
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of January, 2019

Commission File Number 001-38367

SOL-GEL TECHNOLOGIES LTD.

(Translation of registrant's name into English)

7 Golda Meir Street
Ness Ziona 7403650, Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Attached hereto and incorporated by reference herein are the following documents:

[Exhibit 99.1: Sol-Gel Technologies Ltd. Corporate Presentation](#)

SIGNATURES

SOL-GEL TECHNOLOGIES LTD.

Date: January 7, 2019

By: /s/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer



Cautionary Note on Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “future,” “outlook,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “continue,” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this presentation relate to, among other things, statements regarding the commencement of our planned clinical trials for TWIN, the commencement of our planned bioequivalence study for a generic product candidate, our expected date to report top-line data from our pivotal Phase III clinical programs for Epsolay and TWIN and estimated sales of our product candidates. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement, including but not limited to, the following: the fact that we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our ability to complete the development of our product candidates; our ability to obtain and maintain regulatory approvals for our product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; our ability to rely on data from our Phase II TWIN trial to advance the development of SIRS-T; our ability to commercialize our product candidates; our ability to obtain and maintain adequate protection of our intellectual property; our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; our ability to establish adequate sales, marketing and distribution channels; acceptance of our product candidates by healthcare professionals and patients; the possibility that we may face third-party claims of intellectual property infringement; the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their products; intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; potential product liability claims; potential adverse federal, state and local government regulation in the United States, Europe or Israel; and loss or retirement of key executives and research scientists. These and other important factors discussed in the Company’s Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”) on March 26, 2018 and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this presentation. While we may elect to update such forward-looking statements at some point in the future, unless required by applicable law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

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Our Dermatology Company



- Primed to become a global dedicated dermatological company
- Complementary combination of branded and generic topical drugs pipelines
- Proprietary topical microencapsulation delivery system
- Significant inflection points expected from Phase III trials as early as 2019
- Seven established collaborations with two strategic partners on generic candidates
- Tentative approval for 1st generic drug product
- Proven track record combined with broad dermatological knowhow

Common Indications Requiring Better Therapies

Acne Vulgaris

- A disease of the pilosebaceous unit, involving abnormalities in sebum production, follicular epithelial desquamation, bacterial proliferation and inflammation
- Benzoyl peroxide (BPO) and tretinoin are mainstay therapies
- Tretinoin is the most widely used Rx topical retinoid, but is rapidly decomposed by BPO and causes irritation
- BPO/tretinoin combination does not currently exist on the market
- ~\$2.7 billion sales in the U.S. in 2017 of several promoted topical brands and many generics, of which fixed-dose combination drugs account for ~\$900 million
- Dermatologists often prefer branded topical drugs even though cheaper generics and OTC alternatives exist

Papulopustular Rosacea

- A chronic, inflammatory skin condition affecting nearly 5 million people in the US
- ~\$395 million sales in the U.S. in 2017 of topical products: Soolantra®, Finacea® and generic metronidazole
- Poor patient adherence to current drugs

Our Branded Drug Product Candidates

TWIN

acne vulgaris

- **A cream containing a fixed-dose combination of encapsulated tretinoin and encapsulated benzoyl peroxide**
- Major challenges were the instability of tretinoin in the presence of benzoyl peroxide and irritation
- Encapsulation allows stabilization and is also expected to contribute to patient compliance
- Opportunity exists for shift from prescribing tretinoin and existing combinations to prescribing TWIN
- We estimate peak annual sales of \$350M - \$400M^(†).

SIRS-T

acne vulgaris

- **A topical formulation containing encapsulated tretinoin**
- Common side effects of tretinoin include itching, redness, swelling, dryness, peeling and scaling
- Encapsulation was designed to reduce irritation and is therefore expected to contribute to patient compliance
- Potential to be the 1st FDA-approved encapsulated tretinoin and more tolerable than currently available tretinoin drugs

