



Sol-Gel Reports Second Quarter 2025 Financial Results and Provides Corporate Updates

August 15, 2025

- Patient enrollment for our ongoing Phase-3 clinical trial of SGT-610 for Gorlin Syndrome has been completed; top-line results are expected in the fourth quarter of 2026
- Phase-1b proof-of-concept clinical trial of SGT-210 for Darier disease is ongoing
- Sol-Gel and Mayne Pharma Announce the Purchase of EPSOLAY and TWYNEO in the U.S. for a total consideration of \$16 million to be received during 2025
- Following recent transactions, Sol-Gel's cash runway is expected to extend into the first quarter of 2027

NESS ZIONA, Israel, Aug. 15, 2025 (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 second quarter ended June 30, 2025 and provided a corporate update.

Q2 2025 and Recent Corporate Developments

- Subject enrollment for the Phase 3 study in Sol-Gel's key asset SGT-610 has been completed; Top-line results are expected in the fourth quarter of 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 product for the prevention of new BCC lesions in Gorlin syndrome patients and is targeting potential peak revenue exceeding \$300 million annually.
- Sol-Gel's vehicle-controlled proof-of-concept phase-1b clinical trial 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. Due to the circumstances which prevailed in Israel in the last months, recruitment of patients has been slowed down. Therefore, the study completion and top-line results are expected in the fourth quarter of 2025. Pending positive results, we anticipate filing for a Phase 2 IND, promptly following the completion of the present study.
- SGT-210 is currently being used in compassionate treatment in a pediatric patient suffering from Olmsted disease, a debilitating rare skin disorder for which there is no approved treatment. In addition, Sol-Gel supports a request from a leading hospital, for another debilitating skin condition.
- On April 17, 2025, Sol-Gel announced it had entered into a product purchase agreement with a subsidiary of Mayne Pharma Group Limited (Mayne Pharma) for the sale and exclusive license of the U.S. rights to EPSOLAY and TWYNEO. Under the terms of the agreement, Sol-Gel will receive a total of \$16 million in two installments: \$10 million already received during the second quarter of 2025 and \$6 million expected in the fourth quarter of 2025, which is expected to extend the Company's cash runway into the first quarter of 2027. This agreement was executed following the mutual termination by Sol-Gel and Galderma of the exclusive five-year license agreement in the U.S.
- On May 5, 2025, Sol-Gel implemented a 10-for-1 reverse share split of its ordinary shares, reducing shares outstanding from approximately 27.9 million to 2.8 million and adjusting authorized share capital to 5 million shares (par value NIS 1.0); the split, approved by shareholders on April 1, 2025, was intended to raise the per-share price and maintain Sol-Gel's Nasdaq Capital Market listing, with trading continuing under the ticker "SLGL" on a split-adjusted basis.

Mr. Mori Arkin, Executive Chairman of Sol-Gel, stated: "Sol-Gel entered the second half of 2025 in a markedly stronger position. We have now completed enrollment in our pivotal Phase 3 trial of SGT-610 for Gorlin syndrome, keeping us firmly on track to report top-line data in the fourth quarter of 2026. If approved, SGT-610 is expected to be the first therapy designed to prevent new basal cell carcinomas in this underserved population, with peak revenue which we estimate at more than \$300 million annually. Our continuous interaction with physicians and patients of Gorlin disease makes us more conscious than before of the debilitating effects of this disease and the urgent need for a therapy that will improve the quality of life for these patients."

Mr. Arkin further commented "Our second key asset, SGT-210, continues to advance despite certain recruitment impediments. The compassionate-use requests of SGT-210 that we receive support our belief that this drug may have additional important indications beyond Darier disease."

Mr. Arkin added "Commercially, we've taken decisive steps to unlock the full value of our approved products. The agreement with Mayne Pharma extends our cash runway into the first quarter of 2027 and allows us to accelerate investment in our R&D pipeline and, outside the United States, agreements executed last year position TWYNEO and EPSOLAY for launch in most new territories beginning in 2027-2028. According to partner forecasts, royalties from these ex-U.S. markets are expected to grow to potentially approximately \$10 million by 2031."

Lastly, Mr. Arkin noted "As we look ahead, we remain firmly focused on delivering pivotal data for SGT-610, advancing SGT-210, and translating the global demand for TWYNEO and EPSOLAY into meaningful, non-dilutive revenues, all in service of creating long-term value for patients and shareholders alike."

Financial Results for the Second Quarter 2025

Total revenue for the second quarter was \$17.2 million, which primarily consisted of \$0.5 million in royalty revenue from Galderma and \$16 million from sale of IP under the agreement with Mayne, compared to total revenue of \$5.4 million for the same period in 2024, which primarily consisted of \$0.6 million royalty revenue from Galderma and \$4.8 million under the agreement with Beimei.

