



## **UPDATE: Sol-Gel Reports Second Quarter 2024 Financial Results and Provides Corporate Updates**

August 17, 2024

- Following recent transactions and cost-cutting efforts, Sol-Gel's cash runway is expected to extend into the first quarter of 2026
- Ongoing Phase 3 clinical trial of SGT-610 for Gorlin Syndrome with over 30 clinical sites activated; Top-line results are expected by the second quarter of 2026
- SGT-210 proof-of-concept study in patients suffering from Darier disease, a significant unmet medical need in dermatology, is ongoing
- Sol-Gel sells its rights in the Abbreviated New Drug Application (ANDA) drug product generic to Zoryve<sup>®</sup> Cream (roflumilast cream 0.3%)
- Following management realignment, Mr. Mori Arkin, the Company's executive chairman and controlling shareholder to be appointed as Company's interim CEO as of January 1, 2025, subject to shareholders approval
- Sol-Gel recently signed license agreements with respect to TWYNEO and EPSOLAY in Europe and South Africa and is negotiating additional license deals in Latin America and other territories

NESS ZIONA, Israel, Aug. 17, 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<sup>®</sup> and EPSOLAY<sup>®</sup>, today announced financial results for the second quarter ended June 30, 2024, and provided a corporate update.

### **Q2 2024 and Recent Corporate Developments**

- On August 15, 2024, Sol-Gel signed a new agreement with Padagis, which replaces the parties' prior collaborative agreement for the development and commercialization of a drug product generic to Zoryve<sup>®</sup> Cream (roflumilast cream 0.3%). Under this new agreement, Sol-Gel is to unconditionally receive 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 collaborative agreement. The amount to be received by Padagis together with the elimination of future expected expenses related to this asset is expected to enhance our cash position by approximately \$6 million.
- Recognizing that TWYNEO and EPSOLAY have a significant commercial potential also outside the U.S., during July 2024, Sol-Gel has successfully signed six initial license agreements with key partners covering most European countries and South Africa. Sol-Gel expects to sign additional agreements covering the majority of Latin American countries, Australia, New Zealand, South Korea, Spain, Italy and Portugal. These already signed agreements together with agreements we anticipate to sign in the future, are expected to provide upfront and regulatory milestone payments of up to \$3.7 million, which we expect 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 42 experienced clinical centers is ongoing. To date, Sol-Gel has signed agreements with 39 centers in multiple countries, including the U.S., Germany, Italy, France, and the UK, and approximately 29 of these centers have been activated. Top line results are anticipated in Q2 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 million to \$300 million. If we successfully complete this proof-of-concept study and the required pre-clinical studies, we anticipate 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.
- Subject to shareholder approval, Mr. Arkin, the Company's Executive Chairman and controlling shareholder, who has several decades of experience in leading positions in the pharmaceutical industry and in the dermatological space in

particular, will assume the role of interim CEO as of January 1, 2025. During his tenure as interim CEO, Mr. Arkin plans to transition away from the majority of his other business activities in order to dedicate himself to his new full-time position as interim CEO of the Company. Mr. Arkin will not be entitled to any compensation for assuming this position. On July 15, 2024, Sol-Gel announced management realignment whereby pending shareholder approval our CEO Dr. Alon Seri-Levy will step down as CEO and Board Member, effective December 31, 2024, and will then continue to serve the Company as a consultant to our new CEO and management team for at least one year.

- Effective July 12, 2024, Mr. Eyal Ben-Or, the Company's previous Director of Finance, assumed the role of Chief Financial Officer (CFO). Prior to his employment in Sol-Gel Mr. Ben-Or worked at Mobileye and KPMG Israel. Mr. Ben-Or, is a certified public accountant, holds an MBA and a BA in accounting from the College of Management in Israel. Mr. Ben-Or replaces the Company's previous CFO, Mr. Gilad Mamlok, who will facilitate the transition through December 31, 2024.

**Mr. Mori Arkin, Executive Chairman of Sol-Gel, stated:** "We are encouraged by Sol-Gel's financial results for the second quarter of 2024 and our ability to extend our cash runway into the first quarter of 2026. We will continue to explore opportunities for non-dilutive funding to potentially further extend our runway through topline results. In our pipeline, we continue to conduct the pivotal Phase 3 clinical trial of SGT-610 for preventing new basal cell carcinomas in Gorlin Syndrome patients, targeting a market exceeding \$300 million, with top line results anticipated in the second quarter of 2026 along with our proof-of-concept study for SGT-210 (topical erlotinib) in Darier disease patients targeting a market of between \$200 million to \$300 million. These two rare disease projects reflect the huge growth potential of a company of our size. The Sol-Gel management team and I are committed to spare no effort to realize this potential".

### **Financial Results for the Second Quarter 2024**

Total revenue in the second quarter was \$5.4 million, which primarily consisted of licensing revenue from Beimei, Galderma and Searchlight, compared to \$0.6 million revenues for the same period in 2023.