Epsolay®

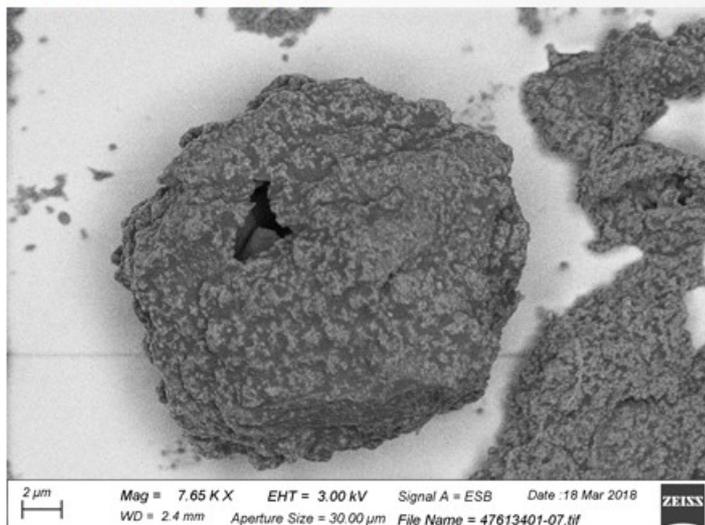
papulopustular
rosacea

- **A cream containing encapsulated benzoyl peroxide, 5%**
- Encapsulation was designed to reduce irritation caused by benzoyl peroxide
- Potential to be the 1st FDA-approved single-active benzoyl peroxide prescription drug product
- We estimate peak annual sales of \$75M - \$100M^(†)

