



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

November 9, 2023

- Sol-Gel on track to advance Orphan Drug candidate, SGT-610 (patidegib) for Gorlin syndrome into Phase 3 testing in late 2023
- Gorlin Syndrome KOL event to be held on December 6, 2023
- Sol-Gel maintains cash runway into the second half of 2025

NESS ZIONA, Israel, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL) ("Sol-Gel"), a dermatology company leveraging innovative approaches to develop pioneering treatments for patients with severe skin conditions, and with two approved large-category dermatology products, TWYNEO<sup>®</sup> and EPSOLAY<sup>®</sup>, today announced financial results for the third quarter ended September 30, 2023 and provided a corporate update.

"We are on track to begin pivotal Phase 3 testing for our Breakthrough-designated, Orphan Drug candidate, SGT-610, or patidegib, for the prevention of basal cell carcinoma in subjects having Gorlin syndrome, which we are planning to initiate this quarter. We anticipate this candidate will have a market potential of over \$300 million as a first-ever therapy in a patient population that currently has no approved therapies," stated Alon Seri Levy, Ph.D., Chief Executive Officer of Sol-Gel.

"As we announced last quarter, SGT-610 is our primary focus due to its promising potential, and we have optimized the Phase 3 trial design and enrollment criteria to maximize the probability of success," he added. "Additionally, we continue to have discussions with prospective partners to secure new international licenses for our marketed products, TWYNEO and EPSOLAY, to generate non-dilutive capital."

### Q3 2023 and Recent Corporate Developments

- Based on Sol-Gel's adoption of cost-saving measures announced in the second quarter, the Company continues to maintain its cash runway into the second half of 2025.
- In the third quarter of 2023, TWYNEO maintained a high recurring base of prescribers compared to the second quarter. In addition, TWYNEO's market access position remains strong with broad commercial formulary coverage on CVS/Caremark, Express Scripts and Optum plans.
- According to IQVIA data, total prescriptions of TWYNEO written in the third quarter approached 27,000 with total prescriptions since launch surpassing 189,000.
- According to IQVIA data, there have been over 13,000 prescriptions of EPSOLAY written in the third quarter of 2023 and over 65,000 prescriptions written to date.
- Sol-Gel's operations remain on-going despite the current war.
- The Company plans to host a KOL event on December 6, 2023 to discuss Gorlin syndrome and the SGT-610 Phase 3 study. Further details are forthcoming and will be available in the Investors/Events & Presentations section of the [www.sol-gel.com](http://www.sol-gel.com) website.

### Financial Results for the Quarter Ended September 30, 2023

Total revenue in the three months was \$0.2 million, which primarily consisted of licensing revenues from Galderma.

Research and development expenses were \$4.7 million compared to \$2.0 million for the same period in 2022. The increase of \$2.7 million was primarily attributed to an increase of \$2.0 million related to the continuing development of SGT-610.

General and administrative expenses for the third quarter of 2023 were \$1.9 million compared to \$1.8 million for the same period in 2022.

Sol-Gel reported a net loss of \$5.7 million for the third quarter of 2023 and a loss of \$0.21 per basic and diluted share, compared to a net loss of \$3.4 million and a net loss of \$0.15 per basic and diluted share for the same period in 2022.

As of September 30, 2023, Sol-Gel had \$26.1 million in cash, cash equivalents and deposits, and \$17.2 million in marketable securities for a total balance of \$43.3 million. 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 smoothed, frizzled 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 TWYNEO

TWYNEO (tretinoin and benzoyl peroxide) Cream, 0.1%/3% is used for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of

age and older.

TWYNEO utilizes a proprietary, patented technology where tretinoin and BPO are encapsulated within silica-based microcapsules to create a barrier between the medication and the skin. The patented microencapsulation technology in TWYNEO Cream segregates and envelopes the active ingredients in silica core shells (microcapsules) so that tretinoin is protected from the oxidizing effects of BPO, allowing the combination of both drugs into one product and gradual release onto the skin.

