

Sol-Gel Technologies Reports Full Year 2021 Financial Results and Corporate Developments

March 30, 2022

- Galderma launched TWYNEO[®] at the Annual Meetings of the American Academy of Dermatology, March 25-29, 2022 in Boston, MA. TWYNEO will be commercially available in Spring 2022.
- 2021 revenue of \$31.3 million
- Sol-Gel to receive \$21.5 million over 24 months in exchange for the transfer of its rights to two marketed generic drugs and eight unapproved generic programs based on a new agreement with Padagis; Sol-Gel to retain collaboration rights on two programs related to four high-value candidates
- Announced innovative pipeline which includes differentiated topical formulations of SGT-510 and SGT-310, which are
 expected to enter the clinic in 2022
- Sol-Gel's cash runway expected to extend through the end of 2023, assuming the timely approval of EPSOLAY

NESS ZIONA, Israel, March 30, 2022 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a 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 full year ended December 31, 2021, and provided recent corporate updates.

2021 Corporate Highlights and Recent Developments

- Sol-Gel's commercial partner, Galderma launched TWYNEO at the recent American Academy of Dermatology Annual Meeting that took place in Boston, MA, March 25-29, 2022, and plans to make the product commercially available in the Spring of 2022. TWYNEO was FDA approved on July 27, 2021, for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older.
- On November 4, 2021, Sol-Gel announced a new agreement with Padagis (formerly a division of Perrigo Company plc) effective November 1, 2021 (the "Agreement"). Under this Agreement, Sol-Gel is to unconditionally receive \$21.5 million over 24 months, in lieu of its share in future gross profits for acyclovir cream and ivermectin cream and its potential gross profits for eight unapproved generic programs. In addition, Sol-Gel ceased paying any outstanding and future operational costs related to the earlier collaborative agreements. Sol-Gel has retained collaboration rights to two generic programs related to four generic drug candidates that it believes to have the most value-generating potential.
- During 2021, Sol-Gel raised a total net proceeds of \$505,413 in an at-the-market (ATM) offering, from the sale of 41,154 shares at an average price of \$12.66 per share.

Alon Seri-Levy, Ph.D., Co-Founder and Chief Executive Officer of Sol-Gel, stated, "Pending the approval of EPSOLAY, Galderma will have the opportunity to promote both TWYNEO and EPSOLAY as products within its microencapsulation technology portfolio. We expect sales from both of these products to make a considerable contribution to Sol-Gel's milestone revenue stream over time. At the same time, we've been prudent to immediately monetize our generics franchise to maximize the development of our high-value early-stage assets."

Dr. Seri-Levy continued, "In parallel, we are excited to advance our innovative formulations of SGT-310 and SGT-510 in the second half of 2022 and view these products as future growth drivers for our company."

Financial Results for the Year Ended December 31, 2021

Total revenue was \$31.3 million, which consisted of \$7.5 million of licensing revenue and \$23.8 million of collaboration revenue, compared to collaboration revenues of \$8.8 million in 2020.

Research and development expenses were \$20.4 million compared to \$27.9 million in 2020. The decrease of \$7.5 million was mainly attributed to a decrease of \$6.4 million in clinical trial expenses, primarily related to the completion of the clinical trials of EPSOLAY and TWYNEO, a decrease of \$0.6 million in payroll and expenses related to share-based compensation.

General and administrative expenses were \$8.5 million in 2021 compared to \$11.1 million in 2020. The decrease of \$2.6 million was mainly attributed to a decrease of \$3.0 million in commercialization expenses.

Sol-Gel reported net income of \$3.2 million in 2021 and earnings of \$0.14 per basic and diluted share, compared to loss of \$29.3 million and loss of \$1.30 per basic and diluted share in 2020.

As of December 31, 2021, Sol-Gel had \$41.5 million in cash, cash equivalents and deposits, and \$1.7 million in marketable securities for a total balance of \$43.2 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, assuming the timely approval of EPSOLAY. As of March 28, 2022, Sol-Gel had \$31.6 million in cash, cash equivalents and deposits, and \$6.2 million in marketable securities, for a total balance of \$37.8 million.

