Sol-Gel Technologies Reports Second Quarter 2020 Financial Results and Corporate Update

August 6, 2020

- *New Drug Application for Epsolay® Submitted; Twyneo® New Drug Application on track for 2H 2020*
- *Top-line generic product revenue of $1.1 million in 2Q 2020*
- *Launch of additional generic product expected in 2Q 2021*

NESS ZIONA, Israel, Aug. 06, 2020 (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, 2020 and provided clinical and regulatory updates on its programs.

"The second quarter had major milestones for Sol-Gel, as we submitted our first NDA for Epsolay for the treatment of papulopustular rosacea," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "We look forward to the FDA confirming acceptance and granting a PDUFA action date in the near future. Also, this quarter, we expanded our collaboration with Perrigo to include three additional generic product candidates. While generic product revenue was lower compared to previous periods due to reduced sales stemming from COVID-19 related stay-at-home orders, we did see positive trends exiting the second quarter. Our cash resources will enable funding of all planned operational and capital expenditures into the third quarter of 2021, excluding revenue we expect to receive based on the sales of a second generic product starting in the second quarter of 2021."

Dr. Seri-Levy continued, "There was no impact from COVID-19 on the NDA submission for Epsolay, and we remain on track to submit our NDA for Twyneo in the second half of this year, another major milestone for the company. We continue our launch preparation for Epsolay and Twyneo, which includes the planned opening of our US headquarters in New Jersey in the coming months and hiring key positions."

Corporate Highlights and Recent Developments

- Sol-Gel submitted an NDA for Epsolay (encapsulated benzoyl peroxide, 5%, cream) in June. If approved, Epsolay has the potential to be the first FDA-approved, single-agent BPO prescription drug product for the treatment of subtype II rosacea.
- Sol-Gel expects to submit an NDA for Twyneo (encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream) in the second half of this year.
- In preparation for commercial launch of Epsolay and Twyneo, and as part of Sol-Gel's go-to-market strategy, the Company plans to open a US headquarters in the coming months in Whippany, NJ and has started the hiring process for key US-based employees.
- In the second quarter of 2020, Sol-Gel generated revenue of $1.1 million from its collaboration agreement with Perrigo Company plc (NYSE; TASE: PRGO).
- Sol-Gel expanded its collaboration with Perrigo Company plc in June to include the development, manufacturing and commercialization of three new generic product candidates.
- Bausch Health Companies, Inc. (NYSE: BHC) filed a patent infringement action regarding Perrigo's Abbreviated New Drug Application for a generic version of Bryhali® (halobetasol propionate) lotion, 0.01%, for the treatment of plaque psoriasis in adults. Halobetasol propionate lotion, 0.01%, is covered under a collaboration between Sol-Gel and Perrigo.
- Sol-Gel has been informed by its collaboration partner that the launch of a second generic drug is expected in the second quarter of 2021. Sol-Gel will receive payments based on product sales beginning at the launch date.
- Results from the ongoing Phase 1 clinical trial of SGT-210 in punctuate palmoplantar keratoderma are expected in 2021, though COVID-19 has caused enrollment delays.
- Sol-Gel has commenced a preclinical animal study with an erlotinib formulation, evaluating multiple concentration strengths for the treatment of UVB-induced actinic keratosis.
- Sol-Gel is starting a collaboration with a leading hospital in Israel to study the potential efficacy of tapinarof in in vivo models of eye diseases. The Company has applied for patents covering the use of tapinarof in ophthalmic disorders including dry eye, uveitis, and blepharitis with or without demodex involvement. Sol-Gel believes this is the first time tapinarof has been evaluated in ophthalmology indications. Pending positive results from this research, Sol-Gel will explore partnerships for further development of these exciting opportunities.

Financial Results for the Three Months ended June 30, 2020

Revenue in the second quarter of 2020 was $1.1 million. The revenue was mainly due to sales of a generic product from the collaboration arrangement with Perrigo. The decrease in revenue from the previous quarter was mainly attributed to COVID-19 related stay-at-home-orders.

Research and development expenses were $6.5 million in the second quarter of 2020 compared to $11.4 million during the same period in 2019. The decrease of $4.9 million was mainly attributed to a decrease of $6.4 million in clinical trial expenses, primarily related to a decrease of clinical trial activity of Epsolay and Twyneo, partially offset by an increase of $1.0 million in manufacturing expenses of Epsolay and Twyneo and an increase of $0.4 million in regulatory expenses, mostly related to preparing for the NDA submissions for Epsolay and Twyneo.

General and administrative expenses were $2.2 million in the second quarter of 2020 compared to $1.6 million during the same period in 2019. The increase of $0.6 million was mainly attributed to an increase of $0.4 million in commercialization expenses and an increase of $0.1 million in other expenses.

Sol-Gel reported a loss of $7.1 million for the second quarter of 2020 compared to loss of $4.9 million for the same period in 2019.

As of June 30, 2020, Sol-Gel had $25.3 million in cash, cash equivalents and deposits and $40.7 million in marketable securities for a total balance of $66.0 million. Based on current assumptions, Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements into the third 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 leverages its proprietary microencapsulation technology platform for the development of Twyneo, under investigation for the treatment of acne vulgaris, and Epsolay, under investigation for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, under investigation for the treatment of palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. For additional information, please visit www.sol-gel.com.

