# 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 July 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 $\boxtimes$ Form 40-F $\square$	
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

On July 25, 2019, Sol-Gel Technologies Ltd. (the "Company") issued a press release announcing the hosting of an Analyst and Investor Day in New York, a Notice of Allowance for a U.S. patent application covering TWIN and a clinical study for SGT-210 in palmoplantar keratoderma (PPK) intended to begin in early 2020. The Company is also posting on its website a presentation titled "Investor & Analyst Day".

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

Exhibit 99.1: Press Release titled "Sol-Gel Technologies Hosting Analyst & Investor Day".

Exhibit 99.2: Corporate presentation titled "Investor & Analyst Day".

### **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: July 25, 2019

By: /s/ Gilad Mamlok Gilad Mamlok

Chief Financial Officer

3

#### **Sol-Gel Technologies Hosting Analyst & Investor Day**

- Notice of allowance for U.S. patent application extends TWIN patent protection to 2038
- Clinical study for SGT-210 in palmoplantar keratoderma (PPK) intended to begin in early 2020
- Webcast of Analyst & Investor Day today at 8:30 a.m. ET

NESS ZIONA, Israel, July 25, 2019 – Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) will host an Analyst and Investor Day today in New York beginning at 8:30 a.m. ET. During the meeting, the company will review the recently announced, positive Phase III EPSOLAY® data in papulopustular rosacea; preliminary U.S. commercial plans; a planned clinical study for SGT-210 in PPK intended to begin in early 2020; and the new allowed patent for TWIN in acne.

#### **Agenda**

- · Introduction and Company Overview
  - o Alon Seri-Levy, PhD, Chief Executive Officer
- Current Challenges in Acne and Rosacea Treatment
  - o Linda Stein Gold, MD, Director of Dermatology Clinical Research at Henry Ford Health System
- · EPSOLAY® Phase III Clinical Study Results
  - o Jeffrey Sugarman, MD, Ph.D., Medical Director Northern California Medical Associates, Assoc. Clinical Professor, University of California, San Francisco
- Technology Overview
  - o Ofer Toledano, VP, Research and Development
- Commercial Overview
  - o John Vieira, U.S. Head of Commercialization
- Pipeline and Active Research Areas
  - o Mori Arkin, Chairman of The Board of Directors
- Financial Overview
  - o Gilad Mamlok, Chief Financial Officer
- Closing Statements and Q&A
  - o Alon Seri-Levy, PhD, Chief Executive Officer

#### **Intellectual Property Update**

Sol-Gel received Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent covering TWIN, a once daily topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide and encapsulated tretinoin using Sol-Gel's proprietary microencapsulation platform.

The patent allowance includes the use of a BPO/tretinoin combination at 3%/0.1% respectively, for the treatment of acne vulgaris. The method includes the stability and release profile of the combination, and their synergistic efficacy and improved safety profile. The newly granted patent will extend protection to July 2038 which the company believes will prevent the launch of any AB-rated generic of TWIN during the life of the patent.

Sol-Gel's current patent estate includes 38 granted and allowed patents and 26 pending US and global patent applications regarding the company's silica-based proprietary processes and methods of use.

#### **Pipeline Additions**

SGT-210, a topical epidermal growth factor receptor inhibitor, has been added to the company's development pipeline. SGT-210 is in development for the treatment of PPK and non-melanoma skin cancer (NMSC). PPK is a group of skin conditions characterized by thickening of the skin on the hands and soles of the feet. Basal cell carcinoma and squamous cell carcinoma are collectively referred to as NMSC.

SGT-210 is designed to be used alone or in combination for the treatment of hyperproliferation and hyperkeratinization disorders, including PPK and NMSC. A 12-week proof of concept study of SGT-210 in PPK is planned to begin in early 2020.

#### Webcast

A live webcast of the event can be accessed on the Events & Presentations section of the company's website at <a href="http://ir.sol-gel.com">http://ir.sol-gel.com</a>. Analysts and Institutional Investors can register for the event at <a href="solgel.troutgroup.com">solgel.troutgroup.com</a>.

### **About Sol-Gel Technologies**

Sol-Gel is a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel's current product candidate pipeline consists of late-stage branded product candidates that leverage the company's proprietary, silica-based microencapsulation technology platform, and several generic product candidates across multiple indications. For additional information, please visit www.sol-gel.com.

### Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forwardlooking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forwardlooking statements are based on information we have when those statements are made or our management's current expectation, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forwardlooking statements. Important factors that could cause such differences include, but are not limited to: (i) the adequacy of our financial and other resources, particularly in light of our history of recurring losses and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; (ii) our ability to complete the development of our product candidates; (iii) our ability to find suitable co-development partners; (iv) 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; (v) our ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our ability to establish adequate sales, marketing and distribution channels; (ix) acceptance of our product candidates by healthcare professionals and patients; (x) the possibility that we may face third-party claims of intellectual property infringement; (xi) 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; (xii) 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; (xiii) potential product liability claims; (xiv) potential adverse federal, state and local government regulation in the United States, Europe or Israel; and (xv) 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 press release. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements to changes in our expectations.

### For further information, please contact:

Sol-Gel Contact: Gilad Mamlok Chief Financial Officer +972-8-9313433

Investor Contact: Chiara Russo Solebury Trout +1-617-221-9197 <u>crusso@soleburytrout.com</u>



Source: Sol-Gel Technologies Ltd.

