#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

Form F-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## Sol-Gel Technologies Ltd.

(Exact Name of Registrant as Specified in its Charter)

**State of Israel** (State or Other Jurisdiction of Incorporation or Organization)

2834

(Primary Standard Industrial Classification Code Number)

**Not Applicable** (I.R.S. Employer Identification No.)

Sol-Gel Technologies Ltd.
7 Golda Meir St., Weizmann Science Park
Ness Ziona, 7403650, Israel
Tel: +972-8-931-3433

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Cogency Global Inc. 10 E. 40th Street, 10th floor New York, NY 10016 Telephone No.: +1 800 221-0102

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Joshua G. Kiernan Nathan Ajiashvili Latham & Watkins LLP 885 Third Avenue New York, NY 10022 Tel: +1 212 906 1200 Fax: +1 212 751 4864 Gene Kleinhendler Perry Wildes Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co. One Azrieli Center Tel Aviv 670201, Israel Tel: +972 3 607 4444 Fax: +972 3 607 4470 Eric W. Blanchard Brian K. Rosenzweig Matthew T. Gehl Covington & Burling LLP The New York Times Building 620 Eighth Avenue New York, NY 10018-1405 Tel: +1 212 841 1000 Fax: +1 212 841 1010

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Approximate date of commencement of proposed sale to the public: As soon as practicable after effectiveness of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.  $\Box$ 

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

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933. Emerging growth company 🗵

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

## **Explanatory Note**

The sole purpose of this Amendment No. 1 to the Registration Statement on Form F-1 is to amend the exhibit index and to submit Exhibits 10.3 and
10.4. Accordingly, this Amendment No. 1 consists only of the facing page, this explanatory note, Part II of the Registration Statement, the signature pages to
the Registration Statement, the exhibit index and the filed exhibits. No changes are being made to the prospectus and, therefore, the prospectus has been
omitted from this filing.

#### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 6. Indemnification of Office Holders (including Directors).

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of a fiduciary duty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association include such a provision. The company may not exculpate in advance a director from liability arising due to the breach of his or her duty or care in the event of a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Israeli Securities Law, 5728-1968, or the Securities Law, a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed by him as an office holder, either in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or imposed on the office holder in favor of another person pursuant to a court judgment, including pursuant to a
  settlement confirmed as judgment or arbitrator's decision approved by a competent court. However, if an undertaking to indemnify an office holder
  with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of
  directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria
  determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events
  and amount or criteria:
- reasonable litigation expenses, including reasonable attorneys' fees, which were incurred by the office holder as a result of an investigation or proceeding filed against the office holder by an authority authorized to conduct such investigation or proceeding, provided that such investigation or proceeding was either (i) concluded without the filing of an indictment against such office holder and without the imposition on him of any monetary obligation in lieu of a criminal proceeding; (ii) concluded without the filing of an indictment against the office holder but with the imposition of a monetary obligation on the office holder in lieu of criminal proceedings for an offense that does not require proof of criminal intent; or (iii) in connection with a monetary sanction;
- a monetary liability imposed on the office holder in favor of all the injured parties by the breach in an Administrative Procedure (as defined below) as set forth in Section 52(54)(a)(1)(a) to the Securities Law;
- expenses expended by the office holder with respect to an Administrative Procedure under the Securities Law, including reasonable litigation expenses and reasonable attorneys' fees; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or which were imposed on the office holder by a court (i) in a proceeding instituted against him or her by the company, on its behalf, or by a third party, (ii) in connection with criminal indictment of which the office holder was acquitted, or (iii) in a criminal indictment which the office holder was convicted of an offense that does not require proof of criminal intent.
- Any other obligation or expense in respect of which it is permitted or will be permitted under applicable law to indemnify an office holder, including, without limitation, matters referenced in Section 56H(b)(1) of the Securities Law.

An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- · a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- a monetary liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and
- expenses incurred by an office holder in connection with an Administrative Procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- · an act or omission committed with intent to derive illegal personal benefit; or
- a fine or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to directors or controlling shareholders, their relatives and third parties in which controlling shareholders have a personal interest, also by the shareholders.

Our amended and restated articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by law. Our office holders are currently covered by a directors' and officers' liability insurance policy. As of the date of this registration statement, no claims for directors' and officers' liability insurance have been filed under this policy and we are not aware of any pending or threatened litigation or proceeding involving any of our office holders, including our directors, in which indemnification is sought.

We have entered into agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, subject to limited exceptions, including, with respect to liabilities resulting from this offering, to the extent that these liabilities are not covered by insurance. This indemnification is limited, with respect to any monetary liability imposed in favor of a third party, to events determined as foreseeable by the board of directors based on our activities. The maximum aggregate amount of indemnification that we may pay to our office holders based on such indemnification agreement is the greater of (1) % of our shareholders' equity pursuant to our audited financial statements for the year preceding the year in which the event in connection of which indemnification is sought occurred, and (2) \$ million (as may be increased from time to time by shareholders' approval). Such

indemnification amounts are in addition to any insurance amounts. Each office holder who agrees to receive this letter of indemnification also gives his approval to the termination of all previous letters of indemnification that we have provided to him or her in the past, if any. However, in the opinion of the SEC, indemnification of office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

#### Item 7. Recent Sales of Unregistered Securities.

In August 2014, we issued a total of 3,388,359 ordinary shares to Arkin Dermatology in connection with the conversion of outstanding preferred shares into ordinary shares following the execution of the Purchase Agreement. In connection with the foregoing conversion, the par value of the ordinary shares (in the amount of approximately \$80) was paid.

In August 2017, we issued one ordinary share to Arkin Dermatology in connection with the transfer of an in-process research and development generic product candidate.

All of the foregoing issuances were made outside of the United States pursuant to Regulation S or to U.S. entities pursuant to Section 4(a)(2) of the Securities Act.

#### Item 8. Exhibits and Financial Statement Schedules.

- (a) Exhibits. See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.
- **(b) Financial Statement Schedules.** Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## Item 9. Undertakings.

- a. The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- b. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- c. The undersigned registrant hereby undertakes that:
  - 1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

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

## **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ness Ziona, State of Israel on September 6, 2017.

## Sol-Gel Technologies Ltd.

By: /s/ Alon Seri-Levy

Name: Alon Seri-Levy Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Alon Seri-Levy	Chief Executive Officer	September 6, 2017
Alon Seri-Levy		
*	Chief Financial Officer	September 6, 2017
Gilad Mamlok		
*	Director	September 6, 2017
Moshe Arkin		
*By /s/ Alon Seri-Levy	_	
Alon Seri-Levy Attorney-in-fact		
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## SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant's duly authorized representative has signed this registration statement on Form F-1 on this 6th day of September, 2017.

By: /s/ Colleen A. DeVries

Name: Colleen A. DeVries

Title: Senior Vice-President on behalf

of Cogency Global Inc.

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## EXHIBIT INDEX

Description

Exhibit No.

