## 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 of the Securities Exchange Act of 1934

For the month of July 2019

Commission File No.: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):

#### INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

The Company is posting on its website the Sol-Gel Technologies Ltd. Corporate Presentation.

Attached hereto and incorporated by reference in this Report on Form 6-K is the following exhibit:

Exhibit 99.1: Sol-Gel Technologies Ltd. Corporate Presentation.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOL-GEL TECHNOLOGIES LTD.

By: /s/ Gilad Mamlok

Gilad Mamlok Chief Financial Officer

Date: July 23, 2019

<u>Exhibit 99.1</u>



## NASDAQ: SLGL



#### 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 bioequivalence study for a generic product candidate, our expected date to report top-line data from our pivotal Phase III clinical program for TWIN, our anticipated NDA submission dates 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 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 21, 2019, 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

This presentation contains trademarks, trade names, and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other parties' trademarks, trade names, or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.





Company and Products Overview | July 2019

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## PIPELINES & UPCOMING MILESTONES



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## FOUNDATION FOR BRANDED PRODUCT PIPELINE



#### WHY SILICA?

1

FDA approved for topical use

Smooth, no-grit feel for user

Physical properties of silica shell tuned to modify release of active ingredient

Strong IP protection to 2032 (Epsolay®) and 2038 (TWIN)

Proprietary process produces high encapsulation efficiency







SOL-GEL PROCESS

Silica monomers and drug substance are emulsified together

Silica monomers migrate to the oil/water interface in a well-controlled process

A silica shell, microcapsule is formed

#### POTENTIAL BENEFITS

3

If approved, will be first core-shell encapsulation system for topical dermatology products

APIs stabilized via microencapsulation, allowing for novel combinations

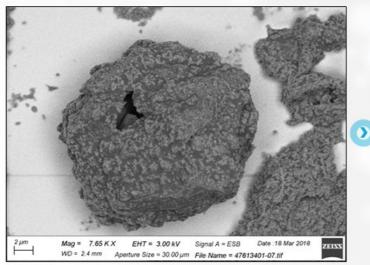
Barrier between entrapped API and skin may reduce irritation and improve compliance

Hurdle for generics to demonstrate similar release profile

## HIGH ENCAPSULATION EFFICIENCY ENHANCES STABILITY

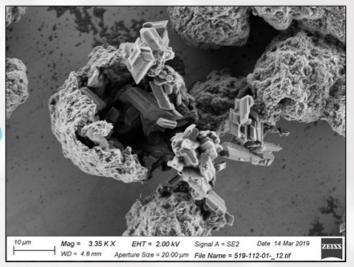


#### **Encapsulated Tretinoin (E-ATRA)**



SEM PICTURE

High encapsulation efficiency protects tretinoin



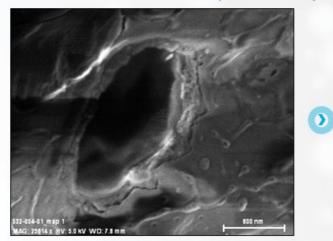
SEM PICTURE

Encapsulated tretinoin is stable in the presence of benzoyl peroxide

## CONTROLLED RELEASE IMPROVES TOLERABILITY

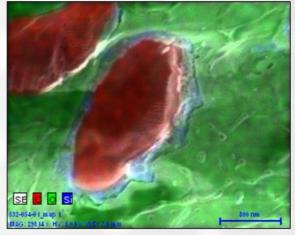


Encapsulated Benzoyl Peroxide (E-BPO)



CRYO-SEM PICTURE

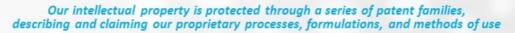
Silica shell wraps BPO crystals and serves as a barrier between benzoyl peroxide crystals and skin, leading to less irritation



ENERGY-DISPERSIVE X-RAY SPECTROSCOPY MAPPING

Skin lipids migrate through the silica shell to promote solubilization of BPO. Dissolved BPO then migrates to skin's sebaceous follicles