### Exhibit 99.2



### 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 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.

### AGENDA



TOPIC	SPEAKER	
Introduction and Company Overview	Alon Seri-Levy CEO, Sol-Gel	
Current Challenges in Acne and Rosacea Treatment	Dr. Linda Stein Gold Director of Dermatology Clinical Research, Henry Ford Health Systems, Michigan	
EPSOLAY <sup>®</sup> Phase III Clinical Studies	Dr. Jeff Sugarman Medical Director, Northern California Medical Associates Associate Clinical Professor, University of California, SF	
Commercial Overview	John Vieira US Head of Commercialization	
Technology Overview	Ofer Toledano  VP., Research and Development	
Pipeline and Active Research Areas	Mori Arkin Chairman, Sol-Gel	
Financial overview	Gilad Mamlok CFO, Sol-Gel	
Closing Statements and Q&A	Alon Seri-Levy CEO, Sol-Gel	

### THREE-FOLD STRATEGY

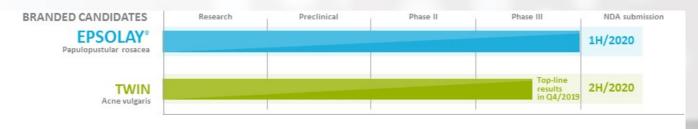


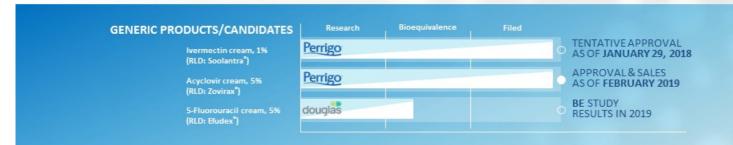


- Successfully commercialize best-in-class dermatology brands in acne and rosacea, and maintain a leadership position in these indications
- Identify targeted opportunities, in other areas of high unmet need, where we can bring innovation and exceed current standard-of-care treatments
- Leverage on our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

### PIPELINES & UPCOMING MILESTONES











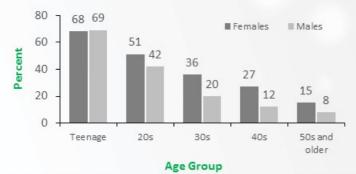
Dr. Linda Stein Gold
Director of Dermatology Clinical Research,
Henry Ford Health Systems

### ACNE: PREVALENCE & PRESENTATION



### PREVALENCE<sup>1,3</sup>

- · Acne is the most common skin condition in the USA, affecting up to 50 million Americans annually
- · About 85% of people between the ages of 12 and 24 experience at least minor acne
- More than 5.1 million people sought medical treatment for acne in 2013, primarily children and young adults<sup>3</sup>



PRESENTATION<sup>2</sup>





- Collier CN, et al. J Am Acad Dermetol. 2008;58:56-59.
   Zeenglein AL. N Engl. J Med. 2018;379:1343-1352.
   AAD 2016 Burden of Disease Report, https://www.aed.org/media/stats/conditions.

### THE IMPACT OF ACNE



- In addition to physical effects such as permanent scarring and disfigurement,
   acne has long-lasting psychosocial effects that affect the patient's quality of life
- Depression, social isolation and suicidal ideation are frequent comorbidities of acne that should not be neglected in the therapy of acne patients
- Research evidence suggests that the impairment of quality of life can be alleviated by appropriate topical acne treatment

Gieler U, et al., J Eur Acad Dermotol Venereol. 2015 Jun;29 Suppl 4:12-4

### TREATMENT ALGORITHM FOR THE MANAGEMENT OF ACNE VULGARIS IN ADOLESCENTS & YOUNG ADULTS 1,2



The multi-faceted nature of acne pathogenesis often requires a combination therapy approach

Treatment	Mild Acne	Moderate Acne	Severe Acne
First-line Treatment	Benzoyl peroxide, topical retinoid, or topical combination therapy	Topical combination therapy; oral antibiotic, topical retinoid, and benzoyl peroxide; oral antibiotic plus topical retinoid; or benzoyl peroxide plus topical antibiotic	Oral antibiotic plus either topical combination therapy or oral isotretinoin
Alternative Treatment	Add topical retinoid or benzoyl peroxide (if not using already), or consider alternative retinoid, or consider topical dapsone	Consider alternative combination therapy, or consider change in oral antibiotic, or add combined oral contraceptive or oral spironolactone (in female patients), or con-sider oral isotretinoin	Consider change in oral antibiotic, or add combined oral contraceptive or oral spironolactone (in female patients), or consider oral isotretinoin

Zaenglein AL, et al. J Am Acad Dermatol. 2015;74:943-73.e33.
 Zaenglein AL. N Engl J Med. 2018;379:1343-1352.