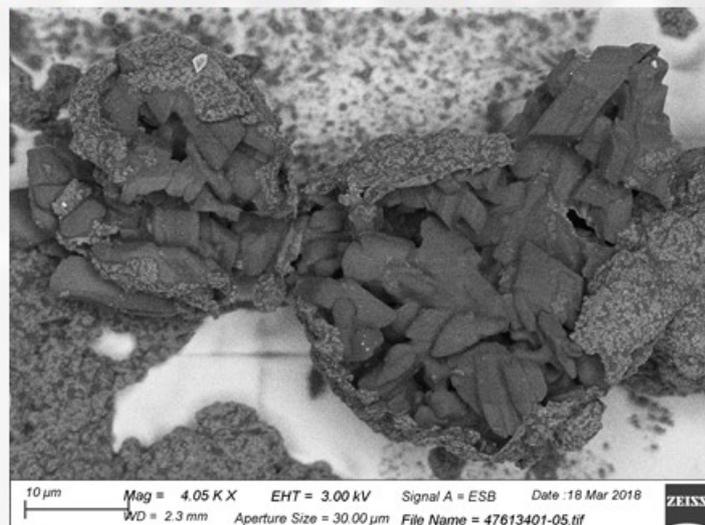


Our Microencapsulation Platform

Encapsulated tretinoin microcapsule

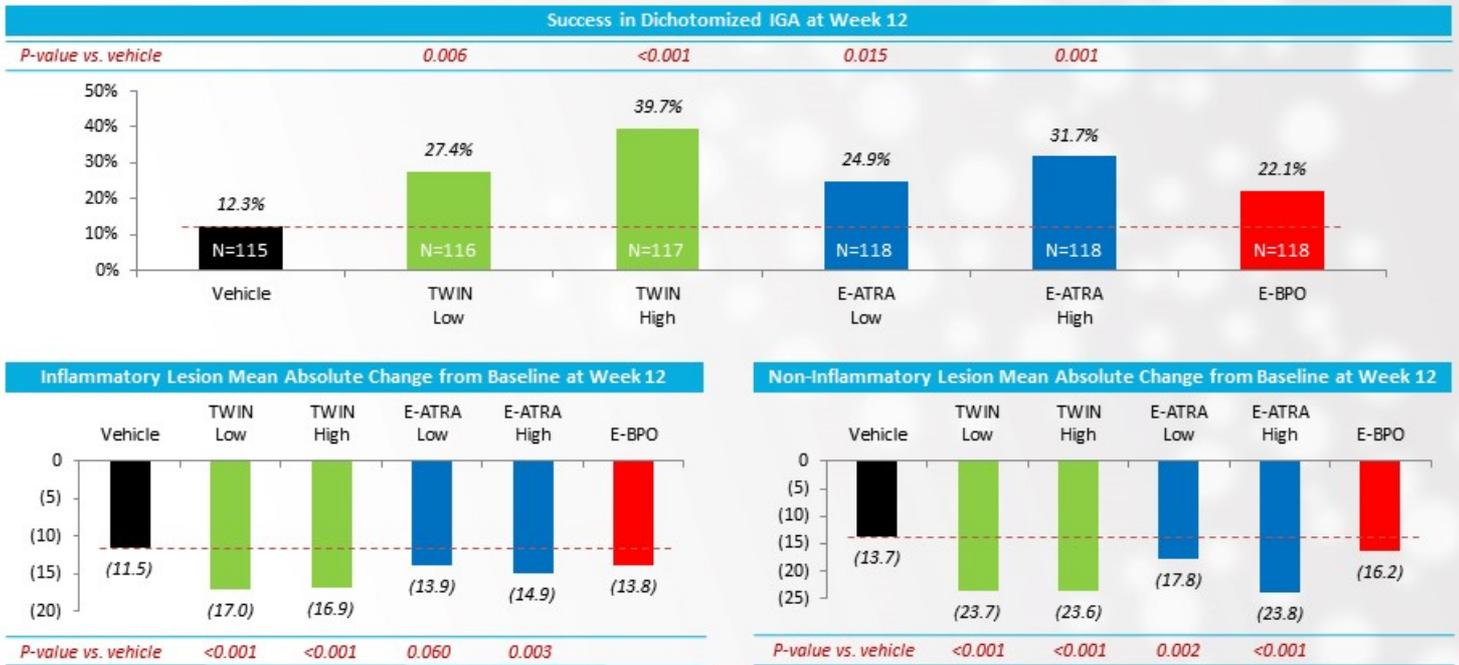


Encapsulated tretinoin crystals inside broken microcapsule



SEM pictures of our silica-based encapsulated tretinoin

Positive TWIN Factorial Phase II Results (ITT)^(†)



^(†) The above calculations were made using Markov Chain Monte Carlo multiple imputation method for handling missing data and without data from one center that discontinued the study. Analyses without imputation (with or without the discontinued center) were highly consistent with the above.

Acne Trials Efficacy Results^(†): Moderate Patients

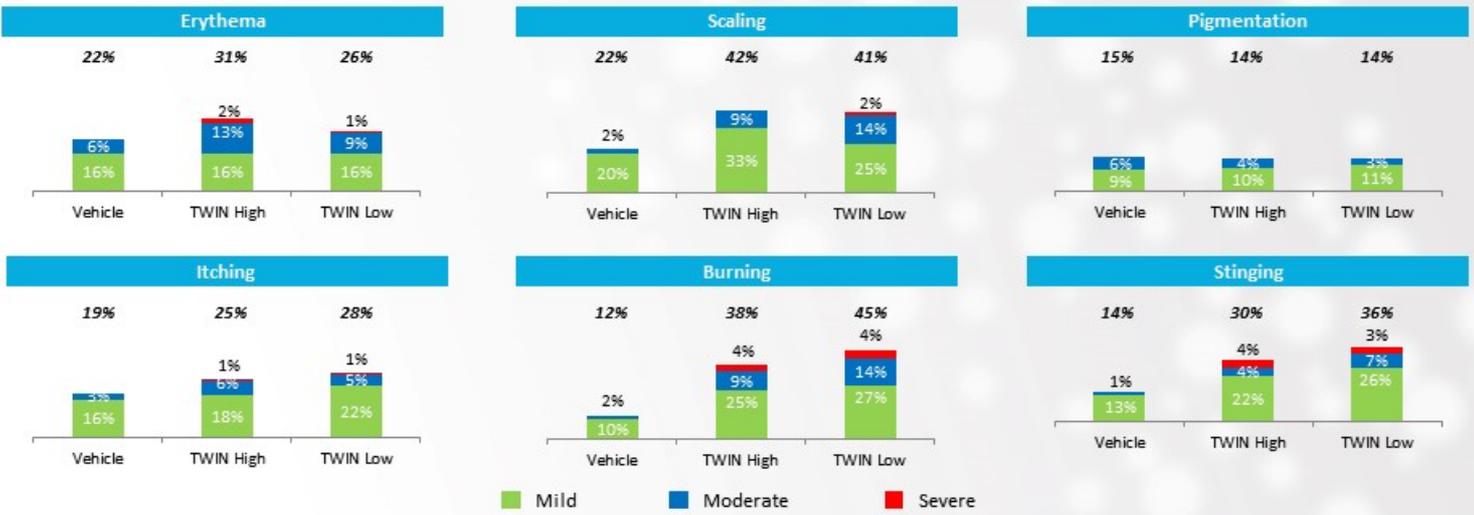


^(†) Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study.

