



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

May 20, 2024

- Phase 3 clinical trial of SGT-610 for Gorlin Syndrome with the first patient screened, is ongoing.
- Sol-Gel and Beimei Pharma announced an Asset Purchase Agreement to commercialize TWYNEO® in China, Hong Kong, Macau, Taiwan and Israel, for a total consideration of up to \$115 million.
- Sol-Gel recently initiated a proof-of-concept study for SGT-210 (topical erlotinib) in patients with Darier disease.
- Highly encouraging clinical response for SGT-210 from a Compassionate use treatment for a pediatric patient suffering from an ultra-rare disease.
- Sol-Gel's collaboration partner, Padagis, submitted First-to-File ANDA Drug Product Generic to Zoryve® Cream.
- Sol-Gel maintains its cash runway into the second half of 2025.

NESS ZIONA, Israel, May 20, 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 first quarter ended March 31, 2024 and provided a corporate update.

Q1 2024 and Recent Corporate Developments

- On May 16, Sol-Gel and Beimei Pharma announced an Asset Purchase Agreement, pursuant to which Beimei purchases and licenses the rights to commercialize and manufacture TWYNEO® in China, Hong Kong, Macau, Taiwan and Israel. Sol-Gel is expected to receive, subject to applicable government approvals, a total consideration of up to \$15 million, out of which \$10 million will be paid as upfront and regulatory milestones, and the remaining \$5 million will be paid as royalties on net sales.
- We initiated a proof-of-concept study for SGT-210 (topical erlotinib) in patients with Darier disease, and have been using SGT-210 in a compassionate use treatment for a pediatric patient suffering from an ultra-rare disease.
- On April 1, 2024, Sol-Gel announced that Padagis Israeli Pharmaceuticals, Sol-Gel's collaboration partner, submitted a first-to-file Abbreviated New Drug Application (ANDA) for Roflumilast Cream 0.3%, a drug product generic to Zoryve® Cream (roflumilast cream 0.3%) indicated for the treatment of plaque psoriasis in patients six years of age and older. On March 26, 2024, Arcutis Biotherapeutics Inc initiated a patent infringement action in the US District Court in New Jersey regarding the Padagis Roflumilast 0.3% ANDA. Should the ANDA be approved by the FDA, Padagis believes that its product may be entitled to 180 days of generic market exclusivity. According to IQVIA, the annual market sales in the 12 months ended in January 2024 for Zoryve® Cream were approximately \$ 95 million.
- SGT-610 Phase 3 clinical trial is ongoing. On November 30, 2023, Sol-Gel announced that it had begun for Gorlin syndrome, with the first patient screened. Sol-Gel acquired topically applied patidegib, a hedgehog signaling pathway blocker 2% from PellePharm Inc. and is currently the only therapy in development to prevent the development of new BCC lesions in Gorlin syndrome patients. SGT-610 is a new topical hedgehog inhibitor to prevent the new basal cell carcinoma (BCC) lesions in patients with Gorlin syndrome that is expected to have an improved safety profile compared to oral hedgehog inhibitors. Sol-Gel is conducting a Phase 3 clinical trial to investigate SGT-610 in approximately 140 subjects at about 40 experienced clinical centers in North America, the United Kingdom, and Europe.
- Total prescriptions for TWYNEO in Q1 2024 totaled approximately 21,000, declining 23% from Q4 2023. Patient refills in Q1 declined by 18% for the same time period. This is in part due to a targeted patient adherence campaign facilitated in Q4 2023 and to the adjustments in the promotional model. TWYNEO new prescribers continue to grow with a 5% quarterly increase. Average weekly TWYNEO prescriptions/prescriber remained relatively constant at 1.6/week for Q1 with commercial managed care coverage for TWYNEO increasing by 1.5M lives since Q4 2023 to 102.2M commercial lives covered.
- Total prescriptions for EPSOLAY in Q1 2024 totaled approximately 12,500, declining 14% from Q4 2023. Patient refills declined by 8% for Q1 2024 vs. Q4 2023. Consistent with TWYNEO, the quarterly decrease for EPSOLAY was negatively impacted by strong prescriptions in Q4 2023 influenced by a targeted patient adherence campaign and to the adjustments

in the promotional model. EPSOLAY new prescribers continue to grow with a 6% increase vs. Q4 2023. Average weekly EPSOLAY prescriptions/prescriber remained consistent at 1.3/week for Q1. Managed care coverage for EPSOLAY has grown since Q4 2023 with total commercial lives covered increasing by over 1M lives to 67.1M commercial lives covered.

Alon Seri-Levy, Ph.D., Chief Executive Officer of Sol-Gel, stated: "We continue to focus on rare indications affecting the skin which have no approved treatments. In this regard, we are continuing to enroll patients for our pivotal Phase 3 clinical trial of SGT-610 for the prevention of new basal cell carcinomas in patients with Gorlin Syndrome, with a potential market estimated at more than \$300 million. We also initiated a proof-of-concept study for SGT-210 (topical erlotinib) in patients with Darier disease, with results expected in H1/2025. In addition, SGT-210 is currently being used in a Compassionate use treatment of a pediatric patient suffering from an ultra-rare disease, and given the preliminary highly encouraging response, the treatment with SGT-210 continues, and the company will explore other commercially viable keratoderma indications."