### UNMET NEED



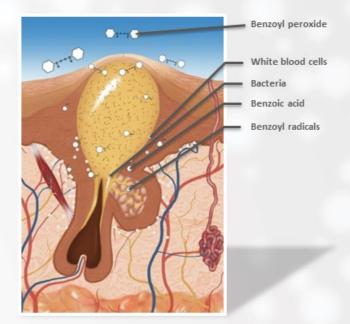
- · There is a strong trend toward and professional recommendation to avoid or be more discerning with antibiotics use in dermatology whenever possible<sup>1</sup>
- Combination products or use of multiple products/modalities is common<sup>2,3</sup>
- · Benzoyl peroxide and tretinoin have both been shown to be effective<sup>2,3</sup>
- · Unable to combine benzoyl peroxide with tretinoin until now

- Sixty-seventh World Health Assembly Antimicrobial resistant
   Zaenglein AL, et al. J Am Acod Dermatol. 2016;74:945-73.e33.
   Zaenglein AL, N Engl J aMed. 2018;379:1343-1352.

### BENZOYL PEROXIDE IN ACNE



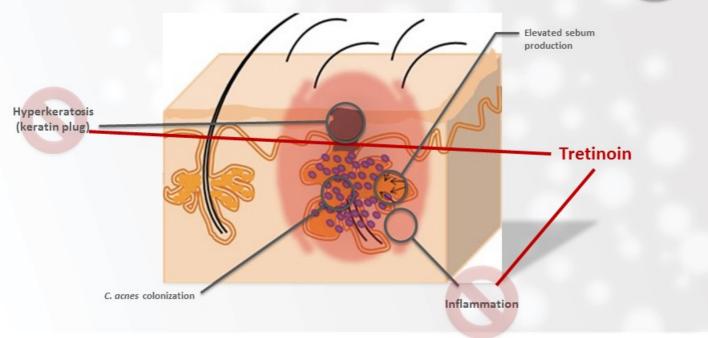
- Benzoyl radicals kill bacteria and inflammatory cells
- Benzoic acid promotes the opening of clogged pores
- Benzoyl peroxide combines with other treatments for synergistic effects



Seth V, et al. Int J Adv Med. 2015;2:1-5.

### TRETINOIN IN ACNE

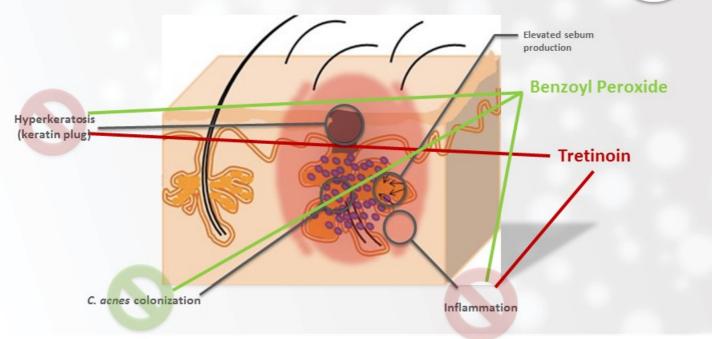




Seth V, et al. Int J Adv Med. 2015;2:1-5.

### TRETINOIN AND BENZOYL PEROXIDE IN ACNE





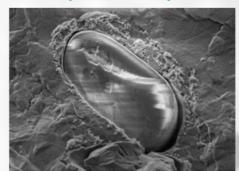
Seth V, et al. Int J Adv Med. 2015;2:1-5.

### TREATMENT TO DATE ...

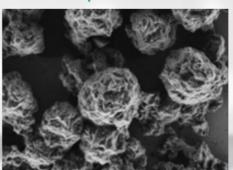


- Preference for dual action, but preferred products unable to be combined until now...
- Encapsulation permits storage and delivery of benzoyl peroxide with tretinoin in strengths repeated shown to be efficacious in patients of acne vulgaris

### SEM Encapsulated Benzoyl Peroxide\*



### **SEM Encapsulated Tretinoin**



\*Freeze fracture preparation



TWIN low and TWIN high demonstrated significant improvements in moderate to severe acne vulgaris after 12 weeks of treatment:

**≪**Sol-Gel

- Statistically significant (P <0.006) improvements were observed in both the IGA and lesion counts (inflammatory and noninflammatory) over vehicle alone
- TWIN low and TWIN high had similar effects on outcome variables. However, at week 12, a higher proportion of subjects (39.7%) achieved clear or almost clear with TWIN high, compared to the TWIN low treatment (27.4%)
- TWIN low and TWIN high were safe and well tolerated with expected dermal incidences of application site dryness, exfoliation (scaling) and pain (mild burning and stinging) typical for the individual components of the two formulations



# ROSACEA IS A CHRONIC INFLAMMATORY SKIN DISEASE<sup>1</sup>

Sol-Gel Assest Spect Street

- Affects approximately 16 million Americans<sup>2</sup>
- Very high emotional and psychological impact<sup>3</sup>
- 5.46% of the adult general population is affected by rosacea<sup>4</sup>
- No latitude-dependent gradient in rosacea prevalence observed<sup>4</sup>
- Multiple subtypes/phenotypes often seen in a single patient<sup>4,5</sup>
- Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440.
- National Rosacea Society, http://www.rosacea.org/rr/2010/winter/article\_1.php
- Moustafa F. J Am Acad Dermatol. 2014;71:973-98
- 4. Gether L, et al. Br J Dermatol. 2018;179:282-289
- Wilkin J. et al. J Am Acad Dermatol. 2004;50:907-912