	· F. ·
1.1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Memorandum of Association of the Registrant.
3.2**	Articles of Association of the Registrant (currently in effect).
3.3*	Form of Amended and Restated Articles of Association of the Registrant to become effective in connection with this offering.
4.1*	Form of Specimen Share Certificate.
5.1*	Opinion of Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Israeli counsel to the Registrant, as to the validity of the ordinary shares.
10.1*#	Form of Amended and Restated 2014 Share Incentive Plan.
10.2*	Form of Registration Rights Agreement.
<u>10.3+</u>	Development, Manufacturing and Commercialization Agreement between Perrigo UK Finco Limited Partnership and Sol-Gel Technologies Ltd., dated as of April 27, 2015.
<u>10.4+</u>	Amendment to the Development, Manufacturing and Commercialization Agreement between the Registrant and Perrigo UK Finco Limited Partnership, dated as of October 26, 2015.
10.5*	Form of Indemnification Agreement.
10.6*#	Compensation Policy.
<u>10.7∞**</u>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of October 10, 2007.
<u>10.8∞**</u>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 29, 2014.
<u>10.9∞**</u>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of March 30, 2016.
<u>10.10∞**</u>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 20, 2016.
<u>10.11∞**</u>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of January 30, 2017.
10.12**	Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 2, 2016.
10.13**	Schedule A, as amended, of Promissory Note by and between the Registrant and Moshe Arkin, dated as of June 28, 2017.
10.14**	Instrument of Conversion of Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 22, 2017.
10.15**	Assignment Agreement between the Registrant and Medicis Pharmaceutical Corporation, dated August 16, 2013.
<u>23.1</u>	Consent of Kesselman and Kesselman, Member Firm of PricewaterhouseCoopers International Limited.
23.2*	Consent of Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Israeli counsel to the Registrant (included in Exhibit 5.1).
24.1**	Power of Attorney (included in the signature page of the Registration Statement).

Exhibit No.	Description
99.1**	Consent of director nominee.
99.2**	Consent of director nominee.
99.3**	Consent of director nominee.
99.4**	Consent of director nominee.
99.5**	Consent of director nominee.
99.6**	Consent of director nominee.

- \* To be filed by amendment
- \*\* Previously filed
- $\infty$  Informal English translation of the original Hebrew document
- + Confidential treatment to be requested
- # Indicates management contract or compensatory plan

# DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION AGREEMENT

This Development, Manufacturing and Commercialization Agreement (the "**Agreement**") is entered into as of April 27, 2015 (the "**Effective Date**") between Perrigo UK Finco Limited Partnership, a United Kingdom limited partnership ("**Perrigo UK**"), and Sol-Gel Technologies Ltd., a **limited liability company incorporated in Israel** ("**Sol-Gel**"). Perrigo UK and Sol-Gel are sometimes each referred to as a "**Party**" and collectively as the "**Parties**."

#### RECITALS

**WHEREAS,** Perrigo UK is an Affiliate (as defined herein) of Perrigo Company, a Michigan corporation ("Perrigo Company") and Perrigo Company and its Affiliates (collectively referred to as "Perrigo") are in the business of developing, manufacturing and marketing pharmaceutical products and Perrigo wishes to develop, formulate, manufacture and sell the Product (as defined herein) in accordance with this Agreement; and

**WHEREAS,** Sol-Gel is in the business of investing and participating in various businesses in the health care space, and Sol-Gel wishes to work with Perrigo in connection with the Product (as defined herein) in accordance with this Agreement.

**NOW THEREFORE,** in consideration of the mutual covenants and promises contained in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Parties agree as follows:

#### **ARTICLE I - DEFINITIONS**

For purposes of this Agreement, the following terms shall have the respective meanings set forth below:

- 1.01 "Act" shall mean the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.
- "Affiliate" shall mean a corporation or any other entity that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, the designated Party, but only for so long as the relationship exists. "Control" shall mean: (i) ownership of shares of stock having at least 50% of the voting power entitled to vote for the election of directors of the general partner in the case of a limited partnership.
- 1.03 **"Agreement"** shall have the meaning set forth in the Preamble.
- 1.03 "ANDA" shall mean, with respect to the Product, an Abbreviated New Drug Application (as defined in Title 21 of the U.S Code of Federal Regulations) submitted to the FDA requesting approval to market the Product.

- 1.04 "cGMP" shall mean those current Good Manufacturing Practices required by the FDA to be followed in connection with the manufacture of pharmaceutical products, as defined from time to time by the Act and related regulations or any successor laws or regulations governing the manufacture, handling, storage and control of the Product in the United States, in the form of laws, regulations or guidance documents (including but not limited to advisory opinions, compliance policy guides and guidelines), which guidance documents are being implemented within the pharmaceutical manufacturing industry for such Product.
- 1.05 **"Commercialization"** shall mean the activities undertaken to launch, market, promote, sell, and service the Product or have it marketed, promoted, sold or serviced in the Territory.
- 1.06 **"Committee"** shall have the meaning set forth in <u>Section 2.1</u>.
- "Confidential Information" shall mean information pertaining to each Party's business, marketing plans, marketing activities, market projections, products and related matters, including related technical information, provided by one Party to the other pursuant to or in furtherance of this Agreement. Confidential Information hereunder shall also include extracts, analyses, compilations, studies or other documents or records prepared by or for a recipient or any of such recipient's directors, officers, managers, employees, legal advisors, and financial advisors to the extent that such extracts, analyses, compilations, studies, documents or records contain or otherwise reflect or are generated from the disclosing Party's Confidential Information. The existence of this Agreement shall constitute Confidential Information.
- 1.08 **"Development Costs"** shall mean, with respect to a given Product, all costs (determined in accordance with U.S. GAAP consistently applied) incurred by a Party prior to the Launch Date in connection with the program for such Product hereunder.
- "Diligent Efforts" shall mean, (i) with respect to the development activities for the Product contemplated hereunder, a Party's use of commercially reasonable efforts and resources consistent with the exercise of prudent business (and/or, if applicable, scientific) judgment, as applied by such Party to other pharmaceutical products of similar potential, market size and legal and competitive environments, and (ii) with respect to Commercialization of the Product contemplated hereunder, use of commercially reasonable efforts and resources consistent with the exercise of prudent business judgment as applied by such Party to other pharmaceutical products of similar potential, market size and legal and competitive environments.
- 1.11 **"Dispute"** has the meaning set forth in <u>Section 14.1</u>.
- 1.12 **"Effective Date"** shall have the meaning set forth in the Preamble.
- 1.13 **"FDA"** shall mean the United States Food and Drug Administration or any successor United States governmental agency performing similar functions with respect to pharmaceutical products, or any foreign equivalent agency or entity having jurisdiction over the manufacture, marketing and/or sale of the Product.
- 1.14 **"Fiscal Quarter"** shall mean any of the three-month periods corresponding with Perrigo's fiscal quarters.
- 1.15 **"Freedom to Operate Analysis"** shall have the meaning set forth in <u>Section 7.2(b)</u>.

- 1.16 **"Fully Allocated Costs"** shall mean Perrigo's, actual direct material costs and labor costs as well as actual and direct fixed and variable overhead costs (including shrinkage, scrap, salvage and obsolescence) for the production, packaging and labeling of the Product.
- 1.17 **"Gross Profits"** shall mean an amount equal to the Net Sales for the applicable Fiscal Quarter, less Fully Allocated Costs related to such Net Sales, as determined in accordance with GAAP, without any markup for "transfer pricing" within the Perrigo group or otherwise, less [\*\*\*] of such Net Sales to cover Perrigo's sales, marketing and distributing activities in respect to the Product.
- "Gross Sales" shall mean, , the total amount invoiced by Perrigo or any of its Affiliates for Sales of the Product in the Territory to any Third Party, including, without limitation, customers, such as wholesalers, drug chains and pharmacies,, as determined in accordance with GAAP, as well as the total value of any consideration or benefits received by Perrigo or any of its Affiliates from a Third Party in exchange for Sales of the Product in the Territory; provided that with respect to Sales in the Territory to any Third Party which are not arm's-length or in the ordinary course of business; or (ii) for less than the seller is then charging in arm's-length transactions for comparable products, while taking into account the then prevailing market conditions, the price invoiced and the consideration per Sale, shall be deemed to be no less than the average Sale price of the Product in arm's-length ordinary course transactions by Perrigo or its Affiliate, as the case may be, for purpose of determining "Gross Sales" with respect to such Sale.
- 1.19 **"Indemnified Party"** shall have the meaning set forth in <u>Section 11.2</u>.
- 1.20 **"Indemnifying Party"** shall have the meaning set forth in <u>Section 11.2</u>.
- **"Intellectual Property"** means (i) patents, patent applications and statutory invention registrations, (ii) copyrights, including registrations and applications for registration thereof, (iii) trademarks, including registrations, applications for registration thereof, and common law rights therein, (iv) design rights, and (v) confidential or proprietary information, including trade secrets, know-how, materials and processes, including but not limited to analytical methods and reference materials.
- 1.22 **"Launch Date"** shall mean the date of first commercial sale of the Product in the Territory by Perrigo or its Affiliates pursuant to the ANDA.
- 1.23 **"Litigation"** shall have the meaning set forth in <u>Section 7.1</u>.
- 1.24 **"Net Sales"** shall mean the Gross Sales (for purposes of determining whether a given sale occurs during a computation period, Product will be considered sold as of the date of shipment by Perrigo to its customers), less the sum of the following (to the extent actually incurred or accrued):
  - a. any and all credits for Product returns in the Territory during such Fiscal Quarter, including, but not limited to, credits for returned, unsold, or short-dated Product, allowances granted or included in the invoice, cash discounts, customer program accruals (overbills, administrative fees, Third Party rebates, sales brokerage, and volume rebates), other adjustments and rebates, including but not limited to Medicaid and other state or governmental rebates, charge backs, floor stock adjustments, and similar items that may be estimated in accordance with U.S. GAAP;

