyd Glenn (incorporated by reference to Exhibit 10.23 to the 2000 10-K).
- 10.23 Change in Control Agreement, dated as of November 30, 2000, between Cell Pathways, Inc. and Lloyd Glenn (incorporated by reference to Exhibit 10.24 to the 2000 10-K).
- 10.24 Restricted Stock Grant, dated December 14, 2001, between Cell Pathways, Inc. and Robert E. Bellet, M.D. (previously filed on March 22, 2002).
- 10.25 Non-Qualified Stock Option Agreement, dated January 11, 2002, between Cell Pathways, Inc. and Brian J. Hayden (previously filed on March 22, 2002).
- 22.1 Subsidiaries.

23.1 Consent of Arthur Andersen LLP.

99.1 Issuer Letter Concerning Auditor Representation.

*Confidential Treatment Requested

(b) REPORT ON FORM 8-K

None

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CELL PATHWAYS, INC.

By: /s/ Robert J. Towarnicki

Robert J. Towarnicki
President and Chief Executive Officer

May 8, 2002

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CONFIDENTIAL DOCUMENT

EXHIBIT 10.4
DISTRIBUTION AGREEMENT

This Agreement ("Agreement") is made and entered into on January 22, 2002 between:

SINCLAIR PHARMACEUTICALS LTD., a corporation duly organized and existing under the laws of England having its place of business at Borough Rd, Godalming, Surrey, United Kingdom GU7 2AB and Sinclair Pharma Srl, a corporation duly organized and existing under the laws of Italy having its place of business at Viale Marche, 15, 20125 Milano, Italy. Sinclair Pharmaceuticals Ltd and Sinclair Pharma Srl are hereinafter collectively referred to as "Company"

and

CELL PATHWAYS, INC., a corporation duly organized and existing under the laws of Delaware having a place of business at 702 Electronic Drive, Horsham, Pennsylvania, 19044 hereinafter referred to as "Distributor".

Whereas Company has the exclusive rights to appoint exclusive distributors for the Product in the Territory as defined below and has the right to supply Products for that purpose.

Whereas Distributor wishes to become the exclusive distributor of such Products in the Territory as set out herein.

Now, therefore, the Parties hereto in consideration of the premises and mutual covenants and undertakings herein contained agree as follows:

ARTICLE 1. DEFINITIONS

1.1 "Affiliate" of a Party hereto shall mean any entity which controls, is controlled by, or is under common control with such party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, more than fifty percent (50%) of the voting equity of the other entity (or other comparable ownership interest for an entity other than a corporation) or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies, whether through ownership of voting securities, by contract, or otherwise, of such other entity.

1.2 "Approved Indication" shall mean the "management and relief of oral

pain, by adhering to the mucosal surface of the mouth for soothing of lesions of various etiologies." The Approved Indication will be deemed amended or changed in scope in accordance with any additional regulatory approvals of the Product in the Territory.

1.3 "Competing Product" shall mean any product other than the Products that is used for the Approved Indication.

1.4 "Effective Date" shall mean the date of receipt by Company of the payment of \$1,000,000 referred to in Section 5.3.

[*]CONFIDENTIAL TREATMENT REQUESTED 1

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1.5 "Force Majeure" is any factor beyond a Party's control, including, without limitation, fire, explosion, accident, riot, flood, drought, storm, earthquake, lightning, frost, civil commotion, sabotage, vandalism, smoke, hail, embargo, act of God or the public enemy, other casualty, strike or lockout, or interference, prohibition or restriction imposed by any government or any officer or agent thereof.

1.6 "Forecast" shall mean forecasts of sales by Distributor as set forth in Section 3.3 of this Agreement.

1.7 "Forecast Range" shall mean for any calendar quarter a quantity +/- 50% of Forecast for that quarter.

1.8 "Know-how" shall mean technical or scientific information (1) regarding the Products which may be necessary, useful or advisable to enable Distributor to promote, market and sell the Products in the Territory, and as is or will be specified in the documentation which Company has delivered or will deliver to Distributor after the Effective Date and during the term of this Agreement; or (2) regarding the manufacture, packaging and labeling of the Product consistent with the Specifications.

1.9 "Net Sales I" shall mean Distributor's (or any sub-distributor's) gross sales of Products actually billed by Distributor or its Affiliates (or sub-distributors) to unrelated third party customers less (a) rejection or return of Products previously sold, and (b) any sales, excise, turnover and similar taxes and any duties and other governmental charges imposed upon the sale of Products.

1.10 "Net Sales II" shall mean Distributor's (or any sub-distributor's) gross sales of Products actually billed by Distributor or its Affiliates (or

sub-distributors) to unrelated third party customers less (a) any direct or indirect credits and allowances and adjustments granted to such customers for the Products, including without limitation credits and allowances on account of price adjustments or on account of the rejection or return of Products previously sold, (b) any trade and/or cash discounts, rebates and distribution fees, and (c) any sales, excise, turnover and similar taxes and any duties and other governmental charges imposed upon the production, importation, use or sale of Products, and (d) transportation, insurance and handling charges on Product.

1.11 "Parties" shall mean Company and Distributor and Party shall mean either of them as the context indicates.

1.12 "Present Product" means Company's Product known as "GELCLAIR" in a box containing 21 packets with 15 ml of Product per packet.

1.13 "Products" in this Agreement shall mean Company's oral gel care formulation(s) for the Approved Indication, including but not limited to GELCLAIR(R) as presently manufactured by Company and any modification thereof which may be agreed between the Parties in future. "Products" does not include Company's product known as "ALOCLAIR".

1.14 "Purchase Price" shall mean the price of Product that Distributor pays Company for the Distributor's purchase of Product from Company.

[*]CONFIDENTIAL TREATMENT REQUESTED 2

CONFIDENTIAL PORTION OMITTED AND FILED SEPARATELY WITH THE COMMISSION

CONFIDENTIAL DOCUMENT

1.15 "Registration" shall mean any official marketing approval, authorization or license regarding the Products by the appropriate and competent authorities in the Territory, allowing the lawful marketing of the Products.

1.16 "Specifications" shall mean the specifications for Product, including its packaging, set forth in Appendix A hereof, which Appendix is incorporated in and made a part of this Agreement. Specifications shall not be modified without prior written agreement by the Parties.

1.17 "Territory" means the United States of America (including its territories and possessions), Canada and Mexico.

1.18 "Year" means calendar year. "Year 1" means 2002; "Year 2" means 2003; "Year 3" means 2004; etc.