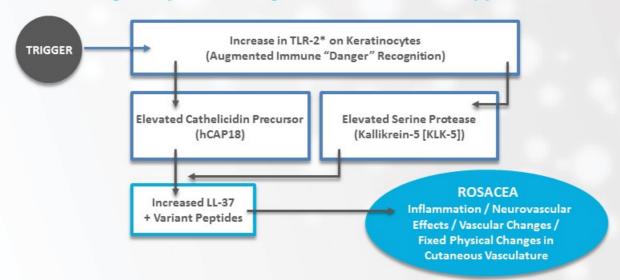
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17

### ROSACEA PATHOPHYSIOLOGY IS COMPLEX



### Pathogenesis of rosacea is thought to be an immune detection dysfunction



- \*TLR-2 Toll+like receptor-2

  1. Yamasaki K et al. Nature Medicine. 2007;13:975-980.

  2. Yamasaki K et al. J Demastol Sci. 2009;53:77-91.

  3. Fleischer AB. J Drugs Dermatol. 2011;10:814-820.

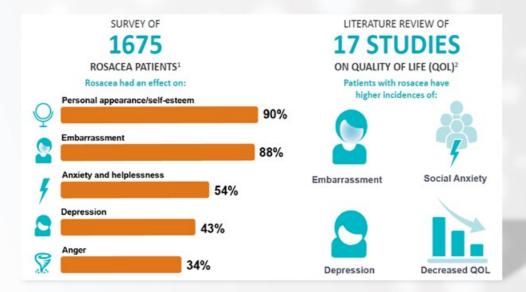
  4. Yamasaki K et al. J linvest Dermatol. 2011;13:12-13. [slide courtesy of James Del Rosso, DO, Las Vegas, NV]

  5. Yamasaki K et al. J linvest Dermatol. 2011;13:12-13. [slide courtesy of James Del Rosso, DO, Las Vegas, NV]

# PATIENTS WITH ROSACEA SUFFER PSYCHOLOGICAL CONSEQUENCES THAT IMPACT THEIR EVERYDAY LIVES

≪Sol-Gel

19



L. National Rosacea Society. http://www.rosacea.org/press/new-rosacea-survey-shows-emotional-tall-facial-redness-equals-impact-bumps-pimples. Accessed November 7, 201

Moustafa F, et al. J Am Acad Dermatol. 2014;71(5):973-980.

# CLEARER SKIN REDUCES IMPACT ON ROSACEA PATIENT QOL



Data from an online global survey of 710 rosacea patients



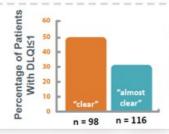
rosacea has at least a moderate impact on their life 55%

**(** 

of high burden patients (DLQI >10) are willing to trade a year or more of their life for a rosacea cure

# 3.5 hours more per week

spent on skin care for patients with high burden



**49%** of "clear" patients reported rosacea had no impact on their QOL vs **30%** for the "almost clear" patients (*P* ≤0.05)

DLQ|=Dermatology Life Quality Index; QOL=quality of life. Tan J, et al. Rosscea. Beyond the visible. 2018 Available at https://hosted.bmj.com/rossceabeyondthevisible. Accessed October 13, 2018.

# SAME WOMAN, DIFFERENT IMPRESSIONS



### WITHOUT ROSACEA



13%	Insecure	33%
2%	Unhealthy	11%
64%	Single	81%
49%	Confident	27%
54%	Нарру	36%
34%	Fun	24%
23%	Stressed	40%
43%	Intelligent	36%
32%	Successful	18%
41%	Reliable	32%
14%	Executive/Manager	6%
10%	Need to improve skin care	73%

### NRS Perception Study. 2010.

WITH ROSACEA\*



\*Digitally enhanced photo.

### ROSACEA IS A LARGELY UNTAPPED MARKET



### Of the approximate 16 million rosacea sufferers in the US:

- Only 10% seek treatment<sup>1</sup>
- Misdiagnosis is common<sup>1,2</sup>
- · There is a clearly understood medical need for effective treatment options

Our goal is to address the underdiagnosis and to offer a safe and effective option to manage rosacea symptoms in order to give patients a better quality of life

National Rosacea Society. www.rosacea.org. Accessed October 10, 2016.
 Prevalence of rosacea. http://www.rosacea.org/rr/index.php. Accessed April 2015.

### WHY NOT BENZOYL PEROXIDE FOR ROSACEA?



- The skin of patients with rosacea is extremely sensitive and hyper-reactive to dietary, environmental, and topical factors<sup>1</sup>
- The use of topical retinoids and benzoyl peroxide has shown to be beneficial in treating rosacea in smaller case series<sup>2</sup>
- Data suggest that topical preparations containing benzoyl peroxide may be effective in rosacea, but that they may be poorly tolerated with frequent itching and burning at treatment sites<sup>3</sup>



1 Drawler 7D | Double Decompted 2005 Sep-Oct-A(5)-557-52

Two AM, et al. J Am Acad Dermatol. 2015;72:761-770.

Goldger C, et al. Am Fam Physician. 2009;80:461-468.

