Sol-Gel Technologies Reports First Quarter 2018 Financial Results

May 15, 2018

NESS ZIONA, Israel, May 15, 2018 (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, 2018 and provided an update on its clinical development programs.

"We are continuing to make progress with our pipeline in our lead indications of acne vulgaris and subtype II rosacea as we prepare to initiate pivotal clinical trials for both programs this year," stated Dr. Alon Seri-Levy, Sol-Gel Technologies' Chief Executive Officer. "With our successful IPO earlier this year, we expect our current cash position to be sufficient to fund the completion of the planned Phase III clinical programs for TWIN and Epsolay® (formerly VERED) while also advancing the development of SIRS-T and our generic product candidates."

Corporate Highlights and Recent Developments

- In February 2018, Sol-Gel presented TWIN Phase II data for the treatment of acne vulgaris and Epsolay Phase II data for the treatment of subtype II rosacea at the 2018 American Academy of Dermatology (AAD) Annual Meeting.
- In February 2018, Sol-Gel completed an initial public offering (IPO) generating aggregate gross proceeds of approximately $86.3 million, before underwriting discounts and commissions and estimated offering expenses.
- In January 2018, Perrigo Company plc (NYSE: TASE: PRGO) was granted a tentative approval from the U.S Food and Drug Administration (FDA) for ivermectin cream, 1%, the active ingredient in Soolantra®, indicated for the treatment of inflammatory lesions of rosacea. Perrigo and Sol-Gel shared development costs and will share the gross profit 50/50.

Clinical Program Update

- Sol-Gel recently held an end-of-phase II meeting with the FDA regarding TWIN and expects to commence the pivotal Phase III trials in acne vulgaris in the second half of 2018 as planned.
- Sol-Gel has submitted a Special Protocol Assessment (SPA) request with the FDA regarding Epsolay and expects to commence the pivotal Phase III trials in subtype II rosacea in the first half of 2018 as planned.
- Sol-Gel plans to commence bioequivalence study for a generic drug candidate in 2018.

Financial Results

First quarter 2018 Financial Results

Research and development expenses were $4.6 million in the first quarter of 2018, compared to $5.0 million during the same period in 2017. The decrease was primarily due to a decrease of $1.6 million in clinical trial expenses, partially offset by an increase of $1.0 million in share-based compensation expenses and an increase of $0.2 million in salary expenses.

General and administrative expenses were $1.1 million in the first quarter of 2018, compared to $0.6 million during the same period in 2017. The increase was primarily due to an increase of $0.3 million in salary expenses and an increase of $0.2 million in share-based compensation expenses.

Sol-Gel reported a loss of $5.7 million for the first quarter of 2018, compared to a loss of $5.6 million for the same period in 2017.

As of March 31, 2018, Sol-Gel had $79.8 million in cash and cash equivalents, compared to $5.0 million as of December 31, 2017.

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.

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 statements regarding the commencement of our planned clinical trials and our existing cash resources being sufficient to fund the completion of our planned Phase III clinical programs for TWIN and Epsolay®. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement, including but not limited to, the following: (i) the fact that we have and expect to continue to incur significant losses; (ii) our need for additional funding, which may not be available; (iii) our ability to complete the development of our product candidates; (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 rely on data from our Phase II TWIN trial to advance the development of SIRS-T; (vi) our ability to commercialize our product candidates; (vii) our ability to obtain and maintain adequate protection of our intellectual property; (viii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (ix) our ability to establish adequate sales, marketing and distribution channels; (x) acceptance of our product candidates by healthcare professionals and patients; (xi) the possibility that we may face third-party claims of intellectual property infringement; (xii) 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; (xiii) 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; (xiv) potential product liability claims; (xv) potential adverse federal, state and local government regulation in the United States, Europe or Israel; and (xvi) 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 26, 2018 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. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	December 31, 2017	March 31, 2018
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,024	$ 79,796
Bank deposit	4,000	4,000
Prepaid expenses and other current assets	1,511	1,357
Advance payment	13	-
TOTAL CURRENT ASSETS	10,548	85,153
NON-CURRENT ASSETS:		
Long-term receivables	1,653	1,600
Restricted long-term deposits	120	120
Property and equipment, net	2,314	2,396
Funds in respect of employee rights upon retirement	680	671
TOTAL NON-CURRENT ASSETS	4,767	4,787
TOTAL ASSETS	$ 15,315	$ 89,940
Liabilities and shareholders' equity (capital deficiency)		
CURRENT LIABILITIES:		
Accounts payable	534	444
Accrued expenses and other	1,332	1,527
Loans from the controlling shareholder	65,338	-
TOTAL CURRENT LIABILITIES	$ 67,204	$ 1,971
LONG-TERM LIABILITIES -		
Liability for employee rights upon retirement	810	932
TOTAL LONG-TERM LIABILITIES	810	932
COMMITMENTS		
TOTAL LIABILITIES	$ 68,014	$ 2,903

CAPITAL DEFICIENCY:		
Ordinary Shares, NIS 0.1 par value – authorized: 8,775,783 as of December 31, 2017 and March 31, 2018; issued and outstanding: 6,290,244 and 18,949,968 as of December 31, 2017 and March 31, 2018, respectiveley	82	520
Additional paid-in capital	42,480	187,491
Accumulated deficit	(95,261)	(100,974)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	(52,699)	87,037
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	$ 15,315	$ 89,940

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(Unaudited)

	Three months ended March 31	
	2017	**2018**
REVENUES	$ -	$ 44
RESEARCH AND DEVELOPMENT EXPENSES	(5,017)	(4,645)
GENERAL AND ADMINISTRATIVE EXPENSES	(611)	(1,142)
TOTAL OPERATING LOSS	$ (5,628)	$ (5,743)
FINANCIAL (INCOME) EXPENSES, net	(2)	30
LOSS FOR THE PERIOD	$ (5,630)	$ (5,713)
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.89	$ 0.39
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	6,290,242	14,523,161

Source: Sol-Gel Technologies Ltd.