## INTELLECTUAL PROPERTY ESTATE



	Patents and	l Trademarks		IP Protection for	Our Branded Products (US)
		# of Patents Relate Company Produc		Product/Indication	IP, Expiry
US Patents	Granted/Allowed	4			
	Pending	16		EPSOLAY® subtype II rosacea	Granted/Allowed, 2032 Pending, 2040
oreign Patents	Granted/Allowed	29	(	>	
	Pending	14		TWIN	Granted/Allowed, 2038
Trademarks	Registered/ Allowed	4 in US, IL, CA, EP	EPSOLAY®	acne vulgaris	Pending, 2040
	Registered/ Allowed	5 in US, CA, EP, IL	TWIN		

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## PAPULOPUSTULAR ROSACEA— INFLAMMATORY CONDITION WITH POOR ADHERENCE TO CURRENT TREATMENTS

Chronic, inflammatory condition that primarily affects the face, and is often characterized by flushing, redness, inflamed bumps, and pustules

## What is papulopustular rosacea?

Affects approximately 16 million in the United States  $^1$  —  $^5$  million have papulopustular  $^2$ 

Topical antimicrobials or anti-mites (metronidazole, clindamycin, ivermectin) and systemic antibiotics (minocycline, doxycycline)

# What are the current treatments shortfalls?

How is it treated?

Insufficient efficacy resulting in poor adherence; contributing to antibiotic resistance; systemic side effects; misdiagnosis is common<sup>1,3</sup>

Erythematotelangiectatic



National Rosscea Society, <u>www.rosscea.org</u>
 Berg, M. and Uden, S. Ada Darm Venerol. 1989;69: 419–425
 Previelance Orossca. <u>http://www.rosscea.org/rr/index.ong</u>
 Gether L et al. Br./ Dermetol. 2018;179:181-289
 Wilkin J et al. J Am Acab Dermetol. 2018;179:181-289
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Multiple subtypes/phenotypes often seen in a single patient<sup>4,5</sup>

## **EPSOLAY**<sup>®</sup> MICROENCAPSULATED BPO CREAM, 5%



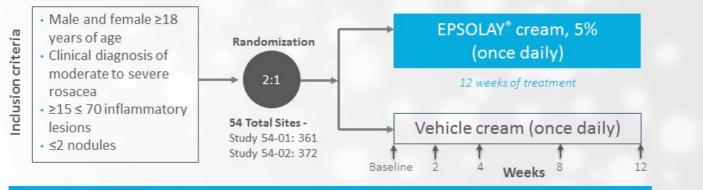
Potential to be more effective than existing treatments

Potential to be the first FDA-approved single-active BPO Rx drug product

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## EPSOLAY® STUDY DESIGN

#### Two phase III, double-blind, randomized, vehicle-controlled studies



#### PRIMARY ENDPOINTS:

- Proportion of patients with the primary measure of success "Clear" (0) or "Almost clear" (1) in the Investigator Global Assessment (IGA) relative to Baseline at Week 12
- Absolute mean change in inflammatory lesion counts from baseline to Week 12

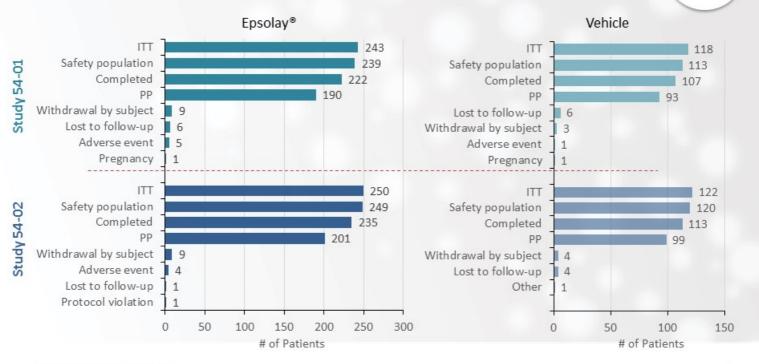
#### SECONDARY ENDPOINTS:

- Inflammatory lesion percentage change from baseline to Week 12
- Absolute mean change in inflammatory lesion counts from baseline at Week 8 and Week 4
- Proportion of patients with the primary measure of success "Clear" (0) or "Almost clear" (1) in the Investigator Global Assessment (IGA) relative to Baseline at Week 8 and Week 4