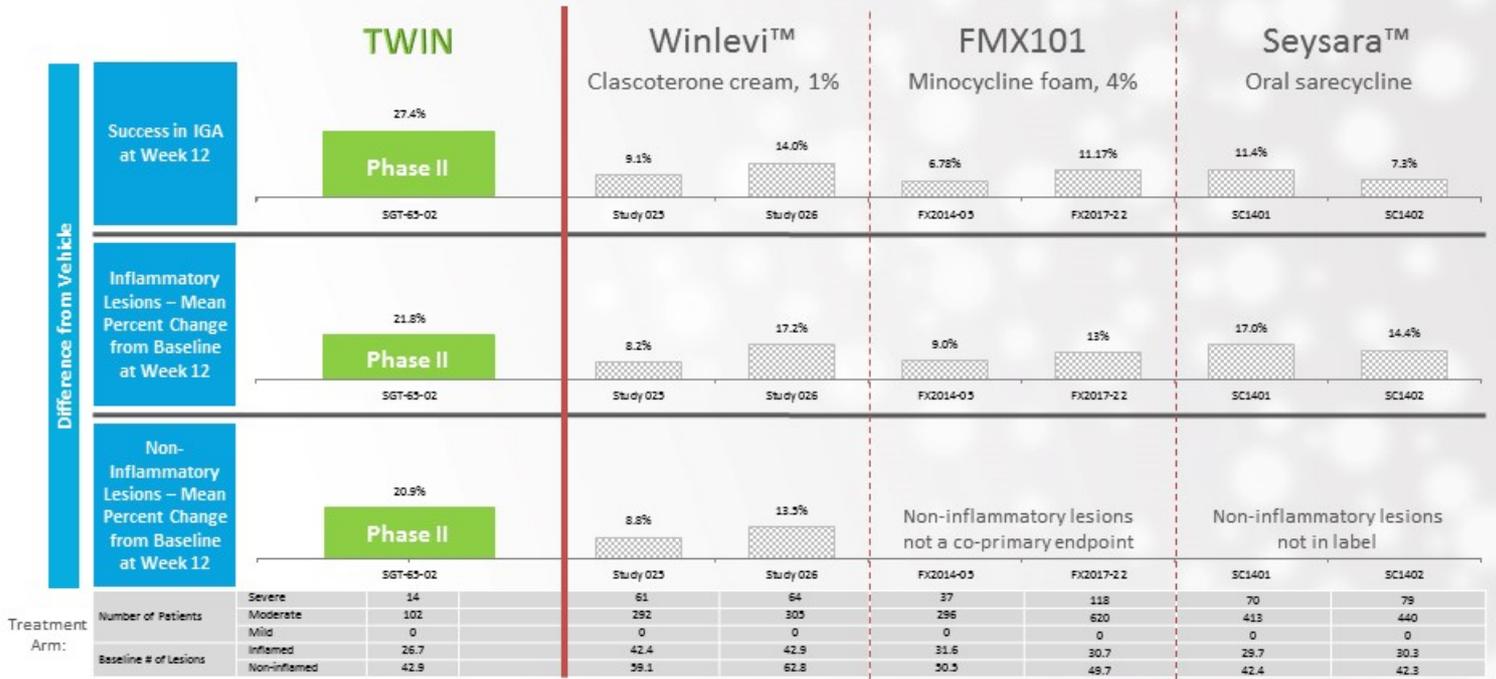
Phase II Cutaneous Tolerability of TWIN

Proportion of Subjects with Post-Baseline Worsening of Cutaneous Side Effects (Safety Population)

Max. Post-Baseline > Baseline



Efficacy Results of Recent Acne Trials^(†)



^(†) Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study.

