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

November 20, 2025

- Sol-Gel intends to pursue high-frequency BCC as an additional indication for its lead drug candidate SGT-610, which, if approved, could at least double the drug's commercial potential
- In September 2025, Sol-Gel announced Health Canada approval of EPSOLAY
- Sol-Gel signed an additional agreement with Viatris covering Australia and New Zealand for both EPSOLAY and TWYNEO

NESS ZIONA, Israel, Nov. 20, 2025 (GLOBE NEWSWIRE) -- **Sol-Gel Technologies, Ltd.** (NASDAQ: SLGL), a dermatology company, pioneering treatments for patients with rare and severe skin conditions, today announced financial results for the third quarter ending September 30, 2025, and provided a corporate update.

Q3 2025 and Recent Corporate Developments

- Sol-Gel's ongoing Phase 3 clinical trial of SGT-610 (patidegib gel, 2%) for Gorlin syndrome, for which top-line results are expected in the fourth quarter of 2026, has led to growing physician interest in its potential use in patients with severe, high-frequency basal cell carcinoma (BCC). One such case, a non-Gorlin patient in France with a devastating form of high-frequency BCC, was found to have a lesion harboring a PTCH-1 mutation, and Sol-Gel agreed to provide SGT-610 for compassionate use. Sol-Gel plans to supply the drug to additional high-frequency BCC patients with at least one PTCH-1 mutated lesion and is evaluating the initiation of a feasibility study in this new indication to further substantiate the rationale for a Phase 3 trial in 2027, subject to the successful completion of the Phase 3 Gorlin syndrome trial. High-frequency BCC is also a rare disease; however, its prevalence is estimated to be at least ten times higher than that of Gorlin syndrome. Even if clinical development focuses only on patients with the most severe forms of high-frequency BCC, a successful outcome is expected to at least double the commercial potential of SGT-610. For many of these patients, there is a significant unmet need for an effective and well-tolerated treatment, as frequent and potentially disfiguring Mohs surgeries are often no longer sustainable.
- Sol-Gel's vehicle-controlled Phase 1b clinical trial (Stage 1) investigating SGT-210 (topical erlotinib) in patients with Darier disease has been challenged by the limited number of eligible patients in Israel. As a result, only seven subjects who completed the treatment were enrolled so far. Consequently, Sol-Gel has decided to conclude the current phase of the trial and to proceed with an open-label extension in which all enrolled patients will receive active treatment with SGT-210. Sol-Gel will release the results of Stage 1 of the trial in December 2025.
- On September 4, 2025, Sol-Gel announced Health Canada marketing approval of EPSOLAY for the treatment of inflammatory lesions of rosacea in adults.
- On August 19, 2025, Sol-Gel signed an additional license agreement for the commercialization of TWYNEO and EPSOLAY in Australia and New Zealand with Viatris Pty Ltd, a subsidiary of Viatris Inc. (NASDAQ: VTRS). This agreement is in addition to the seven agreements Sol-Gel signed during 2024 in various territories covering most European countries, South Africa and South Korea. These already signed agreements, together with agreements we anticipate signing in the future covering Latin American countries, Spain and Portugal, are expected to provide upfront and regulatory milestone payments of up to $3.7 million.

  Based on the forecasts received from Sol-Gel's current and potential partners, Sol-Gel now expects that TWYNEO and EPSOLAY will launch in the majority of these new territories in 2028 and 2027 respectively, and following launch, these transactions are anticipated to provide Sol-Gel with an annual royalty revenue stream with the potential to grow gradually to approximately $10 million for the year 2031 and further.

Mr. Mori Arkin, Executive Chairman of Sol-Gel, stated: "Sol-Gel continued to make steady progress in the third quarter as we advance our late-stage pipeline in dermatologic rare diseases. Our pivotal Phase 3 trial of SGT-610 for Gorlin syndrome is ongoing, and we remain focused on executing this study to deliver top-line results in the fourth quarter of 2026. We are particularly excited about the opportunity of at least doubling the potential of this important drug by adding the unmet need of high-frequency BCC."

Mr. Arkin further commented "The recently announced Health Canada approval of EPSOLAY, alongside our existing ex-U.S. partnerships for TWYNEO and EPSOLAY, underscores our ability to unlock the value of our approved products through collaborations that provide non-dilutive revenue streams. We are delighted that additional companies with strong market presence in their territories have joined our growing partnership network. The number of territories and the identity of our partners make us confident about reaching our target of $10 million EBITDA from this business alone, by 2031. As we look ahead, we remain committed to advancing SGT-610 and SGT-210 to support our strategy of becoming a leader in rare dermatological diseases and to create long-term value for patients and shareholders."