1.19 "\$" means United States Dollars.

1.20 "Aloclair" means a product also containing [*] which Company agrees will in no circumstances contain a concentration of [*] exceeding [*] of the concentration in Gelclair. Company warrants that Aloclair is characterized by a substantially [*]. Company warrants that the Aloclair product is unsuitable for the treatment of severe oral mucosal inflammation or injury, e.g., mucositis, stomatitis and oral surgery.

ARTICLE 2. APPOINTMENT AND ACCEPTANCE

2.1 Subject to the following terms and conditions, which includes the payments set forth in this Agreement, the Company hereby appoints the Distributor as the exclusive distributor to market, sell and distribute Products in the Territory and the Distributor hereby accepts such appointment. Distributor shall have the exclusive right to market, sell and distribute Products, or have those Products marketed, sold or distributed on its behalf in the Territory.

2.2 Company shall not and shall cause its Affiliates not to, directly or indirectly knowingly supply the Product or Competing Product to any Person outside the Territory for resale or use in the Territory. Company shall promptly refer exclusively to Distributor all orders or inquiries received by Company in connection with the sale, marketing and/or distribution of the Product in the Territory. To the extent that either Party becomes aware of a Person outside the Territory re-selling Product in the Territory, each shall notify the other and the Parties shall use best efforts to cooperate and cause such unauthorized sale in the Territory to cease.

2.3 Distributor shall not and shall cause its Affiliates not to, directly or indirectly knowingly supply the Product or Competing Product to any Person in the Territory for resale or use outside the Territory. Distributor shall promptly refer exclusively to Company all orders or inquiries received by Distributor in connection with the sale, marketing and/or distribution of the Product outside the Territory. To the extent that either Party becomes aware of a Person in the Territory re-selling Product outside the Territory, each shall notify the other and the Parties shall use best efforts to cooperate and cause such unauthorized sale outside the Territory to cease.

[*]CONFIDENTIAL TREATMENT REQUESTED 3

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2.4 Distributor and its Affiliates shall not, directly or indirectly, or jointly or in conjunction with any other person, whether as principal, agent,

shareholder, employee, independent contractor or in any other manner whatsoever, distribute, market or sell any Competing Product in the Territory during the term of this Agreement and 12 months thereafter.

2.5 Distributor and its Affiliates shall purchase their entire requirements for the Products from Company, subject to Section 3.9.

2.6 Company warrants that it has not made any written or oral agreement or undertaking with any other Person regarding the rights to distribute or sell Product or Competing Product in the Territory.

2.7 Company warrants that it has the exclusive rights to appoint exclusive distributors for the Product in the Territory as defined herein and that it has the right to supply Products for that purpose.

2.8 If within [*] Distributor has not established a reasonable level of prescriptions from the dental market, the Parties shall meet and discuss in good faith the matter but, if they are not able to agree on a mutually acceptable resolution of the problems within [*] of such meeting, Company shall be entitled [*] to distribute the Products to the dental market in the Territory independently of the Distributor using trademarks which are not confusingly similar to any trademarks used on Products which are sold to Distributor hereunder.

ARTICLE 3. PURCHASE AND SUPPLY OF PRODUCTS

3.1 Within 90 days of the receiving from Distributor all necessary camera ready art work and product insert, Company shall provide Distributor [*] of the Present Product in accordance with the Specifications and within a further [*] shall provide Distributor [*] of the Present Product in accordance with the specifications.

3.2 By October 31, 2002, Distributor shall place an order for the Present Product of at least \$2,000,000 at the price set forth in Section 5.1 below, which order shall be delivered by Company to Distributor on or before December 31, 2002. If Distributor fails to place the order referred to in this Section 3.2, Distributor shall be obliged to pay to Company the amount of \$2,000,000 by December 31, 2002 in any event.

3.3 Upon the Effective Date, Distributor shall submit to Company a non-binding good faith estimate of its requirements of Product for the current Year broken down by quarters. Within and not later than September 30th of each Year of this Agreement, Distributor shall submit to Company a non-binding good faith estimate of its requirements of Product for the subsequent two Years broken down by quarters. The first Year of each two-Year estimate shall serve to amend the second Year of the previous two-Year estimate. The total amount and the quarterly breakdown estimated by Distributor for any Year, as amended by each annual estimate or as further amended in timely fashion, shall be known as the Forecast for such Year.

CONFIDENTIAL DOCUMENT

3.4 Within and not later than ninety (90) days before the beginning of each calendar quarter during the term of this Agreement, Distributor shall place with Company a Firm Order for Product for that calendar quarter. Each Firm Order shall specify the quantity of Product ordered and the delivery date, provided that the terms and conditions of this Agreement shall prevail over any terms and conditions included in any purchase order used in ordering Product. Firm Orders for purchases for Products shall be submitted in writing to the Company at Company's address above or at such other address as Company may indicate in writing. Those orders shall bind Company if within the Forecast Range, and shall otherwise bind Company if accepted by it in writing if outside the Forecast Range. Company shall use reasonable efforts to accommodate orders higher than +50% of Forecast for any calendar quarter.

3.5 Distributor shall place the following minimum annual orders for the Products from Company at the prices referred to in Section 5.1 for the Present Product and such prices as may have been agreed between the Parties for other versions of the Products (if prices have not been agreed for other versions, Distributor shall be obliged to order the Present Product):

| ----- | |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Minimum Annual Order | |
| ----- | |
| Year 1 | \$4,000,000, including \$2,000,000 in respect of the quantities referred to in Section 3.1 and \$2,000,000 for the order referred to in Section 3.2 |
| Year 2 | \$ 3,000,000 |
| Year 3 | \$ 5,000,000 |
| ----- | |

Minimum annual orders for the fourth and subsequent Years of this Agreement shall have been negotiated in good faith and agreed upon by the Parties for each of those Years by each October 1st from October 1, 2004 onward (i.e., one Year at a time on a rolling basis). If the Parties are unable to agree upon a minimum annual order level for any Year after 2004 which is at least 80% of the minimum annual order level for the previous Year, either Party shall have the right to terminate this Agreement upon 90 days' notice in writing to the other Party.

If Distributor fails, by the 31st December of Year 1, Year 2, or Year 3, to place orders for the Products from the Company exceeding the minimum annual

order set out in this Section 3.5 for those Years (and Distributor has not rectified the situation by ordering the shortfall within 90 days of being given notice by the Company of such shortfall), Company may terminate this Agreement upon 90 days notice in writing to Distributor.

