



## Sol-Gel Technologies Reports First Quarter 2021 Financial Results and Corporate Update

May 13, 2021

*- Sol-Gel is in advanced negotiations with a potential partner regarding the commercialization of EPSOLAY® and TWYNEO®*

*- EPSOLAY PDUFA goal date was set for April 26, 2021 . Awaiting FDA's pre-approval inspection*

*- TWYNEO PDUFA goal date set for August 1, 2021*

NESS ZIONA, Israel , May 13, 2021 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, today announced financial results for the first quarter ended March 31, 2021 and provided corporate updates.

### Corporate Highlights and Recent Developments

- Sol-Gel is in advanced negotiations with a potential partner regarding the commercialization of EPSOLAY (benzoyl peroxide, 5%) topical cream and TWYNEO (benzoyl peroxide, 3%, and tretinoin, 0.1%) topical cream.
- With the completion of the development of EPSOLAY and TWYNEO and the advanced negotiations with a potential partner regarding their commercialization, Sol-Gel is turning its attention to the development of its next generation of dermatological treatments for unmet medical needs including SGT-210, erlotinib and preclinical assets tapinarof and roflumilast. As Mr. Mori Arkin was deeply involved in the origination of these products and is the main inventor on many of their new patents, Sol-Gel's CEO, Dr. Alon Seri-Levy, has requested Mr. Arkin to leverage his vast experience in dermatology on behalf of Sol-Gel and dedicate more time to overseeing the development of the new projects. Sol-Gel is grateful to Mr. Arkin for agreeing to Dr. Seri-Levy's request. The Board of Directors has approved a change in Mr. Arkin's title to Executive Chairman to reflect Mr. Arkin's expanded role at the Company.
- In September 2020 , Sol-Gel was informed by the FDA that the PDUFA goal date for EPSOLAY was set for April 26, 2021 . In the most recent written communication with the FDA regarding EPSOLAY, Sol-Gel and the FDA discussed and agreed to the final content of the labeling of the product. On April 27, 2021 , Sol-Gel received confirmation from the FDA that action on the NDA for EPSOLAY has not yet been taken due to the inability of the FDA to conduct a pre-approval inspection of the production site of EPSOLAY as a result of COVID-19 travel restrictions. Sol-Gel's contract manufacturer of EPSOLAY is located in North America , outside the USA , and it underwent on-site inspection by the FDA in the first quarter of 2020.
- In December 2020 , Sol-Gel was informed by the FDA that the PDUFA goal date for TWYNEO is set for August 1, 2021 . Our contract manufacturer of TWYNEO is located outside of North America , and it underwent on-site inspection by the FDA in the fourth quarter of 2019.
- Second generic is expected to be commercialized in the second quarter of this year.

### Financial Results for the Three Months Ended March 31, 2021

Revenue in 2021 was \$0.7million . The revenue was mainly due to sales of a generic product from a collaboration arrangement with Perrigo.

Research and development expenses were \$2.5 million in 2021 compared to \$7.9 million during the same period in 2020. The decrease of \$5.4 million was mainly attributed to a decrease of \$5.1 million in clinical trial expenses related to EPSOLAY and TWYNEO and a decrease of \$0.5 million in manufacturing expenses.

General and administrative expenses were \$2.5 million in 2021 compared to \$2.8 million in 2020. The decrease of \$0.3 million was mainly attributed to a decrease of \$0.2 million in patent related expenses.

Sol-Gel reported a loss of \$4.1 million for the first quarter of 2021 compared to loss of \$7.1 million for the same period in 2020.

As of March 31, 2021 , Sol-Gel had \$34.2 million in cash, cash equivalents and deposits, and \$12.8 million in marketable securities for a total balance of \$47.0 million . Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements into the third quarter of 2022.

### 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 leverages its proprietary microencapsulation technology platform for the development of TWYNEO, under investigation for the treatment of acne vulgaris with an NDA filed with the FDA and a PDUFA goal date set for August 1, 2021 ; and EPSOLAY, under investigation for the treatment of inflammatory lesions of rosacea with an NDA filed with the FDA and a PDUFA goal date which was set for April 26, 2021 . Action on the NDA for EPSOLAY has not yet been taken due to the inability of the FDA to conduct a pre-approval inspection of the production site of EPSOLAY as a result of COVID-19 travel restrictions. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, under investigation for the treatment of palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. For additional information, please visit [www.sol-gel.com](http://www.sol-gel.com).

## About EPSOLAY®

EPSOLAY is an investigational topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea, also known as papulopustular rosacea, in adults. EPSOLAY utilizes a patented technology process to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The silica-based shell is designed to release benzoyl peroxide slowly over time to provide a favorable efficacy and safety profile. If approved, EPSOLAY has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. EPSOLAY is not approved by the FDA and the safety and efficacy has not been established.