Investor and Analyst Day | July 2019

23



# **EPSOLAY® PHASE III CLINICAL STUDY RESULTS**



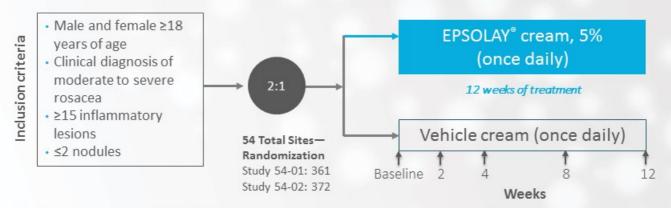
### **DR. JEFF SUGARMAN**

Medical Director, Northern California Medical Associates Associate Clinical Professor, University of California, San Francisco

### STUDY DESIGN



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



### PRIMARY ENDPOINTS:

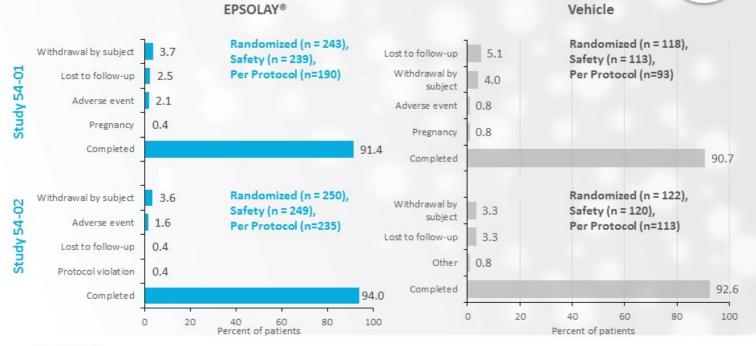
- Proportion of patients with the primary measure of success "Clear" (0) or "Almost clear" (1) in the Investigator Global Assessment (IGA) relative to Baseline at Week 12
- Absolute change in inflammatory lesion counts from baseline to Week 12

### SECONDARY ENDPOINT:

• Percent change in inflammatory lesion count at Week 12

### STUDY POPULATIONS & DISCONTINUATION





intent-to-treat population

## PATIENT CHARACTERISTICS

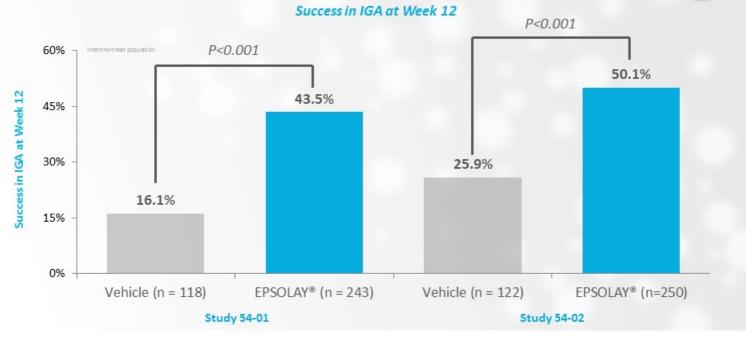


CHARACTERISTIC	Study 54-01		Study 54-02	
	EPSOLAY <sup>e</sup> (n = 243)	Vehicle (n = 118)	EPSOLAY <sup>e</sup> (n = 250)	Vehicle (n = 122)
Age, years				
Mean (SD)	52.8 (13.21)	52.4 (13.26)	49.5 (14.04)	51.5 (12.55)
Median (range)	54.0 (19-81)	52.5 (24-85)	50.0 (18 to 79)	50 (22 to 84)
Sex, n (%)				
Male	60 (24.7)	35 (29.7)	69 (27.6)	35 (28.7)
Female	183 (75.3)	83 (70.3)	181 (72.4)	87 (71.3)
Race, n (%)				
Amer. Indian/Alaska Nat.	0	0	0	2 (1.6)
Asian	9 (3.7)	2 (1.7)	20 (8.0)	8 (6.6)
Black/African American	0	0	2 (0.8)	0
Nat. Hawaiian/Pac. Islander	0	0	3 (1.2)	2 (1.6)
White	233 (95.9)	116 (98.3)	220 (88.0)	110 (90.2)
Multiple/0ther	1 (0.4)	0	5 (2.0)	0
Ethnicity, n (%)				
Hispanic/Latino	86 (35.4)	39 (33.1)	55 (22.0)	30 (24.6)
Not Hispanic or Latino	156 (64.2)	77 (65.3)	195 (78.0)	92 (75.4)
Unknown	1 (0.4)	2 (1.7)	0	0
IGA Severity (%)				
Moderate	210 (86.4)	104 (88.1)	227 (90.8)	112 (91.8)
Severe	33 (13.6)	14 (11.9)	23 (9.2)	10 (8.2)
Lesion Count		Not the plant of the		
Mean (SD)	25.7 (11.07)	26.3 (12.45)	29.8 (14.00)	27.5 (13.04)
Median (range)	22.0 (15-69)	21.0 (15-70)	25.0 (15-70)	22.5 (15-70)