3.6 All Products shipped by or on behalf of Company to Distributor will comply with the Specifications and shall have at least 30 months until the date of product expiry from the date of delivery. The title to any consignment of the Products shall not pass to Distributor until Company has received payment in full for the price of the Products. Risk of loss or damage to any consignment of the Products shall pass to Distributor from the time Company notifies Distributor that the consignment is available for collection or from the time of delivery to the carrier at Company's (or its supplier's) premises, whichever is the earlier. The relevant batch release certificate and certificate of analysis shall accompany each delivery.

[*]CONFIDENTIAL TREATMENT REQUESTED 5

CONFIDENTIAL PORTION OMITTED AND FILED SEPARATELY WITH THE COMMISSION

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3.6.1 Until such time as the title in the Products passes to the Distributor, the Distributor shall be entitled to resell or use the Products in the ordinary course of its business, but it shall be accountable to the Company for the proceeds of sale or otherwise of the Products (such that Distributor shall pay to Company such proportion of such proceeds owing to the Company), whether tangible or intangible, including insurance proceeds, and it shall keep all such proceeds (to the extent of the amounts owed to Company hereunder) separate from any monies or property of the Distributor and third parties, and in the case of tangible proceeds, properly stored, protected and insured;

3.7 If within a reasonable time (not to exceed 30 days after receiving any shipment at the Distributor's designated place of business in the United States) Distributor demonstrates to the satisfaction of Company that any of the Products shipped to it hereunder were defective at the time of delivery to Distributor's designated place of business, Company will replace such defective Products free of costs and delivery charges. As Company may direct, Distributor will either return the defective Products to Company with the freight costs to be at Company's expense or hold or otherwise dispose of such defective Products in accordance with Company's instructions. Company shall replace all Product which is defective hereunder within three (3) months from Company's receipt of such notice from Distributor. Company shall pay the cost of customs, insurance, and freight for any defective Product returned to it. In the event of any unresolved dispute between the Parties concerning the rejection by Distributor of all of or any part of the Product, the Product shall be submitted for testing

to a mutually agreed-upon qualified independent laboratory. If the Parties are unable to agree upon such a laboratory, each will select a qualified independent laboratory and the two laboratories will select a third qualified independent laboratory which shall perform the testing. The parties agree to be bound by the findings of the laboratory. All costs associated with the investigation shall be paid by the unsuccessful party.

3.8 Company will use all reasonable efforts to supply or have supplied Distributor's requirements of Product and will keep Distributor closely informed if there should be any anticipated problem of supply. Company shall be solely responsible for providing all necessary equipment facilities and personnel to manufacture the Product in compliance with GMP and government regulatory requirements in the areas of the Territory where it is marketed, and Company shall comply with all such regulatory and legal requirements in the manufacture of Products both in such areas as well as in the country(s) of manufacture.

3.9 Under a mutually acceptable escrow agreement, Company agrees to deposit in escrow located in the United States copies of specifications and other documents containing the Know How relating to the commercial manufacture of Products, including formulation and packaging information, to enable Distributor to make or have made Products. The escrow agreement shall provide for Distributor's access to such escrowed materials in the event that Company or its nominee is unable or unwilling to meet its obligations under this Agreement to supply Distributor's requirements for Product for more than a 90-day period.

In the event that Company notifies Distributor that it is able to recommence supply of the Present Product or Products to Distributor, Distributor shall within a reasonable time cease to make or have made the Products and thereafter shall purchase its entire requirements for the Products from Company.

[*]CONFIDENTIAL TREATMENT REQUESTED 6

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In respect of any Products which Distributor makes or has made in accordance with this Section 3.9, Distributor shall pay a royalty to Company of [*] the Net Sales II of all such Products sold or otherwise disposed of on a commercial basis by Distributor. Distributor shall keep all such accounts and records as may be necessary for the calculation of such royalty and shall supply copies of such accounts and records to Company upon request. Distributor shall pay such royalty to Company for each calendar quarter within [*] of the end of that calendar quarter and at the same time shall supply to Company a detailed calculation of the royalty concerned.

3.10 Company shall provide batch release certificates and certificates of analysis with each shipment of Product to Distributor (including Product samples).

3.11 Company warrants that all Product provided or sold by it to Distributor under this Agreement shall:

- (a) conform to the Specifications;
- (b) be merchantable;
- (c) be manufactured in accordance with ISO requirements and any other applicable regulations and laws of the Territory and of the jurisdiction of manufacture; and
- (d) be fit for use by humans for the Approved Indication(s).

3.12 Company warrants that it has the capacity to supply conforming Product in accordance with the terms of the Agreement.

ARTICLE 4. REGULATORY MATTERS

4.1 Company shall comply with all applicable laws and regulations in relation to the manufacturing and handling of the Product in the Territory and in any country outside the Territory where Company manufactures Product or has Product manufactured on its behalf. Distributor shall comply with all applicable regulations and laws in relation to the handling, storage, distribution and sale of the Product in those areas of the Territory where the Product is distributed and sold by Distributor.

4.2 Each Party will report to the other all adverse events (hereinafter called "AE"), customer complaints, technical or quality-related incidents and/or issues, which come to its attention relating to the Product, including any that come to a Party's attention through publications in journals or other media. Each party shall report any serious adverse events relating to Product, within 48 hours of receipt, to the other.

4.3 Distributor shall be responsible for preparing and submitting medical device reports ("MDRs") to the FDA or other responsible national governmental authorities in the Territory. Company shall review and evaluate all Product complaints forwarded by Distributor. If Distributor believes that an MDR report needs to be filed, Company shall fully investigate the complaint and shall provide all information necessary to Distributor for Distributor to file the MDR report. With respect to adverse events and the like occurring with the Product outside the

[*]CONFIDENTIAL TREATMENT REQUESTED 7

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Territory, Company shall provide to Distributor all information relating to such complaints that may be or are subject to the FDA's reporting MDR requirements. Distributor shall evaluate this information and shall determine whether an MDR should be submitted. Company shall evaluate such events in relation to the standard operating procedures of Distributor's that will be adopted by Distributor and agreed upon by the parties. Company shall designate Distributor as agent to the FDA for these reporting purposes.

4.4 Within 15 days of the Effective Date of this Agreement, Company shall provide Distributor with copies of all documents relating to or constituting Company's 510(k) filing with the FDA.