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## STUDY POPULATION & DISCONTINUATION



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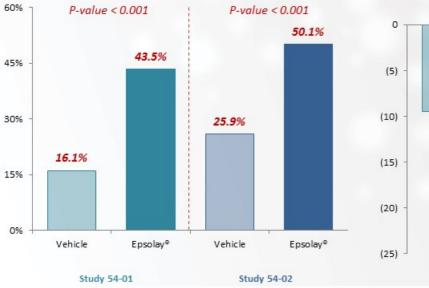
## PATIENT SEVERITY AT BASELINE

	Study	54-01	Study 54-02		
Characteristic	Epsolay®	Vehicle	Epsolay®	Vehicle	
IGA "Moderate"	210 (86.4%)	104 (88.1%)	227 (90.8%)	112 (91.8%)	
IGA "Severe"	33 (13.6%)	14 (11.9%)	23 (9.2%)	10 (8.2%)	
Mean lesion count (SD)	25.7 (11.07)	26.3 (12.45)	29.8 (14.00)	27.5 (13.04)	
Median lesion count (range)	22.0 (15-69)	21.0 (15-70)	25.0 (15-70)	22.5 (15-70)	

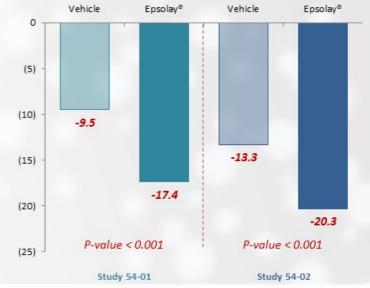
## PRIMARY ENDPOINTS (ITT)



#### Success in IGA @ Week 12



#### Inflammatory Lesion Count Change from Baseline @ Week 12

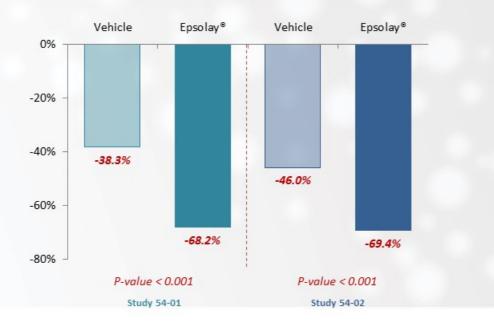


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## SECONDARY ENDPOINT (ITT)



### Inflammatory Lesion Percent Change from Baseline to Week 12



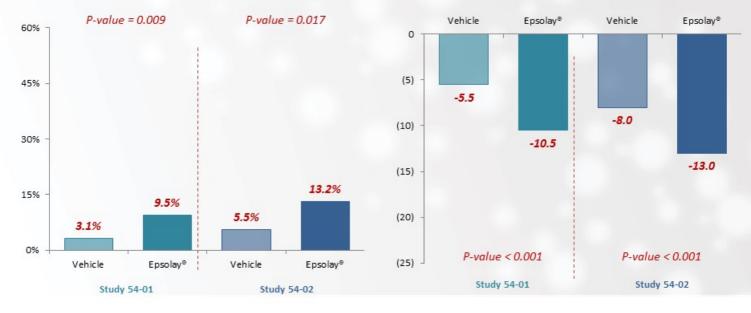
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## EXPLORATORY ENDPOINTS (ITT)

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#### Success in IGA @ Week 2





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## SECONDARY ENDPOINTS (ITT)

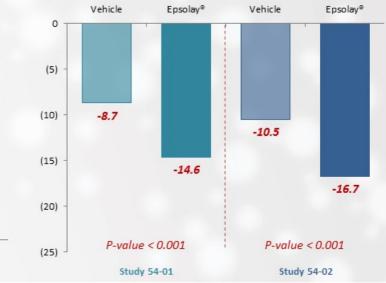
Sol-Gel

#### Success in IGA @ Week 4



#### Inflammatory Lesion Count Change from Baseline @ Week 4

Vehicle



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## SECONDARY ENDPOINTS (ITT)