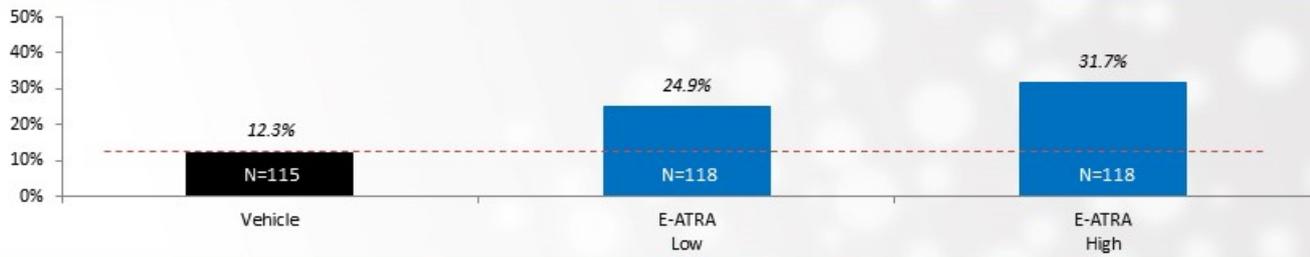
Supportive SIRS-T Clinical Results (ITT)

Success in Dichotomized IGA at Week 12

P-value vs. vehicle

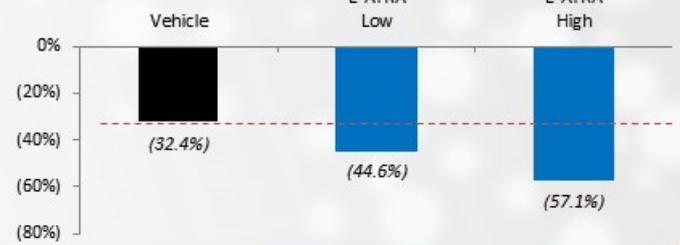
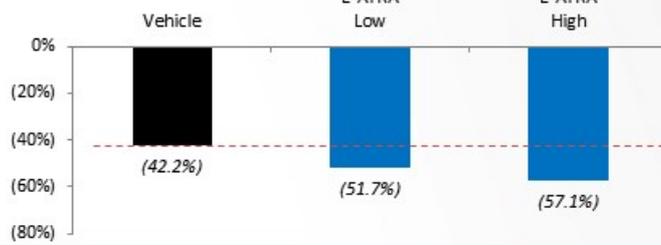
0.015

0.001



Inflammatory Lesion Mean Percent Change from Baseline at Week 12

Non-Inflammatory Lesion Mean Percent Change from Baseline at Week 12



P-value vs. vehicle

0.060

0.003

P-value vs. vehicle

0.002

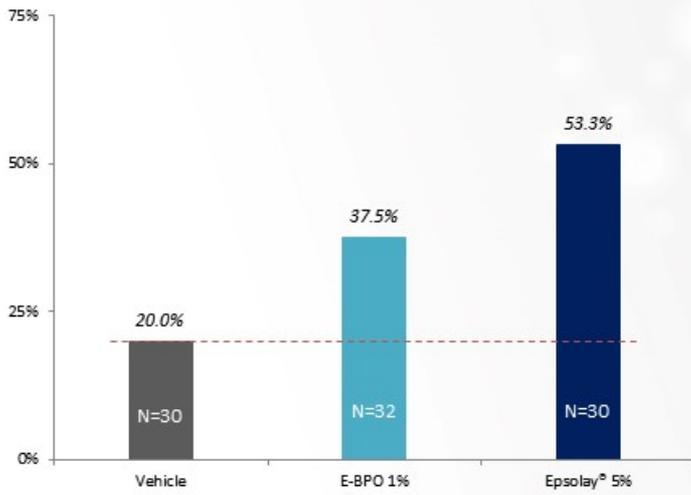
<0.001

Positive Epsolay[®] Phase II Results (ITT)