Research and development expenses were \$2.4 million compared to \$5.3 million for the same period in 2023. The decrease of \$2.9 million was primarily attributed to a decrease of \$0.7 million in manufacturing expenses related to TWYNEO, a decrease of \$0.7 million in clinical development expenses related to a generic product candidate, a decrease of \$0.5 million in payroll expenses due to the adoption of cost saving measures initiated during the third quarter of 2023, a decrease of \$0.5 million related to R&D expenses, a decrease of \$0.3 million in clinical trial expenses related to SGT-610 and a decrease of \$0.2 million in clinical expenses related to SGT-210.

General and administrative expenses were \$1.4 million compared to \$1.8 million for the same period in 2023. The decrease of \$0.4 million was mainly attributed to a decrease in professional expenses.

Sol-Gel reported a net income of \$1.9 million for the second quarter of 2024 and earnings of \$0.07 per basic and diluted share, compared to a net loss of \$6.0 million and a loss of \$0.22 per basic and diluted share for the same period in 2023.

As of June 30, 2024, Sol-Gel had \$15.6 million in cash, cash equivalents, and deposits and \$14.9 million in marketable securities for a total balance of \$30.5 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 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 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](http://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 our agreement with Padagis with respect to the generic drug product to Zoryve<sup>®</sup> Cream (roflumilast cream, 0.3%), the out-licensing Twyneo and Epsolay in additional territories, our expected cash runway, the expected royalties amounts to be received from Galderma, the potential of Sol-Gel’s assets including Twyneo, Epsolay, SGT-610, and SGT-210, the timeline for advancing SGT-610 and SGT-210, and the size of SGT-610’s market. 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, 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, 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.

Sol-Gel Contact:  
Eyal Ben-Or  
Chief Financial Officer  
[info@sol-gel.com](mailto:info@sol-gel.com)  
+972-8-9313429

Source: Sol-Gel Technologies Ltd.

**SOL-GEL TECHNOLOGIES LTD.**  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(U.S. dollars in thousands, except share and per share data)  
(Unaudited)

	December 31, 2023	June 30, 2024
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 7,513	\$ 11,549
Bank deposits	10,012	4,012
Marketable securities	20,471	14,912
Accounts receivables	377	6,059
Prepaid expenses and other current assets	2,794	1,750
<b>TOTAL CURRENT ASSETS</b>	<b>41,167</b>	<b>38,282</b>
<b>NON-CURRENT ASSETS:</b>		
Restricted long-term deposits and cash equivalents	1,284	1,273
Property and equipment, net	434	305
Operating lease right-of-use assets	1,721	1,507
Other long-term assets	55	34
Funds in respect of employee rights upon retirement	626	604
<b>TOTAL NON-CURRENT ASSETS</b>	<b>4,120</b>	<b>3,723</b>
<b>TOTAL ASSETS</b>	<b>\$ 45,287</b>	<b>\$ 42,005</b>
<b>Liabilities and shareholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 154	\$ 679
Other accounts payable	3,921	4,147
Current maturities of operating leases	447	376
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,522</b>	<b>5,202</b>

**LONG-TERM LIABILITIES**

Operating leases liabilities	1,206	1,018
Liability for employee rights upon retirement	915	883
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>2,121</b>	<b>1,901</b>
<b>TOTAL LIABILITIES</b>	<b>6,643</b>	<b>7,103</b>

**SHAREHOLDERS' EQUITY:**

Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2023 and June 30, 2024; issued and outstanding: 27,857,620 as of December 31, 2023 and June 30, 2024.	774	774
Additional paid-in capital	258,173	258,799
Accumulated deficit	(220,303)	(224,671)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>38,644</b>	<b>34,902</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 45,287</b>	<b>\$ 42,005</b>

**SOL-GEL TECHNOLOGIES LTD.**

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Six months ended June 30		Three months ended June 30	
	2023	2024	2023	2024
REVENUE	\$ 894	\$ 5,899	\$ 594	\$ 5,433
RESEARCH AND DEVELOPMENT EXPENSES	14,698	7,783	5,312	2,438
GENERAL AND ADMINISTRATIVE EXPENSES	3,786	3,203	1,809	1,371
OPERATING INCOME (LOSS)	\$ (17,590)	\$ (5,087)	\$ (6,527)	\$ 1,624
FINANCIAL INCOME, net	899	719	557	352
NET INCOME (LOSS) FOR THE PERIOD	\$ (16,691)	\$ (4,368)	\$ (5,970)	\$ 1,976
BASIC AND DILUTED EARNINGS (LOSS) PER ORDINARY SHARE	\$ (0.63)	\$ (0.16)	\$ (0.22)	\$ 0.07
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	26,306,484	27,857,620	27,660,326	27,857,620



Source: Sol-Gel Technologies Ltd.