4.5 Company agrees that it will not modify the Present Product or any other Product whose specifications have been agreed upon by the Parties without prior notification to and approval by Distributor (which approval shall not be unreasonably withheld) so that Distributor can ascertain whether Distributor will need to file any additional Rule 510(k) filings.

4.6 Company will register as the Product manufacturer with the FDA. Distributor will list Product with FDA as approved for marketing.

4.7 Each Party will maintain such records and procedures to ensure that any batch of Products can be effectively and completely recalled from the market in the event that such action is required.

4.8 If, for any reason, it shall become necessary to trace back or recall any particular lot of the Product, or to identify the customer or customers to whom units from such lot will have been delivered, each party shall co-operate fully with the other in doing so. In the event that either Party has reason to believe that one or more lots of the Product should be recalled or withdrawn from distribution in the Territory, such Party shall immediately notify the other Party in writing. To the extent permitted by the circumstances, the Parties will confer before initiating any recall, but the decision as to whether or not to initiate a recall of the Product and to notify regulatory authorities in the Territory shall be Distributor's alone. If the recall is required because of a modification or withdrawal of an approval from a competent regulatory authority or a failure of the Product to conform to its Specifications, Company shall promptly reimburse Distributor for the reasonable costs and expenses of such recall, and, at Distributor's option, Company shall replace the recalled Product free of additional charge, or credit or refund the Purchase Price of the recalled Product. If the recall is required because of a negligent act or omission of Distributor in handling, storage or distribution of the Product, then such recall shall be conducted by Distributor at its sole cost and expense and Distributor shall not be entitled to any such credits, replacements or refunds from Company. If such recall is required because of a joint act or omission of the Parties, Distributor shall conduct the recall, the Parties shall divide the cost of such a recall, and any replacement Product

required by Distributor shall be provided by the Company to the Distributor at cost.

4.9 Each Party shall furthermore notify the other immediately of any information that it receives regarding any threatened or pending action by any Regulatory Authority which may affect the safety or efficacy claims of the Product within the Territory or the continued marketing of same. Upon receipt of any such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting either Party's right to

[*]CONFIDENTIAL TREATMENT REQUESTED 8

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make a timely report of such matter to any Regulatory Authority in the Territory or to take any further action that either Party deems appropriate or is required by applicable law or regulation.

4.10 Distributor will provide a medical information service concerning the Products to the health professionals and patients in the Territory.

ARTICLE 5. PAYMENTS

5.1 For quantities of Product beyond that set forth in Section 3.1, Company shall initially sell Present Product to Distributor at the price of [*] Ex Works Lecco, Italy. The price shall be revised [*] For the avoidance of doubt, there shall be no downward revision of the price due to changes in the above-mentioned index. If during any such two-Year period (or shorter initial period), the documented actual Product manufacturing cost [*] (hereinafter "extraordinary increase"), the then-current price will be adjusted accordingly, provided Product is being manufactured in accordance with best manufacturing practices (e.g., ISO standards). In the event of an extraordinary increase, however, Company shall supply to Distributor (or its agents) details of the manufacturing costs and methods to reasonably justify such an extraordinary increase. Distributor shall be entitled to audit such details on reasonable notice to Company. In the event of an extraordinary increase, the next increase at the end of the two Year period referred to above (or shorter initial period) shall be the percentage increase in the [*] from the date of the extraordinary increase to the end of the two Year period concerned (or shorter initial period). Further increases in price shall be made in the two Year period concerned (or shorter initial period) if supported as described above as a further extraordinary increase. If during any such two-Year period (or shorter

initial period), the documented actual Product manufacturing cost decreases by more than [*] (hereinafter "extraordinary decrease"), the Company will also make an extraordinary decrease in the price of the Present Product due to decreases in manufacturing costs but any such extraordinary decrease shall not take the price of the Present Product to less than [*]

5.2 Payment terms for conforming Product sold by Company under Section 5.1 are [*] from the date of the invoice (which date shall not be earlier than the time of Product delivery under Section 3.6).

5.3 The Distributor will pay Company \$1,000,000 (one million dollars) (U.S.) on the Effective Date of this Agreement, and a further \$2,000,000 (two million dollars) (U.S.) which latter payment will be credited against the amount that would otherwise be due from Distributor to Company in respect of the quantity of Product set forth in Section 3.1, based on the price set out in Section 5.1.

5.4. The Distributor will pay the Company [*] upon issuance of a United States Patent in the name of the Company or its Affiliates with claims covering the Products.

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5.5. Upon Distributor achieving [*] cumulative Net Sales I of Products, Distributor shall pay Company [*].

5.6 Upon Distributor achieving [*] cumulative Net Sales I of Products, Distributor shall pay Company [*].

5.7 Upon the results of the first clinical trial concerning the Products' efficacy appearing in a peer-reviewed journal, Distributor shall pay Company [*]

5.8 All payments made by Distributor to Company shall be in U.S. Dollars and shall be made by transfer to the following U.S. Dollar bank account or such other bank account as Company may notify to Distributor from time to time.

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5.9 The Products to be supplied by Company pursuant to this Agreement shall be sold or otherwise supplied on an Ex Works basis (as defined in the International Chamber of Commerce's Incoterms 2000 edition), and accordingly Distributor shall, in addition to the price (where there is a price), be liable for arranging and paying all costs of transport (including insurance for transport). For the avoidance of doubt, the provisions of this Section 5.9 shall apply to Products supplied in accordance with Sections 3.1, 6.5, 6.6 and 6.7 as well as all other Products supplied under this Agreement.

5.10 If Distributor fails to pay the price for any Products within [*] of the date of the invoice therefor or fails to pay any other amount when due under this Agreement, Company shall be entitled (without limiting any other right or remedy it may have) to:

- (a) cancel or suspend any further delivery to the Distributor under any order until such time as the payment concerned is made;
- (b) sell or otherwise dispose of any Products which are the subject of any orders by Distributor, whether or not appropriated to the order;
- (c) charge Distributor interest on the amount due, both before and after any judgement, at the rate of 4 per cent per annum above the Prime Rate prevailing in the United States from time to time from the date the payment became due until actual payment is made.

ARTICLE 6. PROMOTION/SALES OBLIGATIONS OF COMPANY

6.1 The Company shall use its reasonable endeavors to cooperate with and assist Distributor in its sales and marketing activities in the Territory.