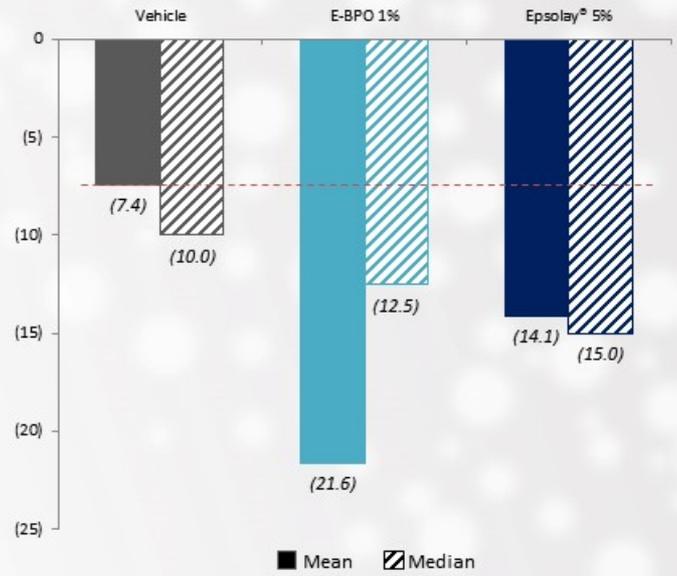
Success in Dichotomized IGA at Week 12^(†)

P-value vs. vehicle

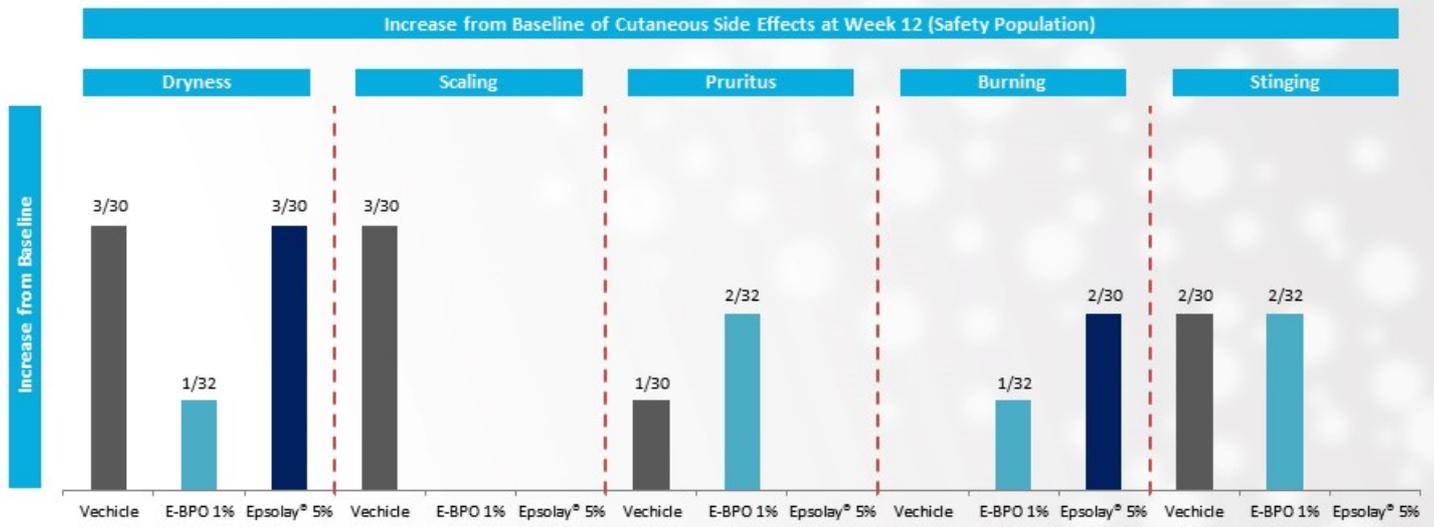
0.0013



Inflammatory Lesion Count – Change from Baseline at Week 12



Phase II Cutaneous Tolerability of Epsolay®



Papulopustular Rosacea Trials Results^(†) (ITT)



(1) "clear" definition: "no inflammatory lesions present with no or very mild erythema immediately localized to and around where inflammatory lesions were present"
 (2) 10-week study

