



Sol-Gel Technologies Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 4, 2022

- *Prescription volumes to date indicate strong uptake, similar to successful dermatology launches*
- *Sol-Gel receives \$3.5 million milestone payment from commercial partner Galderma Holding SA ("Galderma") for FDA approval of EPSOLAY*
- *Sol-Gel's cash runway expected to extend through the end of 2023*
- *SGT-510 to enter clinical trial later this year*

NESS ZIONA, Israel, Aug. 04, 2022 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company focused on identifying, developing, commercializing or partnering branded and generic topical drug products for the treatment of skin diseases, announced today financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"We and our partner Galderma are very pleased to report that the launches in the U.S. of EPSOLAY® and TWYNEO are going well and prescriber reception has been strong," stated Alon Seri-Levy, PhD, Chief Executive Officer of Sol-Gel. "Prescription volume data¹ also support our confidence in a strong dermatology launch trajectory. Galderma has an unparalleled track record of commercializing innovative drugs for acne and rosacea in the U.S. and has been using a mix of commercial strategies to drive adoption. Going forward, as they secure managed care access over the course of the year, we expect net sales and royalty income in line with volume growth."

Dr. Seri-Levy added, "Our next areas of focus are to advance our innovative pipeline assets into clinical trials, with SGT-510 planned to enter a clinical trial later this year, and to explore opportunities to extract additional value from our TWYNEO and EPSOLAY products."

Second Quarter 2022 and Recent Corporate Developments

- On June 2, 2022, Galderma announced the availability in the U.S. of EPSOLAY (benzoyl peroxide cream, 5%) for the treatment of inflammatory lesions of rosacea in adults. EPSOLAY is the first and only benzoyl peroxide topical treatment proven to relieve the bumps and blemishes of rosacea and provides rapid, significant and sustained relief.
- On April 25, 2022, Sol-Gel announced FDA approval of EPSOLAY. Sol-Gel has granted to Galderma the exclusive rights to commercialize EPSOLAY in the U.S. A \$3.5 million milestone payment was received by Sol-Gel from Galderma related to the approval, in accordance with the U.S. commercialization agreement between the two companies and recorded as license revenue.
- Following the introduction of TWYNEO by Galderma at the Annual Meeting of the American Academy of Dermatology, March 25-29 in Boston, MA, Sol-Gel announced TWYNEO was made commercially available to the U.S. market.
- Both the launch of TWYNEO and the approval of EPSOLAY were covered by various trade media outlets in print, video and audio by major beauty, personal care and industry publications and media outlets including [Allure](#) magazine, [Practical Dermatology](#), [The Dermatologist](#), [Medpagetoday.com](#), [Healio.com](#), [Personal Care Insights](#), [Monthly Prescribing Reference \(MPR\)](#) and [Drug Topics](#).
- Sol-Gel plans to progress SGT-510 into a clinical trial later this year and to progress other proprietary assets into clinical studies in the first half of next year.

Second Quarter Financial Results

Revenue was \$3.5 million for the quarter ending June 30, 2022, received from the Company's commercial partner, Galderma, resulting from the FDA approval of EPSOLAY and recorded as license revenue, compared to \$0.9 million of revenue for the same period in 2021 which was recorded as collaborative revenue and primarily related to sales of generic products by its partner Padagis.

Research and development expenses were \$2.4 million for the quarter ending June 30, 2022, compared to \$6.9 million for the same period in 2021. The decrease of \$4.5 million was mainly attributed to a decrease of \$3.0 million in professional expenses related to TWYNEO and EPSOLAY and a decrease of \$1.5 million in research and development expenses related to previously partnered programs of generic product candidates which are now being developed by Padagis, offset by ongoing development of Sol-Gel's proprietary assets.

General and administrative expenses were \$1.6 million for the quarter ending June 30, 2022, compared to \$2.0 million for the same period in 2021. The decrease of \$0.4 million was mainly attributed to winding down of pre-commercialization-related expenses for EPSOLAY and TWYNEO.

Sol-Gel reported a loss of \$0.1 million for the second quarter of 2022 compared to a loss of \$8.0 million for the same period in 2021.

As of June 30, 2022, Sol-Gel had \$26.8 million in cash, cash equivalents and deposits, and \$9.8 million in marketable securities for a total balance of \$36.6 million. As a result of the Company's agreements with Galderma regarding EPSOLAY and TWYNEO and the previously announced generics

sale agreement with Padagis, the Company expects that its cash resources will enable funding of operational and capital expenditure requirements through the end of 2023.

About EPSOLAY

EPSOLAY is a topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults. EPSOLAY utilizes a proprietary technology to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The silica-based shell is designed to slowly release benzoyl peroxide over time to provide a favorable efficacy and safety profile. EPSOLAY is covered by granted patents until 2040 as well as a pending patent application until 2041.