[*]CONFIDENTIAL TREATMENT REQUESTED 10
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6.2 The Company shall from time to time supply Distributor [*] with specimens and artwork (including any electronic files of the same) of displays, promotional and advertising material and literature previously published or prepared by Company, provided that Company shall have no obligation to produce such material for Distributor.

6.3 The Company shall provide Distributor with technical assistance at its request if required and against remuneration as agreed in each case.

6.4 The Company shall assist Distributor if required in training personnel concerned with the marketing of the Products, if Distributor requests such assistance, subject to a maximum obligation on Company to provide the assistance of one person for seven working days under this Agreement.

6.5 The Company shall provide [*] reasonable quantities of Products for the execution of formal clinical trials by or on behalf of Distributor, protocols for which have been approved by Company which approval shall not unreasonably be withheld.

6.6 Company shall provide Product samples to Distributor [*] as follows:

- (a) [*] packets of Product delivered within 90 days of receiving from Distributor all necessary camera ready art work and product insert; and
- (b) samples equal to [*] of all firm commercial Product orders for the [*] of this Agreement;
- (c) samples equal to [*] of firm commercial Product orders for [*] of this Agreement;
- (d) All samples under Sections 6.6(a) - (c) shall be made in accordance with the Specifications and provided in boxes of seven 15 ml packets of Product labeled as "sample use only." [*].

6.7 To the extent that Distributor desires additional samples beyond the amounts set forth in the preceding Section, Company will provide them at [*], provided that Distributor shall not be entitled to purchase as additional samples more than [*] (determined on a per-packet basis) in any given Year.

6.8 If Company or its licensed distributor intends to carry out a controlled and randomized clinical trial of the Products, Company shall provide Distributor a copy of the protocol at least 30 days prior to submission to any institutional review board or regulatory authority (or initiation of the trial if the protocol is not so submitted) to provide Distributor an opportunity to comment on the same. Company shall have no obligation to accept such comments of Distributor. Company shall provide to Distributor a copy of any data produced as a result of such clinical trials, provided Company has the right to do so.

6.9 Company agrees that it and its Affiliates and agents will not conduct or actively permit other distributors outside the Territory to conduct any clinical trial of the Product (or a Competing Product) in the Territory.

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6.10 Company agrees that if Distributor's purchases of Product from Company exceed [*] per year, Company shall as soon as practicable thereafter begin manufacturing Distributor's requirements of Product within the Territory at a location and facility that provides equal or better quality and equal or lower cost to Distributor (including duties) than currently provided under this Agreement.

ARTICLE 7. OBLIGATIONS OF DISTRIBUTOR

7.1 Distributor shall use commercially reasonable efforts to launch the Product in the United States within 90 days of receipt of at least 50% of the quantity of conforming Product set forth in Section 3.1 above and 50% of the conforming samples set forth in Section 6.6(a) above, in Distributor's distribution center in the United States, provided that (1) Company has also supplied to Distributor all regulatory materials specified under Article 4 of Agreement; and (2) the U.S. government authorities have not otherwise precluded Product from being marketed and/or sold in the United States. In the event of any delay due to regulatory authorities or due to Force Majeure, Distributor shall immediately notify Company and the above-mentioned period for launch of the Products shall be extended for as long as any such delay continues. If Distributor has still not launched the Products within 30 days of the end of the 90 day period as referred to above or, if there have been delays as referred to in this Section 7.1, within 90 days of the end of the extended period as referred to in the previous sentence, Company may forthwith terminate this Agreement upon notice in writing to Distributor.

7.2 Distributor shall use all reasonable efforts to sell and distribute the Products in the Territory. With respect to countries in the Territory outside the United States (hereinafter "the non-U.S. Territory"), Distributor shall use all reasonable efforts to maximise its sales of the Products in such countries unless to do so would not be materially profitable to Distributor. In the event that Distributor decides to sell or distribute in the non-U.S. Territory (or any portion thereof), Company shall make all necessary regulatory filings required for Product approval at Company's expense in the part of the non-U.S. Territory concerned.

7.3 During the term of this Agreement, Distributor will spend at least [*] annually on direct sales force expenses relating to Product. Distributor shall also spend at least the following amounts annually on marketing the Product:

With the sales force efforts outlined in this Section 7.3, Distributor shall be permitted to sell, promote, market and distribute other products in addition to Product with the same sales force efforts.

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7.4 Distributor furthermore agrees:

- (a) that as compliance with Section 7.3 above, to ensure that the Territory is covered by adequate and reasonable sales activities including sampling, promotion, distribution of technical and sales matter, demonstrations and other measures for promoting the sale of Products and to use commercially reasonable endeavors to achieve Forecast sales and to bear all expenses above arising in connection with its activities hereunder.
- (b) to ensure that the Products are sold with the name of the manufacturer, Sinclair Pharmaceuticals Limited, on the Product's label and literature.
- (c) not to disclose either during the term of this Agreement or thereafter to any third party any prices or technical or other information of a confidential nature received or obtained from the Company except insofar as may be required for the purpose of selling the Products and complying with any legal or regulatory requirements, and on termination of this Agreement to return all price lists and documents containing such information.
- (d) to procure at Distributor's own expense the execution of clinical trials to support marketing of Products if Distributor feels further trials are necessary for successful commercialization of the Products. For any such randomized and controlled clinical trials, Distributor shall provide Company a copy of the protocol at least 30 days prior to submission to any institutional review board or regulatory authority (or initiation of the trial if the protocol is not so submitted) to provide Company an opportunity to comment on the same. Distributor shall have no obligation to accept such comments of Company.

Distributor shall provide to Company a copy of any data produced as a result of such clinical trials.

7.5 All scientific and clinical data related to Products generated by Distributor or its agents shall be disclosed to the Company. Distributor shall promptly deliver to the Company copies of any new scientific or clinical data related to the Products, as soon as it comes into its possession. Company shall be entitled (free of charge) to use such scientific and clinical data for any purpose.

ARTICLE 8. PRODUCTS LIABILITY AND INSURANCE

8.1 Each Party shall defend, indemnify and hold harmless the other Party and the other's Affiliates, officers, directors, employees and agents, from and against all claims, liabilities, demands, damages, expenses and losses (including reasonable attorneys' fees and expenses) arising out of or connected with:

- (a) any breach by the Party of any of its representations, warranties or covenants under this Agreement; or
- (b) any materially wrongful acts or wrongful omissions contrary to law on the part of the Party or its authorized agents or employees.