- b. shipping costs, sales and excise taxes, other consumption taxes, or other governmental charges to the extent actually included in Gross Sales;
- c. any receivables which have been included in Gross Sales in the books of Perrigo and are deemed to be uncollectible according to Perrigo's internal accounting principles and U.S. GAAP consistently applied. Such bad debt deduction shall be applied to Net Sales in the period in which such receivables are written off and shall be exclusive of any bad debt or uncollectible receivables of Perrigo unrelated to the Product. In the event that any such deducted bad debt is subsequently collected, the amount collected shall be added to the Net Sales.
- "Orange Book" shall mean the Approved Drug Products book published by the FDA most recently and for subsequent years during the term of this Agreement, including its printed, monthly supplements, and on the electronic version of the Electronic Orange Book found at <a href="http://www.fda.gov/cder/ob/default.htm">http://www.fda.gov/cder/ob/default.htm</a>, or as the site address is amended.
- 1.26 **"Party" or "Parties"** shall have the meaning set forth in the Preamble.
- 1.27 **"Perrigo UK"** shall have the meaning set forth in the Preamble.
- 1.28 **"Perrigo Intellectual Property"** means any and all Intellectual Property of Perrigo owned by or assigned to Perrigo as of the Effective Date of this Agreement.
- 1.29 **"Post-Launch Litigation"** shall have the meaning set forth in <u>Section 7.4</u>.
- 1.30 "Product" shall mean an A-rated generic version of Soolantra® (Ivermectin 1%) cream.
- 1.31 **"Product Specifications"** shall mean the manufacturing, testing, labeling, storage and quality control specifications for the Product as set forth in the ANDA as approved by the FDA.
- 1.32 **"Product Technology"** means all Intellectual Property that specifically relates to the Product and is conceived or reduced to practice by Perrigo, Sol-Gel and/or their Affiliates in the conduct of the program.
- 1.33 **"Regulatory Filing"** shall have the meaning set forth in <u>Section 8.2(b)</u>.
- 1.34 **"Raw Materials"** shall mean all excipients, components, raw materials and any other components required to manufacture, package and label the Product.
- 1.35 **"Regulatory Authority"** shall mean any division of the FDA (as applicable) and any other applicable governmental authority in the Territory.
- 1.36 **"Regulatory Filing"** shall have the meaning given such term in <u>Section 8.2(b)</u> hereof.
- **"Sale"**, shall mean, with respect to the Product, the sale, distribution and any other arrangement in which monetary or other consideration is to be exchanged for the use of the Product.
- **"Sol-Gel"** shall have the meaning set forth in the Preamble.

- 1.39 **"Term"** shall have the meaning set forth in <u>Section 13.1</u>.
- 1.40 **"Termination Event"** shall have the meaning set forth in Section 13.2.
- **"Territory"** shall mean the United States, its possessions and territories.
- 1.42 "Third Party" shall mean any entity or person which is not a party to this Agreement and is also not an Affiliate of a Party to this Agreement.
- 1.43 **"Third Party Manufacturer"** shall mean a Third Party which enters into a manufacture and supply agreement with Perrigo for the manufacture and supply of the Product or Raw Materials.
- 1.44 "U.S. GAAP" means United States generally accepted accounting principles.

#### **ARTICLE II - STEERING COMMITTEE**

## 2.1 <u>Establishment and Composition</u>.

Within 30 days of the Effective Date, the Parties shall establish the Committee ("**Committee**") to oversee Product development and clinical studies, with Perrigo having the right to appoint up to 2 representatives on the Committee and Sol-Gel having the right to appoint up to 2 representatives of the Committee. One Committee member of each Party shall also be designated as the primary contact person for his or her respective Party. One of the representatives selected by Sol-Gel shall chair the Committee.

## 2.2 Responsibilities.

- a. The Committee shall meet and/or confer periodically as needed during the period the program is being implemented.
- b. The Committee shall perform such other functions relating to the program as the Parties may agree.
- c. All major program decisions or other decisions in connection with the implementation of this Agreement, such as selecting any material Third Party contractors, including, without limitation, any contract research organization (CRO) and the material terms of engagement of such contractors shall be decided and approved jointly by the Parties.

#### ARTICLE III - DEVELOPMENT PROGRAM

#### 3.1 The Program.

The Parties shall work towards the overall objective of Perrigo obtaining all FDA approvals necessary for the Commercialization of the Product. Within the program, Perrigo shall use its Diligent Efforts to conduct all regulatory, scientific, clinical and technical activities necessary to develop the Product, and prepare and file with the FDA the ANDA. Perrigo shall use its Diligent Efforts to pursue FDA approval of the ANDA and gain FDA clearance to market the Product. A program budget shall be approved by the Parties based on their reasonable estimates of the program costs, including the costs of all Third Party contractors which *inter aila* details all out-of-pocket clinical study costs (including material) and the program budget shall be attached hereto as **Schedule 3.1**.

- a. Perrigo shall, either directly or through its Third Party contractors, be responsible for the development activities commencing on the Effective Date through acceptance of the ANDA by the FDA, including formulation, analytical work, method validation, scale up and validation.
- b. Perrigo shall prepare all appropriate protocols and conduct the required in vitro and in vivo bio-equivalence studies to be undertaken pursuant to the program, provided however that to the extent that Third Party contractors are engaged, including any CRO, Sol-Gel shall be consulted and its consent required pursuant to Section 2.2(c).
- c. Perrigo shall use its Diligent Efforts to draft, submit and maintain the ANDA and obtain FDA approval for the Commercialization of the Product.
- d. Perrigo shall control all Litigation.
- e. Perrigo shall grant Sol-Gel reasonable access to, or provide Sol-Gel with copies of, without additional charge, cost or expense, any and all documentation, reports, Regulatory Filings and other communications with any Regulatory Authority, or any Third Party contractor, as reasonably requested by Sol-Gel.
- f. Perrigo shall provide to Sol-Gel periodic updates at Sol-Gel's request regarding the status of the program.

## 3.2 Sharing of Costs.

Except as set forth below, each Party shall bear its own costs in relation to the performance of this Agreement and Sol-Gel and Perrigo shall each be responsible for [\*\*\*]% of its internal Development Costs, including all costs related to ANDA submission and maintenance.

- a. Sol-Gel and Perrigo shall [\*\*\*] of in-vitro and non-clinical out-of-pocket development costs related to the Product.
- b. Sol-Gel shall be responsible for [\*\*\*]%, and Perrigo shall be responsible for [\*\*\*]%, of all out-of-pocket clinical study costs (including materials) related to the Product as detailed in the program budget.
- c. Sol-Gel and Perrigo [\*\*\*] of all expenses related to Litigation (subject to Section 7.4 below).
- d. In the event that the out-of-pocket clinical study costs (including materials) related to the Product exceed the costs detailed in the program budget by more than 10%, then Perrigo and Sol-Gel shall [\*\*\*] of all such excess costs.