^(†) Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study

Highly-Powered Phase III Trials and Mitigated Risks

Epsolay®

- Each pivotal trial is planned to enroll 350 subjects in a 2:1 ratio, with a power > 99%
- Long-term safety study (LTSS) was initiated in September 2018
- No pediatric and no Phase I clinical trials are required to support our future marketing application
- Subject to favorable results from our Phase III clinical program, we plan to submit an NDA in 2020

TWIN

- Only TWIN and vehicle are required for the pivotal trials, as the requirements of the combination rule act were satisfied in our Phase II trial
- Each pivotal trial is planned to enroll 420 subjects in a 2:1 ratio, with a power of 99%
- No LTSS is required to support our future marketing application, as long as we demonstrate that the systemic exposure of our product is comparable to our reference-listed drug (RLD)
- No pediatric clinical studies are required to support our future marketing application
- Subject to favorable results from our Phase III clinical program, we plan to submit an NDA in 2020

Our Generic Pipeline



Lucrative Pipeline

- A portfolio of generic product candidates with favorable commercial agreements that supplement our branded pipeline and potentially make a meaningful contribution to operating income
- Six collaborations with Perrigo and one with Douglas Pharmaceuticals with 50/50 gross profit sharing

1st Fruition

- Last January Perrigo received tentative approval from the FDA for ivermectin cream, 1%, developed in collaboration with Sol-Gel
- Perrigo was second to file and, as of today, there is no public disclosure of another tentative approval or a third filer to the FDA
- Sales of RLD reached \$150M in the 12 months ending May 2018^(†), and are expected to exceed \$200M annually by 2020

News Flow

- Bioequivalence study results for 5-fluorouracil cream, 5%, in 2019

Financial Profile



- Gross proceeds of \$86.3 million raised in IPO of 7,187,500 ordinary shares on February 5, 2018
- 18,949,968 shares outstanding as of September 30, 2018
- \$73.5 million of cash and investments as of September 30, 2018
- Cash runway expected to be sufficient to fund Phase III clinical programs for TWIN and Epsolay® and a bioequivalence study

Our Upcoming Milestones



Recent Milestones and Next Steps

2017

- Reported positive results from TWIN Phase II trial in acne vulgaris
- Had an EoP11 meeting with the FDA about Epsolay®
- Submitted a Paragraph IV ANDA, for ivermectin cream, 1% (sponsored by Perrigo)

2018

- Obtained tentative ANDA approval for ivermectin cream (sponsored by Perrigo)
- Had an EoP11 meeting with the FDA about TWIN and addressed the combination rule act
- Initiated Epsolay® Phase III program in papulopustular rosacea
- Initiated LTSS for Epsolay®
- Initiated TWIN Phase III program in acne vulgaris
- Initiated a bioequivalence study for 5-fluorouracil cream, 5% in actinic keratosis
- Hired U.S. commercialization leader for the launches of TWIN and Epsolay®

2019

- Plans to have EoP11 meeting with the FDA for SIRS-T
- Plans to report Phase III results for Epsolay® in papulopustular rosacea
- Plans to report Phase III results for TWIN in acne vulgaris
- Plans to report bioequivalence study results for 5-fluorouracil cream, 5%

Wrap-Up



- Epsolay® has the potential to be more effective than existing drugs and the 1st FDA-approved single-active BPO prescription drug product. Topline results of pivotal trials are expected in mid-2019. We estimate peak annual sales of \$75M - \$100M
- TWIN combination of BPO/tretinoin does not currently exist on the market. Pivotal trials are planned for Q4/2018. Opportunity exists for shift from prescribing tretinoin and existing combinations to prescribing TWIN. We estimate peak annual sales of \$350M - \$400M
- SIRS-T has the potential to be more tolerable than currently available tretinoin drugs and the 1st encapsulated tretinoin on the market. EoPII meeting is planned for 2019
- Seven 50/50 gross profit sharing partnerships regarding generics including tentative ANDA approval for ivermectin cream. As of today we are the only ones to have tentative approval and no 3rd filing exists with the FDA



NASDAQ: SLGL

www.sol-gel.com