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8.2 As to the Company's manufacture and Distributor's storage, handling, promotion and sale of Products under this Agreement, each Party agrees to maintain product liability insurance to cover its risks related to the Products and, upon the other Party's request, to provide the other Party with certificates of insurance attesting to the existence of such insurance. During the Term of this agreement and for a period of five (5) years thereafter, to satisfy the obligations in Sections 8.1 above, each Party shall obtain and maintain insurance coverage from a reputable arm's length insurer in an amount of not less than approximately \$1.5 million per incident. Each Party shall add the other Party as an additional insured under its respective insurance policy. Each Party agrees, upon request, to advise the other of the status of the required insurance and of any change in such status. It is understood and agreed that furnishing of such insurance coverage will not relieve the Parties of their respective obligations under this Agreement.

ARTICLE 9. TRADEMARKS

9.1 Company grants Distributor the exclusive right and license to use the trademarks GELCLAIR and SINCLAIR (hereinafter "Trademarks") in connection with the marketing, sale, manufacture (if Distributor manufactures Product under the provisions of Section 3.9 above) and distribution of the Products within the Territory, subject to the terms of this Section 9.1. Company further authorizes Distributor to grant sublicenses of the rights granted under this Section 9.1 to Affiliates on identical terms to those set out in this Section 9.1 and Distributor shall immediately inform Company of the identity of such Affiliates. Distributor shall be entitled to use the Trademarks in ways which are consistent with any regulatory approvals which Company may have for the Products in the Territory. Distributor shall not use the Trademarks in any way which would undermine or have a negative effect upon the reputation of the Company or the strength or validity of Company's rights in the Trademarks. Distributor's licence under this Section 9.1 is conditional on advertising using the Trademarks complying with all applicable laws in the Territory. Distributor shall discontinue all use of the Trademarks upon Company's request or upon termination of this Agreement.

9.2 Distributor shall use the Trademarks on or in connection only with those Products that conform to the Specifications.

9.3 To verify compliance with Article 9 hereof, Distributor will submit to Company samples of promotional materials and any packaging therefor that Distributor has prepared, and other items bearing the Trademarks that Distributor may have prepared, and Company, or its delegate, will inspect such material and inform Distributor of any objections thereto within 15 days. If Company registers no objection after the 15 day period, Company is deemed to have accepted such items as compliant. The Trademarks shall be the exclusive property of the Company, and Distributor shall not seek to register or have registered the Trademarks in the Territory.

9.4 Company agrees that it will file applications for registration of the marks GELCLAIR and SINCLAIR in all the countries in the Territory (if not already filed). Company will:

- (a) Provide Distributor with copies of all such filings and correspondence with the pertinent trademark registration authorities, and provide Distributor the opportunity to comment on the same prior to filing, provided that this obligation

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will be satisfied by Company issuing a standing instruction to its

trademark attorneys to copy all relevant correspondence to Distributor and if Distributor has not objected to any proposed action within 15 days, Distributor will be taken to have accepted the proposed action;

- (b) bear the expense and responsibility of such trademark registration filings, prosecution and maintenance, including filing any statements of use; and
- (c) not allow such trademark registrations to become abandoned without Distributor's permission (which is not to be unreasonably withheld).

Distributor shall reasonably cooperate with Company in supplying Company with any appropriate information and specimens to support the trademark registrations filed for or obtained in accordance with the terms of this Agreement.

9.5 Company agrees that if the "Gelclair" Trademark is unavailable for use in the Territory or any portion thereof, the Parties shall agree upon an alternative trademark to be used on the Products and such trademark shall be owned by Company. The alternative trademark shall be deemed to fall within the definition of 'Trademarks' given in Section 9.1 and the provisions of Sections 9.1 to 9.8 shall apply to the alternative trademark.

9.6 During the term of this Agreement, if either Party becomes aware of a possible third party infringement of a Trademark in the Territory (or any portion thereof) within the license grant in section 9.1, that Party shall immediately notify the other of the possible infringement so that the other Party can investigate the matter. Distributor shall, at its sole option, have the right to enforce such trademark rights against such a third-party infringer in such parts of the Territory as it sees fit using counsel of its own selection and at its own expense. Distributor shall also have the option of joining Company as a party to such an enforcement action, and Company will provide reasonable cooperation in such joinder and in any such enforcement action. If Company is made a party to such action, Distributor shall compensate Company for any reasonable costs, expenses or fees which Company incurs as a result of such action. In any such enforcement action initiated by Distributor, Distributor shall have the option to settle such an action on such terms as it deems reasonable. Any damages awarded as a result of any such infringement action, or any monies recovered in such a settlement shall, in order, first be used to compensate Distributor its costs of initiating and pursuing such an infringement action and second to compensate Distributor and Company for their lost sales as a result of such infringement in a proportion to reflect their respective loss of sales recovered.

9.7 Company warrants that it has no knowledge of any actual or potential Trademark infringement claim by a third party in the Territory that would, if successfully brought and prosecuted, impair the Company's ability to supply Distributor Product consistent with the terms of this Agreement or impair the Distributor's ability to distribute and sell Product in the Territory under the licensed Trademarks. If, at any time during the term of this Agreement either Party learns that any Product distributed or sold by Distributor under this

Agreement is subject to a possible third-party claim of trademark infringement of any of the Trademarks, the Party learning of the claim shall promptly notify the other Party in writing. Company shall indemnify and hold Distributor harmless and accept all legal and financial responsibility for any liability, damage, loss, cost or expense arising out of any such trademark infringement claims in respect of the manufacture, use or sale of the Product bearing the Trademark(s), provided that such

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liabilities are not related to any artwork or packaging that Distributor has asked Company to produce. Distributor shall promptly notify Company of any trademark infringement claims for Company to indemnify and at Company's cost, permit attorneys mutually agreeable to the Parties to handle and control such trademark infringement claims or suits. Distributor agrees to provide Company with reasonable assistance in defending such infringement action or in prosecuting any related action.

9.8 The Distributor and its Affiliates shall at the request of the Company execute such registered user or other agreements in respect of the use of the Trademarks in the Territory as the Company may reasonably require. Each Party will join with the other Party in registering the trademark licence granted hereunder with the registrars of trademarks in the Territory as may be required by the other Party. The Distributor and its Affiliates hereby agree that upon any amendment or termination of this Agreement the Distributor and its Affiliates will execute any documents that the Company may reasonably request for the purpose of applying for variation or cancellation of the entries with the registrars of the Distributor and its Affiliates as licensees of the Trademarks.

