



Sol-Gel Technologies Reports Full Year 2020 Financial Results and Corporate Update

March 4, 2021

- *Epsolay® and Twyneo® PDUFA goal dates set for April 26, 2021 and August 1, 2021 respectively*
- *Top-line generic product revenue of \$8.7 million in fiscal 2020*
- *Signed additional generic product collaboration agreements with Perrigo, bringing the number of collaborations between the companies to 12*

NESS ZIONA, Israel, March 04, 2021 – 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 full year ended December 31, 2020 and provided corporate updates.

"I am very pleased with the major milestones that were achieved by Sol-Gel last year. After announcing positive data from Phase 3 trials of Epsolay and Twyneo and submitting NDAs to the FDA within guided timelines, 2020 was highlighted by positive acceptances of both NDAs and allocated PDUFA dates," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel.

"Given the competitive landscape of the dermatology market and the significant capital that would be needed to directly commercialize our products, our current operational model assumes we will partner with a dermatology company that has a strong market presence. This would enable us to capture market share more quickly without the need to invest in building our own marketing and sales force and would allow us to further invest in the development of our pipeline of products with larger potential markets," continued Dr. Seri-Levy.

Corporate Highlights and Recent Developments

- Sol-Gel announced the U.S. Food and Drug Administration's (FDA) acceptance of New Drug Application (NDA) for Epsolay (benzoyl peroxide, 5%, cream) with a Prescription Drug User Fee Act (PDUFA) goal date set for April 26, 2021. If approved, Epsolay has the potential to be the first FDA-approved, single-agent benzoyl peroxide prescription drug product for the treatment of inflammatory lesions of rosacea.
- Sol-Gel announced FDA acceptance of NDA for Twyneo (benzoyl peroxide, 3%, and tretinoin, 0.1%, cream) with a PDUFA goal date set for August 1, 2021. If approved, Twyneo has the potential to be the first FDA-approved acne treatment that contains fixed-dose combination of benzoyl peroxide and tretinoin.
- Sol-Gel is in discussions with potential partners regarding the commercialization of Epsolay and Twyneo in the United States to occur if the product candidates receive regulatory approval from the FDA.
- In preparation for commercial launch of proprietary products the Company has opened a US headquarters in Whippany, NJ.
- Sol-Gel was informed by its collaboration partner that the launch of an FDA-approved generic drug is expected in the second quarter of 2021. Annual sales of the brand name product exceeded \$180 million in the United States in 2019.
- In 2020, Sol-Gel signed four additional collaboration agreements with Perrigo for the development, manufacture, and commercialization of new generic product candidates, bringing the total number of collaborations between the companies to 12.
- Pre-clinical testing of erlotinib (an epidermal growth factor receptor inhibitor), tapinarof (an investigational aryl hydrocarbon receptor modulator), and roflumilast (an investigational phosphodiesterase 4 inhibitor) is progressing for various new pharmaceutical indications. A total of 25 provisional patent applications for these project candidates have been submitted to date.
- The enrollment of patients in the Phase 1 proof-of-concept study with SGT-210 (erlotinib gel) in patients with palmoplantar keratoderma has been slowed by the COVID-19 pandemic. The Company expects to report top-line data in the third quarter of 2021.
- In 2020, the Company completed financings totaling \$28.0 million in gross proceeds, including the proceeds of the February underwritten public offering of \$23.0 million and from the \$5.0 million invested in April by Sol-Gel's controlling shareholder, M. Arkin Dermatology Ltd.

Financial Results for the Year Ended December 31, 2020

Revenue in 2020 was \$8.8 million. The revenue was mainly due to sales of a generic product from a collaboration arrangement with Perrigo.

Research and development expenses were \$27.9 million in 2020 compared to \$40.6 million during the same period in 2019. The decrease of \$12.7 million was mainly attributed to a decrease of \$17.9 million in clinical trial expenses, mainly due to the completion of the clinical trials of Epsolay and Twyneo towards the end of 2019, a decrease of \$0.4 million in other expenses, mainly due to the purchase of raw material for manufacturing, partially offset by an increase of \$5.4 million in manufacturing expenses.

