# 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 December 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 ⊠ 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): $\Box$					
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): $\Box$					

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

The Company is posting on its website a presentation titled "NASDAQ: SLGL".

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

Exhibit 99.1: Corporate presentation titled "NASDAQ: SLGL".

## **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.

Date: December 26, 2019

By: /s/ Gilad Mamlok

Gilad Mamlok Chief Financial Officer



NASDAQ: SLGL

Company and Products Overview | December 2019

## 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 presentation. 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

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.

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# THREE-FOLD STRATEGY





- Successfully commercialize best-in-class dermatology brands in acne and rosacea, and maintain a leadership position in these indications
- Identify targeted opportunities in other areas of high unmet need where we can bring innovation and exceed current standard-of-care treatments
- Leverage our capabilities to generate significant non-dilutive funding

Company and Products Overview | December 2019

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# NOVEL DELIVERY SYSTEM FOR BEST-IN-CLASS TOPICAL DRUGS



1

Proprietary silica-based microencapsulation EPSOLAY® topical delivery platform for dermatology indications

2

Positive phase III results from clinical trial in papulopustular rosacea in July 2019

NDA submission anticipated in 1H/2020

3

TWYNEO® phase III data in acne vulgaris expected in Q4/2019

NDA submission anticipated in 2H/2020

4

Completed follow-on offering of \$11.5 million in August 2019

Successfully raised \$86.3 million in IPO in February 2018

5

Non-dilutive revenues of \$18.8 million from generic pipeline in the first 9 months

6

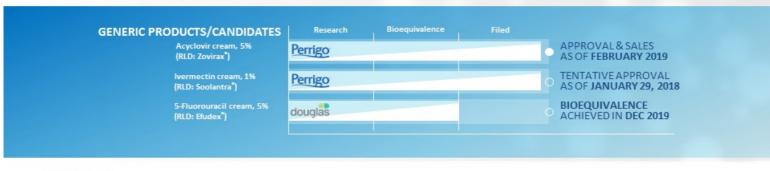
Seasoned management team with proven track record and broad dermatologic experience

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# PIPELINES & UPCOMING MILESTONES







RLD, reference listed drug.

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# FOUNDATION FOR BRANDED PRODUCT PIPELINE



1

#### WHY SILICA?

FDA approved for topical use

Proprietary process produces high encapsulation efficiency

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

Smooth, no-grit feel for user

Strong IP protection to 2032 (EPSOLAY®) and 2038 (TWYNEO®)

2

#### 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

3

#### **POTENTIAL BENEFITS**

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

APIs stabilized via microencapsulation, allowing for novel combinations

Hurdle for generics to demonstrate similar release profile

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

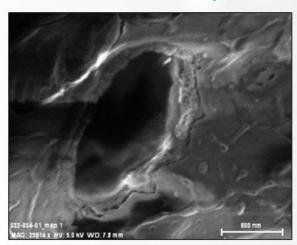
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# CONTROLLED RELEASE IMPROVES TOLERABILITY

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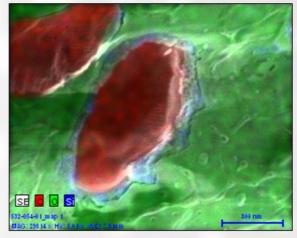


# Encapsulated Benzoyl Peroxide (E-BPO)



CRYO-SEM PICTURE

Silica shell wraps BPO crystals and serves as a barrier between BPO 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

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# INTELLECTUAL PROPERTY ESTATE



Our intellectual property is protected through a series of patent families, describing and claiming our proprietary processes, formulations, and methods of use

	Patents and	l Trademarks	10	IP Protection for Ou	ır Branded Products (US
		# of Patents Relate Company Produc		Product/Indication	IP, Expiry
US Patents	Granted/Allowed	5			
	Pending	15		EPSOLAY®	Granted 2032
	rending	13		subtype II rosacea	Pending 2040
oreign Patents	Granted/Allowed	34			
	Pending	11			
				TWYNEO®	Granted 2038
Trademarks	Registered/ Allowed	4 in US, IL, CA, EP	EPSOLAY <sup>®</sup>	acne vulgaris	Pending 2040
	Registered/ Allowed	5 in US, CA, EP, IL	TWYNEO®		

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## PAPULOPUSTULAR ROSACEA



#### Inflammatory condition with poor adherence to current treatments

What is papulopustular rosacea?

