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

August 13, 2019

- *Top-line generic product revenue of $7.8 million*
- *TWIN Phase 3 trials are fully enrolled and remain on track to report results in 4Q19*

NESS ZIONA, Israel, Aug. 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 second quarter ended June 30, 2019 and provided an update on its clinical development programs.

"With the positive results reported from our Epsolay® Phase 3 trials in papulopustular rosacea and top-line results expected later this year from the now fully enrolled pivotal TWIN program in acne, we remain confident of our ability to lead these programs through both the clinical and regulatory pathways to successful commercial launches," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Additionally, we continue to generate meaningful revenue from our generic collaborations, which support the funding of our ongoing plans for TWIN and Epsolay as well as our proof-of-concept study for SGT-210 which we expect to initiate in the first quarter of 2020."

Corporate Highlights and Recent Developments

- In the second quarter, Sol-Gel generated revenue of $7.8 million from its collaborative arrangement with Perrigo.
- In July 2019, Sol-Gel received Notice of Allowance from the United States Patent and Trademark Office for a patent covering TWIN 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-related generic of TWIN during the life of the patent.

Clinical Program Update

- Epsolay met all primary and secondary endpoints in both Epsolay Phase 3 trials, with statistically significant improvement seen as early as Week 2 compared with vehicle.
- Enrollment in the two pivotal Phase 3 TWIN trials in acne vulgaris has been completed with top-line results expected in the fourth quarter of 2019, as previously announced.
- Results from a bioequivalence study for generic 5-fluorouracil cream, 5%, for actinic keratosis, continue to be expected in 2019 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.
- During an investor event held on July 25th, Sol-Gel announced an expansion to its development pipeline to include 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.

Financial Results for the Three Months Ended June 30, 2019

Revenue in the second quarter of 2019 was $7.8 million. The revenue was due to sales of a generic product from a collaborative arrangement with Perrigo.

Research and development expenses were $11.4 million in the second quarter of 2019 compared to $5.8 million during the same period in 2018. The increase was primarily due to an increase of $6.2 million in clinical trial expenses related to Epsolay and TWIN partially offset by a decrease of $0.2 million in manufacturing expenses for TWIN and a decrease of $0.4 million in share-based compensation expenses.

General and administrative expenses were $1.6 million in the second quarter of 2019 compared to $1.5 million during the same period in 2018. The increase was primarily due to an increase of $0.2 million in legal expenses and an increase of $0.2 million in payroll expenses, partially offset by a decrease of $0.3 million in share-based compensation expenses.

Sol-Gel reported a loss of $4.9 million for the second quarter of 2019 compared to a loss of $6.9 million for the same period in 2018.

As of June 30, 2019, Sol-Gel had $14.4 million in cash, cash equivalents and deposits and $35.5 million in marketable securities for a total balance of $49.9 million. Based on current assumptions, inclusive of the recent offering, 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.

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, 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 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: (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 and studies 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	June 30, 2019
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,325	$ 14,388
Bank deposit	1,000	-
Marketable securities	56,662	35,519
Accounts receivable	-	7,826
Prepaid expenses and other current assets	2,987	1,097
TOTAL CURRENT ASSETS	65,974	58,830
NON-CURRENT ASSETS:		
Restricted long-term deposits	462	467
Property and equipment, net	2,604	2,454
Operating lease right-of-use assets	-	952
Funds in respect of employee rights upon retirement	642	675
TOTAL NON-CURRENT ASSETS	3,708	4,548
TOTAL ASSETS	$ 69,682	$ 63,378
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 2,924	$ 2,767
Other account payable	1,971	4,063
Current maturities of operating leases	-	526
TOTAL CURRENT LIABILITIES	4,895	7,356
LONG-TERM LIABILITIES -		

Operating leases liabilities	-	323
Liability for employee rights upon retirement	878	957
TOTAL LONG-TERM LIABILITIES	878	1,280
COMMITMENTS		
TOTAL LIABILITIES	5,773	8,636
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2018 and March 31, 2019; issued and outstanding: 18,949,968 as of December 31, 2018 and March 31, 2019	520	520
Additional paid-in capital	190,853	192,340
Accumulated deficit	(127,464)	(138,118)
TOTAL SHAREHOLDERS' EQUITY	63,909	54,742
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 69,682	$ 63,378

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

	Six months ended June 30		Three months ended June 30	
	2018	**2019**	**2018**	**2019**
COLLABORATION REVENUES	$ 93	$ 14,151	$ 49	$ 7,793
RESEARCH AND DEVELOPMENT EXPENSES	10,462	22,233	5,817	11,440
GENERAL AND ADMINISTRATIVE EXPENSES	2,660	3,332	1,518	1,638
TOTAL OPERATING LOSS	13,029	11,414	7,286	5,285
FINANCIAL INCOME, NET	(409)	(760)	(379)	(359)
LOSS FOR THE PERIOD	$ 12,620	$ 10,654	$ 6,907	$ 4,926
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.75	$ 0.56	$ 0.36	$ 0.26
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	16,761,158	18,949,968	18,949,968	18,949,968

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Source: Sol-Gel Technologies Ltd.

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