

Tel Aviv, April 3, 2017 Our ref: 13096/2001

# **VIA EDGAR**

Ms. Suzanne Hayes Assistant Director Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

> Re: Sol-Gel Technologies Ltd. Draft Registration Statement on Form F-1 Submitted September 28, 2016 <u>CIK No. 0001684693</u>

Dear Ms. Hayes:

On behalf of Sol-Gel Technologies Ltd. (the "Company"), we provide the Company's response to the comment letter dated October 26, 2016 relating to the above referenced filing.

For your convenience, the relevant comment of the Staff of the Securities and Exchange Commission (the "<u>Staff</u>") has been restated below in its entirety in bold, with the Company's response set forth immediately under it. Capitalized terms used herein but not otherwise defined shall have the meanings ascribed to them in the above referenced Registration Statement on Form F-1 (the "<u>Registration Statement</u>").

#### **Prospectus Summary**

#### Overview of Our Product Candidates, page 2

1. We note that the prospectus states that the only generic product candidate you discuss is ivermectin cream, 1%. According to your description of the current stage of development, this appears to be the product candidate identifies as Product Y on your Website. Please tell us about the product identified as Product X on your website and explain why you have not provided any disclosure about it.

In response to the Staff's comment, the Company has updated its website and removed the reference to Product X, which is currently owned by the controlling shareholder of the Company. In addition, the Registration Statement was revised to identify a new generic product candidate being developed in collaboration with Perrigo UK ("Product Z"), which also appears on the Company's website. The identity of Product Z has not been disclosed at this time as Product Z is a generic product and such disclosure might substantially affect our ability to reach the market before our competitors.

2. Safety and efficacy determinations are solely within the FDA's authority. As your product candidates have not received FDA approval, it is premature to state that they are safe or effective. To the extent that your clinical trials support the statements, you may state that your product candidates have shown to be well tolerated and demonstrated statistically significant improvements. Please revise your statement "VERED demonstrated statistically significant efficacy compared to the control vehicle group" and all other statements indicating that your products are safe and effective.

In response to the Staff's comment, the Company has revised the statements throughout the Registration Statement with respect to the safety and efficacy of its product candidates, and emphasized that based on a Phase II clinical trial that the Company has conducted, and which involved 92 adult patients at ten centers in the United States, the Company observed statistically significant improvements in achieving the IGA success co-primary endpoint and in reducing papulopustular-lesions based on the percentage change in the inflammatory lesion count from baseline at week 12 in the subjects in the VERED group compared to the control vehicle group, as described on pages 80-86.

3. We note your statement in the fourth paragraph that you believe E-06 "will improve patient comfort and compliance as compared to currently approved products." Additionally, we note your disclosure on page 25 indicating that your branded product candidates were not, and will not be subject to head-to-head clinical trials with drugs considered the applicable standard of care. Please revise the referenced statement comparing E-06 and all your other branded products to currently approved products.

In response to the Staff's comment, the Company has revised the foregoing statements on pages 2 and 78 to address the Staff's comment.

# Our Strengths, page 3

4. We note your reference in the second paragraph on page 4 to a "[f]aster NDA approval process compared to new chemical entities." As currently drafted, the disclosure implies that your product candidates will be approved and the process will be easier or faster than the approval process for other chemical entities. Although you may rely upon the FDA's previous findings of safety and efficacy of an approved product, your product is still distinct from prior products approved by the FDA. While it is appropriate for you to say that you will be relying upon prior findings during your development program and the process may be more efficient than if you conducted similar trials, please revise your disclosure to remove any implications that your product candidates will be approved, are more likely to receive FDA approval or will be approved quickly. Please also make similar revisions throughout your prospectus, including in your Business section, as necessary.

In response to the Staff's comment, the Company has revised the disclosure related to the FDA's 505(b)(2) regulatory pathway throughout the Registration Statement, and indicated, per the Staff's recommendation, that such a regulatory pathway may result in a more efficient development program because it permits reliance, in part, on studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and therefore may reduce the number of clinical trials that the Company may be required to independently conduct.

# Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 6

5. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

The Company respectfully advises the Staff that as of the date of this letter it has not made, or authorized anyone to make on its behalf, any written communications, as defined in Rule 405 under the Securities Act of 1933, as amended (the "Securities Act") to potential investors in reliance on Section 5(d) of the Securities Act. If the Company makes, or authorizes anyone to make on its behalf, any written communications, as defined in Rule 405 under the Securities Act, to potential investors in reliance on Section 5(d) of the Securities Act, the Company will provide copies of such communications to the Staff for its review.

6. We note your statement that you may delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. This statement is not consistent with your statement on page 74 which indicates that you have elected to utilize this exemption and will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Please revise your disclosure to provide consistent disclosure about your intent to rely on the extended transition period.

In response to the Staff's comment, the Company has revised the disclosure on page 6 of the Registration Statement to indicate its intention to rely on the extended transition period.

# **Risk Factors**

# The Israeli government grants that we have received..., page 42"

7. Please identify your product candidates that are subject to conditions and restrictions related to Israeli government grants.

