

Edgar Filing: CEL SCI CORP - Form 8-K

CEL SCI CORP
Form 8-K
April 01, 2009

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): March 27, 2009

CEL-SCI CORPORATION

(Exact name of Registrant as specified in its charter)

Colorado	0-11503	84-0916344
-----	-----	-----
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

8229 Boone Blvd. #802
Vienna, VA 22182

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (703) 506-9460

N/A

(Former name or former address if changed since last report)

Item 8.01 Other Events

Effective March 6, 2009, CEL-SCI Corporation entered into a licensing agreement with Byron Biopharma LLC ("Byron") under which CEL-SCI granted Byron an exclusive license to market and distribute CEL-SCI's cancer drug Multikine(R) in the Republic of South Africa. CEL-SCI has existing licensing agreements for Multikine with Teva Pharmaceuticals in Israel and Turkey and Orient Europharma in Taiwan, Singapore, Hong Kong, Malaysia and South Korea, the Philippines, Australia and New Zealand.

Pursuant to the agreement, Byron will be responsible for registering the product in South Africa. Once Multikine has been approved for sale, CEL-SCI will be responsible for manufacturing the product, while Byron will be responsible

Edgar Filing: CEL SCI CORP - Form 8-K

for sales in South Africa. Revenues will be divided equally between CEL-SCI and Byron. To maintain the license Byron, among other requirements, must make milestone payments to CEL-SCI totaling \$125,000 on or before March 15, 2010.

On March 27, 2009, and as further consideration for its rights under the licensing agreement, Byron Biopharma purchased 3,750,000 Units from CEL-SCI at a price of \$0.20 per Unit. Each Unit consisted of one share of CEL-SCI's common stock and two warrants. Each warrant entitles the holder to purchase one share of CEL-SCI's common stock at a price of \$0.25 per share. The warrants will be exercisable at any time after September 8, 2009 and prior to March 6, 2016. The shares of common stock included as a component of the Units were registered by CEL-SCI under the Securities Act of 1933. CEL-SCI will file a new registration statement to register the shares issuable upon the exercise of the warrants.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
-----	-----
5	Opinion of Counsel
10(i)	Distribution Agreement
10(j)	Form of Warrant

2

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.

Date: March 31, 2009

CEL-SCI CORPORATION

By: /s/ Patricia B. Prichep

Patricia B. Prichep, Senior Vice President
of Operations

3

Edgar Filing: CEL SCI CORP - Form 8-K

CEL-SCI CORPORATION

FORM 8-K

EXHIBITS

EXHIBIT 5

March 30, 2009

CEL-SCI Corporation
8229 Boone Boulevard, Suite 802
Vienna, Virginia 22182

This letter will constitute an opinion upon the legality of the sale by CEL-SCI Corporation, a Colorado corporation ("CEL-SCI"), of 3,750,000 shares of common stock, as well as warrants to purchase an additional 7,500,000 shares of CEL-SCI's common stock, all as referred to in the Registration Statement on Form S-3 (File No. 333-151667) filed by CEL-SCI with the Securities and Exchange Commission.

We have examined the Articles of Incorporation, the Bylaws and the minutes of the Board of Directors of CEL-SCI and the applicable laws of the State of Colorado, and a copy of the Registration Statement. In our opinion, CEL-SCI is authorized to issue the shares of stock mentioned above and such shares represent fully paid and non-assessable shares of CEL-SCI's common stock.

Very truly yours,

HART & TRINEN

/s/ William T. Hart

William T. Hart

Edgar Filing: CEL SCI CORP - Form 8-K

EXHIBIT 10(i)

DEVELOPMENT, SUPPLY AND
DISTRIBUTION AGREEMENT

DEVELOPMENT, SUPPLY AND DISTRIBUTION AGREEMENT ("Agreement") dated March 06, 2009, by and between CEL-SCI Corporation, a Colorado corporation ("CEL-SCI"), and Byron Biopharma LLC, a Delaware limited liability company ("Byron Biopharma").