9.9 Distributor shall have the right to use the trademark "Cell Pathways" on the Product, and Company shall cooperate with Distributor to ensure that that mark (as well as any alternative mark under Section 9.5 above) appears on all packaging of Product supplied by Company to Distributor under this Agreement.

ARTICLE 10. PATENTS

10.1 Company grants Distributor an exclusive license to use and sell (and to manufacture in the circumstances referred to in Section 3.9) Products under any patents owned or licensed to the Company claiming Product or improvements or modifications thereto, including such a license under any such patents that claim priority from Italian Patent Application No. MI20000A001732 filed July 28, 2000 and/or PCT/EP/01/08303 filed July 18, 2001.

10.2 Company agrees that as to any of its patent application filings in the Territory within the scope of the preceding section:

- (a) Company will file U.S, Canadian and Mexican patent applications claiming priority from Italian Patent Application No. MI20000A001732 filed July 28, 2000 and/or PCT/EP/01/08303 filed July 18, 2001.
- (b) Company will provide Distributor with copies of all such filings and correspondence to or from the pertinent patent granting authorities, and provide Distributor a reasonable opportunity to comment on correspondence to the patent authorities prior to filing, provided that this obligation will be satisfied by Company issuing a standing instruction to its patent attorneys to copy all relevant correspondence to Distributor and if Distributor has not objected to any proposed action within 15 days, Distributor will be taken to have accepted the proposed action;
- (c) Company will employ counsel mutually agreed upon by the parties;

[*]CONFIDENTIAL TREATMENT REQUESTED 16

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- (d) Such patent filings and prosecution will be at Company's expense;
- (e) Company will pay all maintenance fees and taxes to maintain any issued patents in force in the Territory, and will not allow such issued patents to become abandoned without Distributor's permission (which is not to be unreasonably withheld).

10.3 Company warrants that it or its Affiliates own and have title to Italian Patent Application No. MI20000A001732 filed July 28, 2000 and PCT/EP/01/08303 filed July 18, 2001, and have the right to file corresponding applications in the Territory consistent with this Agreement. Company also warrants that it or its Affiliates own and have title to Know-how regarding the Product, including its formulation, manufacturing, Specifications and the like.

10.4 During the term of this Agreement, if either Party becomes aware of a possible third-party infringement of a patent right within the license grant in section 10.1, that Party shall immediately notify the other of the possible infringement so that the other Party can investigate the matter. Distributor shall, at its sole option, have the right to enforce such patent rights against such a third-party infringer in such parts of the Territory as it sees fit using counsel of its own selection and at its own expense. Distributor shall also have

the option of joining Company as a party to such an enforcement action, and Company will provide reasonable cooperation in such joinder and in any such enforcement action. If Company is made a party to such action, Distributor shall compensate Company for any reasonable costs, expenses or fees which Company incurs as a result of such action. In any such enforcement action initiated by Distributor, Distributor shall have the option to settle such an action on such terms as it deems reasonable. Any damages awarded as a result of any such infringement action, or any monies recovered in such a settlement shall, in order, first be used to compensate Distributor its costs of initiating and pursuing such an infringement action and second to compensate Distributor and Company for their lost sales as a result of such infringement in a proportion to reflect their respective loss of sales recovered.

10.5. Company warrants that it has no knowledge of any actual or potential patent infringement claim that would, if successfully brought and prosecuted, impair the Company's ability to supply Distributor Product consistent with the terms of this Agreement or impair the Distributor's ability to distribute and sell Product in the Territory. If, at any time during the term of this Agreement either Party learns that any Product manufactured by or on behalf of Company or distributed or sold by Distributor under this Agreement is subject to a possible third-party claim of patent infringement within the Territory, the Party learning of the claim shall promptly notify the other Party in writing.

Company shall indemnify and hold Distributor harmless and accept all legal and financial responsibility for any liability, damage, loss, cost or expense arising out of any such patent infringement claims as referred to in this Section 10.5 in respect of the use or sale of the Product by Distributor hereunder. Distributor shall promptly notify Company of any claims for Company to indemnify and at Company's cost, permit attorneys mutually agreeable to the parties to handle and control such patent infringement claims or suits. Distributor agrees to provide Company with reasonable assistance in defending such infringement action or in prosecuting any related action.

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ARTICLE 11. DURATION AND TERMINATION

11.1 This Agreement shall become effective upon the receipt by Company of the sum of \$1,000,000 referred to in Section 5.3 and, subject to the provisions of this Article 11, shall remain in effect for a period of ten (10) years and be automatically renewed thereafter for successive one (1) year periods, unless notice of the election not to renew shall have been given in writing by either Party to the other not less than 180 days before the beginning of any such

renewal period, provided however that the Parties hereto also agree that during the second 6 months of the eighth year of this Agreement they shall meet to determine whether at the end of the ten (10) years term of this Agreement the Agreement shall automatically be extended for a further five (5) year period after the first 10 year term has expired.

11.2 Without prejudice to any other rights or remedies it may have, Company may terminate this Agreement at the time and in the circumstances described in Section 7.1. In the event of such termination by the Company, Company may assign the Territory to another distributor immediately and payments made by Distributor under Section 5.3 above shall not be refundable to Distributor and any amounts owing from Distributor to Company under Section 5.3 at the time that Company notifies Distributor of termination shall forthwith be paid by Distributor to Company.

11.3 Without prejudice to any other rights or remedies it may have (but subject to Section 12 hereof), either Party may terminate this Agreement by prior notice in writing to the other Party ("the Other Party"):

- (a) if the Other Party is in material breach of a material provision this Agreement (including, without limitation, any default by Distributor in the payment when due of any sum owed by Distributor to Company) and, in the case of a breach capable of a remedy, the breach is not remedied within 90 days of the Other Party receiving written notice specifying the breach and requiring its remedy; or
- (b) in the event that the Other Party shall become bankrupt or insolvent, or if any reviewer or trustees shall be appointed for such Party or for all or substantially all of the property of such Other Party and such appointment shall not have been discharged within 30 days or such Other Party shall make an assignment for the benefit of its creditors, then the other Party may terminate this Agreement by tendering written notice to that effect;

11.4 Without prejudice to any other rights or remedies it may have, Company may terminate this Agreement in the circumstances described in Section 3.5.