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

How is it treated?

Topical antimicrobials (metronidazole, clindamycin); topical anti-mite (ivermectin); systemic antibiotics (minocycline, doxycycline)

What are the current treatment shortfalls?

Insufficient efficacy resulting in poor adherence, contributing to antibiotic resistance; systemic side effects

Our solution: EPSOLAY® Encapsulated benzoyl peroxide (E-BPO) Encapsulation aims to reduce irritation of BPO

Potential to be more effective than existing treatments

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



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# EPSOLAY® STUDY DESIGN



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

 Male and female ≥18 EPSOLAY® cream, 5% Inclusion criteria years of age Randomization (once daily) · Clinical diagnosis of moderate to severe 2:1 12 weeks of treatment rosacea ≥15 to ≤70 inflammatory 54 Total Sites Vehicle cream (once daily) lesions Study 54-01: 361 ≤2 nodules Study 54-02: 372 12 Baseline Weeks

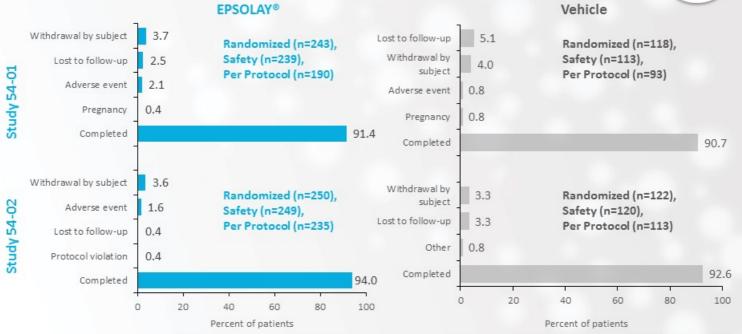
#### PRIMARY ENDPOINTS:

- 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

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## STUDY POPULATIONS & DISCONTINUATION





ntent-to-treat population

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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)

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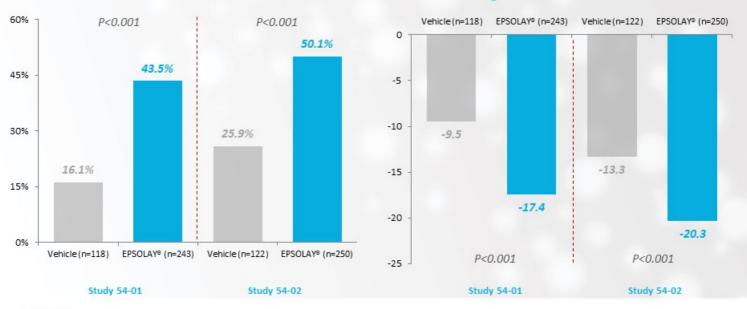
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# PRIMARY ENDPOINTS (ITT)



#### Success in IGA at Week 12

## Inflammatory Lesion Count Change From Baseline at Week 12



TT, intent-to-treat.

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# SECONDARY ENDPOINT (ITT)



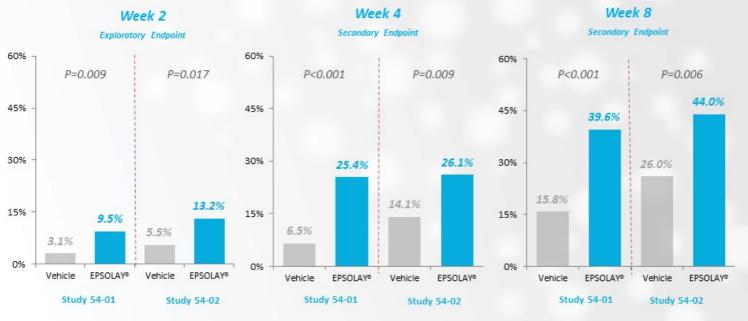
# Inflammatory Lesion Percent Change From Baseline to Week 12



