Sol-Gel Reports Full-Year 2022 Financial Results and Corporate Developments

March 10, 2023

- *Recent acquisition of Phase 3-ready SGT-610 (patidegib), an Orphan Drug candidate, broadens Sol-Gel's pipeline with the potential to be the first therapy for preventing new basal cell carcinomas in Gorlin syndrome*
- *A Phase 3 study of SGT-610 is expected to initiate in the second half of 2023, with results expected by the end of 2025*
- *The base of recurrent* TWYNEO® *prescribers was 82% in Q4 2022, while the* EPSOLAY® *recurrent prescriber base has grown to 64% during the same period*
- *Following recent financing, Sol-Gel's cash runway expected to extend into the second half of 2025*

NESS ZIONA, Israel, March 10, 2023 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company with two innovative dermatology products that were launched in the U.S. and an innovative pipeline, today announced financial results for the full year ended December 31, 2022 and provided a corporate update.

2022 Corporate Highlights and Recent Developments

- On January 27, 2023, Sol-Gel announced the acquisition of topically applied patidegib, a hedgehog signaling pathway blocker, for the treatment of Gorlin syndrome from PellePharm, Inc. for an upfront payment of $4.7 million, total development and NDA acceptance milestones of up to $6.0 million, and based on the expected market potential up to $64.0 million in commercial milestones, as well as single digit royalties. Gorlin syndrome is a rare disease with no currently approved therapies by the U.S. Food and Drug Administration (FDA) or European Medical Association (EMA). Investigational compound SGT-610 has the potential to be the first-ever drug for treatment of Gorlin syndrome, if approved. The Company is suspending the development of SGT-310 and SGT-510 in psoriasis to allow for accelerated development of SGT-610 targeted for an underserved indication.
- Related to the acquisition, Sol-Gel announced the pricing of $22.8 million in parallel registered direct and private placement offerings, the proceeds from which will be used to support the Phase 3 trial of patidegib beginning in late 2023 and for general corporate purposes. Shareholder approval of the $10 million private placement is still pending and is expected by end of March.
- Prescribers reported positive experiences with TWYNEO (launched in April 2022), with the recurring base of prescribers increasing to a high of 82% in Q4 2022, from 66% in Q3 2022. The recurring base of prescribers, defined as the percentage of all TWYNEO prescribers who have written since launch and continue to prescribe, is a positive indicator of the drug's acceptance. According to IQVIA data, there have been over 106,000 prescriptions written for TWYNEO in 2022.
- Only 6 months post its June 2022 launch, EPSOLAY captured the #2 branded topical position in rosacea in Q4 2022. EPSOLAY's recurring base of prescribers increased to 64% of its total prescribers in Q4 2022, from 22% in Q3 2022, showcasing sizeable post-trial adoption. According to IQVIA data, there have been over 26,000 prescriptions of EPSOLAY written in 2022,
- In the first year of market availability, TWYNEO cream has achieved broad managed care adoption and coverage of 60% of commercial covered lives across the three major Pharmacy Benefit Managers (PBMs). Additionally, commercial payer coverage for EPSOLAY is now at over 40% of commercial covered lives.
- Throughout the year, Galderma has had a presence promoting TWYNEO and EPSOLAY at major dermatology meetings and supporting peer-to-peer engagement. At the American Academy of Dermatology taking place on March 17-21, 2023 in New Orleans, Louisiana, Galderma plans to host several medical education events and to support brand visibility of both TWYNEO and EPSOLAY with dedicated expert presentations.

Alon Seri-Levy, Ph.D., Chief Executive Officer of Sol-Gel, stated, "With the recent acquisition of patidegib, a Breakthrough-designated Orphan Drug candidate with a market potential of over $300 million, Sol-Gel has successfully pivoted towards the attractive rare disease segment and the major unmet need for Gorlin syndrome patients. We are also extremely encouraged by the rapid market uptake of our Galderma-partnered products, TWYNEO and EPSOLAY, by prescribers, patients, and payors during their first year on the market and remain confident about prospects to improve TWYNEO and EPSOLAY reimbursement and profitability over time. We will seek to out-license non-U.S. rights for TWYNEO and EPSOLAY and generate non-dilutive income."

Financial Results for the Year Ended December 31, 2022

Total revenue was $3.9 million, which consisted of $3.9 million of licensing revenue compared to revenues of $31.3 million in 2021 which consisted of $7.5 million of licensing revenue and $23.8 million of collaboration revenue.

Research and development expenses were $12.7 million compared to $20.4 million in 2021. The decrease of $7.7 million was mainly attributed to a decrease in professional expenses related to EPSOLAY and TWYNEO.

General and administrative expenses were $7.4 million in 2022 compared to $8.5 million in 2021. The decrease of $1.1 million was mainly attributed to a decrease in commercialization expenses related to EPSOLAY and TWYNEO.

Sol-Gel reported net loss of $14.9 million in 2022 and loss of $0.65 per basic and diluted share, compared to net income of $3.2 million and earnings of $0.14 per basic and diluted share in 2021.