Intent-to-treat population

## PRIMARY ENDPOINT (IGA)

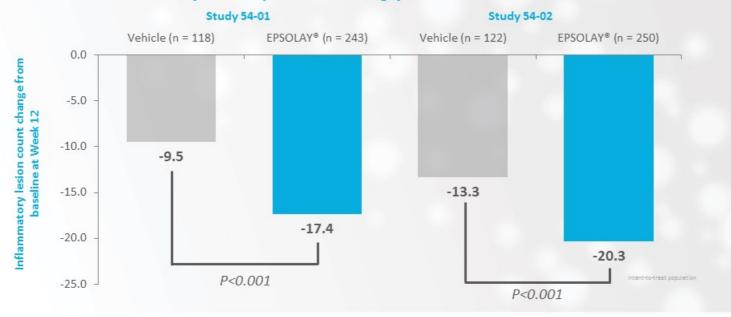




# PRIMARY ENDPOINT (CHANGE IN LESION COUNT)



### Inflammatory lesion count change from baseline at Week 12

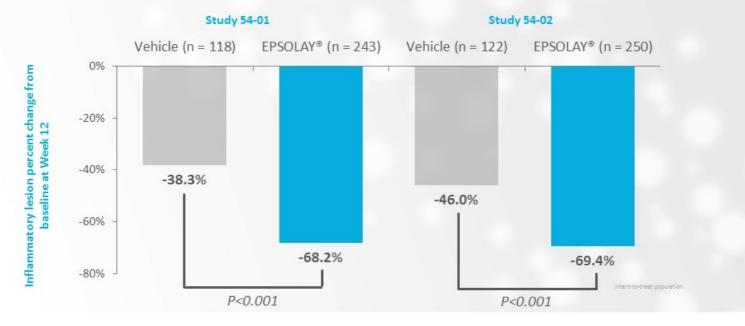


# SECONDARY ENDPOINT (% CHANGE IN LESIONS)



30

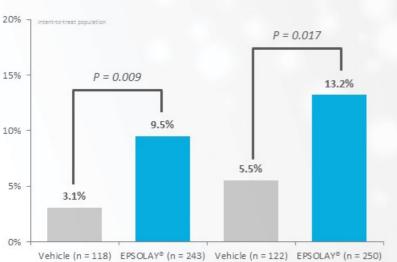
### Inflammatory lesion percent change from baseline at Week 12



## EXPLORATORY ENDPOINT (EFFICACY AT 2 WEEKS)

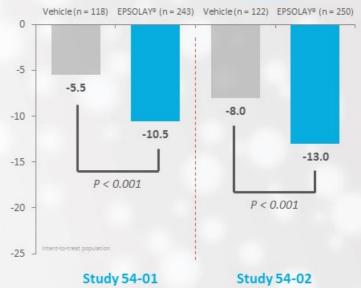


#### Success in IGA at Week 2



Study 54-02

## Inflammatory lesion count change from baseline at Week 2



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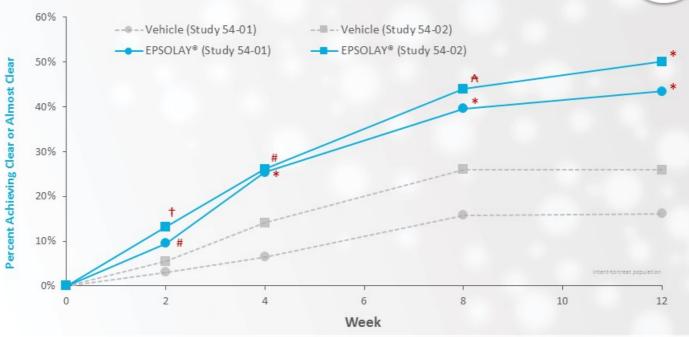
Study 54-01

31

<sup>\*</sup> Intent-to-treat population

## SUCCESS IN IGA OVER TIME

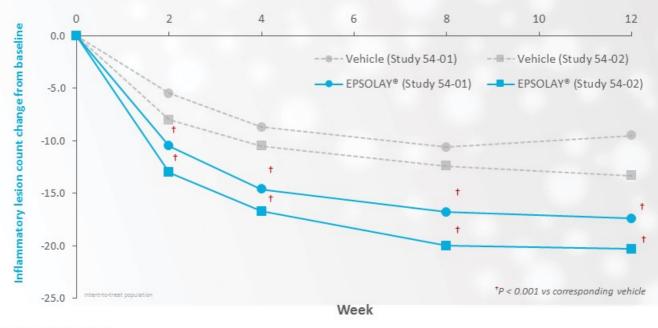




 $^\dagger P = 0.017, \ ^\sharp P = 0.009, \ ^\star P = 0.006, \ ^\ast P < 0.001 \text{ vs corresponding vehicle}$ 

# ABSOLUTE CHANGE IN INFLAMMATORY LESION COUNT FROM BASELINE OVER TIME





## IMPROVEMENT OVER TIME





## IMPROVEMENT OVER TIME

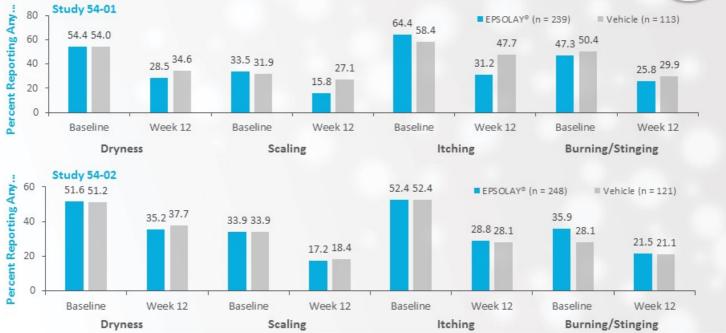




#### SKIN TOLERABILITY



36



Safety population

## TEAE SUMMARY



37

No. (%) of Subjects	Study 54-01		Study 54-02	
TEAEs, n (%)	EPSOLAY ® (n = 239)	Vehicle (n = 113)	EPSOLAY <sup>®</sup> (n = 249)	Vehicle (n = 120)
AnyTEAE	49 (20.5%)	17 (15.0%)	50 (20.2%)	22 (18.2%)
Serious TEAE	0	1 (0.4%) <sup>1</sup>	1 (0.4%)2	0
Severe TEAE	2 (0.8%)	0	2 (0.8%)3	0
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%)	0