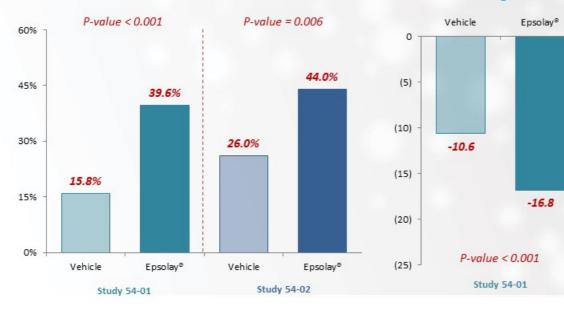
Epsolay®

#### Success in IGA @ Week 8

#### Inflammatory Lesion Count Change from Baseline @ <u>Week 8</u>

Vehicle

-12.4



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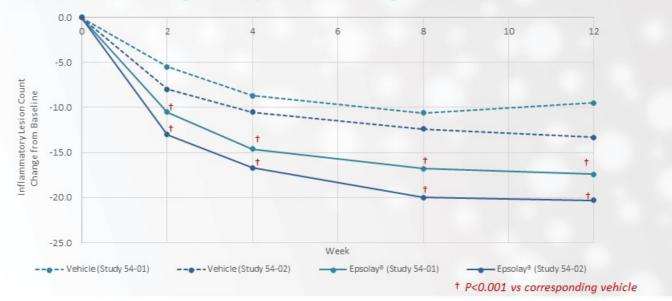
-20.0

P-value < 0.001

Study 54-02

## ABSOLUTE CHANGE IN INFLAMMATORY LESION COUNT FROM BASELINE OVER TIME (ITT)

Demonstrated statistical significant improvement in reducing inflammatory lesions as of Week 2

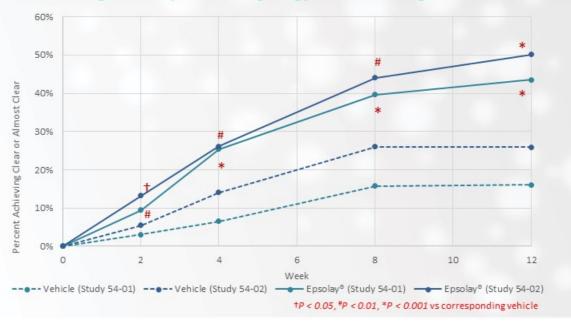


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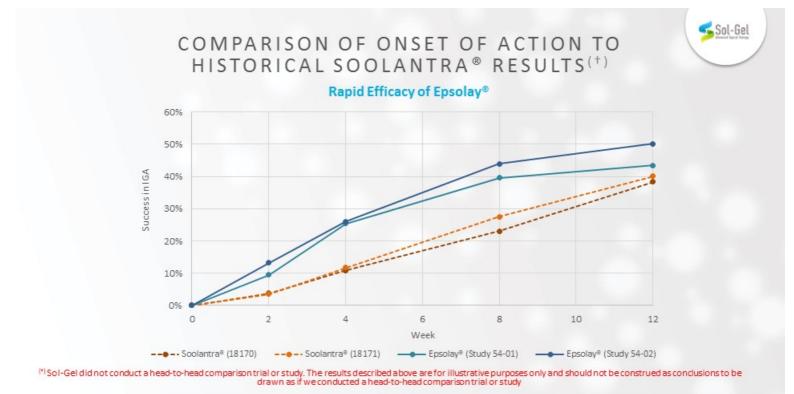
## SUCCESS IN IGA OVER TIME (ITT)

Statistical significant improvement in getting patients to the stage of "clear" or "almost clear"



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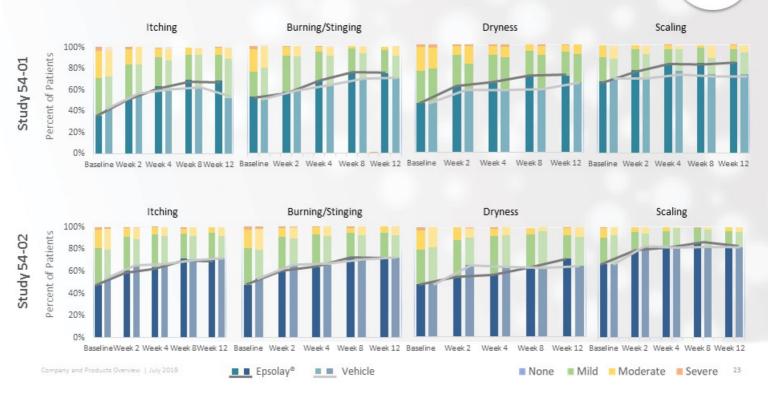
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# PRIMARY ENDPOINTS HISTORICAL COMPARISONS(+)