11.5 Distributor may terminate this Agreement upon one year's written notice to the Company.

11.6 Upon termination of the Agreement for any reason, Distributor shall, at Company's written request which must be made within [*] sell to Company at Distributor's cost [*] any or all Products then in Distributor's inventory which are in saleable condition and shall return to Company all price lists, catalogues and other advertising literature furnished by Company to Distributor. Should Company not request to buy Distributor's inventory under this Section, Distributor shall be

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permitted to sell such inventory, or otherwise dispose of it in the Territory in accordance with all applicable laws.

11.7 Distributor shall have no claim and compensation from Company in case of termination of this Agreement by Company under Sections 3.5, 7.1 or 11.3 above. In the event of termination by Company, Distributor shall have no claim against Company for loss of distribution rights, loss of goodwill or any similar loss.

11.8 Termination of this Agreement shall not affect rights which have accrued as of the date of termination or obligations to maintain confidentiality, which shall continue in force.

ARTICLE 12. FORCE MAJEURE

Neither Distributor nor Company shall have any liability hereunder if either is prevented from performing any of its obligations hereunder by reason of Force Majeure. Such affected Party shall give to the other Party prompt notice of any such event of Force Majeure, the date of commencement thereof and its probable duration and shall give a further notice in like manner upon the termination thereof. Each Party hereto shall endeavor with due diligence to resume compliance with its obligations hereunder at the earliest date and shall do all that it reasonably can to overcome or mitigate the effects of any such Force Majeure upon both Party's obligations under this Agreement. Should the Force Majeure continue for more than six (6) months, then the other Party shall have the right to cancel this Agreement and the Parties shall seek an equitable agreement on the Parties' reward of interests. To the extent that an event of Force Majeure occurs that inhibits Company's ability to supply Product for more than 90 days, there shall be no cancellation of this Agreement by Company and the provisions of Section 3.9 shall control.

ARTICLE 13. MISCELLANEOUS PROVISIONS

13.1 The relationship between Company and Distributor hereunder is solely that of seller and purchaser. Distributor is not an agent of the Company for any purpose hereof. Distributor shall have no power or authority to bind Company in any manner and shall not hold itself out as the agent of the Company for any purpose.

13.2 To the extent that the Products are modified consistent with the terms of this Agreement (i.e., by mutual agreement of the Parties) the term "Products" as used herein shall be deemed to include the Products as so amended.

13.3 In the event of a conflict between the terms of this Agreement and Company's General Terms and Conditions of Sales, this Agreement shall govern.

13.4 The headings of this Agreement have been provided for convenience only and shall have no legal effect in connection with any interpretation of any of the provisions of this Agreement. If one or more provisions of this Agreement will be or should become invalid, this shall not affect the validity of the remaining provisions and the Parties shall replace the invalid provision by a valid and operable arrangement which achieves to the greatest extent possible the economic results intended by the invalid provision.

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13.5 Condition Precedent - This Agreement shall be of no force and effect until Company has received the sum of \$1,000,000 referred to in Section 5.3.

13.6 In construing this Agreement:-

- words importing a person shall include a firm or corporation;
- words importing the singular shall include the plural and vice versa.

13.7 Any notice required to be given by either Party in this Agreement shall be duly given when mailed by registered mail, postage prepaid, or by Federal Express to the other party at its address set forth above or at such other address as shall have been designated by such other Party by written notice.

13.8 This Agreement cancels and supersedes all previous agreements relating to any matter covered by this Agreement, except for the confidentiality agreement between the Parties dated 18th October 2001.

13.9 Any dispute in connection with this Agreement shall be finally settled by arbitration in London by a single arbitrator in accordance with the rules of arbitration of the International Chamber of Commerce.

ARTICLE 14. GOVERNING LAW

This Agreement shall in all aspects be construed and operated as an English contract and in accordance with English law.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate.

SINCLAIR PHARMACEUTICALS LTD.

Signed by: Michael J. Flynn

Signature:

Position: President & CEO

Date: January ___, 2002

CELL PATHWAYS INCORPORATED

Signed by: Robert J. Towarnicki

Signature:

Position: President & C.E.O.

Date: January ___, 2002

SINCLAIR PHARMA SRL

Signed by: Michael J. Flynn

Signature:

Position: President

Date: January ___, 2002

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APPENDIX A

SPECIFICATIONS

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[SINCLAIR LOGO]

PRODUCT SPECIFICATION

PRODUCT: GELCLAIR (R)

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APPENDIX A

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[*]CONFIDENTIAL TREATMENT REQUESTED

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APPENDIX A

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BIOKOSMES S.R.L.

=====
MATERIAL SAFETY DATA SHEET
=====

1. IDENTIFICATION

CHEMICAL NAME: NOT APPLICABLE

CHEMICAL FORMULA: AS PER INGREDIENT LIST MENTIONED ON THE PACKAGING

CAS NO.:

DOT LABEL(S)

2. PHYSICAL DATA

APPEARANCE AND ODOR DESCRIPTION: gelified, straw-coloured solution and characteristic odour.

SPECIFIC GRAVITY @ 25/25 C: 1,040 +/- 0,05

VAPOR PRESSURE: not measurable

FLASH POINT: not measurable

SOLUBILITY IN WATER: good solubility

BOILING POINT: 99(degree)C

PH @25 C: 6,0 +/- 0,5

3. HAZARDOUS INGREDIENTS

NO HAZARDOUS OR TOXIC INGREDIENTS.

4. PHYSICAL HAZARDOUS

FIRE PROTECTION INFORMATION: not inflammable

REACTIVITY DATA:

STABILITY: stable from +5(degree)C to +40(degree)C

INCOMPATIBILITY:

APPENDIX A

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[*]CONFIDENTIAL TREATMENT REQUESTED

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HAZARDOUS COMPOSITION OR DECOMPOSITION: -----

HAZARDOUS POLYMERIZATION: will not occur

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BIOKOSMES S.R.L.

=====
MATERIAL SAFETY DATA SHEET
=====

5. HEALTH HAZARDOUS

THRESHOLD LIMIT VALUE: none known

OSHA PERMISSIBLE EXPOSURE LIMIT: none

PRIMARY ROUTES OF ENTRY: normally only a nuisance problem

EFFECT OF OVEREXPOSURE: none known

6. EMERGENCY & FIRST AID PROCEDURES

EYES: wash with water

SKIN: wash with water

INGESTION: emetic normally not recommended, if problems consult physician

INHALATION: send away person from polluted zone, keeping in warm and well-aired room. Consult physician

7. SAFE HANDLING

SPILL OR LEAK PROCEDURES

Normally dry store. Away from high heat

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