About TWYNEO

TWYNEO is a topical cream containing a fixed-dose combination of tretinoin, 0.1%, and benzoyl peroxide, 3%, for the treatment of acne vulgaris in

adults and pediatric patients nine 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 microencapsulate tretinoin crystals and benzoyl peroxide crystals enabling inclusion of the two active ingredients in the same cream.

About EPSOLAY

EPSOLAY is a topical cream containing benzoyl peroxide, 5%, under FDA review 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 protected by granted patents until 2040.

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 under review 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 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 TWYNEO, the regulatory approval of EPSOLAY, our expected cash runway, and the benefits we expect to receive under our agreement with Galderma. 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 TWYNEO and/or EPSOLAY, the risk that 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 March 4, 2021 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)

	 December 31			
	2020		2021	
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	\$ 7,122	\$	20,085	
Bank deposits	21,400		21,448	

Marketable securities	21,652		1.709
Receivables from collaborative arrangements	2,153		13,065
Prepaid expenses and other current assets	1,074		800
TOTAL CURRENT ASSETS	 53,401	-	57,107
NON-CURRENT ASSETS:			·
Long-term receivables from collaborative arrangements	-		7,402
Restricted long-term deposits and cash	1,293		1,298
Property and equipment, net	1,817		1,051
Operating lease right-of-use assets	1,896		1,501
Funds in respect of employee rights upon retirement	754		830
TOTAL NON-CURRENT ASSETS	 5,760		12,082
TOTAL ASSETS	\$ 59,161	\$	69,189
Liabilities and shareholders' equity			
CURRENT LIABILITIES:			
Accounts payable	\$ 1,203	\$	766
Other accounts payable	4,088		10,145
Current maturities of operating leases	673		781
TOTAL CURRENT LIABILITIES	 5,964		11,692
LONG-TERM LIABILITIES:			_
Operating leases liabilities	1,299		810
Liability for employee rights upon retirement	 1,049		1,093
TOTAL LONG-TERM LIABILITIES	 2,348		1,903
COMMITMENTS			
TOTAL LIABILITIES	 8,312		13,595
SHAREHOLDERS' EQUITY:			
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2020 and 2021, respectively; issued and outstanding: 23,000,782 and			
23,126,804 as of December 31, 2020 and December 31, 2021, respectively	635		638
Additional paid-in capital	231,577		233,098
Accumulated deficit	 (181,363)		(178,142)
TOTAL SHAREHOLDERS' EQUITY	 50,849		55,594
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 59,161	\$	69,189

SOL-GEL TECHNOLOGIES LTD. CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year ended December 31,				
		2019		2020	 2021
COLLABORATION REVENUES	\$	22,904	\$	8,771	\$ 23,772
LICENSE REVENUES		-		-	7,500
TOTAL REVENUES		22,904		8,771	 31,272
RESEARCH AND DEVELOPMENT EXPENSES		40,578		27,913	20,381
GENERAL AND ADMINISTRATIVE EXPENSES		8,276		11,091	8,451
OTHER INCOME, net		-		-	 524
TOTAL OPERATING INCOME (LOSS)		(25,950)		(30,233)	2,964
FINANCIAL INCOME, net		1,374		943	257
INCOME (LOSS) BEFORE INCOME TAXES		(24,576)		(29,290)	3,221
INCOME TAXES		(33)		-	 -
NET INCOME (LOSS) FOR THE YEAR	\$	(24,609)	\$	(29,290)	\$ 3,221
BASIC INCOME (LOSS) PER ORDINARY SHARE	\$	(1.26)	\$	(1.30)	\$ 0.14
DILUTED INCOME (LOSS) PER ORDINARY SHARE		(1.26)		(1.30)	0.14
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED INCOME (LOSS) PER SHARE:					
BASIC		19,534,562		22,574,688	23,063,493
DILUTED		19,534,562		22,574,688	23,566,182



Source: Sol-Gel Technologies Ltd.