Sol-Gel Technologies received U.S. Food and Drug Administration (“FDA”) approval for TWYNEO Cream on July 27, 2021, and granted exclusive rights to Galderma to commercialize the treatment in the U.S.

#### **About EPSOLAY**

EPSOLAY is a topical cream containing encapsulated benzoyl peroxide (BPO), 5%, for the treatment of 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.

Sol-Gel Technologies received FDA approval for EPSOLAY Cream on April 22, 2022, and granted exclusive rights to Galderma to commercialize the treatment in the U.S.

#### **About Sol-Gel Technologies**

Sol-Gel Technologies, Ltd. 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 under investigation 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](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 timing of beginning the Phase 3 clinical trial of SGT-610, success of any clinical studies, and obtaining regulatory approval for our product candidates including SGT-610; our expected cash runway; our ability to out-license additional international rights for TWYNEO and EPSOLAY; and the commercial acceptance and profitability of TWYNEO and EPSOLAY. 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, a delay in the timing of our clinical trials, including the timing of beginning the Phase 3 clinical trial of SGT-610, 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, 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 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.*

For further information, please contact:

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#### **Sol-Gel Technologies**

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	<b>December 31, 2022</b>	<b>September 30, 2023</b>
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 12,448	\$ 14,135
Bank deposits	12,500	12,000
Marketable securities	8,678	17,183
Receivables from collaborative arrangements	7,858	-
Prepaid expenses and other current assets	1,571	2,154
<b>TOTAL CURRENT ASSETS</b>	<b>43,055</b>	<b>45,472</b>
<b>NON-CURRENT ASSETS:</b>		
Restricted long-term deposits and cash	1,288	1,290
Property and equipment, net	660	499
Operating lease right-of-use assets	876	1,921
Funds in respect of employee rights upon retirement	749	680
<b>TOTAL NON-CURRENT ASSETS</b>	<b>3,573</b>	<b>4,390</b>
<b>TOTAL ASSETS</b>	<b>\$ 46,628</b>	<b>\$ 49,862</b>
<b>Liabilities and shareholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 251	\$ 234
Other accounts payable	2,360	3,806
Current maturities of operating leases	718	467
<b>TOTAL CURRENT LIABILITIES</b>	<b>3,329</b>	<b>4,507</b>
<b>LONG-TERM LIABILITIES:</b>		
Operating leases liabilities	54	1,222
Liability for employee rights upon retirement	1,032	1,007
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>1,086</b>	<b>2,229</b>
<b>TOTAL LIABILITIES</b>	<b>4,415</b>	<b>6,736</b>
<b>SHAREHOLDERS' EQUITY:</b>		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2022 and September 30, 2023; 23,129,469 and 27,857,620 as of December 31, 2022 and September 30, 2023, respectively.	638	774
Additional paid-in capital	234,640	257,819
Accumulated deficit	(193,065)	(215,467)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>42,213</b>	<b>43,126</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 46,628</b>	<b>\$ 49,862</b>

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

	<b>Nine months ended September 30</b>		<b>Three months ended September 30</b>	
	<b>2022</b>	<b>2023</b>	<b>2022</b>	<b>2023</b>
<b>LICENSE REVENUES</b>	\$ 3,783	\$ 1,107	\$ 261	\$ 213
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	8,465	19,370	2,042	4,672
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	5,357	5,649	1,844	1,862
<b>OTHER INCOME, net</b>	-	14	-	14
<b>OPERATING LOSS</b>	(10,039)	(23,898)	(3,625)	(6,307)
<b>FINANCIAL INCOME, net</b>	901	1,496	218	596
<b>LOSS FOR THE PERIOD</b>	\$ (9,138)	\$ (22,402)	\$ (3,407)	\$ (5,711)
<b>BASIC AND DILUTED LOSS PER ORDINARY SHARE</b>	(0.40)	(0.84)	(0.15)	(0.21)
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE</b>	23,128,469	26,826,458	23,129,469	27,844,212



Source: Sol-Gel Technologies Ltd.