Sol-Gel Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

November 15, 2024

- Mori Arkin's appointment as interim CEO as of January 1, 2025 approved by shareholders
- Phase 3 clinical trial of SGT-610 for Gorlin Syndrome is ongoing with over 40 clinical sites activated
- SGT-210 proof-of-concept study in patients suffering from Darier disease is ongoing

NESS ZIONA, Israel, Nov. 15, 2024 (GLOBE NEWSWIRE) -- **Sol-Gel Technologies, Ltd.** (NASDAQ: SLGL), a dermatology company, pioneering treatments for patients with severe skin conditions, conducting a Phase-3 clinical trial of SGT-610 (patidegib gel, 2%) for Gorlin syndrome, and with two approved large-category dermatology products, TWYNEO® and EPSOLAY®, today announced financial results for the third quarter ended September 30, 2024, and provided a corporate update.

Q3 2024 and Recent Corporate Developments

- On November 4, 2024, Sol-Gel's shareholders approved the appointment of our Chairman, Mr. Mori Arkin, as Interim CEO as of January 1, 2025. Mr. Arkin will replace Sol-Gel's founder and current CEO, Dr. Alon Seri-Levy, who will remain as a consultant to the Company for a period of at least one year.
- On November 13, 2024, Sol-Gel received approval from Nasdaq to transfer the listing of its Ordinary Shares from The Nasdaq Global Market to The Nasdaq Capital Market. The transfer became effective as of November 15, 2024. This transfer has been requested in order to be provided with a second 180-day compliance period to regain compliance with The Nasdaq Stock Market LLC's ("Nasdaq") minimum bid price rule. Sol-Gel's Ordinary Shares will continue to trade under the symbol "SLGL" and trading of its Ordinary Shares will not be affected by this transfer. The Nasdaq Capital Market is a continuous trading market that operates in substantially the same manner as The Nasdaq Global Market. The approval of the second compliance period and the transfer to the Nasdaq Capital Market are expected based upon the Company meeting all other applicable requirements for initial listing on the Capital Market, except for the bid price requirement, the Company's written notice of its intention to cure the deficiency by effecting a reverse stock split, if necessary, and additional supporting information provided in its application.
- On August 15, 2024, Sol-Gel signed a new agreement with Padagis, which replaced the parties' prior collaboration agreement for the development and commercialization of a generic drug product to Zoryve® Cream (roflumilast cream 0.3%). Under this new agreement, Sol-Gel is to unconditionally receive eight quarterly payments which will be paid over 24 months and low single digit royalties from gross profits from sales of roflumilast cream for a period of five years, in lieu of its 50% share in future gross profits from such sales. In addition, Sol-Gel will cease paying any outstanding and future costs related to this prior collaboration agreement. The amount to be received from Padagis, together with the elimination of future expected expenses related to this asset, is expected to enhance Sol-Gel's cash position by approximately $6 million.
- On September 27, 2024, Sol-Gel signed an additional license agreement for the commercialization of Twyneo and Epsolay in South Korea. This Agreement is in addition to the six agreements Sol-Gel signed during July 2024 in various territories covering most of European countries and South Africa. These already signed agreements, together with agreements we anticipate to sign in the future covering Latin American countries, Australia, New Zealand, Spain, Italy and Portugal, are expected to provide upfront and regulatory milestone payments of up to $3.7 million, which Sol-Gel expects to utilize on adapting TWYNEO and EPSOLAY to the regulatory requirements of these new territories. Based on the forecasts received from Sol-Gel's current and potential partners, Sol-Gel expects that TWYNEO and EPSOLAY will launch in the majority of these new territories in 2027 and 2026 respectively, and following launch, these transactions are anticipated to provide Sol-Gel with an annual royalty revenue stream starting with approximately $1 million to $2 million in 2026 and growing gradually to approximately up to $10 million for the year 2030 and further.
- The Phase 3 study in Sol-Gel's key asset SGT-610 in approximately 140 subjects (with 100 subjects required to complete the Study) at about 40 experienced clinical centers is ongoing. To date, Sol-Gel has signed agreements with 43 centers in multiple countries, including the U.S., Spain, The Netherlands, Germany, Italy, France and the UK, and approximately 40 of these centers have been activated. Top line results are anticipated in H2 2026. SGT-610 is a *topically applied patidegib, a hedgehog signaling pathway blocker* 2% gel If approved, SGT-610 is expected to be the first approved product for the prevention of new BCC lesions in Gorlin syndrome patients and is targeting a market exceeding $300 million annually.
- Sol-Gel's proof-of-concept study for SGT-210 (topical erlotinib) in patients with Darier disease is ongoing. Darier disease is a significant unmet medical need, with a market potential estimated between $200 to $300 million. If Sol-Gel successfully completes this proof-of-concept study and the required pre-clinical studies, it anticipates filing for a Phase 2 IND in Q2 2025. SGT-210 is currently being used in a compassionate use treatment of a pediatric patient suffering from a rare disease, and given the preliminary highly encouraging response, we are cautiously optimistic about the potential for success in other viable keratoderma indications, recognizing that further research and clinical studies are necessary to validate any broader applications of our therapy.