#### ARTICLE IV- DISCLOSURE OF INFORMATION: PERFORMANCE OF DUTIES

- 4.1 <u>Disclosure</u>. Upon execution of this Agreement and during the Term, each Party shall disclose to the other Party (and such Party's Affiliates and designated representatives) such Confidential Information as is reasonably requested regarding the program and Commercialization.
- 4.2 <u>Confidentiality.</u> Except as specifically authorized by this Agreement, each Party shall, for the Term and for 7 years after the expiration or termination of this Agreement, keep confidential, not disclose to others and use only for the purposes provided for or permitted under this Agreement, the other Party's Confidential Information. Notwithstanding the foregoing, such Confidential Information may be (i) disclosed to Regulatory Authorities or other governmental agencies and others where such Confidential Information is required to be included in Regulatory Filings permitted under the terms of this Agreement or in patent applications filed within the United States Patent and Trademark Office or corresponding international patent offices; (ii) provided to Third Parties under appropriate terms and conditions including confidentiality provisions substantially equivalent to those in this Agreement, in connection with the receiving Party's clinical or bioequivalence testing, consulting, regulatory activities, manufacturing and marketing activities with respect to the Product undertaken pursuant to or as permitted by this Agreement; (iii) published, if and to the extent such publication has been approved by both Parties; or (iv) disclosed to the extent required by applicable laws or regulations or as ordered by a court or other regulatory body having competent jurisdiction. In each of the foregoing cases (i) through (iv), the receiving Party shall disclose only the minimum of information required to be published or disclosed. In the case of a required disclosure under clause (iv) above, the Party required to make the disclosure shall promptly notify the original disclosing Party and shall provide reasonable assistance, if requested by the original disclosing Party and at such disclosing Party's expense, to assist the original disclosing Party in its attempts to prevent or limit the disclosure or obtain confidential treatment of the Confidential Information.
- 4.3 <u>Exclusions</u>. The obligations contained herein governing the use and disclosure of Confidential Information shall not apply to any information which is (i) already known to the receiving Party prior to the date of disclosure as evidenced by its written records made prior to such date; (ii) publicly known prior to or after disclosure other than through unauthorized acts or omissions of the recipient; (iii) disclosed in good faith to the recipient by a Third Party lawfully and contractually entitled to make such disclosure; or (iv) developed by or for the receiving Party without the use of any Confidential Information of the disclosing Party, as evidenced by the receiving Party's written records.
- 4.4 <u>Ownership</u>. Ownership of Confidential Information shall remain with the disclosing Party. Nothing herein is intended to transfer the ownership of any Confidential Information. All Confidential Information furnished to the receiving Party hereunder (and all copies made by the receiving Party) will be returned to the disclosing Party or destroyed immediately upon request. As an exception to the requirement to return or destroy materials incorporating Confidential Information, the receiving Party may retain one copy of the Confidential Information in its legal files solely for the purposes of monitoring its ongoing obligations under this Agreement.
- 4.5 <u>Compliance with Laws.</u> Each Party shall comply with all laws and regulations applicable to it in carrying out its responsibilities and duties as described in this Agreement. Each Party represents that neither it nor any of its employees has been debarred or is subject to debarment proceedings by the FDA. If any such proceedings are commenced against a Party hereto (or any of its employees) during the Term, such Party shall as promptly as practicable, but in no event later than 5 business days following the commencement of such proceedings, notify the other Party in writing and shall keep the other Party informed, on a regular basis, of the status of such proceedings.

#### ARTICLE V - LICENSE AND OWNERSHIP

- 5.1 [\*\*\*] <u>Intellectual Property</u>. Except as otherwise provided in this Agreement, [\*\*\*] shall be and remains the property of [\*\*\*]. [\*\*\*] shall acquire no right, title or interest in the [\*\*\*].
- Product Technology. [\*\*\*] shall solely own [\*\*\*]. [\*\*\*] hereby assigns to [\*\*\*]. [\*\*\*] shall perform, during and after the Term, [\*\*\*] reasonably deems necessary or desirable to permit and assist [\*\*\*], at [\*\*\*] expense, in obtaining, perfecting and enforcing the full benefits, enjoyment, rights and title throughout the world in the [\*\*\*]. [\*\*\*] shall have the [\*\*\*].

#### ARTICLE VI - MANUFACTURE OF THE PRODUCT

#### 6.1 <u>Manufacturing Responsibility</u>.

- a. Prior to the Launch Date, Perrigo shall use Diligent Efforts to manufacture the Product for the pivotal in vitro and in vivo bioequivalence studies and the Product process validation batches. Manufacturing shall be designed to enable Perrigo to lawfully market the Product in the Territory in accordance with the approved ANDA.
- b. After the Launch Date and during the Term, Perrigo shall manufacture, test, release, sell, market and distribute the Product in the Territory in accordance with this Agreement.
- 6.2 <u>Obligations of Perrigo</u>. Without limiting the foregoing, Perrigo shall be responsible for:
  - a. filing and qualifying with the FDA the manufacturing site of Perrigo;
  - b. filing and maintaining distribution shipping records for the Product;
  - c. procuring the active pharmaceutical ingredient for the Product that, to the best of its knowledge, does not violate, infringe, or otherwise conflict or interfere with the Intellectual Property of any Third Party in the Territory;
  - d. conducting all required testing including, without limitation, stability testing for each batch of Product manufactured for use in bioequivalence studies contemplated under this Agreement; and conducting, as required by the ANDA, cGMPs, and FDA regulations, as amended, any and all such testing for all validation batches and all commercial batches of Product; and
  - e. manufacturing, packaging and labeling the Product according to applicable FDA regulations, and all other applicable laws and regulations. Perrigo shall have the exclusive right to define (i) the shape, color, size, embossing and imprinting of each unit or Product, and (ii) packaging and labeling, including package inserts, and all related artwork for containers and any advertising.

- 6.3 <u>Quality Control</u>. Perrigo shall manufacture, test, label, package, and ship all Product, or cause the Product to be manufactured, tested, labeled, packaged, and shipped in accordance with the ANDA, Product Specifications, cGMPs, this Agreement, and applicable law.
- 6.4 <u>Notice of Inspections</u>. Perrigo shall notify Sol-Gel promptly of any inspection of its Affiliates' facilities (or of any facilities of its licensees, distributors, contractors or agents), related to the Product by any Regulatory Authority, including the FDA, and shall upon Sol-Gel's request, send Sol-Gel copies of any written reports or correspondence to or from any Regulatory Authority relating to such inspection.
- Recalls. Subject to Section 11.1 below, in the event that the FDA or any other Regulatory Authority issues or requests a recall or takes similar action in connection with the Product, or in the event Perrigo determines an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, Perrigo shall promptly advise Sol-Gel thereof. Any such market recall or withdrawal shall be controlled by Perrigo. Perrigo shall bear the expenses of any recall including, without limitation and without duplication, the expenses of notification and destruction or return of the recalled Product, the sum paid for the manufacture of the recalled Product, and costs relating to the testing, packaging, shipping and retail trade related costs of the recalled Product. In the event that the recall is based upon acts whose fault cannot be attributed to Perrigo (for example, if the FDA withdraws the entire product (brand and generic) from the market) or any of Perrigo's facilities (or of any facilities of its licensees, distributors, contractors or agents), including, if applicable, its Third Party Manufacturer, the costs shall be allocated based upon the profit split set forth in Section 9.1.