WHEREAS, CEL-SCI and Byron Biopharma are engaged in the development and distribution, respectively, of pharmaceutical products; and

WHEREAS, Byron Biopharma wishes to obtain from CEL-SCI exclusive marketing and distribution rights in the Territory with respect to CEL-SCI's pharmaceutical Product (as defined) manufactured and developed by CEL-SCI, and wishes to have CEL-SCI supply it with such Product; and

WHEREAS, CEL-SCI wishes to grant Byron Biopharma exclusive marketing and distribution rights for cancer indications and to supply Byron Biopharma with such Product for resale in the Territory;

NOW, THEREFORE, in consideration for the mutual promises contained herein, the parties agree as follows:

1. Definitions

As used in this Agreement, the following definitions shall apply:

a. "Commencement Date" shall mean, with respect to the Product, the date of the first commercial sale of such Product in The Republic of South Africa.

b. "Contract Year" shall mean a calendar year, according to the USA calendar.

c. "FOB" shall have the meaning ascribed in the Uniform Commercial Code in effect in Maryland, USA. "FOB point of origin" shall mean FOB at the CEL-SCI manufacturing or packaging site or at its contractor's site where such activities are performed, for the Product in the USA.

d. "MCC" shall mean the Medical Control Council, the South African health authorities, or its successors.

e. "IND" shall mean an Investigational New Drug application filed with the U.S. or Canadian health authorities or any other national health authority recognized by the Medicines Control Council in the Republic of South Africa covering manufacture of the Product dosage form(s) being evaluated in clinical trials under such IND.

1

f. "Labeling" shall mean all package inserts, vial labels and carton imprints and all other markings on packaging for, or other similar materials related to, the Product for commercial sale that are defined as labeling under

Edgar Filing: CEL SCI CORP - Form 8-K

any applicable law or regulation. "Labeling" shall also mean such labeling applicable to the use of clinical supplies (e.g., Investigational Drug Brochure).

g. "Manufacturing Cost" shall mean CEL-SCI's fully-burdened direct and indirect manufacturing costs and expenses associated in producing the Product, including, but not limited to, cost of materials, supplies, utilities, rent, labor (including taxes, benefits, overheads), third party contract expenses, administration, depreciation for plant and equipment and any other direct expenses.

h. "Gross Selling Price" is (1) the national reimbursement price approved by The Republic of South Africa, or (2) in the event that The Republic of South Africa does not grant the approval to reimburse the payments, Gross Selling Price is the contract price between Byron Biopharma and the major hospitals in the Republic of South Africa.

i. "Net Sales" - the total amount actually received by Byron Biopharma or its Affiliates from the arms length sale of the Product, provided that as to sales other than at arms length, the term "Net Sales" shall mean the total amount that would have been due in an arms length sale, according to the then current conditions for such sale or - in the absence of such current conditions - according to reasonable conditions for such sale, in all cases after deduction of:

- o sales taxes (including value added taxes) to the extent applicable to sales of the Product and not collected separately from the counter-party to such sales; and
- o credits or allowances, if any, actually granted, and approved by Supplier, on account of price adjustments, recalls, rejections or return of the Product previously sold; and
- o all shipment, storage, transportation and other direct administrative expenses required for the distribution of the Product.

j. "Specifications" shall mean, with respect to the Product, the specifications set forth in the IND for such Product approved by the health authorities in the Territory.

k. "Product" shall mean CEL-SCI's Leukocyte Interleukin Injection (Multikine(TM)), plus any improvements thereto, which shall comply with the Specifications, approved by health authorities in the Territory.

l. "Purchase Price" is the transfer price of Product for commercial sale from CEL-SCI to Byron Biopharma as specified in Section 8.1.

m. "Quarter" means a complete period consisting of the months of January to March, April to June, July to September, and October to December, all inclusive.

2

n. "Term" shall have the meaning ascribed to it in Section 3(a) hereof.

o. "Territory" shall mean the Republic of South Africa.

2. Authorization and Acceptance of Distribution

a. Subject to the terms and conditions herein contained, CEL-SCI hereby appoints Byron Biopharma, following regulatory approval for sale, as its exclusive distributor to market, distribute and sell the Product for human cancer indications in the Territory.

