



Sol-Gel Technologies Reports Full Year 2019 Financial Results and Corporate Update

March 24, 2020

- *Top-line generic product revenue of \$22.8 million in fiscal 2019*
- *New Drug Applications for Epsolay® and Twyneo® remain on track for the second quarter and second half 2020, respectively*

NESS ZIONA, Israel, March 24, 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 provided a corporate update and reported financial results for the full year ended December 31, 2019.

"I am very proud of the major milestones that were accomplished by Sol-Gel in 2019. We announced positive top-line data from not one, but two clinical dermatological programs, Epsolay® in papulopustular rosacea and Twyneo® in acne vulgaris," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Our goals for 2020 are no less ambitious as we plan to file two New Drug Applications (NDA) in the U.S. – Epsolay in the second quarter of 2020 and Twyneo in the second half. In parallel, we are planning commercialization efforts and advancing development of our proprietary pipeline, while benefiting from our strong generic collaborations."

"In terms of COVID-19 impact," continued Dr. Seri-Levy, "given that Sol-Gel has completed the clinical programs required to support the NDAs for both Epsolay and Twyneo, and given that Sol-Gel recently strengthened its balance sheet, we remain on track to file both NDAs in the previously communicated timelines. This is of course, a dynamic situation which we will be monitoring closely."

Corporate Highlights and Recent Developments

- Strengthened balance sheet with underwritten public offerings of \$23 million of gross proceeds in February 2020 and \$11.5 million of gross proceeds in August 2019; Sol-Gel's controlling shareholder, M. Arkin Dermatology Ltd., has agreed to invest an additional \$5 million on the same terms as the February 2020 public offering, subject to shareholder approval.
- In the fiscal year 2019, Sol-Gel generated revenue of \$22.8 million from its collaboration agreement with Perrigo.
- In September 2019, Sol-Gel was granted a patent from the United States Patent and Trademark Office for a patent covering Twyneo for the treatment of acne vulgaris. The newly granted patent will extend protection to July 2038, which Sol-Gel believes will prevent the launch of AB-rated generics of Twyneo during the life of the patent

Clinical Program Updates

- In December 2019, Sol-Gel announced that Twyneo met all co-primary endpoints in the treatment of patients with acne vulgaris. Sol-Gel expects to file a NDA in the second half of 2020. If approved, Twyneo has the potential to become a preferred treatment for acne.
- In July 2019, Sol-Gel announced that Epsolay met all primary and secondary endpoints in both Phase 3 trials in papulopustular rosacea. Epsolay also demonstrated a rapid onset of action with statistically significant improvement seen as early as Week 2 compared with vehicle. Sol-Gel expects to file a NDA in the first half 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 subtype II rosacea.
- 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. Data is expected in the first half of 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.

Financial Results for the Twelve Months Ended December 31, 2019

Revenue in 2019 was \$22.9 million. The revenue was mainly due to sales of a generic product from the collaboration arrangement with Perrigo.

Research and development expenses were \$40.6 million in 2019 compared to \$28.1 million during the same period in 2018. The increase of \$12.5 million was mainly attributed to an increase of \$12.5 million in clinical trial expenses, mainly related to clinical trials of Epsolay and Twyneo, an increase of \$0.5 million in manufacturing expenses and an increase of \$0.5 million in other expenses, mainly due to the purchase of raw material for manufacturing, partially offset by a decrease of \$1.1 million in payroll and related expenses, mainly related to stock based compensation expenses.

General and administrative expenses were \$8.3 million in 2019 compared to \$5.5 million during the same period in 2018. The increase of \$2.8 million was mainly attributed to an increase of \$0.9 million in legal fees, an increase of \$1.5 million in commercialization expenses and an increase of \$0.3 million in professional service expenses.

Sol-Gel reported a loss of \$24.6 million for 2019 compared to loss of \$32.2 million for the same period in 2018.

As of December 31, 2019, Sol-Gel had \$9.4 million in cash, cash equivalents and deposits and \$41.0 million in marketable securities for a total balance of \$50.4 million, not including the proceeds from the Company's underwritten public offering in February 2020. Based on current assumptions, Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements into the middle of the second quarter of 2021, excluding the additional \$5 million investment that Sol-Gel's controlling shareholder has agreed to make, subject to shareholder approval. As previously disclosed, Sol-Gel does not plan to raise additional dilutive capital to fund pre-commercialization activities.

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 Twynéo, 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 Twynéo®

Twynéo 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 upcoming events and presentations, the clinical progress of our product candidates, plans and timing for the release of clinical data, our expectations surrounding the progress of our generic product pipeline, and the sufficiency of our cash resources to meet our operating 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 Twynéo 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)

	December 31	
	2018	2019
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 5,325	\$ 9,412
Bank deposits	1,000	-
Marketable securities	56,662	40,966
Receivables from collaborative arrangements	-	4,120
Prepaid expenses and other current assets	2,987	1,293
TOTAL CURRENT ASSETS	65,974	55,791
NON-CURRENT ASSETS:		
Restricted long-term deposits	462	472
Property and equipment, net	2,604	2,314
Operating lease right-of-use assets	-	2,040
Funds in respect of employee rights upon retirement	642	684
TOTAL NON-CURRENT ASSETS	3,708	5,510
TOTAL ASSETS	\$ 69,682	\$ 61,301
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,924	\$ 1,710
Other accounts payable	1,971	4,123
Current maturities of operating leases	-	672
TOTAL CURRENT LIABILITIES	4,895	6,505
LONG-TERM LIABILITIES:		
Operating leases liabilities	-	1,373
Liability for employee rights upon retirement	878	958
TOTAL LONG-TERM LIABILITIES	878	2,331
COMMITMENTS		
TOTAL LIABILITIES	5,773	8,836
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2018 and 2019, respectively; issued and outstanding: 18,949,968 and 20,402,800 as of December 31, 2018 and December 31, 2019, respectively	520	561
Additional paid-in capital	190,853	203,977
Accumulated deficit	(127,464)	(152,073)
TOTAL SHAREHOLDERS' EQUITY	63,909	52,465
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 69,682	\$ 61,301

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)

	Year ended December 31,		
	2017	2018	2019
COLLABORATION REVENUES	\$ 174	\$ 129	\$ 22,904
OPERATING EXPENSES			
Research and Development	25,805	28,146	40,578

General and Administrative	6,002	5,504	8,276
TOTAL OPERATING LOSS	31,633	33,521	25,950
FINANCIAL INCOME, net	(65)	(1,318)	(1,374)
LOSS BEFORE INCOME TAXES	31,568	33,203	24,576
INCOME TAXES	-	-	33
LOSS FOR THE YEAR	\$ 31,568	\$ 32,203	\$ 24,609
BASIC AND DILUTED LOSS PER ORDINARY SHARE	\$ 5.02	\$ 1.80	\$ 1.26
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	6,290,244	17,867,589	19,534,562

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
crusso@soleburytrout.com

Source: Sol-Gel Technologies Ltd.



Source: Sol-Gel Technologies Ltd.