<sup>1</sup>Femur fracture

<sup>1</sup>Spinal compression fractur

\*One subject with spinal compression fracture

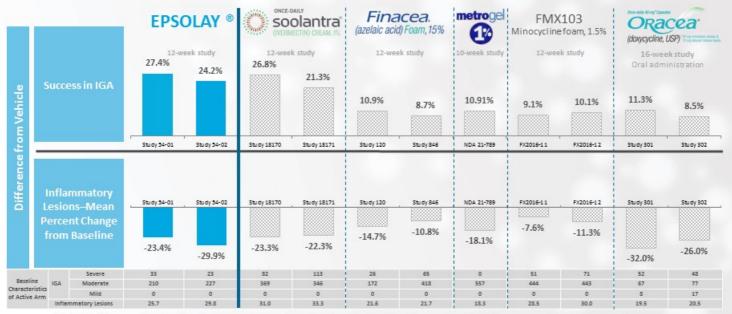
\*Urinary Tract Infection—Discontinuation classified as "other reason"

TEAEs, Treatment-Emergent Adverse Event:

Safety population

# 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



## **COMMERCIAL OVERVIEW**

John Vieira, US Head of Commercialization

### 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 on our capabilities to generate significant non-dilutive revenues

## MARKET POTENTIAL FOR ACNE & ROSACEA



#### ACNE

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

\$1.8 billion branded topical market (WAC)\*

Treated with topicals 56% of the time,

remaining is oral\*

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

Combining treatments is the best



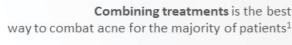
Approximately 16 million people in the US suffer from rosacea 5-6 million type 2 (>30 years)

\$478 million branded topical market (WAC)\*

Treated with topical products 76% of the time\*

Dermatologists account for 80% of treatments

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



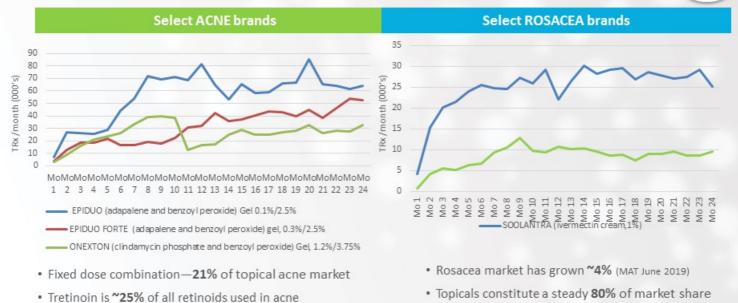
\*Sources: Symphony Health; Syneos Research & Insights "Treatment Answers"; June 2019

1. https://www.aad.org/practicecenter/quality/clinical-guidelines/acne/topical-therapies

## 24 MONTH LAUNCH ALIGNED PERFORMANCE



42



1. Syneos Health. Data on file.

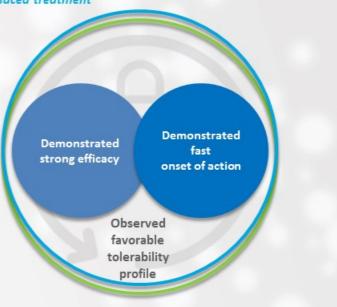
• ~ 20% of all acne treatments involve benzoyl peroxide

## **EPSOLAY®**

# Sol-Gel

#### Potential to advance rosacea treatment

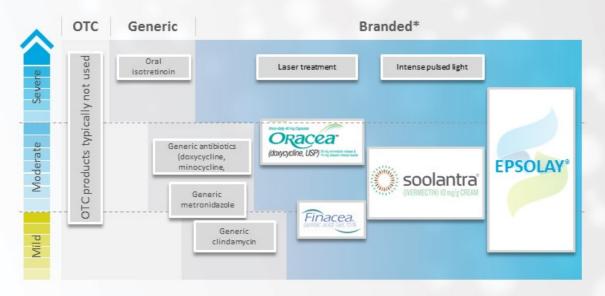
- · Advanced technology platform
- Trusted API
- · Topical cream
- · Non-systemic
- · Antibiotic-free
- · Complimentary mechanism



## CAPTURE SIGNIFICANT OPPORTUNITY IN ROSACEA



#### Rosacea subtype II treatments by phase & severity



Note: \*Branded products may have generic equivalent Source: L.E.K. interviews and analysis; company websites

