

Sol-Gel Technologies Reports Third Quarter 2018 Financial Results

November 13, 2018

NESS ZIONA, Israel, Nov. 13, 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 third quarter ended September 30, 2018 and provided an update on its clinical development programs.

"The third quarter was very busy as we made advancements on both the branded and generic pipelines. Progress was made on finalizing the trial design for the Phase III program for TWIN, we reached 50% enrollment in the pivotal clinical trials for Epsolay® and we also entered into our fifth generic product candidate agreement with Perrigo," commented Dr. Alon Seri-Levy, Sol-Gel's Chief Executive Officer. "We look forward to executing on the remaining 2018 planned milestones in the fourth quarter of this year and being in a position to report top-line data from the pivotal Phase III clinical programs for Epsolay and TWIN in 2019."

Corporate Highlights and Recent Developments

- The Company announced it entered into two collaborative agreements with Perrigo Israel, an affiliate of Perrigo Company plc ("Perrigo") (NYSE; TASE: PRGO); one in November and one in August. The agreements are each for the development, manufacturing and commercialization of a generic product candidate. Under the terms of the agreements, Perrigo will seek regulatory approval with the U.S. Food and Drug Administration ("FDA") for these generic product candidates.
- In September 2018, Sol-Gel announced it had completed enrollment of half of the patients in its pivotal Phase III clinical trials of Epsolay in subjects with papulopustular rosacea (also known as subtype II rosacea). The pivotal Phase III clinical program is being conducted in accordance with Special Protocol Assessment ("SPA") agreements with the FDA and consists of two randomized, multi-center, double-blind, vehicle-controlled clinical trials at 50 sites in the United States.
- In September 2018, Sol-Gel announced the addition of Jonathan B. Siegel to the Company's board of directors.
- In September 2018, Sol-Gel announced that it had completed an End-of-Phase II meeting with the FDA for TWIN in the treatment of acne vulgaris. The Company also announced that it had reached an agreement with the FDA regarding an SPA for TWIN. The SPA provides agreement that the protocol design, clinical endpoints and statistical analysis approach for Sol-Gel's Phase III program evaluating TWIN for the treatment of patients with acne vulgaris will be deemed adequate to support a New Drug Application filing for marketing approval.

Clinical Program Update

- Sol-Gel expects to commence the pivotal Phase III clinical trials evaluating the safety and efficacy of TWIN in subjects with acne vulgaris in the fourth quarter of 2018.
- Sol-Gel plans to commence a bioequivalence study for a generic product candidate in the fourth quarter of 2018.
- Sol-Gel expects to report top-line data from the pivotal Phase III clinical programs for Epsolay and TWIN in 2019.

Financial results for the three months ended September 30, 2018

Research and development expenses were \$7.1 million in the third quarter of 2018, compared to \$12.0 million during the same period in 2017. The decrease was primarily due to a decrease in clinical trial expenses of \$4.3 million related to the completion of Phase II clinical trials for TWIN in 2017 and a decrease in manufacturing expenses of \$0.5 million related to the production of the clinical batches for TWIN and Epsolay.

General and administrative expenses were \$1.3 million in the third quarter of 2018, compared to \$2.3 million during the same period in 2017. The decrease was primarily due to a decrease of \$0.6 million in legal and accounting expenses and a decrease of \$0.4 million in share-based compensation expenses.

Sol-Gel reported a loss of \$7.7 million for the third quarter of 2018, compared to a loss of \$14.3 million for the same period in 2017.

As of September 30, 2018, Sol-Gel had \$14.3 million in cash, cash equivalents and deposits and \$59.2 million in marketable securities, for a total of \$73.5 million.

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. 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 forwardlooking statement, including but not limited to, the following: the fact that we have and expect to continue to incur significant losses, our need for additional funding, which may not be available; our ability to complete the development of our product candidates; 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; our ability to rely on data from our Phase II TWIN trial to advance the development of SIRS-T; our ability to commercialize our product candidates; our ability to obtain and maintain adequate protection of our intellectual property; our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; our ability to establish adequate sales, marketing and distribution channels; acceptance of our product candidates by healthcare professionals and patients; the possibility that we may face third-party claims of intellectual property infringement; 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; 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; potential product liability claims; potential adverse federal, state and local government regulation in the United States, Europe or Israel; and 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.

SOL-GEL TECHNOLOGIES LTD.

BALANCE SHEETS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	December 31,	September 30,		
	2017	2018		
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	\$ 5,024	\$ 13,267		
Bank deposit	4,000	1,000		
Prepaid expenses and other current assets	1,511	3,390		
Marketable securities	-	59,202		
Advance payment	13	122		
TOTAL CURRENT ASSETS	10,548	76,981		
NON-CURRENT ASSETS:				
Long-term receivables	1,653	27		
Restricted long-term deposits	120	466		
Property and equipment, net	2,314	2,520		
Funds in respect of employee rights upon retirement	680	650		
TOTAL NON-CURRENT ASSETS	4,767	3,663		
TOTAL ASSETS	\$ 15,315	\$ 80,644		
Liabilities and shareholders' equity (of capital deficiency)				
CURRENT LIABILITIES:				
Accounts payable	534	3,355		
Accrued expenses and other	1332	1,468		
Loans from the controlling shareholder	65,338	-		
TOTAL CURRENT LIABILITIES	\$ 67,204	\$ 4,823		
LONG-TERM LIABILITIES -				
Liability for employee rights upon retirement	810	907		
TOTAL LONG-TERM LIABILITIES	810	907		
COMMITMENTS				
TOTAL LIABILITIES	\$ 68,014	\$ 5,730		
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SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):

Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of		
December 31, 2017 and September 30, 2018; issued and outstanding:		
6,290,244 and 18,949,968 as of December 31, 2017 and September 30,		
2018, respectively	82	520
Additional paid-in capital	42,480	189,982
Accumulated deficit	(95,261)	(115,588)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	(52,699)	74,914
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	15,315	\$ 80,644

SOL-GEL TECHNOLOGIES LTD.

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			
	2017		2018		2017		2018	
REVENUES	-	\$	131		-	\$	38	
OPERATING EXPENSES								
Research and development	21,389		17,545		12,013		7,083	
General and administrative	4,781		3,974		2,321		1,314	
TOTAL OPERATING LOSS	26,170		21,388		14,334		8,359	
FINANCIAL INCOME, net	(52)		(1,061)		(48)		(652)	
LOSS FOR THE PERIOD	\$ 26,118	\$	20,327	\$	14,286	\$	7,707	
BASIC AND DILUTED LOSS PER ORDINARY SHARE	\$ 4.15	\$	1.16	\$	2.27	\$	0.40	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING								
USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER								
SHARE	6,290,244	1	7,501,491	6	,290,244	18	3,949,968	

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