In response to the Staff's comment, the Company has revised the disclosure on page 42 to identify the product candidates that are subject to conditions and restrictions related to Israeli government grants.

#### As a foreign private issuer whose shares are listed on the NASDAQ, page 49

8. We note your disclosure on page 55 and throughout the prospectus that you intend to follow home country corporate governance practices. Please revise to provide a concise summary of all material differences between corporate governance practices in Israel and required by NASDAQ for domestic companies.

In response to the Staff's comment, the Company has revised the disclosure on page 49 of the Registration Statement to provide a concise summary of all material differences between corporate governance practices in Israel and required by NASDAQ for domestic companies. In addition, the Company has added a section on home country corporate governance practices on pages 139-140.

# Market and Industry Data, page 55

9. You state "[w]e have not independently verified any of the data from third-party sources nor have we ascertained the underlying economic assumptions relied upon therein." To eliminate any inference that you are not liable for all of the information in your registration statement, please delete this statement or include a statement specifically acknowledging your liability for information that appears in your registration statement that was obtained from third party sources.

In response to the Staff's comment, the Company has deleted the foregoing statement.

# Use of Proceeds, page 56

10. Please revise the discussion to identify the stage of development you expect to achieve with the proceeds of the offering. To the extent you expect to begin particular stage of development but do not expect to complete it, please indicate that you will need to raise additional funding to complete that stage of development.

In response to the Staff's comment, the Company has revised the disclosure under "Use of Proceeds" on pages 57-58 to address the Staff's comment.

11. We note your statement that "[a]s of the date of this prospectus, we cannot predict with certainty any or all the particular uses for the net proceeds., [a]s a result, our management will have broad discretion in the application of the net proceeds." Please revise to clarify whether any of the proceeds from the offering may be used to repay indebtedness, which totaled \$19.7 million. Please provide the disclosure required by 3.C of Form 20-F.

In response to the Staff's comment, the Company has revised the disclosure under "Use of Proceeds" on page 57 to indicate that the proceeds from the offering will not be used for the repayment of any of its indebtedness.

# Management's Discussion and Analysis of Financial Condition and Results of Operations

# Collaboration Agreements, page 64

12. We note that ivermectin cream, 1% is being developed in collaboration with a major generic drug company. Identify your collaborative partner throughout your filing. File the agreement as an exhibit or provide an analysis supporting your determination that you are not required to file it pursuant to Item 601(b)(10) of Regulation S-K.

In response to the Staff's comment, the Company has revised the Registration Statement to identify the collaborative partner, Perrigo UK Finco Limited Partnership ("Perrigo UK"). In addition, the Company will file the agreement with Perrigo UK as an exhibit as soon as practicable. The Company also notes that confidential treatment will be requested for this exhibit.

13. Please expand the discussion of your collaborative agreement related to ivermectin cream, 1% to disclose termination provisions and each party's obligations under the agreement, including cost sharing provisions and expenses related to potential patent infringement litigation.

In response to the Staff's comment, the Company has expanded the description of the terms of the collaboration agreement related to ivermectin cream, 1%, on pages 65 and 91.

14. Please file your agreement with Perrigo Israel as an exhibit or provide an analysis supporting your determination that you are not required to file it pursuant to Item 601(b)(1) of Regulation S-K. Furthermore, please also describe all termination provisions and disclose when the obligation to pay royalties terminates.

The Company acknowledges the Staff's request and notes that it will file the agreement with Perrigo Israel as an exhibit as soon as practicable. The Company also notes that confidential treatment will be requested for this exhibit. In addition, the Company has expanded the description of the terms of the agreement with Perrigo Israel on pages 65 and 91.

# Significant Accounting Policies and Estimates

#### Stock-Based Compensation, page 71

15. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

The Company acknowledges the Staff's comment. The Company shall supplementally provide the information requested by the Staff once such information becomes available.

16. As a related matter, we note that you performed a retrospective valuation in April 2016 in which you determined your enterprise value and allocated it among the different elements of your share capital using an option pricing model. Please tell us how the August 4, 2014 securities purchase agreement with Arkin Dermatology in exchange for a cash payment of approximately \$10.5 million in addition to an earn out payment of up to \$17.0 million based on the achievement of certain development and revenue-related milestones was considered in the calculation of your enterprise value.

In response to the Staff's comment, the Company respectfully advises the Staff that the Company's value, as reflected in the August 2014 purchase agreement, was based on the Company's financial position at that time, which resulted in the suspension of the development of all of its projects. However, the valuation as of April 2015 took into consideration the additional investment of \$5.6 million made by the Company's controlling shareholder and the renewal of the Company's projects, resulting in an enterprise value of approximately \$41.3 million.

## Business, page 75

17. We note your statement on page 1 indicating that you believe your microencapsulation delivery system enables you to develop topical dermatological drug products "with potentially significant advantages over existing marketed drug products" and your similar discussion under "[proprietary microencapsulation drug delivery system" on page 4. Please revise this discussion to provide the basis for your belief. Alternatively, remove statements indicating that your technology enables you to develop products with advantages to existing products.