Edgar Filing: CEL SCI CORP - Form 8-K

b. Byron Biopharma will be entitled to appoint sub-distributors for the Territory with respect to marketing, distributing and selling the Product and to perform any of the obligations undertaken by it under this Agreement through any corporation or entity controlling or under common control with Byron Biopharma. These appointments will be subject to CEL-SCI approval which approval will not be unreasonably withheld.

3. Term

a. The term of this Agreement shall commence on the date hereof and shall terminate on the twentieth anniversary date of the Commencement Date for the Product. The 20-year term may hereinafter be referred to as the "Term."

b. After the 20-year period has expired, the exclusive Term for the Product shall automatically be extended for successive two-year periods unless at least six months before the expiration of the then current period for such Product, either party gives written notice to the other that it does not wish to extend the exclusive Term.

c. Following the expiration of this Agreement, all rights of Byron Biopharma to the Product, as well as any discoveries, inventions, or improvements to the Product will expire and revert to CEL-SCI. In addition, Byron Biopharma will sign over to CEL-SCI any rights that Byron Biopharma may retain in the Product (e.g. product registration in the countries of the Territory). Byron Biopharma will also return all data and/or documents that relate to the Product. Notwithstanding anything herein to the contrary, Byron Biopharma shall have the right to sell Product obtained from CEL-SCI hereunder in its possession after termination of this Agreement.

e. Notwithstanding anything herein to the contrary, this Agreement will expire on March 15, 2010 unless Byron Biopharma pays CEL-SCI a milestone payment totaling \$125,000 by such date.

4. Regulatory Approvals

a. Byron Biopharma shall file substantially complete and correct applications in the Territory.

3

b. After receiving from CEL-SCI all pertinent documentation required by various regulatory authorities, Byron Biopharma, at its own expense and as promptly as possible, shall file substantially complete and correct applications for all approvals necessary to market, sell and distribute the Product in the Territory. In support of such filings, CEL-SCI agrees to provide pertinent information and technical assistance to Byron Biopharma in seeking these approvals. CEL-SCI shall provide to a third party chosen by CEL-SCI, all pertinent process technology information necessary for registration of the Product to the extent that is permitted by the applicable laws and regulations in the Territory. The third party will forward such information to the health authorities for the purpose of completing the Byron Biopharma application(s).

c. In addition to the provisions of Sections 4(b), Byron Biopharma shall, at its own expense and as promptly as possible, use all due diligence to obtain all additional governmental and other approvals which may subsequently become necessary for Byron Biopharma to import and market, sell and distribute such Product for human cancer indications throughout the Territory.

d. Byron Biopharma shall promptly provide to CEL-SCI copies, along with English translations, of all of its product registrations and other approvals for the marketing, distribution and sale of the Product in the Territory. Byron

Edgar Filing: CEL SCI CORP - Form 8-K

Biopharma shall comply with all applicable laws in the Territory in conducting clinical studies and in marketing, distributing and selling the Product.

e. All preclinical and clinical data generated in the Territory shall belong to CEL-SCI for CEL-SCI's use in Product registrations outside the Territory.

5. Manufacturing and Packaging of Product

a. CEL-SCI will manufacture the Product and deliver as finished Product suitable for sale where the country allows.

b. Byron Biopharma will provide label copy to be used on vials and patient packs in all cases where English is not acceptable.

c. Byron Biopharma shall be responsible for ensuring the accuracy of the information and the form of the Labeling for the Product and their compliance with applicable laws within the Territory.

d. Byron Biopharma may market, sell and/or distribute the Product under the trademark owned or used by CEL-SCI (e.g., Multikine(TM)). Upon Byron Biopharma's request, CEL-SCI shall license Byron Biopharma to use its trademark in the Territory. Byron Biopharma may market, sell and/or distribute the Product in the Territory under any trademark owned or used by it as it may from time to time choose. Such trademarks shall become the sole property of CEL-SCI.