	Success in IGA		Epsolay® 12-week study 27.4% 24.2%		ONCE-DAILY SOCIANTRA (VERMECTIN) CREAM, IS 12-week study 26.8% 21.3%		Finacea. (azelaic acid) Foam, 15% 12- week study		ID-week study FMX103 FMX103 Minocycline foam, 1.5% 12-week study		(daycycline, USP) The most same to I6-week study Oral administration		
Difference from Vehicle			510dy 34-01	Study 34-02	Study 18170	Study 18171	10.9%	8.7%	10.91%	9.1%	10.1%	11.3%	8.5%
lifference		mmatory ns–Mean	Study 34-01	Study 54-02	Study 18170	Study 18171	Study 120	Study 846	NDA 21-789	FX2016-11	FX2016-12	Study 301	Study 302
-		nt Change Baseline						-10.8%		-7.6%			
	nom		-23.4%	-29.9%	-23.3%	-22.3%	-14.7%	-10,8%	-18.1%		-11.3%	-32.0%	-26.0%
		Severe	-23.4% 33	-29.9% <sup>23</sup>		-22.3%	-14.7% 25	-10.8%	-18.1% º	51	-11.3% 71	-32.0% 52	
Baselin	ne IGA				-23.3%					51 444			-26.0%
Baselin Character of Active	ne IGA	Severe	33	23	-23.3% sz	113	26	65	0	and the second se	71	52	-26.0% 48

<sup>(\*)</sup>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

## SKIN TOLERABILITY



## TREATMENT EMERGENT ADVERSE EVENTS (\*) SAFETY POPULATION

No. (%) of Subjects	Study	54-01	Study 54-02		
	Epsolay®	Vehicle	Epsolay∘	Vehicle	
Subjects reporting any TEAE	49 (20.5%)	17 (15.0%)	50 (20.2%)	22 (18.2%)	
Serious TEAE		1 (0.4%) <sup>1</sup>	1 (0.4%) <sup>2</sup>		
Severe TEAE	2 (0.8%)		2 (0.8%) <sup>3</sup>		
Discontinuation	5 (2.1%)	1 (0.9%)	4 (1.6%)	1 (0.8%)4	
Treatment-related	14 (5.9%)	3 (2.7%)	9 (3.6%)		

<sup>1</sup>Femur fracture

<sup>2</sup> Spinal compression fracture

<sup>3</sup> One subject with spinal compression fracture

<sup>4</sup> Urinary tract infection – Discontinuation defined as "other" reason

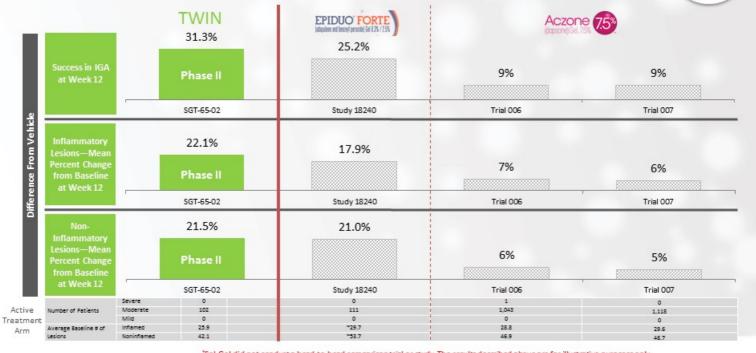
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## ACNE VULGARIS — MULTIFACTORIAL DISEASE REQUIRING POWERFUL COMBINATION TREATMENTS