Financial Results for the Third Quarter 2025

Total revenue for the third quarter was $0.4 million, which primarily consisted of license revenue from ex-US licensing agreements, compared to total revenue of $5.4 million for the same period in 2024, which primarily consisted of $0.4 million royalty revenue from Galderma, $0.6 royalty revenue from Searchlight, $3.8 million under the agreement with Padagis and $0.5 million under the ex-US licensing agreements.

Research and development expenses were $5.7 million compared to $4.8 million for the same period in 2024. The increase of $0.9 million was primarily attributed to an increase of $0.8 million in manufacturing development expenses related to SGT-610 and an increase of $0.7 million in clinical trial expenses for SGT-610, offset by a decrease of $0.4 million in professional expenses related to ex-US activities in EPSOLAY and TWYNEO and a decrease of $0.3 million in professional expenses related to a generic product candidate.

General and administrative expenses were $1 million compared to $1.4 million for the same period in 2024. The decrease is mainly attributed to a decrease in payroll and expenses due to the adoption of cost saving measures during 2024.

Sol-Gel reported a net loss of $5.9 million for the third quarter of 2025 and loss of $2.13 per basic and diluted share, compared to a net loss of $0.4 million and loss of $0.13 per basic and diluted share for the same period in 2024.

As of September 30, 2025, Sol-Gel had $6.8 million in cash, cash equivalents, and deposits and $14.1 million in marketable securities for a total balance of $20.9 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 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 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 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, lower than anticipated annual revenue from our current and future licensing agreements or a delay in generating revenue, the risk that the market for SGT-610 and SGT-210 will not be as anticipated, including with respect to High-Frequency BCC for SGT-610, our ability to enter into further 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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Source: Sol-Gel Technologies Ltd.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands)

(Unaudited)

	December 31, 2024	September 30, 2025
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,489	$ 6,705
Bank deposits	12	12
Marketable securities	4,425	14,126
Accounts receivables	3,595	9,846
Prepaid expenses and other current assets	3,774	962
TOTAL CURRENT ASSETS	31,295	31,651
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash equivalents	1,291	1,312
Long-term receivables	1,024	-
Property and equipment, net	202	145
Operating lease right-of-use assets	1,426	1,132
Other long-term assets	13	-
Funds in respect of employee rights upon retirement	595	352
TOTAL NON-CURRENT ASSETS	4,551	2,941
TOTAL ASSETS	$ 35,846	$ 34,592
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 1,265	$ 828
Other accounts payable	3,590	4,827
Current maturities of operating leases	430	491
TOTAL CURRENT LIABILITIES	5,285	6,146
LONG-TERM LIABILITIES:		
Operating leases liabilities	878	592
Liability for employee rights upon retirement	833	424
Other long-term Liability	-	1,400
TOTAL LONG-TERM LIABILITIES	1,711	2,416
TOTAL LIABILITIES	6,996	8,562
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 1 par value – authorized: 5,000,000 as of December 31, 2024 and September 30, 2025; issued and outstanding: 2,785,787 as of December 31, 2024 and September 30, 2025 *.	774	774
Additional paid-in capital	258,959	259,279
Accumulated deficit	(230,883)	(234,023)
TOTAL SHAREHOLDERS' EQUITY	28,850	26,030
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 35,846	$ 34,592

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands)

(Unaudited)

	Nine months ended September 30	Three months ended September 30

	2024	2025	2024	2025
REVENUE	$ 11,260	$ 18,692	$ 5,361	$ 400
RESEARCH AND DEVELOPMENT EXPENSES	12,606	19,220	4,823	5,731
GENERAL AND ADMINISTRATIVE EXPENSES	4,569	3,599	1,366	957
OPERATING LOSS	(5,915)	(4,127)	(828)	(6,288)
FINANCIAL INCOME, net	1,181	987	462	346
NET LOSS FOR THE PERIOD	$ (4,734)	$ (3,140)	$ (366)	$ (5,942)
BASIC AND DILUTED LOSS PER ORDINARY SHARE	(1.7)	(1.13)	(0.13)	(2.13)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED 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.