Sol-Gel Technologies Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 12, 2023

- *Positive trends continue for TWYNEO® and EPSOLAY® with recurrent prescriber bases at 98% for TWYNEO and 92% for EPSOLAY during Q1 2023*
- *Sol-Gel on track to advance Orphan Drug candidate, SGT-610 (patidegib) for Gorlin syndrome into Phase 3 testing in late 2023*
- *Phase 1 trial for SGT-210 (erlotinib) demonstrated no systemic absorption-related adverse events; Sol-Gel intends to advance this drug candidate*
- *Sol-Gel has cash runway into the second half of 2025*

NESS ZIONA, Israel, May 12, 2023 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company with two innovative dermatology products, EPSOLAY and TWYNEO, that were launched in the U.S., SGT-610, which is Phase 3-ready, and an earlier-stage SGT-210, today announced financial results for the first quarter ended March 31, 2023 and provided a corporate update.

“This year we turned our focus towards a high-value segment of dermatology and helping those patients with significant unmet needs. We remain on track with our plans to initiate the pivotal Phase 3 trial for SGT-610, or patidegib, our recently acquired, Breakthrough-designated, Orphan Drug candidate with a market potential of over $300 million for the treatment of Gorlin syndrome, in late 2023,” stated Alon Seri-Levy, Ph.D., Chief Executive Officer of Sol-Gel. “In parallel, we continue to be pleased by the pace of uptake by prescribers, patients and payors for our Galderma-partnered products, TWYNEO and EPSOLAY. Galderma had an impressive presence to support both brands at the American Academy of Dermatology in March of this year, hosting several educational events and thought-leader presentations for physicians, and then held a targeted sales force training on EPSOLAY ahead of peak rosacea season. We remain confident about prospects to improve TWYNEO and EPSOLAY reimbursement and profitability over time and continue to seek out-licensing opportunities for our non-U.S. rights to both drugs.”

Q1 2023 and Recent Corporate 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; in addition, Sol-Gel agreed to pay PellePharm 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.
- 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 support the Phase 3 trial of patidegib expected to begin in the fourth quarter of 2023 and for general corporate purposes. The $10 million private placement portion of the offering was approved by shareholders on March 30, 2023 and received in April 2023.
- Prescribers continue to report positive experiences with TWYNEO (launched in April 2022), with the recurring base of prescribers increasing to a high of 98% in the first quarter of 2023, from 82% in the fourth quarter of 2022, with consistent prescribing quantities per healthcare provider and increasing patient refill rates. The recurring base of prescribers, defined as the percentage of all TWYNEO prescribers who have written since launch and continue to prescribe, continues to be a positive indicator of the drug’s acceptance. According to IQVIA data, there have been over 28,000 prescriptions written for TWYNEO in the first quarter of 2023.
- As of Q1 2023, nine months post its June 2022 launch, EPSOLAY remains at the #2 position among branded topical rosacea treatments. EPSOLAY’s recurring base of prescribers increased to 92% of its total prescribers in Q1 2023, from 64% in the fourth quarter of 2022, and prescriptions written per provider continue to increase along with patient refill rates. According to IQVIA data, there have been over 12,000 prescriptions of EPSOLAY written in the first quarter of 2023.
- Since launching, TWYNEO and EPSOLAY have improved their commercial managed care accessibility, reaching over 60% and 40% of commercial covered lives respectively. Beyond broad managed care adoption of TWYNEO across the three major Pharmacy Benefit Managers (PBMs), the drug was moved by CVS Corporation to preferred status on its formulary as of January 1, 2023; while EPSOLAY is now also covered by Express Scripts Holding Company and OptumRx, Inc.
- Galderma hosted several medical education events to support brand visibility of both TWYNEO and EPSOLAY at the American Academy of Dermatology in March and also held targeted sales force education and training activities for EPSOLAY ahead of Rosacea Awareness Month in April, during peak rosacea season, to drive increased prescription volumes.