"We recently signed an agreement with Beimei Pharma for the commercialization of TWYNEO in China, Hong Kong, Macau, Taiwan and Israel. This agreement demonstrates the potential of TWYNEO, and we expect to announce other agreements regarding the commercialization of both our FDA-approved assets, TWYNEO and EPSOLAY, in other territories," further added Dr. Seri-Levy.

Financial Results for the First Quarter Year Ended March 31st, 2024

Total revenue in the first quarter was \$0.5 million, which primarily consisted of licensing revenue from Galderma and Searchlight, compared to \$0.3 million revenues for the same period in 2023. As disclosed in connection with the filing of the June 30, 2023, financial statements, in the first quarter of 2023, wholesaler ordering patterns were disrupted ahead of Galderma's implementation of a new enterprise resource planning system, which impacted its standard forecasting procedures and its quarterly assessment of rebate accruals. As a result, previously reported revenue for the first quarter of 2023 was revised as reflected in the below income statement.

Research and development expenses were \$5.3 million compared to \$9.4 million for the same period in 2023. The decrease of \$4.1 million was primarily attributed to a decrease of \$1.8 million in R&D expenses related to SGT-610 and SGT-210, a decrease of \$1.4 million in expenses related to clinical development of a generic product candidate, a decrease of \$0.3 million in payroll expenses, and a decrease of \$0.3 in general R&D expenses.

General and administrative expenses were \$1.8 million compared to \$2.0 million for the same period in 2023. The decrease of \$0.2 million was mainly attributed to a decrease in professional expenses.

Sol-Gel reported a net loss of \$6.3 million for the first quarter of 2024 and a loss of \$0.23 per basic and diluted share, compared to a net loss of \$10.7 million and a loss of \$0.43 per basic and diluted share for the same period in 2023.

As of March 31, 2024, Sol-Gel had \$16.2 million in cash, cash equivalents, and deposits and US\$16.8 million in marketable securities for a total balance of \$33.0 million. The Company expects its cash resources to fund 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 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. Both drugs are exclusively licensed to and commercialized by Galderma in the US; and are exclusively licensed to Searchlight in Canada. TWYNEO was purchased and licensed by Beimei Pharma to be exclusively commercialized by them in China, Hong Kong, Macau, Taiwan and Israel.

The Company's pipeline also includes a 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 to be received under the agreement with Beimei, out-licensing Epsolay and Twyneo in additional territories, the potential of Sol-Gel's assets including Twyneo, Epsolay SGT-610, and SGT-210, and SGT-610's market value. 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, 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 :
 Gilad Mamlok
 Chief Financial Officer
info@sol-gel.com
 +972-8-9313433

Source: Sol-Gel Technologies Ltd.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 (U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Three months ended March 31	
	2023	2024
LICENSE REVENUES	\$ 300	\$ 466
RESEARCH AND DEVELOPMENT EXPENSES	9,386	5,345
GENERAL AND ADMINISTRATIVE EXPENSES	1,977	1,833
OPERATING LOSS	\$ 11,063	\$ 6,712
FINANCIAL INCOME, net	(342)	(368)
LOSS FOR THE PERIOD	\$ 10,721	\$ 6,344
BASIC AND DILUTED LOSS PER ORDINARY SHARE	0.43	0.23
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	24,944,220	27,857,620

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

	December 31,	March 31,
	2023	2024

Assets

CURRENT ASSETS:

Cash and cash equivalents	\$	7,513	\$	11,210
Bank deposits		10,012		5,012
Marketable securities		20,471		16,795
Accounts receivables		377		869
Prepaid expenses and other current assets		2,794		2,121
TOTAL CURRENT ASSETS		41,167		36,007

NON-CURRENT ASSETS:

Restricted long-term deposits and cash equivalents		1,284		1,264
Property and equipment, net		434		366
Operating lease right-of-use assets		1,721		1,612
Other long-term assets		55		45
Funds in respect of employee rights upon retirement		626		617
TOTAL NON-CURRENT ASSETS		4,120		3,904
TOTAL ASSETS	\$	45,287	\$	39,911

Liabilities and shareholders' equity

CURRENT LIABILITIES:

Accounts payable	\$	154	\$	582
Other accounts payable		3,921		4,257
Current maturities of operating leases		447		386
TOTAL CURRENT LIABILITIES		4,522		5,225

LONG-TERM LIABILITIES:

Operating leases liabilities		1,206		1,133
Liability for employee rights upon retirement		915		902
TOTAL LONG-TERM LIABILITIES		2,121		2,035
TOTAL LIABILITIES		6,643		7,260

SHAREHOLDERS' EQUITY:

Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2023 and March 31, 2024, respectively; issued and outstanding: 27,857,620 and 27,857,620 as of December 31, 2023 and March 31, 2024, respectively	774	774
Additional paid-in capital	258,173	258,524
Accumulated deficit	(220,303)	(226,647)
TOTAL SHAREHOLDERS' EQUITY	38,644	32,651
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 45,287	\$ 39,911

¹ All \$ amounts are in U.S. dollars



Sol-Gel Technologies Ltd.