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# SUCCESS IN IGA (ITT)

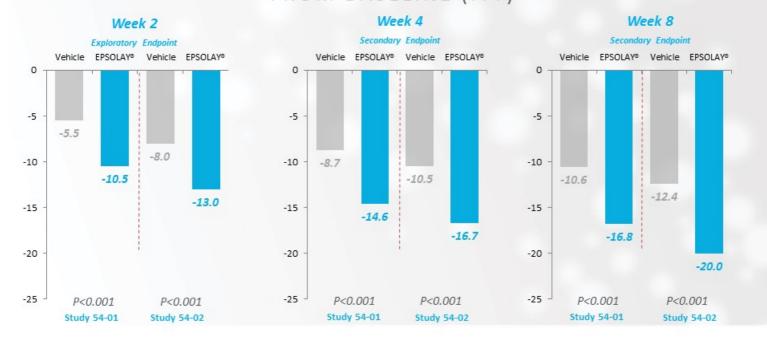




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# INFLAMMATORY LESION COUNT CHANGE FROM BASELINE (ITT)



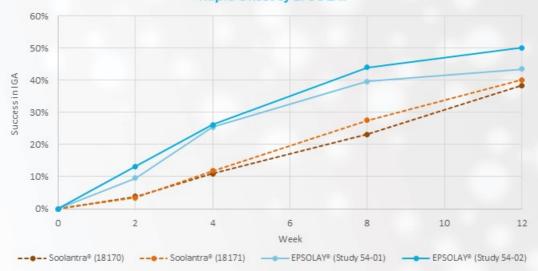


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# COMPARISON OF ONSET OF ACTION TO HISTORICAL SOOLANTRA® RESULTS\*



# Rapid Onset of EPSOLAY®

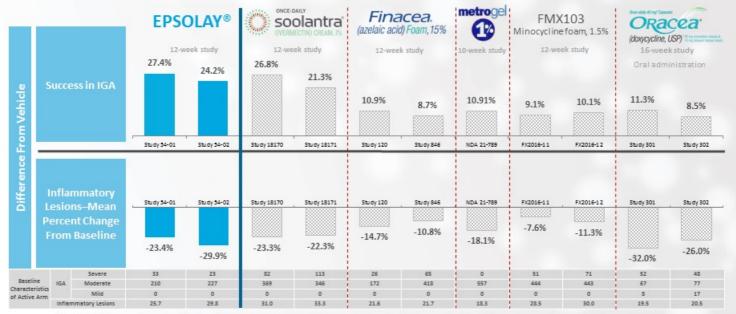


\*Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as condusions to be drawn as if we conducted a head-to-head comparison trial or study.

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# SIDE-BY-SIDE WITH OTHER HISTORICAL TRIAL RESULTS\*





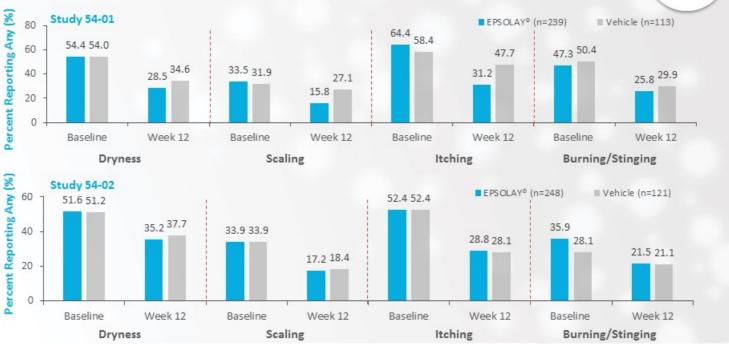
<sup>\*</sup>Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study.