4

6. Supply of the Product for Commercial Sale

a. No later than six months prior to the first day of each Contract Year of the Term, Byron Biopharma will provide to CEL-SCI a non-binding forecast of Byron Biopharma's annual requirements of the Product for the succeeding Contract Year. CEL-SCI shall advise Byron Biopharma within thirty (30) days of its receipt of such forecast of CEL-SCI's anticipated ability to supply the forecasted amount for the applicable period (such confirmed amount, the "Forecasted Amount").

b. If at any time during the Term, CEL-SCI is or expects that it will be unable to satisfy the Forecasted Amount of Product for any period of a Contract Year, in full or in part, CEL-SCI shall so notify Byron Biopharma promptly, detailing the extent to which it will not meet such Forecasted Amount.

c. It shall be the responsibility of CEL-SCI to maintain reasonably adequate manufacturing capabilities of the Product, using its reasonable commercial best efforts to supply the Forecasted Amounts.

d. CEL-SCI will be the exclusive and sole supplier of Product to Byron Biopharma during the Term of this Agreement.

7. Shipment of Product for Commercial Sale

a. Byron Biopharma shall place all orders for Product by delivering to CEL-SCI a written purchase order specifying the Product, quantity and delivery date (which delivery date shall not be less than 180 days after the date such purchase order is delivered to CEL-SCI).

b. After accepting any written purchase order, CEL-SCI shall use reasonable commercial efforts to fill each order by the specified delivery date and shall notify Byron Biopharma of anticipated delays in filling any order.

Edgar Filing: CEL SCI CORP - Form 8-K

c. With each shipment of Product to Byron Biopharma hereunder, CEL-SCI shall invoice Byron Biopharma for the Product included in such shipment at the Purchase Price as set forth in Section 8.1. Payment shall be made in U.S. dollars, by Confirmed Irrevocable Letter of Credit from an internationally recognized bank to CEL-SCI's US bank.

d. Product shall be shipped FOB point of origin. Byron Biopharma shall arrange for the carrier or shipping agent to transport each shipment of Product from CEL-SCI's loading dock at the point of origin to desired destination. Byron Biopharma will ensure that adequately monitored freezer (-20(Degree)C +/- 3(Degree)C) space is maintained for Product storage prior to its distribution. Byron Biopharma shall arrange for carrier / shipment of Product to maintain frozen condition.

8. PRICE AND TERMS OF PAYMENT

8.1 Price: The amounts to be paid by Byron Biopharma to Supplier in connection with the supply of Product shall be as follows:

5

The greater of: (i) fifty (50%) percent of the Net Sales of such Product, and (ii) one hundred fifty percent (150%) of Supplier's Manufacturing Cost for such quantity of Product.

8.2 With every delivery of the Product to Byron Biopharma, Supplier shall send Byron Biopharma an invoice. For commercial supplies of Product, the initial transfer price for each unit of Product shall be based upon the average Net Sales per unit as described in the latest Sales Certificate (defined below). All payments shall be made within thirty (30) days from the last day of the month in which the invoice was issued, in a manner of a bank transfer to a bank account number, provided by Supplier to Byron Biopharma sufficient time in advance of such bank transfer.

8.3 Within thirty (30) days of the end of each Quarter, Byron Biopharma shall prepare and deliver to Supplier a certificate ("the Sales Certificate") setting out details of the Net Sales of the Product by Byron Biopharma during the relevant Quarter, including the gross selling price and any deductions described in the definition of Net Sales. Notwithstanding the foregoing, Byron Biopharma shall prepare and deliver the first Sales Certificate together with its first order of Products for non-clinical use. All Sales Certificates for periods prior to the Launch Date will include Byron Biopharma's reasonable non binding estimate of the anticipated sales price and relevant deductions.

8.4 At the end of each calendar year, Byron Biopharma will prepare a summary of the previous year's Net Sales and will calculate the payments already paid by Byron Biopharma and a true-up payment will be made by the applicable party in order to reconcile the amounts paid with the purchase prices described in Clause 8.1.

8.5 To the extent that sales are effected by Byron Biopharma, other than in United States Dollars, Byron Biopharma shall convert the sum of such sales into US Dollars in accordance with the selling rate for such currency quoted in the Wall Street Journal last published on the business day on which Byron Biopharma remits payment to Supplier.