#### **ARTICLE VII - IP LITIGATION**

## 7.1 <u>Cooperation</u>.

Subject to assuring that any and all defense and/or legal privileges remain intact, each Party shall provide reasonable cooperation to the other Party in its efforts to defend against any patent litigation in the United States alleging infringement by the Product. In the event that such litigation is threatened or actually filed prior to the Launch Date, such lawsuit or threat of such lawsuit shall be defined as "Litigation." To this end, the Parties have entered into a Common Legal Interest/Joint Defense Agreement dated as of March 6, 2015.

## 7.2 <u>Intellectual Property Review</u>.

- a. [\*\*\*] shall control any Intellectual Property issues that may arise regarding the Product, including without limitation, the selection and retention of outside legal counsel. Nonetheless, the Parties shall reasonably cooperate to ensure that the development, manufacture, marketing and sale of the Product does not infringe the Intellectual Property rights of any Third Party, each using commercially reasonable efforts to recommend and implement measures to avoid infringement and/or develop evidence to invalidate or render unenforceable Intellectual Property owned by a Third Party.
- b. [\*\*\*] shall be responsible for obtaining from outside legal counsel opinions as to whether the Product as developed and manufactured by Perrigo, including Perrigo's formulation, process and/or active pharmaceutical ingredient, would infringe any Third Party Intellectual Property (such determination of outside counsel the "Freedom to Operate Analysis"). [\*\*\*] shall be responsible for (i) analyzing such Freedom to Operate Analysis as it pertains to the development, manufacture, marketing and/or sale of the Product in the Territory; and for (ii) analyzing the infringement, validity, and/or enforceability of Intellectual Property identified in the Freedom to Operate Analysis.

- 7.3 <u>Patent Certification</u>. The Parties agree that as of the Effective Date there are several patents listed in the Orange Book for the Product for which a Paragraph IV certification is expected to be filed and may have to be litigated.
- Litigation and Settlement. In the event the Product is the subject of Litigation or any actual or threatened litigation based on alleged infringement of a patent, whether listed in the Orange Book subsequent to the Launch Date or of a patent asserted by any Third Party after the Launch Date (collectively "Post-Launch Litigation(s)") in the United States, [\*\*\*] shall direct and control any such Litigation and/or Post-Launch Litigation and shall make Diligent Efforts to conduct any such Litigation and/or Post-Launch Litigation to a successful conclusion, including settlement. [\*\*\*] shall notify [\*\*\*] and seek [\*\*\*] input prior to ceasing to defend, settling or otherwise disposing of Litigation and/or Post-Launch Litigation or a claim in the Litigation and/or Post-Launch Litigation, but the final decision in that regard shall be made by [\*\*\*]. [\*\*\*].

#### **ARTICLE VIII - COMMERCIALIZATION AND SUPPLY**

## 8.1 <u>Commercialization</u>.

a. As soon as reasonably practical after final approval by the FDA of the ANDA, Perrigo shall use Diligent Efforts to Commercialize the Product in the Territory and to maximize the Gross Profits. Perrigo shall not engage any Third Party as a distributor or reseller of the Products in the Territory or permit a Third Party to engage directly or indirectly in the Sale of the Product (by way of license or otherwise), but shall itself engage in all the required sales, marketing and distributing activities in respect to the Product. [\*\*\*].

## 8.2 <u>Regulatory Responsibilities</u>.

- a. Following the approval by the FDA of the ANDA, Perrigo shall be solely responsible for maintaining the ANDA including any necessary periodic reporting requirements. Furthermore, Perrigo shall be responsible for all adverse-event reporting as required by the Act and related regulations, or any successor laws or regulations and any and all other applicable laws in the Territory. Perrigo shall use Diligent Efforts to perform, or cause to be performed, these activities in accordance with this Agreement and in compliance in all material respects with the requirements of any applicable law, and the Product Specifications.
- b. Perrigo shall own all right, title and interest in and to any and all regulatory filings, applications, permits and authorizations, including, but not limited to the ANDA, relating to the approval, manufacture, marketing, sale or licensing of the Product or ingredients for inclusion therein as may be required or useful in the Territory (a "Regulatory Filing"). Perrigo shall also be responsible for filing, obtaining, maintaining, and shall retain the exclusive control of and responsibility for, each such Regulatory Filing including all amendments, supplements and all other communications with the applicable Regulatory Authority.

#### **ARTICLE IX - PAYMENTS**

- 9.1 <u>Payments by Perrigo to Sol-Gel</u>. Within 45 days after the end of each Fiscal Quarter in which the Product is sold in the Territory, Perrigo shall pay Sol-Gel 50% of Perrigo's Gross Profits accruing during the immediately-preceding Fiscal Quarter. Payment shall be accompanied by a report detailing Gross Sales, Net Sales (along with sufficient details on adjustments), and Gross Profits (along with sufficient details on the Fully Allocated Costs).
- Manner of Payment. All payments due hereunder shall be made in United States dollars and, unless otherwise agreed in writing, shall be made by wire transfer to such bank as the Parties may designate in writing. Both Parties shall pay all taxes and levies that by applicable law (including existing treaties for bilateral taxation) they are required to pay on all payments accruing under this Agreement and shall withhold from sums otherwise payable to the other Party all such taxes and levies and shall pay the amount of such withholding taxes to the proper governmental authority in a timely manner. Each Party shall notify the other Party of its intention to withhold in advance of payment being made and shall promptly transmit to the other Party an official tax certificate or other evidence of such tax obligations together with proof of payment from the relevant governmental authority of all amounts deducted and withheld sufficient to enable such Party to claim such payment of taxes. To the extent that either Party withholds any taxes or levies on payments to the other Party pursuant to applicable law, both Parties agree that such expense shall be an expense of, and borne solely by, the payee and the withholding Party shall not be obligated to gross-up any such amounts; provided that the withholding Party shall provide the other Party with reasonable assistance to enable such Party to recover such withholding taxes as permitted by applicable law.
- Books of Account; Audit. Each Party shall maintain true and complete books of account containing an accurate record of all data necessary for the 9.3 proper computation of amounts costs incurred by it during the program and payments due from it under this Agreement and shall cause its Affiliates, to maintain such records. Each Party shall have the right, through an independent certified public accounting firm mutually and reasonably agreed to by the Parties, to audit the books and records of the other Party as such books and records relate to this Agreement, at any time within 3 years after the date of the payment or charges to which they relate (but not more than once in each calendar year or once with regard to any period unless a material discrepancy or error is found, in which case the number of audits shall be in the reasonable discretion of the auditing Party) for the purpose of verifying the amount of such payments or charges and the accuracy of such books and records. Audits shall be made during normal business hours (and without undue disruption to the business or personnel of the Party being audited) at the place of business of the Party being audited. The Parties agree that information furnished as a result of any such audit shall be limited to a written statement by such certified public accounting firm to the effect that it has reviewed the books and records of the Party being audited (or of any Affiliate thereof if applicable) and either (i) the amounts paid or charged under this Agreement are in conformity with such books and records and the applicable provisions of this Agreement, or (ii) setting forth any required adjustments. The fees and expenses of the accounting firm performing such verification shall be borne by auditing Party. If any such examination shows any underpayment or overpayment, or overcharge or undercharge, a correcting payment or refund shall be made within 30 clays after receipt of the written statement described above provided the Party being audited agrees with the findings of the certified public accounting firm performing the audit. If the Party being audited disagrees with such findings, the Parties will attempt, in good faith, to resolve the difference. If after 30 days the Parties fail to settle the difference, the dispute resolution provisions of Article XIV will be followed. Notwithstanding the foregoing, if any such examination indicates that the Party being audited has either overpaid or been overpaid by more than 5% of the total amount owing for such audited period, then the Party being audited shall promptly pay the auditing Party the reasonable out-of-pocket costs and expenses actually incurred in conducting such audit.