As of December 31, 2022, Sol-Gel had $24.9million in cash, cash equivalents and bank deposits, and $8.7 million in marketable securities for a total balance of $33.6million. Following the $22.8 million raised in the recent financing, the Company expects that its cash resources will enable funding of operational and capital expenditure requirements into the second half of 2025.

About Gorlin Syndrome and SGT-610

SGT-610, a hedgehog signaling pathway blocker, has the potential to be the first ever treatment for Gorlin syndrome, if approved. Gorlin syndrome, an autosomal dominant genetic disorder affecting approximately 1 in 27,000-31,000 people in the U.S., is mostly caused by inheritance of one defective copy of the tumor suppressor patched homolog 1 (PTCH1) gene. Normally, the PTCH1 gene blocks the smoothened, frizzle class receptor (SMO) gene, turning off the hedgehog signaling pathway when it is not needed. Mutations in the PTCH1 gene may cause a loss of PTCH1 function, release of SMO, and may allow basal cell carcinoma (BCC) tumor cells to divide uncontrollably. Patidegib, the active substance in SGT-610, is designed to block the SMO signal, thus, allowing cells to function normally and reducing the production of new tumors.

About Sol-Gel Technologies

Sol-Gel is a dermatology company focused on identifying, developing and commercializing or partnering drug products for the treatment of skin diseases. Sol-Gel developed TWYNEO which is approved by the FDA for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, which is approved by the FDA for the treatment of inflammatory lesions of rosacea in adults. Both drugs are exclusively licensed to and commercialized by Galderma in the U.S.

The Company's pipeline includes Orphan Drug candidate, SGT-610 for the prevention of new basal cell carcinomas in Gorlin syndrome patients, and also includes topical drug candidate SGT-210 under investigation for the treatment of rare skin keratodermas.

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; the benefits of and projections of our future financial performance as a result of our acquisition of SGT-610; the timing and success of any clinical studies and obtaining of regulatory approval for our product candidates, including SGT-610; our expected cash runway, and our ability to out-license non-U.S. rights for TWYNEO and EPSOLAY and generate non-dilutive income. *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 the initiation or results of the Phase 3 study for SGT-610 will be delayed or not occur, the risk that our annual net sales from* SGT-610, if approved, *will be lower than expected, risks that our cash runway will be shorter than expected, risks relating to the current global macroeconomic climate 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 10, 2023, 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 LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	December 31	
	2021	**2022**

Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 20,085	$ 12,448
Bank deposits	21,448	12,500
Marketable securities	1,709	8,678
Receivables from collaborative and licensing arrangements	13,065	7,858
Prepaid expenses and other current assets	800	1,571
TOTAL CURRENT ASSETS	57,107	43,055
NON-CURRENT ASSETS:		
Long-term receivables from collaborative arrangements	7,402	-
Restricted long-term deposits and cash	1,298	1,288
Property and equipment, net	1,051	660
Operating lease right-of-use assets	1,501	876
Funds in respect of employee rights upon retirement	830	749
TOTAL NON-CURRENT ASSETS	12,082	3,573
TOTAL ASSETS	$ 69,189	$ 46,628
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 766	$ 251
Other accounts payable	10,145	2,360
Current maturities of operating leases	781	718
TOTAL CURRENT LIABILITIES	11,692	3,329
LONG-TERM LIABILITIES:		
Operating leases liabilities	810	54
Liability for employee rights upon retirement	1,093	1,032
TOTAL LONG-TERM LIABILITIES	1,903	1,086
TOTAL LIABILITIES	13,595	4,415

COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2021 and 2022, respectively; issued and outstanding: 23,126,804 and 23,129,469 as of December 31, 2021 and December 31, 2022, respectively	638	638
Additional paid-in capital	233,098	234,640
Accumulated deficit	(178,142)	(193,065)
TOTAL SHAREHOLDERS' EQUITY	55,594	42,213
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 69,189	$ 46,628

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

	Year ended December 31,		
	2020	**2021**	**2022**
COLLABORATION REVENUES	$ 8,771	$ 23,772	$ -
LICENSEREVENUES	-	7,500	3,883
TOTAL REVENUES	8,771	31,272	3,883
RESEARCH AND DEVELOPMENT EXPENSES	27,913	20,381	12,682
GENERAL AND ADMINISTRATIVE EXPENSES	11,091	8,451	7,445
OTHER INCOME,net	-	524	-
TOTAL OPERATING INCOME (LOSS)	(30,233)	2,964	(16,244)
FINANCIAL INCOME, net	943	257	1,321
NET INCOME (LOSS)FOR THE YEAR	$ (29,290)	$ 3,221	$ (14,923)
BASIC EARNINGS (LOSS) PER ORDINARY SHARE	$ (1.30)	$ 0.14	$ (0.65)
DILUTED EARNINGS (LOSS) PER ORDINARY SHARE	(1.30)	0.14	(0.65)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:			
BASIC	22,574,688	23,063,493	23,128,722

DILUTED	22,574,688	23,566,182	23,128,722