What is acne vulgaris?	A multifactorial disease of the pilosebaceous unit, involving abnormalities in sebum production, follicular epithelial desquamation, bacterial proliferation, and inflammation
How is it treated?	BPO, retinoids, antibiotics and their combinations are the mainstays of Rx topical therapies. Isotretinoin and antibiotics are the mainstays of Rx systemic therapies
What are the current treatments shortfalls?	Insufficient efficacy negatively affects self-esteem; contributes to antibiotic resistance; systemic side effects
TWIN:	Encapsulation allows combining two highly effective APIs, BPO & ATRA, that have a complementary mechanism of action
E-ATRA/E-BPO cream	Encapsulation may reduce the irritation of both BPO and ATRA
	Potential to be more effective than existing topical treatments

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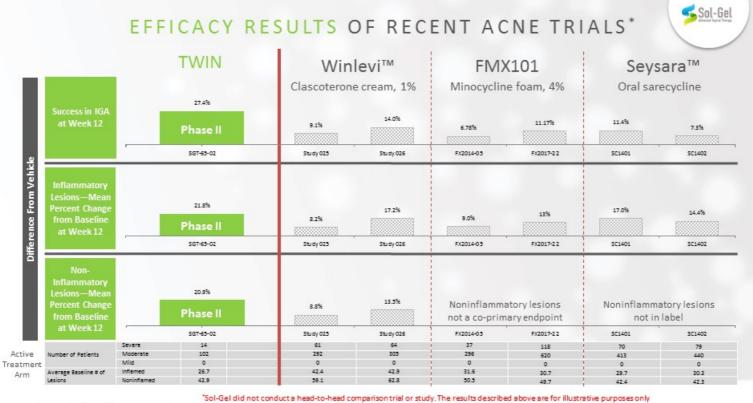
## ACNE TRIALS EFFICACY RESULTS\*: MODERATE PATIENTS



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\*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

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Sol-Gel did not conduct a head-to-head companison trial or study. The results described above are for illustrative purpl and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study.

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## TWIN PHASE III TRIAL DESIGNS

Two 12-week, randomized, double-blind, vehicle controlled studies in patients with acne vulgaris Enrollment of ~420 subjects per study at a ratio of 2:1, yielding 99% powering



#### PRIMARY ENDPOINTS:

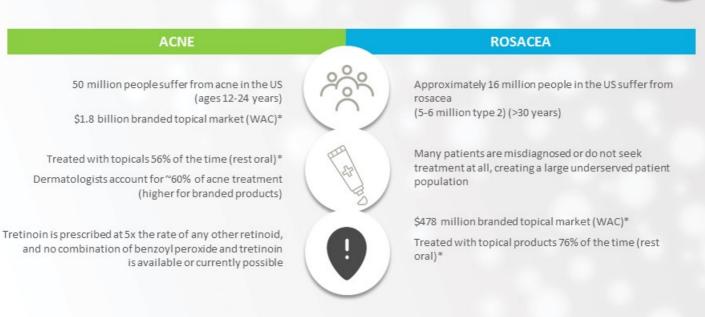
- Proportion of patients in active treatment versus vehicle cream with an assessment of clear or almost clear with at least a 2-grade improvement in IGA at Week 12
- Absolute change from Baseline in inflammatory and non-inflammatory lesion count at Week 12

#### **TOPLINE RESULTS EXPECTED IN Q4 2019**

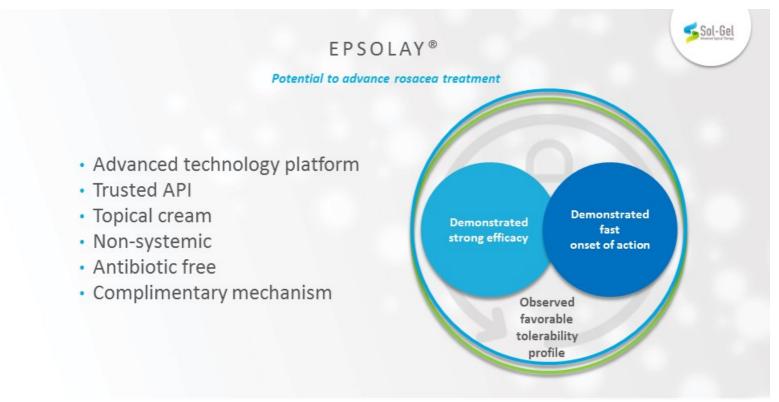
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## MARKET POTENTIAL FOR ACNE & ROSACEA