8.6 Byron Biopharma shall keep full and true books of account and other records in accordance with generally accepted accounting practice in the Republic of South Africa so that details of sales of the Product, and Byron

Edgar Filing: CEL SCI CORP - Form 8-K

Biopharma's payment obligations in respect thereof, may be properly ascertained. Byron Biopharma shall preserve such books and records for three (3) years after the calendar year to which they pertain. Such books and records shall be open to inspection by an independent certified public accountant selected by Supplier, and subject to confidentiality obligations as strict as in this Agreement, at Supplier's expense, during normal business hours upon ten (10) business days' prior written notice, for the purpose of verifying the accuracy of the reports and computations rendered by Byron Biopharma. In the event Byron Biopharma underpaid the amounts due to Supplier with respect to the audited period by more than five percent (5%), Byron Biopharma shall pay the reasonable cost of such examination, together with the deficiency not previously paid, within thirty (30) days of the last day of the month of the date of receipt of notice from Supplier.

6

8.7 As further consideration for its rights under this Agreement, Byron Biopharma agrees to purchase 3,750,000 Units from CEL-SCI at a price of \$0.20 per Unit. Each Unit consists of one share of CEL-SCI's common stock and two warrants. Each warrant will entitle the holder to purchase one share of CEL-SCI's common stock at a price of \$0.25 per share. The warrants will be exercisable at any time after September 08, 2009 and prior to March 06, 2016. CEL-SCI will use its existing shelf registration statement to register the shares of common stock included as a component of the Units. CEL-SCI will file a new registration statement to register the shares issuable upon the exercise of the warrants.

9. CEL-SCI's Warranty and Liability

a. CEL-SCI warrants and guarantees that, prior to Byron Biopharma taking possession, upon delivery FOB point of origin, the Product shall meet the Specifications and shall not be adulterated or misbranded as required by the health authorities within the Territory ("Warranty").

b. CEL-SCI will provide Byron Biopharma with a Certificate of Analysis for each shipment of Product, stating test results and the Specifications for such shipment of Product.

c. Other than as in the specifications provided for in this Agreement, CEL-SCI makes no other warranties with respect to the Product. CEL-SCI does not make any implied warranties with respect to the effectiveness of this Product.

d. CEL-SCI shall indemnify, defend and hold harmless Byron Biopharma from all actions, losses, claims, demands, damages, costs, and liabilities to which Byron Biopharma is or may become liable insofar as they arise out of, or in connection with, any breach by CEL-SCI of any of its obligations or Warranty under this Agreement.

10. Regulatory Compliance

a. It shall be the responsibility of CEL-SCI to ensure that the Product sold by CEL-SCI to Byron Biopharma pursuant hereto meets the Specifications at the time of delivery to Byron Biopharma FOB point of origin.

b. Byron Biopharma shall comply with all applicable laws in the Territory with respect to packaging, marketing, distributing, selling, promoting and advertising the Product in the Territory.

11. Representations, Warranties and Covenants

a. Byron Biopharma and CEL-SCI represent and warrant to each other that

Edgar Filing: CEL SCI CORP - Form 8-K

each party has all requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby.

7

b. CEL-SCI further represents, warrants and covenants that:

i) The Product sold to Byron Biopharma hereunder does not infringe any patent or third party rights in the United States and the Territory related to the manufacture of the Product; and

ii) CEL-SCI possesses good title to the Product sold to Byron Biopharma hereunder; and

iii) CEL-SCI will not market, distribute or sell, to any party other than Byron Biopharma, the Product in the Territory except as provided for by this Agreement; and

iv) This Agreement shall be binding upon either party's lawful successors and assigns without changing any terms and conditions hereof.

