Sol-Gel Technologies Reports Full Year 2018 Financial Results and Provides Corporate Update

March 21, 2019

Company met all milestones in 2018 and this year expects to report Phase III top-line results for Epsolay® and TWIN, potentially best-in-class papulopustular rosacea and acne vulgaris topical medications

Recent approval of Perrigo's generic acyclovir cream, 5%, has already provided revenue during the first quarter of 2019

NESS ZIONA, Israel, March 21, 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 year ended December 31, 2018 and provided a corporate update.

"Sol-Gel made significant clinical progress in 2018 with two branded product candidates entering Phase III development and the launch of our first generic product by Perrigo in February 2019," stated Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "We look forward to an exciting 2019 as we expect to have clinical data from our pivotal trials for Epsolay® and TWIN."

Corporate Highlights and Recent Developments

- On February 6, 2019, Sol-Gel announced that Perrigo (NYSE; TASE: PRGO) received final approval from the U.S. Food and Drug Administration (FDA) for the first generic version of Zovirax® (acyclovir) cream, 5%. The product was developed in a collaboration between Sol-Gel and Perrigo in which they shared development costs and will equally share the gross profits generated from sales of the product. Perrigo has launched acyclovir cream and sales are in line with Sol-Gel's expectations.

- On January 15, 2019, Sol-Gel announced the appointment of John M. Vieira as U.S. Head of Commercialization. Mr. Vieira's background includes 25 years of pharmaceutical industry experience in commercial operations, regulatory affairs, sales and marketing, pricing strategy, reimbursement and business development within the healthcare and biopharmaceutical industries in the U.S. with a focus on specialty dermatology products. Mr. Vieira joined Sol-Gel from Leo Pharmaceuticals where he served in U.S. and Global Marketing roles.

- On December 17, 2018, Sol-Gel announced dosing of the first subject in the pivotal Phase III clinical program evaluating the safety and efficacy of TWIN in subjects with acne vulgaris. TWIN is a cream containing a fixed-dose combination of encapsulated tretinoin and encapsulated benzoyl peroxide using Sol-Gel's proprietary microencapsulation platform.

- On December 4, 2018, Sol-Gel announced it has entered into a sixth collaborative agreement with Perrigo Israel, an affiliate of Perrigo, for the development, manufacturing and commercialization of a generic product candidate. The fifth collaboration with Perrigo was announced on November 1, 2018.

Program Update

- Plans to have pivotal Phase III Epsolay top-line results in papulopustular rosacea in mid-2019.

- Plans to have pivotal Phase III TWIN top-line results in acne vulgaris in the fourth quarter of 2019.

- Plans to report bioequivalence study results for a generic 5-fluorouracil cream, 5%, indicated for actinic keratosis, and to submit an abbreviated new drug application (ANDA) during 2019.

- Sol-Gel has decided to hold the development of SIRS-T, focusing resources on more lucrative products.

Full Year 2018 Financial Results

Revenues were $0.1 million for the year ended December 31, 2018 compared with $0.2 million for the same period in 2017. The revenues were comprised from royalty payments to Sol-Gel.

Research and development expenses were $28.1 million for the year ended December 31, 2018 compared to $25.8 million for the same period in 2017. The increase of $2.3 million was mainly attributed to an increase of $1.0 million in payroll and related expenses due to share-based compensation, salary increases, and an increase in the number of research and development personnel; an increase of $2.4 million (due to a $1.9 million increase in manufacturing expenses related to our Phase III clinical program for TWIN and a generic drug product candidate, and a $0.5 million increase in regulatory expenses mainly related to our Phase III clinical program for TWIN and Epsolay); an increase of $4.1 million in clinical trial expenses; and an increase of $1.0 million in depreciation, patents and other expenses; offset by a decrease of $6.2 million due to acquiring an in-process research and development product candidate in 2017.

General and administrative expenses were $5.5 million for the year ended December 31, 2018 compared to $6.0 million for the same period in 2017.

The decrease of $0.5 million was mainly attributed to a decrease of $0.5 million in professional fees which were capitalized in 2018 as part of our IPO.

Sol-Gel reported a loss of $32.2 million for the year ended December 31, 2018, compared to a loss of $31.6 million for the year ended December 31, 2017.

As of December 31, 2018, Sol-Gel had $63.0 million in cash and cash equivalents, deposits and marketable securities compared to $9.0 million as of December 31, 2017. The increase resulted from the Company's initial public offering in the first quarter of 2018.

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 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 rely on data from our Phase II TWIN trial to advance the development of SIRS-T; (vi) our ability to commercialize our pharmaceutical 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. More information about the risks and uncertainties that can affect the realization of forward-looking statements is set forth in the Company's final prospectus filed with the Securities and Exchange Commission ("SEC") on February 2, 2018 relating to our Registration Statement on Form F-1, and our other reports filed with the SEC, including the Company's Annual Report on Form 20-F to be filed with the SEC. All forward-looking statements included in this press release are made only 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 prospectus to conform these statements to actual results or to changes in our expectations.

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

	December 31,	
	2017	**2018**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,024	$ 5,325
Bank deposit	4,000	1,000
Marketable securities	-	56,662
Prepaid expenses and other current assets	1,524	2,987
TOTAL CURRENT ASSETS	10,548	65,974
NON-CURRENT ASSETS:		
Long term receivables	1,653	-
Restricted long-term deposits	120	462
Property and equipment, net	2,314	2,604
Funds in respect of employee rights upon retirement	680	642
TOTAL NON-CURRENT ASSETS	4,767	3,708
TOTAL ASSETS	$ 15,315	$ 69,682
Liabilities and shareholders' equity (capital deficiency)		
CURRENT LIABILITIES:		
Accounts payable	$ 534	$ 2,924
Other account payable	1,332	1,971
Loans from the controlling shareholder	65,338	-
TOTAL CURRENT LIABILITIES	67,204	4,895

LONG-TERM LIABILITIES –		
Liability for employee rights upon retirement	810	878
TOTAL LONG-TERM LIABILITIES	810	878
COMMITMENTS		
TOTAL LIABILITIES	68,014	5,773
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2017 and 2018, respectively; issued and outstanding: 6,290,244 and 18,949,968 as of December 31, 2017 and December 31, 2018, respectively	82	520
Additional paid-in capital	42,480	190,853
Accumulated deficit	(95,261)	(127,464)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	(52,699)	63,909
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)	$ 15,315	$ 69,682

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

	Year ended December 31,		
	2016	**2017**	**2018**
REVENUES	$ -	$ 174	$ 129
OPERATING EXPENSES			
Research and Development	17,023	25,805	28,146
General and Administrative	3,733	6,002	5,504
TOTAL OPERATING LOSS	20,756	31,633	33,521
FINANCIAL EXPENSES (INCOME), net	15	(65)	(1,318)
LOSS FOR THE YEAR	$ 20,771	$ 31,568	$ 32,203
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 3.30	$ 5.02	$ 1.80
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	6,290,242	6,290,244	17,867,589

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Source: Sol-Gel Technologies Ltd.