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

May 13, 2022

- *FDA approval for EPSOLAY® (benzoyl peroxide, cream, 5%) represents Sol-Gel's second approved product within less than a year; EPSOLAY is patent protected until 2040*
- *Partner Galderma to launch two products in the U.S. this quarter: TWYNEO launched in the U.S. market in April for the topical treatment of acne vulgaris in patients nine years of age and older and EPSOLAY to launch in the second quarter for the treatment of inflammatory lesions of rosacea in adults*
- *Sol-Gel's cash runway expected to extend through the end of 2023*

NESS ZIONA, Israel, May 13, 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 first quarter ended March 31, 2022 and provided a corporate update.

"We have made great strides following the close of the first quarter with the prominent and well-received U.S. commercial launch of our acne drug, TWYNEO by our partner, Galderma, and the U.S. Food and Drug Administration (FDA) approval of our rosacea drug, EPSOLAY, to be launched this quarter, both of which generated significant media attention," stated Alon Seri-Levy, PhD, Chief Executive Officer of Sol-Gel. "We now have two FDA-approved drugs within the last twelve months that we developed with our proprietary formulation capabilities from bench to market. When used as indicated, both TWYNEO and EPSOLAY have the potential to change the treatment landscape for patients afflicted with either acne vulgaris or inflammatory lesions of rosacea, respectively.

Dr. Seri-Levy continued, "We are confident that our partner, Galderma, who has an unparalleled track record of introducing innovative drugs in the United States, will maximize the availability of our dermatological therapies to patients. Our expectation is that both drugs will become the preferred treatments of choice in acne and rosacea. We will now deploy the capital generated from the Galderma and Padagis agreements to advance our proprietary assets into clinical trials."

Q1 2022 and Recent Corporate Developments

- On April 25, Sol-Gel announced FDA approval of EPSOLAY topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults. Sol-Gel has granted to Galderma Holding SA ("Galderma") the exclusive rights to commercialize EPSOLAY in the United States. Founded in 1981, Galderma is the world's largest independent dermatology company.
- Galderma introduced TWYNEO at the Annual Meeting of the American Academy of Dermatology, March 25-29 in Boston, MA and on April 14, 2022 Sol-Gel announced TYWNEO was made commercially available to the U.S. market. The EPSOLAY launch is pending.
    - 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 initiate Phase 2 studies for a roflumilast combination product as well as an undisclosed formulation of tapinarof during 2023. A Phase 1/2 study for erlotinib is also planned during 2023.

First Quarter Financial Results

Revenue was nominal for the quarter ending March 31, 2022, due to the sale of royalty-generating generic assets to Padagis, compared to $0.7 million for the same period in 2021.

Research and development expenses were $4.0 million in 2022 compared to $2.5 million for the same period in 2021. The increase of $1.5 million was mainly attributed to an increase of $1.4 million in professional expenses related to TWYNEO and EPSOLAY.

General and administrative expenses were $1.9 million in 2022 compared to $2.5 million for the same period in 2021. The decrease of $0.6 million was mainly attributed to lower pre-commercialization-related expenses for EPSOLAY and TWYNEO.

Sol-Gel reported a loss of $5.6 million for the first quarter of 2022 compared to a loss of $4.1 million for the same period in 2021.

As of March 31, 2022, Sol-Gel had $30.2 million in cash, cash equivalents and deposits, and $6.1 million in marketable securities for a total balance of

$36.3 million. As a result of our agreements with Galderma regarding EPSOLAY and TWYNEO and the 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

EPSOLAY is contraindicated in patients with a history of a serious hypersensitivity reactions to benzoyl peroxide or any component of the formulation in EPSOLAY.

WARNINGS AND PRECAUTIONS

- Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with the use of benzoyl peroxide products. (5.1)
- Skin irritation/contact dermatitis: Erythema, scaling, dryness, stinging/burning, irritation and allergic contact dermatitis may occur with use of EPSOLAY and may necessitate discontinuation.
- Photosensitivity: Avoid or minimize exposure to natural or artificial sunlight and use sun protection measures while using EPSOLAY.

ADVERSE REACTIONS

- The most common adverse reactions were application site reactions: pain (2%), erythema (2%), pruritis (1%) and edema (1%).

To report suspected adverse reactions, contact Sol-Gel Technologies Inc. at [1-866-SGT-AERS (748-4377)] or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information here: https://ml.globenewswire.com/Resource/Download/097577b9-ee42-41fa-bc32-b9d3dce386c6

About Inflammatory Lesions of Rosacea

Rosacea is a chronic and recurrent skin condition that can potentially worsen over time. More than 82% of people with rosacea feel that their condition is uncontrolled and rosacea can deeply affect self-esteem and mental health.

Inflammatory lesions of rosacea is a chronic and recurrent skin disorder that affects millions of Americans. The condition is especially common 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 inflammatory lesions often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

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.

The Company's pipeline also includes early-stage 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 commercial launch of EPSOLAY and/or TWYNEO; the benefits we expect to receive under our agreement with Galderma; and our 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 of a delay in the commercial availability of EPSOLAY and/or TWYNEO, 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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SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	December 31, 2021	March 31, 2022
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,085	$ 21,254
Bank deposits	21,448	9,000
Marketable securities	1,709	6,060
Receivables from collaborative arrangements	13,065	9,660
Prepaid expenses and other current assets	800	747
TOTAL CURRENT ASSETS	57,107	46,721
NON-CURRENT ASSETS:		
Long-term receivables from collaborative arrangements	7,402	4,966
Restricted long-term deposits and cash	1,298	1,301
Property and equipment, net	1,051	931
Operating lease right-of-use assets	1,501	1,324
Funds in respect of employee rights upon retirement	830	814

TOTAL NON-CURRENT ASSETS	12,082	9,336
TOTAL ASSETS	$ 69,189	$ 56,057
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 766	$ 1,110
Other accounts payable	10,145	2,336
Current maturities of operating leases	781	766
TOTAL CURRENT LIABILITIES	11,692	4,212
LONG-TERM LIABILITIES:		
Operating leases liabilities	810	600
Liability for employee rights upon retirement	1,093	1,122
TOTAL LONG-TERM LIABILITIES	1,903	1,722
TOTAL LIABILITIES	13,595	5,934
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2021 and March 31, 2022; issued and outstanding: 23,126,804 and 23,127,669 as of December 31, 2021 and March 31, 2022, respectively.	638	638
Additional paid-in capital	233,098	233,224
Accumulated deficit	(178,142)	(183,739)
TOTAL SHAREHOLDERS' EQUITY	55,594	50,123
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 69,189	$ 56,057

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

	Three months ended March 31	
	2021	**2022**

COLLABORATION REVENUES	$ 701	$ 3
RESEARCH AND DEVELOPMENT EXPENSES	2,466	4,042
GENERAL AND ADMINISTRATIVE EXPENSES	2,459	1,911
TOTAL OPERATING LOSS	$ 4,224	$ 5,950
FINANCIAL INCOME, net	(161)	(353)
LOSS FOR THE PERIOD	$ 4,063	$ 5,597
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.18	0.24
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	23,003,425	23,127,484

Sol-Gel Technologies Ltd.