#### ARTICLE X - REPRESENTATIONS AND WARRANTIES

#### 10.1 Warranties.

- a. Each Party represents and warrants that neither the execution and delivery of this Agreement by such Party nor its performance hereunder conflicts with or results in any violation or breach of, or constitutes (with or without due notice or lapse of time or both) a default under any of the terms or conditions of any note, bond, mortgage, indenture, license, agreement or other instrument or obligation to which it is a party or by which it or any of its properties or assets may be bound, or violates any statute, law, rule, regulation, writ, injunction, judgment, order or decree of any court, administrative agency or governmental authority binding on it or any of its properties or assets, excluding any such breaches or defaults that, individually or in the aggregate, would not have a material adverse effect on its business or financial condition or its ability to perform its obligations hereunder.
- b. Perrigo represents and warrants that all Products manufactured and sold under this Agreement in the Territory shall be manufactured, packaged, labeled, stored and sold according to the ANDA, cGMPs, and all applicable laws and regulations.

#### ARTICLE XI - INDEMNIFICATION/INSURANCE

Mutual Indemnity. Each Party shall indemnify, defend and hold harmless the other Party and its Affiliates, employees or directors from any and all costs, expenses, damages, judgments and liabilities (including reasonable attorneys' fees and the cost of any recalls) incurred by or rendered against the other Party or its Affiliates, employees or directors in any Third Party claim made or suit brought to the extent resulting from any of the following: (i) a breach by such Party or any of the subcontractors retained by such Party of its obligations, representations and warranties pursuant to this Agreement (except to the extent that such claim or suit is based on the other Party's negligence or breach of its representations and warranties, or its other obligations under this Agreement; (ii) the breach by such Party of its obligations under this Agreement; (iii) the negligence or willful misconduct of such Party or its subcontractors in connection with the Product; or (iv) solely with respect to Perrigo, Perrigo's or its Affiliate's manufacture outside of the Product Specifications, use or sale of the Product.

- Indemnification Process. Upon the occurrence of an event giving rise to indemnification hereunder, the Party entitled to indemnification hereunder (the "Indemnifying Party") shall (i) give prompt notice to the Party providing indemnification (the "Indemnifying Party"), (ii) permit the Indemnifying Party's attorneys to handle and control the defense of such claims, at the Indemnifying Party's expense, and (iii) shall cooperate in the defense thereof. There shall be no settlements, whether agreed to in court or out of court, without the prior written mutual consent of the Parties, except that the Indemnifying Party may settle a claim without the consent of the Indemnified Party if (i) the settlement is purely monetary, (ii) the Indemnifying Party hereunder admits in writing its liability to the Indemnified Party hereunder, and (iii) concurrently with such settlement, the Indemnifying Party pays the full amount owed hereunder. Notwithstanding the foregoing, in the event the Indemnifying Party does not assume the defense of any such claim or litigation in accordance with the terms hereof within the earlier of (i) 90 days following written notice from the Indemnified Party or (ii) the 15th day preceding the due date for response to any complaint filed, then the Indemnified Party may defend against such claim or litigation in such manner as it may deem appropriate, including, but not limited to, settling such claim or litigation, after giving notice of the same to the Indemnifying Party, on such terms as the Indemnified Party may deem appropriate. In any action by the Indemnified Party seeking indemnification from the Indemnifying Party in accordance with the provisions hereof, the Indemnifying Party shall not be entitled to object to the manner in which the Indemnified Party defended such claim or the amount of or nature of any such settlement.
- Mitigation. In the event of any occurrence which may result in either Party becoming required to indemnify the other Party under this Article 11, the Indemnified Party shall, to the extent the Indemnified Party is aware of any mitigating measures that are available to it and commercially reasonable, attempt in good faith to mitigate the damages that may be payable by the Indemnifying Party hereunder.
- 11.4 <u>Apportionment of Damages and Post-Launch Litigation Costs</u>. In the event of a Third Party claim relating to [\*\*\*] Perrigo does not have an obligation of indemnification in accordance with Section 11.1 even if Sol-Gel had been added as a defendant to such Third Party claim, [\*\*\*] to the extent such Third Party claim is not covered by the Parties' insurance.

#### 11.5 <u>Insurance</u>.

- a. <u>General Requirements.</u> Perrigo shall obtain and maintain at its expense during the Term and for a period of at least five (5) years after the termination or expiration of this Agreement, all insurance coverage required by law as well as appropriate insurance coverage to protect against any and all claims or liabilities that may arise directly or indirectly as a result of its performance of its obligations under this Agreement. Insurance shall be placed with a carrier with an A.M. Best rating of at least A- for financial strength and a size rating of at least VIII. Coverage shall be occurrence based, unless occurrence coverage is unavailable, in which case "claims made" coverage is acceptable, provided retroactive coverage is provided prior to the inception of the business relationship between Perrigo and Sol-Gel. None of the requirements contained herein as to coverage types or limits of insurance required to be maintained by the Parties shall be construed to limit in any manner the liability of either Party to the other Party hereunder.
- b. <u>Subcontractors.</u> In the event that Perrigo subcontracts any of its obligations, then it shall require the same insurance coverage and limits from its subcontractors, and require said subcontractors to so certify insurance coverage to such Party prior to the commencement of any work.
- c. <u>Proof of Insurance.</u> Perrigo shall deliver to Sol-Gel, upon request, Certificates of Insurance evidencing the following: (i) the effective and expiration dates of the policies; (ii) for each of the policies, the limits of liability per occurrence and in the aggregate; (iii) that Sol-Gel has been named as an additional insured under each of the policies; and (iv) that Sol-Gel shall be given thirty (30) calendar days advance written notice prior to any cancellation, non-renewal or material change of any of the policies. Perrigo shall provide to Sol-Gel current Certificates of Insurance evidencing renewal of insurance throughout the Term promptly after any change or renewal of the policies.

d. <u>Specific Minimum Coverages.</u> At a minimum, each Party shall keep the following policies in place during the Term:

#### **Required Coverages and Minimum Policy Limit**

Required Coverage	Policy Limit
Worker's Compensation	Statutory
Employer's Liability	\$1,000,000 (U.S.)
Bodily Injury & Property Damage	\$2,000,000
	(U.S. Combined Single Limit,
	per occurrence)
Automobile Liability	\$1,000,000
·	(U.S. Combined Single Limit,
	per occurrence)
Products Liability	\$10,000,000
	(U.S. Combined Single Limit,
	per occurrence)
Umbrella/Excess Liability	\$5,000,000
y	(U.S. Combined Single Limit,
	per occurrence)

#### ARTICLE XII- LIMITATION OF LIABILITY

12.1 EXCEPT FOR THE PARTIES' INDEMNIFICATION OBLIGATIONS UNDER <u>ARTICLE XI</u>, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES, WHETHER THE CLAIM IS BASED UPON CONTRACT, WARRANTY, NEGLIGENCE OR STRICT LIABILITY THEORIES OR OTHERWISE RELATES TO THE FAILURE TO PERFORM ANY OBLIGATIONS SET FORTH HEREIN.