Research and development expenses were \$4.6 million compared to \$2.4 million for the same period in 2024. The increase of \$2.2 million was primarily attributed to an increase of \$1.7 million in manufacturing development expenses related to SGT-610 and an increase of \$1.0 million in clinical trial expenses for SGT-610, offset by a decrease of \$0.3 million in payroll and stock-based compensation expenses mainly due to the adoption of cost saving measures during 2024.

General and administrative expenses were \$1.4 million compared to \$1.4 million for the same period in 2024.

Sol-Gel reported a net income of \$11.6 million for the second quarter of 2025 and earnings of \$4.17 per basic and diluted share, compared to a net loss of \$1.9 million and earnings of \$0.71 per basic and diluted share for the same period in 2024.

As of June 30, 2025, Sol-Gel had \$10.2 million in cash, cash equivalents, and deposits and \$14 million in marketable securities for a total balance of \$24.2 million. The Company expects its cash resources to fund cash requirements into the first quarter of 2027.

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 smoothed, 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 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 hyperkeratinization 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 expected to be received under our current and future licensing agreements our expected cash runway, the size of the markets for SGT-610 and SGT-210, the timeline for advancing SGT-610 and SGT-210, including the timing for top-line results and the timing for payments from Mayne Pharma. 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 amounts received from our current and future licensing agreements will not be as anticipated, the risk that the market for SGT-610 and SGT-210 will not be as anticipated, our ability to enter into further collaborations, lower than anticipated annual revenue income from new collaborations, a delay in the timing of our clinical trials, top-line results and regulatory filings, a delay in receipt of payments from Mayne Pharma and others, 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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SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS (U.S. dollars in thousands)

(Unaudited)

	<u>December 31, 2024</u>	<u>June 30, 2025</u>
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 19,489	\$ 10,221
Bank deposits	12	12
Marketable securities	4,425	14,054
Accounts receivables	3,595	10,040
Prepaid expenses and other current assets	3,774	1,935
TOTAL CURRENT ASSETS	<u>31,295</u>	<u>36,262</u>
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash equivalents	1,291	1,308
Long-term receivables	1,024	-
Property and equipment, net	202	162
Operating lease right-of-use assets	1,426	1,230
Other long-term assets	13	-
Funds in respect of employee rights upon retirement	595	345
TOTAL NON-CURRENT ASSETS	<u>4,551</u>	<u>3,045</u>
TOTAL ASSETS	<u>\$ 35,846</u>	<u>\$ 39,307</u>
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,265	\$ 1,165
Other accounts payable	3,590	3,308
Current maturities of operating leases	430	482
TOTAL CURRENT LIABILITIES	<u>5,285</u>	<u>4,955</u>
LONG-TERM LIABILITIES:		
Operating leases liabilities	878	700
Liability for employee rights upon retirement	833	415
Other long-term Liability	-	1,355
TOTAL LONG-TERM LIABILITIES	<u>1,711</u>	<u>2,470</u>
TOTAL LIABILITIES	<u>6,996</u>	<u>7,425</u>
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 1 par value – authorized: 5,000,000 as of December 31, 2024 and June 30, 2025, respectively; issued and outstanding: 2,785,787 as of December 31, 2024 and June 30, 2025, respectively *	774	774
Additional paid-in capital	258,959	259,189
Accumulated deficit	(230,883)	(228,081)
TOTAL SHAREHOLDERS' EQUITY	<u>28,850</u>	<u>31,882</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 35,846</u>	<u>\$ 39,307</u>

*All share amounts have been retroactively adjusted to reflect a 1-for-10 reverse share split.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands)

(Unaudited)

	Six months ended June 30		Three months ended June 30	
	2024	2025	2024	2025
REVENUE	\$ 5,899	\$ 18,292	\$ 5,433	\$ 17,261
RESEARCH AND DEVELOPMENT EXPENSES	7,783	13,489	2,438	4,646
GENERAL AND ADMINISTRATIVE EXPENSES	3,203	2,642	1,371	1,385
OPERATING INCOME (LOSS)	\$ (5,087)	2,161	\$ 1,624	\$ 11,230
FINANCIAL INCOME, net	719	641	352	380
NET INCOME (LOSS) FOR THE PERIOD	\$ (4,368)	2,802	\$ 1,976	\$ 11,610
BASIC AND DILUTED EARNINGS (LOSS) PER ORDINARY SHARE	\$ (1.57)	\$ 1.01	\$ 0.71	\$ 4.17
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE *	2,785,787	2,785,787	2,785,787	2,785,787

*All share amounts have been retroactively adjusted to reflect a 1-for-10 reverse share split.



Source: Sol-Gel Technologies Ltd.