## About Papulopustular Rosacea

Papulopustular rosacea is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans. The condition is common, especially in fair-skinned people of Celtic and northern European heritage. Onset is usually after age 30 and typically begins as flushing and subtle redness on the cheeks, nose, chin or forehead. If left untreated, rosacea can slowly worsen over time. As the condition progresses the redness becomes more persistent, blood vessels become visible and pimples often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

## About TWYNEO®

TWYNEO is an investigational topical cream containing a fixed-dose combination of benzoyl peroxide, 3%, and tretinoin, 0.1%, cream for the treatment of acne vulgaris. If approved, TWYNEO will be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin, which are separately encapsulated in silica using Sol-Gel's proprietary microencapsulation technology. Tretinoin and benzoyl peroxide are widely prescribed separately as a combination treatment for acne; however, benzoyl peroxide causes degradation of the tretinoin molecule, thereby potentially reducing its effectiveness if used at the same time or combined in the same formulation. The silica-based microcapsule is designed to protect tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability of the active drug ingredients. The silica-based shell is also designed to release the ingredients slowly over time to provide a favorable efficacy and safety profile. TWYNEO is not approved by the FDA and the safety and efficacy has not been established.

## About Acne Vulgaris

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

## 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, including, but not limited to, statements regarding the timing of the approval of an NDA for TWYNEO and the negotiations with a potential partner regarding the commercialization of EPSOLAY and TWYNEO. These forward-looking 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. Forward-looking 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 forward-looking statements. Important factors that could cause such differences include, but are not limited to, the risk that we may not execute an agreement for the commercialization of EPSOLAY and TWYNEO and risks related to the terms thereof, the risk that our contract manufacturer of EPSOLAY and TWYNEO will not meet applicable requirements relating to the manufacture of EPSOLAY and TWYNEO, the risk of the delay in receipt of approval, if any, of the NDA for TWYNEO, the risk of a further delay in receipt of approval, if any, of the NDA for EPSOLAY, risks relating to the effects of COVID-19 (coronavirus) as well as the following factors: (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, the potential delay in receiving such regulatory approvals 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 4, 2021 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.

## SOL-GEL TECHNOLOGIES LTD.

## CONSOLIDATED BALANCE SHEETS

( U.S. dollars in thousands, except share and per share data )  
(Unaudited)

December 31 ,  
2020

March 31 ,  
2021

**Assets****CURRENT ASSETS:**

Cash and cash equivalents	\$ 7,122	\$ 12,646
Bank deposits	21,400	21,600
Marketable securities	21,652	12,744
Receivables from collaborative arrangements	2,153	706
Prepaid expenses and other current assets	1,074	581
<b>TOTAL CURRENT ASSETS</b>	<b>53,401</b>	<b>48,277</b>

**NON-CURRENT ASSETS:**

Restricted long-term deposits and cash	1,293	1,288
Property and equipment, net	1,817	1,610
Operating lease right-of-use assets	1,896	1,707
Funds in respect of employee rights upon retirement	754	728
<b>TOTAL NON-CURRENT ASSETS</b>	<b>5,760</b>	<b>5,333</b>

<b>TOTAL ASSETS</b>	<b>\$ 59,161</b>	<b>\$ 53,610</b>
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**Liabilities and shareholders' equity****CURRENT LIABILITIES:**

Accounts payable	\$ 1,203	\$ 1,620
Other accounts payable	4,088	2,199
Current maturities of operating leases	673	640
<b>TOTAL CURRENT LIABILITIES</b>	<b>5,964</b>	<b>4,459</b>

**LONG-TERM LIABILITIES -**

Operating leases liabilities	1,299	1,074
Liability for employee rights upon retirement	1,049	1,019
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>2,348</b>	<b>2,093</b>

**COMMITMENTS**

<b>TOTAL LIABILITIES</b>	<b>8,312</b>	<b>6,552</b>
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**SHAREHOLDERS' EQUITY:**

Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2020 and March 31, 2021 ; issued and outstanding: 23,000,782 and 23,028,264 as of December 31, 2020 and March 31, 2021 , respectively.	635	635
Additional paid-in capital	231,577	231,849
Accumulated deficit	(181,363)	(185,426)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>50,849</b>	<b>47,058</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 59,161</b>	<b>\$ 53,610</b>

**SOL-GEL TECHNOLOGIES LTD.****CONSOLIDATED STATEMENTS OF OPERATIONS**

( U.S. dollars in thousands, except share and per share data)

(Unaudited)

	<b>Three months ended 31-Mar</b>	
	<b>2020</b>	<b>2021</b>
<b>COLLABORATION REVENUES</b>	\$ 3,465	\$ 701
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	7,930	2,466
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	2,761	2,459
<b>TOTAL OPERATING LOSS</b>	\$ 7,226	\$ 4,224
<b>FINANCIAL INCOME, net</b>	(116)	(161)
<b>LOSS FOR THE PERIOD</b>	\$ 7,110	\$ 4,063
<b>BASIC AND DILUTED LOSS PER ORDINARY SHARE</b>	\$ 0.33	\$ 0.18
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE</b>	21,361,514	23,003,425

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