#### ARTICLE XIII - TERM AND TERMINATION: MODIFICATION OF RIGHTS

- 13.1 <u>Term.</u> The term of this Agreement shall commence on the Effective Date and shall continue until the lapse of a twenty (20) year period from the Launch Date or until the occurrence of a Termination Event pursuant to <u>Section 13.2</u> (the "**Term**").
- 13.2 <u>Termination Events</u>. This Agreement shall only be terminated prior to its scheduled expiration upon the occurrence of any of the events set forth in this <u>Section 13.2</u> (each a "**Termination Event**"):

- a. The Parties may terminate this Agreement at any time by written mutual agreement.
- b. Either Party may terminate this Agreement upon a material breach by the other Party; provided that the terminating Party shall provide the breaching Party with a written notice reasonably detailing such breach and such breach or default is not cured within 30 days after receipt of such notice.
- c. Sol-Gel may terminate this Agreement upon 10 days written notice to Perrigo, in the event that prior to the Launch Date, Sol-Gel in its good faith judgment determines that a significant adverse change has occurred and that Perrigo's potential market for the Product envisaged at the time of entering into this Agreement has been reduced by [\*\*\*], including without limitation, a reduction in the market due to regulatory changes, or the entering into the market of two generic competitors, including an authorized generic. It is clarified that in the event of such termination, Perrigo may continue the program and may Commercialize the Product without payment to Sol-Gel and Perrigo shall assume all development costs related to the program that are due and payable following the termination of this Agreement. If however, Perrigo determines to terminate the program, then any expenses, or future cancellation fees, which were approved by the Committee prior to the termination date and which cannot be cancelled or mitigated, shall be reimbursed by Sol-Gel in accordance with Section 3.2.
- d. Either Party may terminate this Agreement upon 10 days written notice to the other Party, in the event that Perrigo's external counsel determines that Perrigo's Product formulation or manufacturing process [\*\*\*].
- e. Without prior written notice, a Party may terminate in the event that: (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; or (iii) this Agreement is assigned by such other Party for the benefit of creditors. It is clarified however that once Sol-Gel has completed its investment in the Product development, Perrigo shall not be entitled to terminate the Agreement pursuant to this section.
- f. Either Party may terminate this Agreement upon 30 days written notice to the other Party, in the event that Gross Profits relating to sales of the Product do not exceed [\*\*\*].
- Rights on Termination. Termination of this Agreement for any reason shall be without prejudice to (i) either Party's rights under this Agreement with respect to claims arising out of events occurring prior to such termination; (ii) either Party's right to receive all payments owed or accrued to it under this Agreement for periods prior to the date of termination; and (iii) any other remedies which either Party may otherwise have. In the event of termination based on Sections 13.2 (b), 13.2(d) or 13.2 (e) (with Perrigo being the breaching in the case of Section 13.2(b), the terminating Party (in the case of Section 13.2(d), or the insolvent Party (in the case of Section 13.2 (e)), Perrigo shall grant to Sol-Gel an exclusive license to all rights, title and interest in and to the Perrigo Intellectual Property and to Product Technology for the purpose of allowing Sol-Gel to commercialize the applicable Product in the Territory. If Sol-Gel does commercialize the Product, Sol-Gel will pay Perrigo [\*\*\*]. In case of termination based on Section 13.2(b) with Perrigo being the breaching Party or if Perrigo terminates under Section 13.2(d), Perrigo will (if so elected by Sol-Gel) manufacture the Product for Sol-Gel until the expiration of the conclusion of the last day of the 20th full calendar year following the Launch Date of the Product and charge the Fully Allocated Costs plus a [\*\*\*]. In the event of termination based on Section 13.2(e), with Perrigo being the insolvent Party, the license to the Perrigo Intellectual Property and the Product Technology granted herein will be deemed a license of rights to Intellectual Property for purposes of Section 365(n) of the U.S. Bankruptcy Code and Sol-Gel will retain and may fully exercise all of its rights and elections under and in accordance with the U.S. Bankruptcy Code.

#### ARTICLE XIV - DISPUTE RESOLUTION

#### 14.1 Dispute Resolution.

- a. Except as otherwise provided in subsection (b) of this <u>Section 14.1</u>, all disputes or claims which may arise under, out of or in connection with this Agreement (each, a "**Dispute**") will be referred in writing by the Party raising the Dispute to the Committee for attempted resolution by good faith negotiations. If the Dispute remains unresolved for more than 10 business days after the notice of such Dispute, the Parties will submit the Dispute to the next step in the dispute resolution process set forth in subsection (b).
- b. If any Dispute is not resolved in accordance with subsection (a), the Dispute will be referred in writing to Sol-Gel's executive responsible for the business unit for which this Agreement pertains and to Perrigo's executive responsible for the business unit for which this Agreement pertains for attempted resolution by good faith negotiations. If they are unable to resolve any Dispute within 10 business days after the referral of such Dispute to them, the Parties shall be allowed to utilize any dispute resolution process.

#### **ARTICLE XV - MISCELLANEOUS**

- Waiver and Amendment. Failure of any Party to require, in one or more instances, performance by the other Party in strict accordance with the terms and conditions of this Agreement shall not be deemed a waiver or relinquishment of the future performance of any such terms or conditions or of any other terms and conditions of this Agreement. A waiver by either Party of any term or condition of this Agreement shall not be deemed or construed to be a waiver of any other term or condition of this Agreement. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement of either Party. This Agreement may not be amended except in writing, signed by both Parties.
- Relationship of the Parties. For all purposes of this Agreement, Perrigo and Sol-Gel shall be deemed to be independent entities and anything in this Agreement to the contrary notwithstanding, nothing herein shall be deemed to constitute Perrigo and Sol-Gel as partners, joint ventures, co-owners, an association or any entity separate and apart from each Party itself, nor shall this Agreement constitute any Party hereto (or any of such Party's personnel) an employee or agent, legal or otherwise, of the other Party for any purposes whatsoever. Neither Party hereto is authorized to make any statements or representations on behalf of the other Party or in any way obligate the other Party, except as expressly authorized in writing by said other Party. Anything in this Agreement to the contrary notwithstanding, no Party hereto shall assume nor shall be liable for any liabilities or obligations of the other Party, whether past, present or future.

- 15.3 <u>Headings</u>. The headings set forth at the beginning of the various Articles of this Agreement are for reference and convenience and shall not affect the meanings of the provisions of this Agreement.
- 15.4 <u>Notices</u>. All notices hereunder shall be delivered by facsimile (confirmed by overnight delivery), or by overnight delivery with a reputable overnight delivery service, to the following address of the respective Parties:

If to Sol-Gel: Sol-Gel Technologies Ltd.

Weizmann Science Park 7 Golda Meir St. Ness Ziona 74036, Israel

Attn: Chief Executive Officer Phone: +972-8-9313433 Fax: +972-8-93134346

If to Perrigo: Perrigo UK Finco Limited Partnership

Wrafton, Braunton Devon EX33 2DL

England

Attn: Perrigo International Holdings II, Inc.

General Partner

and

c/o Perrigo Company 515 Eastern Avenue Allegan, Michigan 49010 Attn: Chief Executive Officer Facsimile: 269-673-1386

With a copy to: Perrigo Company

515 Eastern Avenue Allegan, Michigan 49010 Attn: General Counsel Facsimile: 269-673-1386

All notices shall be deemed to be effective on the day of receipt. Either Party may change the address at which notice is to be received by written notice pursuant to this Section 15.4.

Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, it shall be stricken and the remaining provisions shall remain in full force and effect. However, if a provision is stricken so as to significantly alter the economic arrangements of this Agreement, the Parties agree to negotiate in good faith modifications to this Agreement to effectuate the initial intent of this Agreement.

