Sol-Gel Technologies Reports First Quarter 2020 Financial Results and Corporate Update

May 14, 2020

- *New Drug Applications for Epsolay® and Twyneo® remain on track for the second quarter and second half 2020, respectively*
- *Completed a $23 million underwritten public offering in February with an additional $5 million investment from Sol-Gel's controlling shareholder in April, providing cash runway into mid-2021 and funds pre-commercialization efforts for Epsolay and Twyneo*
- *Top-line generic product revenue of $3.4 million in first quarter 2020*

NESS ZIONA, Israel, May 14, 2020 (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, 2020 and provided an update on its clinical development programs.

"In the first quarter of 2020, we strengthened our balance sheet through a $23 million underwritten public offering in February and a subsequent $5 million private placement that closed just after the end of the first quarter. This capital from new and existing shareholders, including our controlling shareholder, M. Arkin Dermatology Ltd., extends our cash runway to mid-2021, and funds our pre-commercialization efforts for Epsolay and Twyneo," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "We remain on track to file our New Drug Application (NDA) for Epsolay with the FDA in the second quarter of this year and our NDA for Twyneo in the second half this year, both exciting milestones for the company."

"I also want to acknowledge the efforts of our employees and the whole healthcare system in working to keep our community safe during the ongoing COVID-19 pandemic," continued Dr. Seri-Levy. "At Sol-Gel, we have been fortunate to have seen only minimal impact to our operations to date, largely due to the advanced clinical status of our two lead programs, Epsolay and Twyneo."

Corporate Highlights and Recent Developments

- Strengthened balance sheet with $28.0 million in gross proceeds from the February underwritten public offering of $23.0 million and from the $5.0 million that Sol-Gel's controlling shareholder, M. Arkin Dermatology Ltd., invested in April. Despite market conditions, the April purchase of ordinary shares and warrants was at the same terms as the February underwritten public offering, $11.00 per ordinary share and an accompanying warrant to purchase 0.80 of an ordinary share. The warrants have an initial exercise price of $14.00 per share, subject to certain adjustments, and will expire on February 19, 2023.

- In the first quarter of 2020, Sol-Gel generated revenue of $3.4 million from its collaboration agreement with Perrigo.

- In response to COVID-19, Sol-Gel immediately implemented policies and procedures to protect the health, safety and welfare of employees and their families and to help mitigate the spread of the coronavirus including mandatory work-from-home and frequent on-site sterilization.

Clinical Program Updates

- Sol-Gel expects to file an NDA for Epsolay (encapsulated benzoyl peroxide, 5%, cream) in the second quarter of 2020. If approved, Epsolay has the potential to be the first FDA-approved single-agent BPO prescription drug product and to redefine the standard of care for the treatment of inflammatory lesions associated with rosacea.

- Sol-Gel expects to file an NDA for Twyneo (encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream) in the second half of 2020. If approved, Twyneo has the potential to become a preferred treatment for acne.

- In January, Sol-Gel announced positive topline results from an open-label long-term safety study of Epsolay. Of the 209 patients (57.6%) that completed 52 weeks of treatment with Epsolay, 153 (73.2%) reached "clear" or "almost clear", 46 (22%) reached "mild" rosacea, only 10 (4.8%) had "moderate" rosacea, and none had "severe" rosacea on a Global Assessment (IGA) 5-point scale. Additionally, at the end of the study, more than 90% of these patients had "none" or "mild" cutaneous signs or symptoms (burning or stinging, itching, dryness and scaling) and no "severe" scores were recorded.

- A proof of concept clinical study of SGT-210, erlotinib gel, a topical epidermal growth factor receptor inhibitor, for the potential treatment of punctuate palmoplantar keratoderma type 1 initiated in January 2020. This clinical study was recently expanded to include other types of palmoplantar keratoderma. Patient enrollment is expected to be renewed subject to Israel Ministry of Health guidelines for COVID-19. Data is expected in 2021.

- In early 2020, Sol-Gel added to its pre-clinical pipeline tapinarof, an aryl hydrocarbon receptor agonist, and roflumilast, a PDE4 inhibitor, each to be developed for potential treatment of psoriasis, as mono or combination therapies and other dermatological indications. Sol-Gel continues to work to advance these assets into the clinic.

Financial Results for the Three Months ended March 31, 2020

Revenue in the first quarter 2020 was $3.5 million. The revenue was mainly due to sales of a generic product from the collaboration arrangement with Perrigo. The decrease in revenue from the previous quarter follows from continued generic competition.

