Sol-Gel Technologies Reports Third Quarter 2019 Financial Results and Corporate Update

November 13, 2019

- *Top-line generic product revenue of $4.7 million in the third quarter*
- *Results from TWIN Phase 3 trials in acne vulgaris remain on track for the fourth quarter of 2019*

NESS ZIONA, Israel, Nov. 13, 2019 (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 third quarter ended September 30, 2019 and provided an update on its clinical development programs.

"We continue to expect top-line data from our pivotal TWIN Phase 3 trials in acne vulgaris by the end of the year and we expect to file a New Drug Application (NDA) in the U.S. for Epsolay® in papulopustular rosacea in the first half of next year," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "2020 will be an exciting year for Sol-Gel as we continue to advance our proprietary assets and also continue to see benefit from our generic collaborations, adding more non-dilutive funding to further support the advancement of our branded pipeline towards NDA approvals and commercialization."

Corporate Highlights and Recent Developments

- In August 2019, Sol-Gel completed an underwritten public offering for $11.5 million of gross proceeds.
- In the third quarter, Sol-Gel generated revenue of $4.7 million from its collaboration arrangement with Perrigo.
- The Food and Drug Administration (FDA) has granted provisional approval of the brand name Twyneo® cream (microencapsulated benzoyl peroxide, 3% and microencapsulated tretinoin, 0.1%) (formerly TWIN) which is currently being investigated in two pivotal Phase 3 trials for acne vulgaris.

Clinical Program Update

- Top-line results of the two pivotal Phase 3 trials evaluating Twyneo® cream in acne vulgaris continue to be expected in the fourth quarter of 2019.
- Preparations are underway for the New Drug Application submission for Epsolay® microencapsulated benzoyl peroxide, 5%, in papulopustular rosacea in the first half of 2020.
- Results from a bioequivalence study for generic 5-fluorouracil cream, 5%, for actinic keratosis, continue to be expected by the end of the year followed by a filing in the U.S. of an abbreviated New Drug Application expected in 2020. This study is part of a collaboration with Douglas Pharmaceuticals.
- Planning continues around the development of SGT-210, a topical epidermal growth factor receptor inhibitor, for the potential treatment of palmoplantar keratoderma (PPK) and non-melanoma skin cancer. A proof of concept study of SGT-210 in PPK is expected to begin in the first quarter of 2020.
- In October, Sol-Gel participated in the Fall Clinical Dermatology Conference® in Las Vegas, Nevada where additional data were presented related to Epsolay®, Sol-Gel's investigational topical drug candidate. Oral presentations and poster highlights included;
    - Safety and efficacy data from two 12 week Phase 3 studies (SGT-01, SGT-02) which showed significant and rapid improvement in patients with moderate-to-severe papulopustular rosacea treated with Epsolay® versus a vehicle
    - Characterization of the company's proprietary microencapsulation technology platform designed to improve topical drug delivery and supported by the results observed from the Epsolay® Phase 3 program.

Financial Results for the Three Months Ended September 30, 2019

Revenue in the third quarter of 2019 was $4.7 million. The revenue was due to sales of a generic product from the collaboration arrangement with Perrigo. The decrease in revenue from the previous quarter follows the entry of an authorized generic product to the market.

Research and development expenses were $9.9 million in the third quarter of 2019 compared to $7.1 million during the same period in 2018. The increase was primarily due to an increase of $2.4 million in clinical trial expenses related to Epsolay and Twyneo®, an increase of $0.1 million in manufacturing expenses for Twyneo®, and an increase of $0.3 million in other expenses.

General and administrative expenses were $2.5 million in the third quarter of 2019 compared to $1.3 million during the same period in 2018. The increase was primarily due to an increase of $0.9 million in consulting expenses, an increase of $0.2 million in payroll expenses and an increase of $0.3 million in legal and professional expenses, partially offset by a decrease of $0.2 million in share-based compensation expenses.

Sol-Gel reported a loss of $7.4 million for the third quarter of 2019 compared to loss of $7.7 million for the same period in 2018.

As of September 30, 2019, Sol-Gel had $7.6 million in cash, cash equivalents and deposits and $50.1 million in marketable securities for a total balance of $57.7 million. Based on current assumptions, Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements into the first quarter of 2021.

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 our proprietary, silica-based microencapsulation technology platform, and several generic product candidates across multiple indications. For additional information, please visit www.sol-gel.com.

About Twyneo®

Twyneo® cream is a novel non-antibiotic topical 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.

About Epsolay®

Epsolay® is an innovative topical cream containing microencapsulated benzoyl peroxide, 5%, in development 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.

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: (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.

SOL-GEL TECHNOLOGIES LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	December 31, 2018	September 30, 2019
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,325	$ 7,640
Bank deposit	1,000	-
Marketable securities	56,662	50,086
Receivables from collaborative arrangements	-	4,798
Prepaid expenses and other current assets	2,987	966
TOTAL CURRENT ASSETS	65,974	63,490
NON-CURRENT ASSETS:		
Restricted long-term deposits	462	471
Property and equipment, net	2,604	2,410
Operating lease right-of-use assets	-	820
Funds in respect of employee rights upon retirement	642	691
TOTAL NON-CURRENT ASSETS	3,708	4,392
TOTAL ASSETS	$ 69,682	$ 67,882
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 2,924	$ 2,459
Other account payable	1,971	5,025
Current maturities of operating leases	-	660
TOTAL CURRENT LIABILITIES	4,895	8,144
LONG-TERM LIABILITIES -		
Operating leases liabilities	-	187
Liability for employee rights upon retirement	878	980
TOTAL LONG-TERM LIABILITIES	878	1,167
COMMITMENTS		
TOTAL LIABILITIES	5,773	9,311
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2018 and September 30, 2019; issued and outstanding: 18,949,968 and 20,387,468 as of December 31, 2018 and September 30, 2019, respectively.	520	561
Additional paid-in capital	190,853	203,481
Accumulated deficit	(127,464)	(145,471)
TOTAL SHAREHOLDERS' EQUITY	63,909	58,571
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 69,682	$ 67,882

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

	Nine months ended September 30		Three months ended September 30	
	2018	2019	2018	2019
COLLABORATION REVENUES	$ 131	$ 18,884	$ 38	$ 4,733
RESEARCH AND DEVELOPMENT EXPENSES	17,545	32,146	7,083	9,913

GENERAL AND ADMINISTRATIVE EXPENSES	3,974	5,816	1,314	2,484
TOTAL OPERATING LOSS	21,388	19,078	8,359	7,664
FINANCIAL INCOME, NET	(1,061)	(1,071)	(652)	(311)
LOSS FOR THE PERIOD	$ 20,327	$ 18,007	$ 7,707	$ 7,353
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 1.16	$ 0.94	$ 0.40	$ 0.37
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	17,501,491	19,230,070	18,949,968	19,787,194

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