Visit www.epsolay.com for further information, including full Prescribing Information.

About TWYNEO

TWYNEO is a topical cream containing a fixed-dose combination of tretinoin, 0.1% and benzoyl peroxide, 3% cream for the treatment of acne vulgaris in adults and pediatric patients 9 years of age and older. TWYNEO is the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin. Tretinoin and benzoyl peroxide are widely prescribed separately for acne vulgaris; 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. TWYNEO uses silica (silicon dioxide) core shell structures to separately micro-encapsulate tretinoin crystals and benzoyl peroxide crystals enabling inclusion of the two active ingredients in the cream. TWYNEO is patent protected until 2038.

Visit www.twyneo.com for further information, including full Prescribing Information.

About Sol-Gel Technologies

Sol-Gel is a dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel leveraged its proprietary microencapsulation technology platform for TWYNEO, which is approved for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, which is approved for the treatment of inflammatory lesions of rosacea in adults. Both drugs are exclusively licensed to Galderma for U.S. commercialization. Founded in 1981, Galderma is the world's largest independent dermatology company.

The Company's pipeline also includes topical drug candidates SGT-210, SGT-310 and SGT-510 under investigation for the treatment of plaque psoriasis and other dermatologic 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, statements regarding the benefits we expect to receive under our agreement with Galderma; expected net sales and royalty income in line with volume growth of EPSOLAY and/or TWYNEO; and our expected cash runway. 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 expectations 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, the risk that we will not receive all of the anticipated benefits under our agreement with Galderma, the risk that EPSOLAY and/or TWYNEO will not provide treatment to the number of patients anticipated, risks relating to the effects of COVID-19 (coronavirus) 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, the potential delay in receiving such regulatory approvals 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 April 4, 2022, as amended, 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. Except as required by law, we undertake no obligation to update any forward-looking statements in this press release.

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Sol-Gel Technologies

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

	December 31, 2021	June 30, 2022
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 20,085	\$ 5,765
Bank deposits	21,448	21,000
Marketable securities	1,709	9,846
Receivables from collaborative arrangements	13,065	10,176
Prepaid expenses and other current assets	800	1,691
TOTAL CURRENT ASSETS	57,107	48,478
NON-CURRENT ASSETS:		
Long-term receivables from collaborative arrangements	7,402	2,499
Restricted long-term deposits and cash	1,298	1,289
Property and equipment, net	1,051	826
Operating lease right-of-use assets	1,501	1,153
Funds in respect of employee rights upon retirement	830	738
TOTAL NON-CURRENT ASSETS	12,082	6,505
TOTAL ASSETS	\$ 69,189	\$ 54,983
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	\$ 766	\$ 860
Other accounts payable	10,145	1,664
Current maturities of operating leases	781	701
TOTAL CURRENT LIABILITIES	11,692	3,225
LONG-TERM LIABILITIES		

Operating leases liabilities	810	369
Liability for employee rights upon retirement	1,093	1,038
TOTAL LONG-TERM LIABILITIES	1,903	1,407
TOTAL LIABILITIES	\$ 13,595	\$ 4,632

SHAREHOLDERS' EQUITY:

Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2021 and June 30, 2022; issued and outstanding: 23,126,804 and 23,129,469 as of December 31, 2021 and June 30, 2022, respectively.

	638	638
Additional paid-in capital	233,098	233,586
Accumulated deficit	(178,142)	(183,873)
TOTAL SHAREHOLDERS' EQUITY	55,594	50,351
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 69,189	\$ 54,983

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

	Six months ended		Three months ended	
	June 30		June 30	
	2021	2022	2021	2022
COLLABORATION REVENUES	\$ 1,629	-	\$ 928	-
LICENSE REVENUES	-	3,521	-	3,518
TOTAL REVENUES	\$ 1,629	\$ 3,521	\$ 928	\$ 3,518
RESEARCH AND DEVELOPMENT EXPENSES	9,399	6,422	6,933	2,380
GENERAL AND ADMINISTRATIVE EXPENSES	4,496	3,512	2,037	1,601
TOTAL OPERATING LOSS	12,266	6,413	8,042	463
FINANCIAL INCOME, net	(170)	(682)	(9)	(329)
LOSS FOR THE PERIOD	\$ 12,096	\$ 5,731	\$ 8,033	\$ 134
BASIC AND DILUTED LOSS PER ORDINARY SHARE	\$ 0.53	\$ 0.25	\$ 0.35	\$ 0.01

**WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING
USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER
SHARE**

23,016,104

23,127,958

23,028,508

23,128,429

¹ IQVIA data, July 2022



Sol-Gel Technologies Ltd.