About Epsolay®

Epsolay is an investigational topical cream containing encapsulated benzoyl peroxide, 5%, for the treatment of papulopustular rosacea. Epsolay utilizes a patented technology process to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The slow migration of medication from the microcapsules is designed to deliver an effective dose of benzoyl peroxide onto the skin, while reducing the ability of benzoyl peroxide to induce skin irritation, such as erythema, burning and stinging. If approved, Epsolay has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. Epsolay is not approved by the FDA and the safety and efficacy has not been established.

About Papulopustular Rosacea

Papulopustular rosacea is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans. The condition is common, especially in fair-skinned people of Celtic and northern European heritage. Onset is usually after age 30 and typically begins as flushing and subtle redness on the cheeks, nose, chin or forehead. If left untreated, rosacea can slowly worsen over time. As the condition progresses the redness becomes more persistent, blood vessels become visible and pimples often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

About Twyneo®

Twyneo is an investigational, antibiotic-free, fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris. If approved, it will be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin, which are separately encapsulated in silica using Sol-Gel's proprietary microencapsulation technology. Tretinoin and benzoyl peroxide are widely prescribed separately as a combination treatment for acne; however, benzoyl peroxide causes degradation of the tretinoin molecule, thereby potentially reducing its effectiveness if used at the same time or combined in the same formulation. The silica-based microcapsule is designed to protect tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability of the active drug ingredients. The silica-based shell is also designed to release the ingredients slowly over time to provide a favorable efficacy and safety profile. Twyneo is not approved by the FDA and the safety and efficacy has not been established.

About Acne Vulgaris

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

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, statements regarding the timing of the submission of an NDA for Twyneo and the FDA's granting of a PDUFA action date for Epsolay, the expectation to receive payments from the product sales of a generic drug starting in the second quarter of 2021, the timing of results of the ongoing Phase 1 clinical trial of SGT-210, the Company's plans to open US headquarters in Whippany, NJ, the potential development and commercialization of three new generic product candidates, and the Company's expectations regarding its liquidity and ability to fund 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, risks relating to the effects of COVID-19 (coronavirus), the timing of a launch of a branded tapinarof product and the launch of a branded topical roflumilast in the U.S., risks related to the timing of the submission of an NDA for Epsolay and an NDA for Twyneo as well as the following factors: (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 24 , 2020 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.

SOL-GEL TECHNOLOGIES LTD.

UNAUDITED CONDENSED

CONSOLIDATED BALANCE SHEET

(The amounts are stated in U.S. dollars in thousands, except share and per share data)

	December 31, 2019	June 30, 2020
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,412	$ 5,444
Bank deposit	-	19,900
Marketable securities	40,966	40,678
Receivables from collaborative arrangements	4,120	1,171
Prepaid expenses and other current assets	1,293	1,494
TOTAL CURRENT ASSETS	55,791	68,687
NON-CURRENT ASSETS:		
Restricted long-term deposits	472	1,284
Property and equipment, net	2,314	2,202
Operating lease right-of-use assets	2,040	1,777
Funds in respect of employee rights upon retirement	684	682
TOTAL NON-CURRENT ASSETS	5,510	5,945
TOTAL ASSETS	$ 61,301	$ 74,632
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 1,710	$ 1,232
Other accounts payable	4,123	5,154
Current maturities of operating leases	672	525
TOTAL CURRENT LIABILITIES	6,505	6,911
LONG-TERM LIABILITIES -		
Operating leases liabilities	1,373	1,227
Liability for employee rights upon retirement	958	973
TOTAL LONG-TERM LIABILITIES	2,331	2,200
COMMITMENTS		
TOTAL LIABILITIES	8,836	9,111
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2019 and June 30, 2020; issued and outstanding: 20,402,800 and 22,996,948 as of December 31, 2019 and June 30, 2020, respectively.	561	635
Additional paid-in capital	203,977	231,139
Accumulated deficit	(152,073)	(166,253)

TOTAL SHAREHOLDERS' EQUITY	52,465	65,521
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 61,301	$ 74,632

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UNAUDITED CONDENSED

CONSOLIDATED FINANCIAL STATEMENTS

OF OPERATIONS

(The amounts are stated in U.S. dollars in thousands, except share and per share data)

	Six months ended June 30		Three months ended June 30	
	2019	**2020**	**2019**	**2020**
COLLABORATION REVENUES	$ 14,151	$ 4,598	$ 7,793	$ 1,133
RESEARCH AND DEVELOPMENT EXPENSES	22,233	14,381	11,440	6,451
GENERAL AND ADMINISTRATIVE EXPENSES	3,332	4,994	1,638	2,233
TOTAL OPERATING LOSS	11,414	14,777	5,285	7,551
FINANCIAL INCOME, net	(760)	(597)	(359)	(481)
LOSS FOR THE PERIOD	$ 10,654	$ 14,180	$ 4,926	$ 7,070
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.56	$ 0.64	$ 0.26	$ 0.31
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	18,949,968	22,143,099	18,949,968	22,920,557

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