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# SKIN TOLERABILITY





Safety population

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# TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs) SUMMARY



Study 54-01

Study 54-02

TEAEs, n (%)	EPSOLAY® (n=239)	Vehicle (n=113)	EPSOLAY® (n=249)	Vehicle (n=120)
AnyTEAE	49 (20.5%)	17 (15.0%)	50 (20.2%)	22 (18.2%)
Serious TEAE	0	1 (0.4%)*	1 (0.4%)†	0
Severe TEAE	2 (0.8%)	0	2 (0.8%)‡	0
Discontinuation	5 (2.1%)	1 (0.9%)	4 (1.6%)	1 (0.8%)§
Treatment-related	14 (5.9%)	3 (2.7%)	9 (3.6%)	0

'Femur fracture.

'Spinel compression fracture.

'One subject with spinel compression fracture.

'Urinary tract infection—Discontinuation classified as "other reason."

Safety population.

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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?

Topical BPO, retinoids, antibiotics, and their combinations; isotretinoin and antibiotics are mainstays of systemic therapy

What are the current treatment shortfalls?

Insufficient efficacy negatively affects selfesteem; contributes to antibiotic resistance; systemic side effects

Our solution: TWYNEO® E-BPO + E-ATRA Cream Encapsulation allows combining 2 highly effective APIs, BPO and ATRA, that have complementary mechanisms of action 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



		DI		EPIDUO FORTE     Indeputere and feeting personal fail 12% / 23%     25.2%	Aczone 75%		
ı	Success in IGA at Week 12				9%	9%	
횾			SGT-65-02	Study 18240	Trial 006	Trial 007	
From Vehicle	Inflammatory Lesions—Mean		22.1%	17.9%			
Difference Fr	Percent Change From Baseline at Week 12		Phase II		7%	6%	
ille.			SGT-65-02	Study 18240	Trial 006	Trial 007	
۵	Non- Inflammatory		21.5%	21.0%			
	Lesions—Mean Percent Change From Baseline		Phase II		6%	5%	
	at Week 12		SGT-65-02	Study 18240	Trial 006	Trial 007	
Active Treatment Arm	Number of Patients  Average Sasoline A of Lesions	Sovere Medicate Mild Inflamed Non-inflamed	0 102 0 25.9 42.1	0 111 0 79,7 78.7	1 1,043 0 25.5 46.9	0 1,118 0 29.6 46.7	

\*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.

# EFFICACY RESULTS OF RECENT ACNE TRIALS\*



		TWYNEO®		levi™ e cream, 1%		<b>(101</b> e foam, 4%		ara™ ecycline
Success in IGA at Week 12		Phase II SGT-65-02	9.1% Study 025	14.0% Study 026	6.78% FX2014-05	11.17% FX2017-22	11.4% SC1401	7.3% SC1402
Inflammatory Lesions—Mean Percent Change From Baseline at Week 12		21.8% Phase II	8.2%	17.2%	9.0%	13%	17.0%	14.4%
		SGT-65-02	Study 025	Study 026	FX2014-05	FX2017-22	SC1401	SC1402
Non- Inflammatory Lesions—Mean Percent Change From Baseline		20.9% Phase II	8.8%	13.5%	Noninflamm not a co-prim	atory lesions nary endpoint	Noninflamm not in	atory lesions label
at Week 12  Number of Patients	Severe Moderate Mild	SGT-65-02	Study 025	Study 02 6 e4 sos	FX2014-05 57 296	FX2017-22	SC1401	SC1402
Average Sessions # of Lesions	Inflamed Non-inflamed	26.7 42.9	42.4 59.1	42.9 62.8	51.6 50.5	50.7 49.7	29.7 42.4	50.5 42.5

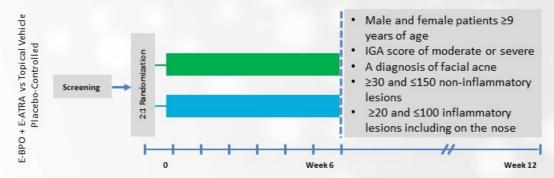
\*Sol-Gel did not conduct a head-to-head comparison trial or study. The results described above are for illustrative purposes only and should not be construed as conclusions to be drawn as if we conducted a head-to-head comparison trial or study.

