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

May 22, 2019

Top-line results from Phase III Epsolay® and TWIN trials remain on track; mid-2019 and 4Q19, respectfully

Reports top-line generic product revenues of $6.3 million

NESS ZIONA, Israel, May 22, 2019 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) ("Sol-Gel" or the "Company"), 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, 2019 and provided an update on its clinical development programs.

"This year is an exciting year for Sol-Gel as we reach two critical inflection points with the pivotal Phase III read-outs of our proprietary branded product candidates, Epsolay® and TWIN," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "We believe our expertise in formulation chemistry will yield supporting data for much-needed effective and differentiated products for both rosacea and acne. Additionally, we are delighted to report revenues from the sales of acyclovir cream, 5% and we congratulate Perrigo for their success on the launch of this complex product. We look forward to continued collaborations in our generics pipeline."

Corporate Highlights and Recent Developments

- In the first quarter, Sol-Gel realized first-time revenues of $6.3 million from the sale of a first generic version of Zovirax® (acyclovir) cream, 5% with partner Perrigo.
- On April 15, 2019, Sol-Gel announced that it had completed 50% patient enrollment in both pivotal Phase III clinical trials of TWIN for the treatment of acne vulgaris. TWIN is a once daily topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide and encapsulated tretinoin using Sol-Gel's proprietary microencapsulation platform.

Clinical Program Update

- Top-line results from the pivotal Phase III Epsolay® trials in papulopustular rosacea continue to be expected in mid-2019.
- Top-line results from the two pivotal Phase III TWIN trials in acne vulgaris continue to be expected in the fourth quarter of 2019.
- Results from a bioequivalence study for generic 5-fluorouracil cream, 5%, indicated for actinic keratosis, continue to be expected in 2019 with a planned abbreviated new drug application (ANDA) during 2019. This study is part of a generics collaboration with partner Douglas Pharmaceuticals.

Financial Results for the Three Months Ended March 31, 2019

Sol-Gel reported revenue of $6.4 million for the first quarter of 2019 compared to $0.0 million for the same period of 2018. Of this amount, $6.3 million is attributed to sales of our partnered generic product, acyclovir cream, 5%.

Research and development expenses were $10.8 million in the first quarter of 2019 compared to $4.6 million during the same period in 2018. The increase was primarily due to an increase of $5.7 million related to clinical trial expenses and an increase of $0.6 million in manufacturing expenses.

General and administrative expenses were $1.7 million in the first quarter 2019 compared to $1.1 million during the same period in 2018. The increase is mainly due to an increase of $0.3 million in share-based compensation expense resulting from a fair value adjustment accounted for in the first quarter of 2018 and an increase of $0.1 million in insurance expenses. Sol-Gel reported a loss of $5.7 million for the first quarter of 2019 compared to loss of $5.7 million for the same period in 2018.

As of March 31, 2019, Sol-Gel had $9.2 million in cash, cash equivalents and deposits and $45.2 million in marketable securities for a total balance of $54.4 million. Based on current assumptions, Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements through mid-2020.

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 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	March 31, 2019
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,325	$ 8,175
Bank deposit	1,000	1,000
Marketable securities	56,662	45,253
Accounts receivable	-	6,354
Prepaid expenses and other current assets	2,987	2,518
TOTAL CURRENT ASSETS	65,974	63,300
NON-CURRENT ASSETS:		
Restricted long-term deposits	462	466
Property and equipment, net	2,604	2,507
Operating lease right-of-use assets	-	1,058
Funds in respect of employee rights upon retirement	642	662
TOTAL NON-CURRENT ASSETS	3,708	4,693
TOTAL ASSETS	$ 69,682	$ 67,993
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 2,924	$ 4,093
Other account payable	1,971	2,898
Current maturities of operating leases	-	647
TOTAL CURRENT LIABILITIES	4,895	7,638
LONG-TERM LIABILITIES -		
Operating leases liabilities	-	445
Liability for employee rights upon retirement	878	940
TOTAL LONG-TERM LIABILITIES	878	1,385
COMMITMENTS		
TOTAL LIABILITIES	5,773	9,023

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	191,642
Accumulated deficit	(127,464)	(133,192)
TOTAL SHAREHOLDERS' EQUITY	63,909	58,970
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 69,682	$ 67,993

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

	Three months ended March 31,	
	2018	**2019**
REVENUES	$ 44	$ 6,358
RESEARCH AND DEVELOPMENT EXPENSES	4,645	10,793
GENERAL AND ADMINISTRATIVE EXPENSES	1,142	1,694
TOTAL OPERATING LOSS	$ 5,743	$ 6,129
FINANCIAL INCOME, NET	(30)	(401)
LOSS FOR THE PERIOD	$ 5,713	$ 5,728
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.39	0.30
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	14,523,161	18,949,968

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Source: Sol-Gel Technologies Ltd.

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