- Sol-Gel has completed a Phase 1 study of SGT-210, or erlotinib, an EGFR inhibitor. The trial was designed as a single-center, single-blind, parallel-group, maximal use systemic exposure (MUSE) study evaluating the pharmacokinetics, safety and tolerability of erlotinib topical treatment in healthy volunteers. A total of 12 healthy adult subjects were assigned to two doses of erlotinib treatment in a 1:1 ratio. The subjects were treated once daily for 28 days. Study results showed the topical therapy had no systemic absorption-related adverse events affecting patient treatment adherence and minimal systemic absorption was detected. Study drug-related adverse events were mainly designated as mild, and all were resolved during study duration. Results from this Phase 1 study support further development of this product candidate.

Financial Results for the Quarter Ended March 31, 2023

Total revenue in the first quarter was $0.8 million, which primarilyconsisted of licensing revenue compared to nominal revenues for the same period in 2022.

Research and development expenses were $9.4 million compared to $4.0 million for the same period in 2022. The increase of $5.4 million was primarily attributed to the $4.7 million upfront payment associated with the acquisition of topically applied patidegib.

General and administrative expenses were $2.0 million in 2023 compared to $1.9 million for the same period in 2022. The increase of $0.1 million was mainly attributed to an increase in professional expenses.

Sol-Gel reported net loss of $10.3 million for the first quarter of 2023 and a loss of $0.41 per basic and diluted share, compared to a net loss of $5.6 million and a loss of $0.24 per basic and diluted share for the same period in 2022.

As of March 31, 2023, Sol-Gel had $20.3 million in cash, cash equivalents and deposits, and $18.4 million in marketable securities for a total balance of $38.7 million. The balance as of March 31, 2023, does not include $10 million received in April 2023 as part of 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 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, the commercial acceptance, profitability and reimbursement of TWYNEO and EPSOLAY, our ability to out-license non-U.S. rights for TWYNEO and EPSOLAY*, and the potential of SGT-210. 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, 2022	March 31, 2023
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 12,448	$ 6,806
Bank deposits	12,500	8,500
Marketable securities	8,678	18,439
Receivables from collaborative and licensing arrangements	7,858	5,806
Prepaid expenses and other current assets	1,571	1,128
TOTAL CURRENT ASSETS	43,055	40,679
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash	1,288	1,296
Long-term bank deposits	-	5,000
Property and equipment, net	660	632
Operating lease right-of-use assets	876	707
Funds in respect of employee rights upon retirement	749	729
TOTAL NON-CURRENT ASSETS	3,573	8,364
TOTAL ASSETS	$ 46,628	$ 49,043
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 251	$ 339
Other accounts payable	2,360	3,040
Current maturities of operating leases	718	544
TOTAL CURRENT LIABILITIES	3,329	3,923
LONG-TERM LIABILITIES:		
Operating leases liabilities	54	30
Liability for employee rights upon retirement	1,032	1,028
TOTAL LONG-TERM LIABILITIES	1,086	1,058
TOTAL LIABILITIES	4,415	4,981
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2022 and March 31, 2023, respectively; issued and outstanding: 23,129,469 and 25,702,237 as of December 31, 2022 and March 31, 2023, respectively	638	712
Additional paid-in capital	234,640	246,678
Accumulated deficit	(193,065)	(203,328)
TOTAL SHAREHOLDERS' EQUITY	42,213	44,062
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 46,628	$ 49,043

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

	Three months ended March 31	
	2022	2023
LICENSE REVENUES	$ 3	$ 758
RESEARCH AND DEVELOPMENT EXPENSES	4,042	9,386
GENERAL AND ADMINISTRATIVE EXPENSES	1,911	1,977
OPERATING LOSS	$ 5,950	$ 10,605
FINANCIAL INCOME, net	(353)	(342)
LOSS FOR THE PERIOD	$ 5,597	$ 10,263

BASIC AND DILUTED LOSS PER ORDINARY SHARE	0.24	0.41
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	23,127,484	24,944,220

Source: Sol-Gel Technologies Ltd.