12. Protection Rights

a. Except as otherwise provided by this Agreement, CEL-SCI shall not grant any third party the right to sell, ship and/or distribute the Product to any person or entity outside the Territory who CEL-SCI knows intends to sell, ship and/or distribute the Product (in bulk or dosage form) in or to the Territory for human cancer indications. In the event CEL-SCI becomes aware during the time that Byron Biopharma has exclusive rights pursuant to this Agreement, that any third party with whom CEL-SCI contracts to distribute Product outside the Territory is selling or distributing Product in the Territory directly or indirectly, CEL-SCI shall promptly advise such third party to cease selling and distributing Product in the Territory. In the event that such third party continues to sell or distribute Product in the Territory following such notice, CEL-SCI shall commence legal action against such party to terminate such activity.

b. During the Term of this Agreement, Byron Biopharma shall not directly or indirectly manufacture, develop, ship, market, sell or distribute any immunotherapeutic product that competes with Product in the Territory for the indications of head & neck cancer, adenocarcinoma of the nasal pharynx or cervical cancer. In addition, Byron Biopharma shall not directly or indirectly manufacture, develop, ship, market, sell or distribute any product that is a cytokine mixture, for any indication.

c. Byron Biopharma shall not directly or indirectly manufacture, develop, ship, market, sell or distribute Product outside the Territory.

d. If there are any new discoveries, inventions, patents, or other intellectual property as the result of this Agreement, CEL-SCI shall own such intellectual property.

13. Confidentiality

a. Any information pertaining to the Product and/or the respective operations of the parties that has been or will be communicated by CEL-SCI to Byron Biopharma or by Byron Biopharma to CEL-SCI, including, without limitation, trade secrets, business methods, and pricing, cost, supplier, manufacturing and customer information, shall be treated by CEL-SCI and Byron Biopharma

respectively, and their respective affiliates, employees and agents, as confidential information and shall not be used or revealed to third parties except as necessary in connection with the performance of their respective obligations hereunder; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this section to the extent that such confidential information:

i) is available in the public literature or otherwise in the public domain, or after disclosure by one party to the other becomes public knowledge through no fault of the party receiving such confidential information;

ii) was known through legitimate means to the party receiving such confidential information prior to the receipt of such confidential information by such party from the disclosing party, as evidenced by such receiving party's written records, whether received before or after the date of this Agreement;

iii) is obtained in good faith by the party receiving such confidential information from a source other than the party supplying such confidential information who was not under an obligation of confidence or secrecy to either party at the time of such disclosure; or

iv) 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 (with prior notice to the disclosing party and opportunity to contest by such party to the extent legally possible); or

(B) any lawful action of a governmental or regulatory agency (with prior notice to the disclosing party and opportunity to contest by such party to the extent legally possible); or

v) is required to be disclosed to a prospective, bona fide purchaser of the shares or assets of either party hereto, provided all such prospective purchasers agree in writing to be bound by the standards of confidentiality.

b. Each party shall take all such precautions as it normally takes with its own confidential information to prevent any improper disclosure of such confidential information to any independent third party; provided, however, that such confidential information may be disclosed within the limits required to obtain any authorization from the Medical Control Council authorities or any other governmental or regulatory agency in the Territory or, with the prior written consent of the other party, which shall not be unreasonably withheld, as may otherwise be required in connection with the purposes of this Agreement.

14. Force Majeure

If either Byron Biopharma or CEL-SCI shall be delayed, hindered,

Edgar Filing: CEL SCI CORP - Form 8-K

interrupted in or prevented from the performance of any of its obligations hereunder (other than the obligation to pay monies) by reason of force majeure ("Force Majeure"), including, without limitation, fire, earthquake, flood or other acts of God, strike, lockouts, war (declared or undeclared), civil disturbances, embargo, riots, unavailability of essential materials or transportation facilities, orders of any governmental authority (not caused by a default or other action of the party invoking such Force Majeure) or other similar events beyond the control of such party, such party shall not be liable to the other for damages, and the time for performance of such obligation shall be extended for a period of time equal to the duration of the contingency which occasioned such delay, hindrance, interruption or prevention. Byron Biopharma understands that the Product is difficult to manufacture and test. Therefore, Byron Biopharma understands that there may be manufacturing problems, due to reasons outside of CEL-SCI's control, where CEL-SCI may not be able to supply the Product in a timely manner. CEL-SCI will make best efforts to minimize any delay or interruption in supply.