Mr. Mori Arkin, Executive Chairman of Sol-Gel, stated: "The quarterly results reflects our continuous effort to maximize the value of our assets,

while exploring business opportunities for non-dilutive funding. We continue to conduct the pivotal Phase 3 clinical trial of SGT-610 as planned and are encouraged by the rate of recruitment of patients. We believe that our approach for preventing new basal cell carcinomas in Gorlin Syndrome patients can ease the suffering of patients and bring cure to an unmet medical need, in a target market that exceeds $300 million. In addition, our proof-of-concept study for SGT-210 (topical erlotinib) in Darier disease patients, targeting a market of between $200 million to $300 million, continues. The Company's strategy, with our two leading assets, pave the way for further strengthening Sol-Gel's business and competitive position."

Financial Results for the Third Quarter 2024

Total revenue in the third quarter was $5.4 million which primarily consisted of licensing revenue from Padagis, Galderma, Searchlight and seven new license agreements, compared to $0.2 million revenues for the same period in 2023.

Research and development expenses were $4.8 million compared to $4.7 million for the same period in 2023. The increase of $0.1 million was primarily attributed to an increase of $0.7 million in clinical trial expenses related to SGT-610, an increase of $0.5 million in expenses related to the commercialization of Epsolay and Twyneo in other territories and an increase of $0.3 million in clinical expenses related to SGT-210, offset by a decrease of $0.4 million in clinical development expenses related to a generic product, a decrease of $0.5 million in payroll expenses due to the adoption of cost saving measures initiated during the third quarter of 2023 and a decrease of $0.5 million related to R&D and Operations expenses due to cost measures savings.

General and administrative expenses were $1.4 million compared to $1.9 million for the same period in 2023. The decrease of $0.5 million was mainly attributed to a decrease of $0.4 million in professional expenses and a decrease of $0.1 million in payroll expenses due to the adoption of cost saving measures initiated during the third quarter of 2023.

Sol-Gel reported a net loss of $0.4 million for the third quarter of 2024 and loss of $0.01 per basic and diluted share, compared to a net loss of $5.7 million and a loss of $0.21 per basic and diluted share for the same period in 2023.

As of September 30, 2024, Sol-Gel had $14.6 million in cash, cash equivalents, and deposits and $14.6 million in marketable securities for a total balance of $29.2 million. The Company expects its cash resources to fund cash requirements into the first quarter of 2026.

About TWYNEO and EPSOLAY

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.

EPSOLAY is a topical cream containing benzoyl peroxide (BPO), 5%, for the treatment of bumps and blemishes (inflammatory lesions) of rosacea in adults. EPSOLAY utilizes a proprietary, patented technology to encapsulate BPO within silica-based microcapsules to create a barrier between the medication and the skin. The silica-based shell is designed to slowly release BPO over time to provide a tolerable and effective treatment.

About Gorlin Syndrome and SGT-610

SGT-610, a hedgehog signaling pathway blocker, has the potential to be the first ever treatment for prevention of BCCs in Gorlin syndrome patients, 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 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 Darier Disease and SGT-210

SGT-210 is a topical erlotinib drug candidate that is formulated for the treatment of Darier Disease and other hyperkeratosis-related indications. Erlotinib is a tyrosine kinase receptor inhibitor that acts on the epidermal growth factor receptor, a protein present on cell surfaces that plays a key role in promoting cell growth and division. Darier Disease is a rare, genetic keratinization disorder which is classically characterized scaly crusted papules in a seborrheic distribution and in skin folds.