"Sources: Symphony Health; Syneos Research & Insights "Treatment Answers"; June 2019 MAT,



## APPROACH TO BUILDING A COMMERCIAL ORGANIZATION - EFFICIENT AND EFFECTIVE -



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## ADDRESSING ACCESS & UM FOR EPSOLAY<sup>®1,2,3</sup>

Positive payer response to EPSOLAY® - Competitive pricing likely equals parity access in rosacea

#### **PAYER RESPONSE TO CLINICAL PROFILE**

COMPELLING TO DRIVE FORUMLARY CONSIDERATION

Most would cover at preferred or non-preferred level depending on cost

#### PAYER UM POSITION **BASED ON HIGHER NET-TO-PLAN PRICE**

#### LIKELY:

- · Step-through generics
- Quantity limits

#### POSSIBLE:

 Prior authorization to label

Al5 Health, 2019. http://www.aishealth.com/about.
 MMIT Network, 2019. http://www.mmitnetwork.com
 Data on file. NPG Health primary market research, 201

COMPETITIVE

PRICING

#### COVERED OR BETTER:

- 92% Commercial
- 40% Part D
- 74% Medicaid

Sol-Gel

State "If priced like Finacea, it would get parity access; 15%-20% rebate expected with WAC at parity to Finacea."

## COMMERCIAL APPROACH

Significant potential for sales force efficiency and addressing a challenging reimbursement environment

Efficient reach to 80% dermatology market for acne and rosacea

Targeted high-value and focus use of resources and effort

Build a highly effective organizational model that is flexible and scalable



Exploit Innovative *channel* and *payment* strategies to reduce access hurdles and ensure pull-through.

Leverage consumer activation in high patientengagement categories

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Symphony Health IDV Vantage, 10/18

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## REVENUE-GENERATING GENERICS PARTNERSHIPS







Multiple Collaborations A portfolio of generic product candidates with favorable commercial agreements that supplement our branded pipeline

Seven collaborations with Perrigo and one with Douglas Pharmaceuticals with 50/50 gross profit sharing

In January 2018, 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 a third filer to the FDA. Sales of RLD reached \$175 million in 2018.

#### **FDA Approvals**

In February 2019, Perrigo received approval from the FDA and launched the sale of acyclovir cream, 5%, developed in collaboration with Sol-Gel. As of today, there is no public disclosure of another filer to the FDA. The sales of the RLD were ~\$92 million in 2018.

Recent Developments

Bioequivalence (BE) study results for 5-fluorouracil cream, 5%, expected in 2H2019





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 June 30, 2019

\$49.8 million of cash and investments as of June 30, 2019

Approximately \$7.0 million in revenue from acyclovir cream in Q2/2019

Cash runway expected to be sufficient to fund Phase III clinical programs for TWIN, regulatory activities for Epsolay<sup>®</sup>, a bioequivalence study, and our activities until the end of Q3/2020

## RECENT MILESTONES & NEXT STEPS

2019	2020	2021
Obtained ANDA approval for acyclovir cream (sponsored by Perrigo)	File NDA for EPSOLAY® in 1H/2020	US commercial organization fully operational
Recognized non-dilutive revenues early form launch of acyclovir cream (by Perrigo)	(Collaboration with Perrigo) ANDA for 5- fluorouracil cream, 5% filed in 1H/2020	O Approval and launch of EPSOLAY® first in 2021
Reported positive Phase III results for EPSOLAY® in papulopustular rosacea	File NDA for TWIN in 2H/2020	Approval and launch of TWIN product second in 2021
Receive notice of allowance extending TWIN market protection from $2032 \rightarrow 2038$	US pre-launch commercial preparations	
O Start PoC for Palmoplantar Keratoderma Q4/2019		
Plans to report Phase III results for TWIN in acne vulgaris End of 2019		
<ul> <li>Plans to report BE study results for</li> <li>5-fluorouracil cream, 5%</li> </ul>		

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#### NASDAQ: SLGL www.sol-gel.com

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