15. Termination

a. This Agreement may be terminated in its entirety immediately upon written notice of termination given by:

i) The non-defaulting party in the event that the other party shall:

- (A) commit a material breach or default under this Agreement, 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 in default; or
- (B) have made a material misrepresentation of any representation or warranty contained herein;

ii) Either party in the event that any free trade agreements affecting the countries, is abrogated, amended or modified so as to materially and adversely affect the commercial benefits inuring to either party under this Agreement as in effect on the date hereof;

iii) Either party if the other party ceases to function as a going concern or if proceedings in bankruptcy or insolvency are taken against the other party and not remedied within thirty (30) days or if its property or business or its shares be confiscated or expropriated by any government or subdivision thereof;

16. Indemnification

a. CEL-SCI shall indemnify and hold harmless Byron Biopharma and its affiliates, successors and permitted assigns and their respective officers, directors, stockholders, partners and employees from and against any claim,

10

action, suit, proceeding, loss liability, damage or expense (other than special or consequential damages but including reasonable attorneys' fees and expenses) arising from or related to (i) any material breach of any representation, warranty or covenant made by CEL-SCI hereunder, including without limitation any failure to manufacture the Product in conformity with the Warranty and (ii) any negligent storage or handling of Product by CEL-SCI or its employees prior to Product transfer to Byron Biopharma (delivery to Byron Biopharma FOB point of origin).

b. Byron Biopharma shall indemnify and hold harmless CEL-SCI and its

Edgar Filing: CEL SCI CORP - Form 8-K

affiliates, successors and permitted assigns and their respective officers, directors, stockholders, partners and employees from and against any claim, action, suit, proceeding, loss liability, damage or expense (other than special, incidental or consequential damages, but including reasonable attorneys' fees) arising from or related to (i) any material breach of any representation, warranty or covenant made by Byron Biopharma hereunder, (ii) the storage, handling, use or sale of Product following delivery Byron Biopharma FOB point of origin, or (iii) packaging instructions provided by Byron Biopharma.

17. Customer Complaints; Recall

a. Pursuant to the United States Code of Federal Regulations Title 21 Section 314.80 , as the same may be amended from time to time, regarding the reporting of adverse drug experiences, Byron Biopharma shall immediately report to CEL-SCI any information concerning adverse drug experiences associated with the use of Product, whether or not considered drug-related, and including but not necessarily limited to: an adverse event occurring in the course of the use of Product in clinical trials, or in professional practice; an adverse event occurring from overdose, whether accidental or intentional; or any significant failure of expected pharmacological action. Additionally, reports of routine adverse drug experiences shall be summarized and exchanged between the parties once per calendar year. Byron Biopharma shall report potentially serious or unexpected adverse drug experiences as defined in Title 21 Section 314.80, as amended, to CEL-SCI as soon as possible, but in no event later than three (3) days after initial receipt of the information by Byron Biopharma and shall maintain a record of each such experience as required under Title 21 Section 314.80(c)(iii). Byron Biopharma agrees to cooperate with CEL-SCI in arriving at a mutually acceptable course of action regarding the handling of such information; however, nothing contained herein shall be construed as restricting the right or duty of either party to report the information to the appropriate regulatory bodies.

b. In the event of any recall of Product, as suggested or requested by any governmental authority, or any recall to which both parties agree in writing, Byron Biopharma shall perform the recall, and the reasonable documented costs thereof, including CEL-SCI's and Byron Biopharma's respective costs of manufacturing and distributing the Product recalled, will be borne by CEL-SCI or by Byron Biopharma if said recall can be attributed to Byron Biopharma's fault.

11

18. Patent & Trademark Ownership

CEL-SCI will maintain ownership of its Product patents, trademarks and know how and is responsible for maintaining, prosecuting and defending these patents and trademarks in the Territory.

19. Notices

Any notice or request required or permitted to be given under or in connection with this Agreement shall be in writing in the English language and shall be deemed to have been duly given on the date of delivery if delivered personally, by confirmed facsimile or by courier on the party to whom such notice or request is to be given, or, if sent by certified or registered mail, or the equivalent, postage prepaid, on the tenth (10th) day after the date mailed.

20. Governing Law; Arbitration

The formation, validity, construction and performance of this Agreement

Edgar Filing: CEL SCI CORP - Form 8-K

shall be governed by the laws the Commonwealth of Virginia, USA. All disputes arising in connection with this Agreement shall be finally settled by binding arbitration under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules. Any such arbitration shall be conducted in English. The arbitration shall take place in Virginia, USA. The judgment of the arbitration shall be final and binding to both parties.