# APPROACH TO BUILDING A COMMERCIAL ORGANIZATION—EFFICIENT AND EFFECTIVE





## SCALABLE MARKETING INVESTMENT



An integrated approach built from the ground up



Based on ~107 **MILLION** LIVES1

## ADDRESSING ACCESS & UM FOR EPSOLAY®1,2,3



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

#### COMPETITIVE **PRICING**



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



- Al5 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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47

### 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

Symphony Health IDV Vantage, 10/18



## **TECHNOLOGY OVERVIEW**

Ofer Toledano, VP Research and Development

# FOUNDATION FOR BRANDED PRODUCT PIPELINE



50

1

#### WHY SILICA?

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

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**

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

APIs stabilized via microencapsulation, allowing for novel combinations

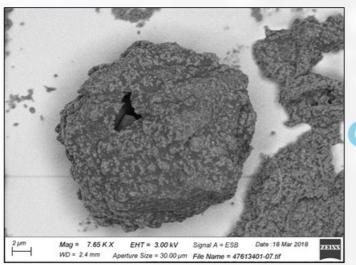
Barrier between entrapped API and skin may reduce irritation and improve compliance

Hurdle for generics to demonstrate similar release profile

# HIGH ENCAPSULATION EFFICIENCY ENHANCES STABILITY

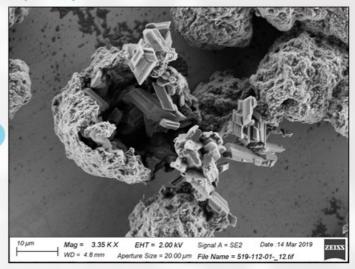


**Encapsulated Tretinoin (E-ATRA)** 





High encapsulation efficiency protects tretinoin



SEM PICTURI

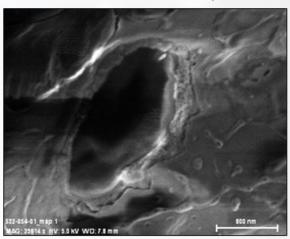
 $Encapsulated\ tretinoin\ is\ stable\ in\ the\ presence\ of\ benzoyl\ peroxide$ 

## CONTROLLED RELEASE IMPROVES TOLERABILITY

0

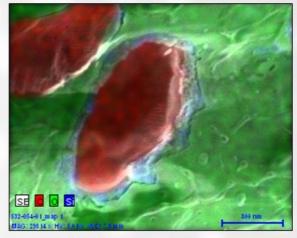


### Encapsulated Benzoyl Peroxide (E-BPO)



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



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

Patents and Trademarks			IP Protection fo	IP Protection for Our Branded Products (US)		
		# of Patents Related Company Product		Product/Indication	IP, Expiry	
US Patents	Granted/Allowed	4				
	Pending	16		EPSOLAY® subtype II rosacea	Granted/ <i>Allowed</i> , 2032 Pending, 2040	
oreign Patents	Granted/Allowed	29		2	2020000	
	Pending	14		TWIN	NEWLY GRANTED/ALLOWED	
Trademarks	Registered/ Allowed	4 in US, IL, CA, EP	EPSOLAY®	acne vulgaris	PATENT EXTENSION 2038 Pending, 2040	
	Registered/ Allowed	5 in US, CA, EP, IL	TWIN			



## LIFECYCLE



PROJECT	DESCRIPTION
SGT-129	EPSOLAY® + alpha agonist for the treatment of rosacea type I and II
SGT-138  TWIN + immune modulator for the treatment of severe of —Hydradenitis Suppurativa	

## PIPELINE AND EARLY RESEARCH



PROJECT	DESCRIPTION
SGT-210	Topical treatment of hyper-keratinization disorders — Palmoplantar Keratoderma
	Non-melanoma skin cancer NMSC (BCC/SCC)

# TOPICAL TREATMENT OF HYPERKERATINIZATION DISORDERS



#### Palmoplantar keratoderma (PPK)

- A group of skin conditions characterized by thickening of the skin on the hands and soles of the feet<sup>1</sup>
- Can be a manifestation of various syndromes<sup>2</sup>
  - · Inherited:
    - o Due to mutations that result in keratin abnormalities
    - o Can be autosomal recessive or autosomal dominant
- Acquired due to<sup>1,2</sup>:
  - Drugs, malnutrition, chemicals, systemic disease, cancer, infection
- Treatment options are very limited and of limited effectiveness.<sup>3,4</sup>
   (Topical keratolytics, Benzoic acid, oral retinoids, topical calcipotriol)





- Genetic and Rare Diseases information Center. 2019. https://rarediseases.info.nin.gov/diseases/816.
- Charny JW, James WD. 2019. https://emedicine.medscape.com/article/1108406-overview#s6
- Skalim M 2019 https://emedicine.medicine.com/article/110205-queryieu

Investorand Analyst Day, July 2019

2/



## 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  $^{\sim}$ \$92 million in 2018

Recent Developments

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



60



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®, a bioequivalence study, and our activities until the end of Q3/2020





62



Effective and efficient commercial organization on track

Highly positive Phase III results imply EPSOLAY® as best-in-class

New patent allowance extends value for TWIN from 2032 to 2038

Phase III topline results for TWIN on track in 4Q/19

NDA submissions for EPSOLAY® and TWIN planned for 2020

Lifecycle extension projects for acne and rosacea

R&D exploratory projects in areas of high unmet needs

Significant non-dilutive revenues ahead of plan