- Assignment. This Agreement shall not be assigned by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that either Party may assign this Agreement, in whole or in part, to any successor (including the surviving company in any consolidation, reorganization or merger) or successor in interest to such Party's Product-related business or to an Affiliate of such Party. This Agreement will be binding upon any permitted assignee of either Party. No assignment shall have the effect of relieving any Party to this Agreement of any of its obligations hereunder.
- Event of Force Majeure. Neither Party shall be responsible or liable to the other hereunder for the failure or delay in the performance of this Agreement due to any civil unrest, war, fire, earthquake, act of terrorism, hurricane, accident or other casualty, or any labor disturbance or act of God or the public enemy, or any other contingency beyond the Party's reasonable control. In the event of the applicability of this Section 15.7, the Party failing or delaying performance shall use its Diligent Efforts to eliminate, cure and overcome any of such causes and resume the performance of its obligations. Upon the occurrence of an event of force majeure, the Party failing or delaying performance shall promptly notify the other Party, in writing, setting forth the nature of the occurrence, its expected duration and how such Party's performance is affected. The failing or delaying Party shall resume performance of its obligations hereunder as soon as practicable after the force majeure event ceases.
- 15.8 <u>Limitation of Disclosure</u>. Except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission, and except as may be authorized in <u>Section 15.9</u>, no information concerning this Agreement and the transactions contemplated herein shall be made public by either Party without the prior written consent of the other.
- Publicity. Neither Party shall make any publicity releases, interviews or other dissemination of information concerning this Agreement or its terms, or either Party's performance hereunder, to communication media, financial analysts or others without the prior written approval of the other Party. Notwithstanding anything to the contrary in this Agreement, the Parties understand and agree that either Party, may, if so required, disclose some or all of the information included in this Agreement or other Confidential Information of the other Party (a) in order to comply with its obligations under the law, including the United States Securities Act of 1933, as amended, and the United States Securities Exchange Act of 1934, as amended; (b) in order to comply with the listing standards or agreements of any national or international securities exchange, including the Tel Aviv Stock Exchange, the NASDAQ Stock Market or the New York Stock Exchange or other similar laws of a governmental authority; (c) to respond to an inquiry of a governmental authority or Regulatory Authority as required by law; or (d) in a judicial, administrative or arbitration proceeding. In any such event referred to in clause (c) or (d) the Party making such disclosure shall to the extent legally permitted (i) provide the other Party with as much advance notice as reasonably practicable of the required disclosure, (ii) reasonably cooperate with the other Party in any attempt to prevent or limit the disclosure, and (iii) limit any disclosure to the specific purpose at issue.
- 15.10 <u>Survival</u>. <u>Articles IV, V, VII, X, XI and XII</u> and <u>Sections 6.5, 9.3</u> and this <u>Section 15.10</u> shall survive the termination for any reason of this Agreement.

- Power; Authorization. Each Party represents that is has all requisite power and corporate authority to enter into and perform its obligations in accordance with this Agreement. Perrigo Company guarantees to Sol-Gel the performance of Perrigo under this agreement. The above obligation of the Perrigo Company constitutes a continuing guarantee of performance to the extent that Perrigo has failed to cure (within 30 days) any default of its obligations and shall be absolute and unconditional.
- 15.12 <u>Entire Agreement</u>. This Agreement, including the appendices hereto, sets forth the entire understanding between the Parties hereto as to the subject matter hereof and supersedes all other documents, agreements, verbal consents, arrangements and understandings by or between the Parties with respect to the subject matter hereof.
- 15.13 <u>Limitation of Grant</u>. Nothing in this Agreement shall be construed as granting by implication, estoppel, or otherwise, any license or rights than otherwise set forth herein.
- 15.14 <u>Governing Law</u>. This Agreement shall he governed by, and construed, and enforced in accordance with the substantive laws of the State of New York, without giving effect to its rules concerning conflicts of laws.

**IN WITNESS WHEREOF,** the Parties hereto have caused this Agreement to be executed as of the date first written above by their duly authorized representatives.

## PERRIGO UK FINCO LIMITED PARTNERSHIP

Date:

April 29, 2015

## SOL-GEL TECHNOLOGIES LTD.

By:	Perrigo International Holdings II, Inc. General Partner		
Signature:	/s/ John T. Hendrickson	Signature:	/s/ Alon Seri-Levy
Name:	John T. Hendrickson	Name:	Alon Seri-Levy
Title:	Executive Vice President	Title:	Chief Financial Officer
Date:	April 29, 2015	Date:	April 29, 2015
We hereby agree to that stated in <u>Section 15.11</u> above and undertake to act accordingly.			
PERRIGO (	COMPANY		
Signature:	/s/ John T. Hendrickson		
Name:	John T. Hendrickson		
Title:	Executive Vice President		

#### AMENDMENT TO DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION AGREEMENT

This is an Amendment to the Development, Manufacturing and Commercialization Agreement (the "<u>Agreement</u>") dated April 27, 2015, between Perrigo UK Finco Limited Partnership, a United Kingdom limited partnership ("**Perrigo UK**"), and Sol-Gel Technologies Ltd., a **limited liability company incorporated in Israel** ("**Sol-Gel**"). Perrigo UK and Sol-Gel may hereafter be referred to collectively as the "<u>Parties</u>" and individually as a "<u>Party</u>." The Effective Date of this Amendment is October 26, 2015 (the "<u>Effective Date</u>").

#### **BACKGROUND**

- A. Perrigo UK and Sol-Gel entered into the Agreement on April 27, 2015.
- B. The parties desire to amend the Agreement on the terms and subject to the conditions set forth herein.

Accordingly, the parties agree as follows:

- 1. Amend Section 3.2b to now read as follows:
  - b. Sol-Gel shall be responsible for 100% of the out-of-pocket clinical study costs (including materials); provided that in the event that the results of the clinical study are insufficient for obtaining FDA approval for the commercialization of the Product, Perrigo shall participate in Sol-Gel's losses by reimbursing Sol-Gel, upon cessation of the clinical study, an amount equal to 40% of the out-of-pocket clinical study costs paid by Sol-Gel pursuant to this Section 3.2(b).
- 2. Amend Section 3.2c to now read as follows:
  - Perrigo shall be responsible for 100% of all expenses related Litigation, until such time as the Litigation costs incurred by Perrigo equals [\*\*\*]% of the amount that Sol-Gel has paid pursuant to Section 3.2b, and, thereafter, each of Perrigo and Sol-Gel shall be responsible for [\*\*\*]% all expenses related to Litigation (subject to Section 7.4 below).
- 3. Add Section 3.2e to now read as follows:
  - In the event that, as of the cessation of Litigation proceedings, the Litigation related expenses incurred by Perrigo are less than [\*\*\*]% of the amount that Sol-Gel has paid pursuant to Section 3.2b, Perrigo will pay to Sol-Gel [\*\*\*]% of the positive difference between such amount and the amount of Litigation expenses actually incurred by Perrigo.

- 3. No Other Modification; Conflict. On and after the date of this Amendment each reference in the Agreement to "this Agreement," "hereunder," "hereof," or words of like import referring to the Agreement shall mean and be a reference to the Agreement as amended by this Amendment. The Agreement, as amended by this Amendment, is and shall continue to be in full force and effect in accordance with its terms, and except as expressly set forth in this Amendment no other amendment or modification to the Agreement is agreed to or implied. If there is any conflict between the provisions of this Amendment at the provisions of the Agreement, the provisions of this Amendment will control.
- 4. <u>Governing Law</u>. This Amendment shall be governed by, and construed in accordance with, the laws of the State of New York, without regard to choice or conflict of law principles that would result in the application of any laws other than the laws of the State of New York.
- 5. <u>Counterparts</u>. This Amendment may be executed and delivered (including by facsimile or electronic transmission) in one or more counterparts, and by each party hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

The parties have executed this Amendment as of the Effective Date.

PERRIGO UK FINCO LIMITED PARTNERSHIP		SOL-GEL T	ECHNOLOGIES LTD.
By:	Perrigo International Holdings II, Inc. General Partner		
Signature:	/s/ Douglas Boothe	_ Signature:	/s/ Alon Seri-Levy
Name:	Douglas Boothe	Name:	Alon Seri-Levy
Title:	Executive Vice President and General Manager, Rx Pharmaceuticals for Perrigo	Title:	Chief Financial Officer
Date:	10/26/2015	Date:	10/26/2015



## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this amendment No. 1 to the Registration Statement on Form F-1 of Sol-Gel Technologies Ltd. of our report dated March 30, 2017 relating to the financial statements, which appears in such Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

Tel-Aviv, Israel September 6, 2017 /s/ Kesselman & Kesselman

Certified Public Accountants (Isr.)

A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel, P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il