21. Miscellaneous

Entire Agreement

This Agreement constitutes the entire Agreement between the parties relating to the subject matter hereof, and supercedes all prior agreements and understandings, oral or written between the parties. Any change to this Agreement must be in writing and signed by an authorized officer of each party, and specifically state that it is an amendment to this Agreement.

Product Improvements

During the Term of this Agreement, Byron Biopharma will have rights to improvements to the Product at no additional cost.

Independent Contractors

Each party is an independent contractor under this Agreement. Neither party is an agent, partner or legal representative of the other.

12

Late Payments

All amounts due and owing to a party under this Agreement that are not paid by the other party when due shall bear interest at the rate of 1 1/2% per month, or if lower, the maximum rate allowed by law, in either case calculated from the date the amount was first due.

Withholding Taxes

Payments to CEL-SCI shall be made without deduction other than such amount (if any) as Byron Biopharma is required by law to deduct or withhold. Byron Biopharma shall obtain a receipt from the relevant taxing authorities for all withholding taxes paid and forward such receipts to CEL-SCI to enable CEL-SCI to claim any tax credits for which it may be eligible. Byron Biopharma shall use reasonable efforts to minimize such withholdings and to assist CEL-SCI to claim exemption from withholdings under any double taxation treaty or similar agreement.

Export Law Compliance

Byron Biopharma understands that the Product and other materials may be subject to the export regulations of the US Department of Commerce or other US regulations related to the export of drugs. Byron Biopharma represents that it is familiar with and agrees to comply with all such regulations. Byron Biopharma agrees that it will not export or reexport outside of the Territory, directly or indirectly, any Product, clinical supplies or clinical data relating to the Product without prior written consent of CEL-SCI. Byron Biopharma agrees to obtain the same agreement from each of its subdistributors in the Territory.

Government Inquiries

Edgar Filing: CEL SCI CORP - Form 8-K

Each party shall promptly advise the other of any governmental inquiries about the Product and shall furnish to the other party, within five days of receipt, any report or correspondence issued by the governmental authority in connection with such inquiry, purged only of trade secrets.

Publicity

The parties agree that news releases, public announcements (written or oral), professional publications or any publicity relating to this Agreement, including the initial announcement of the Agreement, clinical results, regulatory filings and marketing approvals of the Product in the Territory, shall be mutually agreed by the parties, such approval not to be unreasonably withheld. Notwithstanding this Section 21, CEL-SCI may disclose, without approval from Byron Biopharma, any information, including confidential information (1) required by law or regulation (including, without exception, in connection with filings with the US Securities and Exchange Commission); (2) in response to a valid order of a court or other governmental body of the US or any country in the Territory or of any political subdivision thereof; (3) otherwise required by applicable laws; (4) otherwise necessary to file or prosecute patent applications, prosecute or defend litigation or otherwise enforce obligations under this Agreement; or (5) required by authorities, investigators, or Institutional Review Boards in conjunction with performing clinical development

programs, provided that the receiving party shall use reasonable efforts to restrict disclosure and to cause such authorities, investigators or IRBs not to disclose the information to any third party.

Records

With respect to the Gross Selling Price of Product sold in the Territory, if Gross Selling Price falls under definition 1 h, then Byron Biopharma will, upon request and subject to confidentiality, provide to CEL-SCI copies of the contracts between the major hospitals and Byron Biopharma showing price provisions. If these copies are not in English, Byron Biopharma will translate the price provisions into English. CEL-SCI shall have the right to these records during the Term of this Agreement and this right shall expire six months following termination or expiration of this Agreement.

Surviving Obligations

Termination or expiration of this Agreement shall not relieve either party of its obligations under Sections 4(e), 12(d), 13, 16, 17, 19, 20 and 21.

IN WITNESS HEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Byron Biopharma LLC

CEL-SCI Corporation

By: /s/ Edward Smith

By: /s/ Geert Kersten

Edward Smith
President

Geert Kersten
Chief Executive Officer

EXHIBIT 10(j)