About Sol-Gel Technologies

Sol-Gel Technologies, Ltd. is a dermatology company focused on identifying, developing and commercializing or partnering drug products to treat 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.

The Company's pipeline also includes Phase 3 clinical trial of Orphan and breakthrough drug candidate SGT-610, which is a new topical hedgehog inhibitor being developed to prevent the new basal cell carcinoma lesions in patients with Gorlin syndrome that is expected to have an improved safety profile compared to oral hedgehog inhibitors as well as topical drug candidate SGT-210 under investigation for the treatment of rare hyper keratinization disorders.

For additional information, please visit our new website: 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 amounts to be received under our current and future licensing agreements and under our agreement with Padagis with respect to the generic drug product to Zoryve® Cream (roflumilast cream, 0.3%), the out-licensing of Twyneo and Epsolay in additional territories, our expected cash runway, the potential of Sol-Gel's assets including Twyneo, Epsolay, SGT-610, and SGT-210, the timeline for advancing SGT-610 and SGT-210, the size of SGT-610's and SGT-210 markets and our ability to receive a second 180 days period to regain compliance with the Nasdaq requirement. 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, delays in regulatory milestones, such as a delay in the filing for a Phase 2 IND for SGT-210 and

a delay in topline results for our SGT-610 clinical trial, our ability to enter into further collaborations, lower than anticipated annual revenue income from new collaborations and a delay in the timing of our clinical trials, the success of our clinical trials, and an increase in our anticipated costs and expenses, 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 collaborators' ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our collaborators' ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our collaborators' 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, China, Europe or Israel; and (xv) loss or retirement of key executives and research scientists; (xvi) general market, political and economic conditions in the countries in which the Company operates; and, (xvii) the current war between Israel and Hamas and any deterioration of the war in Israel into a broader regional conflict involving Israel with other parties. These factors 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 13, 2024, 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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CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	December 31, 2023	September 30, 2024
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,513	$ 13,420
Bank deposits	10,012	-
Marketable securities	20,471	14,631
Accounts receivables	377	7,020
Prepaid expenses and other current assets	2,794	2,881
TOTAL CURRENT ASSETS	41,167	37,952
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash equivalents	1,284	1,285
Property and equipment, net	434	250
Operating lease right-of-use assets	1,721	1,397
Other long-term assets	55	1,542
Funds in respect of employee rights upon retirement	626	554
TOTAL NON-CURRENT ASSETS	4,120	5,028
TOTAL ASSETS	$ 45,287	$ 42,980
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 154	$ 1,519
Other accounts payable	3,921	4,631
Current maturities of operating leases	447	384
TOTAL CURRENT LIABILITIES	4,522	6,534
LONG-TERM LIABILITIES:		
Operating leases liabilities	1,206	922
Liability for employee rights upon retirement	915	819
TOTAL LONG-TERM LIABILITIES	2,121	1,741
TOTAL LIABILITIES	6,643	8,275
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2023 and September 30, 2024; issued and outstanding: 27,857,620 as of December 31, 2023 and September 30, 2024.	774	774
Additional paid-in capital	258,173	258,968
Accumulated deficit	(220,303)	(225,037)
TOTAL SHAREHOLDERS' EQUITY	38,644	34,705
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 45,287	$ 42,980

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

	Nine months ended September 30		Three months ended September 30	
	2023	2024	2023	2024
REVENUES	$ 1,107	$ 11,260	$ 213	$ 5,361
RESEARCH AND DEVELOPMENT EXPENSES	19,370	12,606	4,672	4,823
GENERAL AND ADMINISTRATIVE EXPENSES	5,649	4,569	1,862	1,366
OTHER INCOME, net	14	-	14	-
OPERATING LOSS	(23,898)	(5,915)	(6,307)	(828)
FINANCIAL INCOME, net	1,496	1,181	596	462
NET LOSS FOR THE PERIOD	$ (22,402)	$ (4,734)	$ (5,711)	$ (366)
BASIC AND DILUTED LOSS PER ORDINARY SHARE	(0.84)	(0.17)	(0.21)	(0.01)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	26,826,458	27,857,620	27,844,212	27,857,620

Source: Sol-Gel Technologies Ltd.