Research and development expenses were $7.9 million in the first quarter of 2020 compared to $10.8 million during the same period in 2019. The decrease of $2.9 million was mainly attributed to a decrease of $2.6 million in clinical trial expenses, mainly related to clinical trials of Epsolay and a decrease of $0.5 million in manufacturing expenses of Epsolay and Twyneo, partially offset by an increase of $0.2 million in regulatory expenses, mainly related to preparing for the NDA submissions for Epsolay and Twyneo.

General and administrative expenses were $2.8 million in the first quarter of 2020 compared to $1.7 million during the same period in 2019. The increase of $1.1 million was mainly attributed to an increase of $1.0 million in commercialization expenses and an increase of $0.1 million in other expenses.

Sol-Gel reported a loss of $7.1 million for the first quarter of 2020 compared to loss of $5.7 million for the same period in 2019.

As of March 31, 2020, Sol-Gel had $20.4 million in cash, cash equivalents and deposits and $45.8 million in marketable securities for a total balance of $66.2 million, excluding the additional $5.0 million investment by Sol-Gel's controlling shareholder which closed in April. Based on current assumptions, Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements into mid-2021. As previously disclosed, Sol-Gel does not plan to raise additional dilutive capital to fund pre-commercialization activities for Epsolay and Twyneo.

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 Twyneo, for the treatment of acne vulgaris, and Epsolay, for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, for the treatment of punctate palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. 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 microcapsules to create a barrier between the medication and the skin. The slow migration of medication from the microcapsules delivers treatment doses onto the skin, while the barrier reduces the ability of benzoyl peroxide to induce the strong oxidation process that can result in significant skin irritation, such as erythema, burning and stinging. Silica is chemically inert, photochemically and physically stable, and is safely used in topical products. If approved, Epsolay has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product.

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, antibiotic-free, 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 proprietary microencapsulation technology. Tretinoin and benzoyl peroxide are widely believed to be highly effective as a combination treatment for acne; however, benzoyl peroxide causes degradation of the tretinoin molecule, thereby reducing its effectiveness. The silica microcapsule protects tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability of the active drug ingredients. The silica shell also allows for an extended drug delivery time and creates a barrier between the drug substances and the skin, which may reduce the irritation typically associated with topical application of benzoyl peroxide and tretinoin on acne-affected skin.

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 progress of our product candidates, the timing of the submission of an NDA for Epsolay and an NDA for Twyneo, and the Company's expectations regarding its liquidity and ability to fund operational and capital expenditure requirements. 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), the timing of a launch of a branded tapinarof product and the launch of a branded topical roflumilast in the U.S., risks related to the timing of the submission of an NDA for Epsolay and an NDA for Twyneo 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 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 24 , 2020 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, 2019	March 31, 2020
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,412	$ 2,199
Bank deposit	-	18,200
Marketable securities	40,966	45,762
Receivables from collaborative arrangements	4,120	3,594
Prepaid expenses and other current assets	1,293	863
TOTAL CURRENT ASSETS	55,791	70,618
NON-CURRENT ASSETS:		
Restricted long-term deposits	472	1,268
Property and equipment, net	2,314	2,363
Operating lease right-of-use assets	2,040	1,904
Funds in respect of employee rights upon retirement	684	663
TOTAL NON-CURRENT ASSETS	5,510	6,198
TOTAL ASSETS	$ 61,301	$ 76,816
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 1,710	$ 1,926
Other accounts payable	4,123	4,972
Current maturities of operating leases	672	525
TOTAL CURRENT LIABILITIES	6,505	7,423
LONG-TERM LIABILITIES -		
Operating leases liabilities	1,373	1,315
Liability for employee rights upon retirement	958	946
TOTAL LONG-TERM LIABILITIES	2,331	2,261
COMMITMENTS		
TOTAL LIABILITIES	8,836	9,684
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2019 and March 31, 2020; issued and outstanding: 20,402,800 and 22,514,488 as of December 31, 2019 and March 31,	561	622

2020, respectively.		
Additional paid-in capital	203,977	225,693
Accumulated deficit	(152,073)	(159,183)
TOTAL SHAREHOLDERS' EQUITY	52,465	67,132
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 61,303	$ 76,816

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CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three months ended March 31	
	2019	**2020**
COLLABORATION REVENUES	$ 6,358	$ 3,465
OPERATING EXPENSES		
Research and Development	10,793	7,930
General and Administrative	1,694	2,761
TOTAL OPERATING LOSS	$ 6,129	$ 7,226
FINANCIAL INCOME, net	(401)	(116)
LOSS BEFORE INCOME TAXES	$ 5,728	$ 7,110
INCOME TAXES	-	-
LOSS FOR THE PERIOD	$ 5,728	$ 7,110
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.30	$ 0.33
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	18,949,968	21,361,514

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