General and administrative expenses were \$11.1 million in 2020 compared to \$8.3 million in 2019. The increase of \$2.8 million was mainly attributed to an increase of \$3.0 million in commercialization expenses and an increase of \$0.4 million in patent related expenses, partially offset by a decrease of \$0.7 million in stock based compensation expenses.

Sol-Gel reported a loss of \$29.3 million for the full year of 2020 compared to loss of \$24.6 million for the same period in 2019.

As of December 31, 2020, Sol-Gel had \$28.5 million in cash, cash equivalents and deposits, and \$21.7 million in marketable securities for a total balance of \$50.2 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, and Epsolay, under investigation for the treatment of inflammatory lesions of rosacea. The Company's pipeline also includes SGT-210 (erlotinib gel), under investigation for the treatment of palmoplantar keratoderma, and three pre-clinical assets – erlotinib, tapinarof and roflumilast – currently being tested for various pharmaceutical indications. For additional information, please visit www.sol-gel.com.

About Epsolay®

Epsolay is an investigational topical cream containing encapsulated benzoyl peroxide, 5%, for the treatment of papulopustular rosacea. 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 slow migration of medication from the microcapsules is designed to deliver an effective dose of benzoyl peroxide onto the skin, while reducing the ability of benzoyl peroxide to induce skin irritation, such as erythema, burning and stinging. 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, fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris. If approved, it 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 PDUFA goal dates for Epsolay (benzoyl peroxide, 5%, cream) and Twyneo, the timing of commercialization of Epsolay and Twyneo, the timing and expected launch of an FDA-approved generic drug in the second quarter of 2021, and the timing of the Phase 1 data readout of SGT-210. 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, 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 to be 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)

December 31**2019****2020****Assets****CURRENT ASSETS:**

Cash and cash equivalents	\$	9,412	\$	7,122
Bank deposits		-		21,400
Marketable securities		40,966		21,652
Receivables from collaborative arrangements		4,120		2,153
Prepaid expenses and other current assets		1,293		1,074
TOTAL CURRENT ASSETS		55,791		53,401

NON-CURRENT ASSETS:

Restricted long-term deposits and cash		472		1,293
Property and equipment, net		2,314		1,817
Operating lease right-of-use assets		2,040		1,896
Funds in respect of employee rights upon retirement		684		754
TOTAL NON-CURRENT ASSETS		5,510		5,760

TOTAL ASSETS	\$	61,301	\$	59,161
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Liabilities and shareholders' equity**CURRENT LIABILITIES:**

Accounts payable	\$	1,710	\$	1,203
Other accounts payable		4,123		4,088
Current maturities of operating leases		672		673
TOTAL CURRENT LIABILITIES	6,505		5,964	

LONG-TERM LIABILITIES:

Operating leases liabilities	1,373	1,299
Liability for employee rights upon retirement	958	1,049
TOTAL LONG-TERM LIABILITIES	2,331	2,348
COMMITMENTS		
TOTAL LIABILITIES	8,836	8,312
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2019 and 2020, respectively; issued and outstanding: 20,402,800 and 23,000,782 as of December 31, 2019 and December 31, 2020, respectively	561	635
Additional paid-in capital	203,977	231,577
Accumulated deficit	(152,073)	(181,363)
TOTAL SHAREHOLDERS' EQUITY	52,465	50,849
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 61,301	\$ 59,161

SOL-GEL TECHNOLOGIES LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

Year ended December 31,

2018	2019	2020
COLLABORATION REVENUES	\$ 129	\$ 22,904
OPERATING EXPENSES		
Research and Development	28,146	40,578
General and Administrative	5,504	8,276
TOTAL OPERATING LOSS	33,521	25,950
FINANCIAL INCOME, net	(1,318)	(1,374)
LOSS BEFORE INCOME TAXES	32,203	24,576
INCOME TAXES	-	33
LOSS FOR THE YEAR	\$ 32,203	\$ 24,609
BASIC AND DILUTED LOSS PER ORDINARY SHARE	\$ 1.80	\$ 1.26

**WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN
COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE**

17,867,589

19,534,562

22,574,688

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