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## TWYNEO® 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 vs 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**

Company and Products Overview | December 2019

# MARKET POTENTIAL FOR ACNE & ROSACEA



#### ACNE

50 million people suffer from acne in the US (ages 12-24 years)

~\$1.9 billion branded topical market (WAC)1

Treated with topicals **56**% of the time; remaining is oral<sup>1</sup>

Dermatologists account for **~60**% of acne treatments (higher for branded products)

Combining treatments is the best way to combat acne for the majority of patients<sup>2</sup>



Approximately **16 million people** in the US suffer from rosacea; **5-6 million** have type 2 (age **>30 years**)

~\$800 million branded topical market (WAC)1

Treated with topical products 76% of the time1

Dermatologists account for 80% of treatments

Many patients are misdiagnosed or do not seek treatment at all, creating a large underserved patient population



Symphony Health. Syneos Research & Insights "Treatment Answers"; June 2019 MAT

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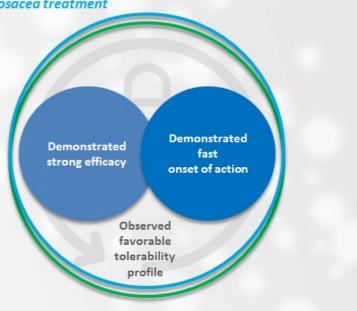
American Academy of Dermatology. https://www.aad.org/practicecenter/quality/clinical-guidelines/acrie/topical-therapie.

# **EPSOLAY®**



## Potential to advance rosacea treatment

- · Advanced technology platform
- Trusted API
- · Topical cream
- · Non-systemic
- · Antibiotic-free
- · Complimentary mechanism



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# APPROACH TO BUILDING A COMMERCIAL ORGANIZATION—EFFICIENT AND EFFECTIVE





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# Based on ~107 **MILLION** LIVES1

# ADDRESSING ACCESS & UM FOR EPSOLAY® 1-3



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

**PAYER RESPONSE TO CLINICAL PROFILE** 

COMPELLING TO DRIVE FORMULARY 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



## COVERED OR BETTER3:

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





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

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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 1 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.

#### 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. An authorized generic product entered the market in the third quarter of 2019.

## Recent Developments

In December 2019, bioequivalence and superiority to vehicle was achieved for generic 5-fluorouracil cream, 5%, for actinic keratosis. An abbreviated New Drug Application expected to be filed in the U.S. in 2020.

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Gross proceeds of \$86.3 million raised in IPO of 7,187,500 ordinary shares on February 5, 2018

Gross proceeds of \$11.5 million raised in a public follow-on offering on August 12, 2019

20,387,468 shares outstanding as of September 30, 2019

\$57.7 million of cash and investments as of September 30, 2019

\$18.8 million in generic product revenue in the first 9 months of 2019

Cash resources will enable funding of operational and capital expenditure requirements into the first quarter of 2021

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# RECENT MILESTONES & NEXT STEPS



	2019	2020		2021
$\odot$	Obtained ANDA approval for acyclovir cream (collaboration with Perrigo)	○ File NDA for EPSOLAY® in 1H/2020	() L	IS commercial organization fully operational
$\odot$	Recognized non-dilutive revenues early from launch of acyclovircream (by Perrigo)	○ File NDA for TWYENO® in 2H/2020	( A	pproval and launch of EPSOLAY®
$\odot$	Reported <b>positive phase III results</b> for EPSOLAY® in papulopustular rosacea	File ANDA for 5-fluorouracil cream, 5% in 2H/2020 (collaboration with Douglas)	( )	pproval and launch of TWYNEO® following PSOLAY®
$\odot$	TWYNEO® granted market protection out to 2038	US pre-launch commercial preparations		
$\odot$	Bioequivalence achieved for 5-fluorouracil cream, 5%			
$\bigcirc$	Plans to report phase III results for TWYNEO® in acne vulgaris at end of 2019			
$\bigcirc$	Start PoC for palmoplantar keratoderma Q4/2019			

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NASDAQ: SLGL www.sol-gel.com

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