In response to the Staff's comment, the Company has revised its disclosure on pages 1, 64 and 76 to indicate that the basis for such a belief are the results of a nonclinical study conducted by the Company.

# Branded Product Candidates, page 80

18. Please identify the product candidates that were partially funded based on OCE grants and quantify your royalty obligations with respect to these product candidates. Additionally, revise the description of ivermectin cream, 1%.

In response to the Staff's comment, the Company has revised the Registration Statement on pages 42 and 106 to identify the product candidates that were partially funded based on OCS grants. Quantitative information on the royalty obligations is disclosed on pages 105-106 of the Registration Statement.

19. To the extent there were any serious adverse effects related to treatment with any of your branded or generic product candidates, please revise your disclosure to describe the effects.

In response to the Staff's comment, the Company has revised the Registration Statement on page 78 to indicate that as of the date hereof, no deaths or other serious adverse events were reported during the ongoing clinical trials.

20. We note on page 81 that during the Phase II trial for VERED the first co-primary endpoint was the proportion of patients with a two grade reduction in investigator global assessment, or IGA, scored clear or almost clear. Please describe any guidance that was provided in determining what constituted "clear" or "almost clear."

In response to the Staff's comment, the Company has revised the Registration Statement on page 81 to describe its definitions of "clear" or "almost clear" in the VERED Phase II trial and its correspondence with the FDA on this matter.

# Our Topical Drug Delivery Technology Platform, page 90

21. We note your statement on page 91 that "[t]he FDA preliminarily accepted [your] suggested in-process specification and analytical procedures for the encapsulated product candidates." Please summarize the nature and extend of your communications, if any, with the FDA regarding your product candidates and clinical trials.

In response to the Staff's comment, the Company has revised the Registration Statement on page 91 to remove the reference to the correspondence with the FDA regarding the preliminarily acceptance of the Company's suggested in-process specification and analytical procedures for the encapsulated product candidates.

# Intellectual Property, page 91

22. Please expand your disclosure to indicate the products related to your current patents and patent applications. Additionally, clarify the type of patent protection such as composition of matter, use of process; provide patent expiration dates or expected expiration dates for patent applications; and identify the applicable jurisdictions for existing patents and pending patent applications.

In response to the Staff's comment, the Company has revised the Registration Statement on page 92 to clarify that a portion of its patent portfolio is related to its product candidates while the remainder of Company's patent portfolio relates to other technologies unrelated to its product candidates. In addition, the Company has revised this section of the Registration Statement to include

the types of protection afforded by these patents. As noted on page 92 of the Registration Statement, the Company believes that only one U.S. patent and one pending U.S. patent application are material to its business. Therefore, the Company has only included the expiration dates relating to this material patent and patent application, as well as supplemented the disclosure to provide further information regarding these patents' foreign counterparts.

23. We note your disclosure on page F-13 that you licensed certain commercialization rights with respect to Yissum patents. Please tell us whether any of your product candidates are dependent on technology you licensed from Yissum.

The Company's agreement with Yissum subjects the Company to royalty payments for products covered by the Yissum patents and/or other Company patents as defined by that agreement. The Company's encapsulated products (VERED, TWIN, and SIRS-T) are dependent on the technology we license from Yissum.

# Exhibits, page II-3

24. Please file your employment or services agreements with your executive officers and the 2014, 2015 and 2016 loan agreements with Arkin Dermatology as exhibits.

The Company respectfully advises the Staff that it is a 'foreign private issuer' that furnishes compensatory information required by Items 6.B and 6.E.2 of Form 20-F, and it is therefore deemed compliant with Item 402(a)(1) of Regulation S-K. Accordingly, the Company respectfully advises the Staff that it is exempt from filing the employment or service agreements with its executive officers as exhibits pursuant to Item 601(b)(10)(c)(5) of Regulation S-K. The Company has filed the loan agreements with Mr. Moshe Arkin as exhibits to the Registration Statement. The Company also notes that it has modified disclosure about such loan agreements on page 131.

25. Please tell us the basis for your determination not to file your lease agreement for your facility in Weizmann Science Park referenced on page 106.

In response to the Staff' comment, the Company has filed informal English translations of the lease agreements as exhibits to the Registration Statement.

#### Other

26. Please submit all outstanding exhibits as soon as practicable. We may have further comments upon examination of these exhibits.

The Company acknowledges the Staff's request and notes that it is filing additional exhibits on the date hereof and intends to file the balance of the exhibits as soon as practicable. The Company also notes for the Staff that confidential treatment will be requested for certain exhibits filed on the date hereof.

27. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

In response to the Staff' comment, the Company advises the Staff that it may provide graphic, visual or photographic information to the Staff under separate cover with sufficient time for the Staff to review prior to the circulation of preliminary prospectuses.

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We would be happy to discuss any questions or comments you might have regarding the response set forth herein. Please do not hesitate to call the undersigned at +972-3-607-4444.

Very Truly Yours,

/s/ Gene Kleinhendler

Gene Kleinhendler, Adv. Gross Kleinhendler Hodak Halevy Greenberg & Co.

cc: Alon Seri-Levy, Chief Executive Officer, Sol-Gel Technologies Ltd.