UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of March 2024

Commission File Number 001-38367

SOL-GEL TECHNOLOGIES LTD.

(Translation of registrant's name into English)

7 Golda Meir Street
Ness Ziona 7403650, Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On March 13, 2024, Sol-Gel Technologies Ltd. (the "Company") issued a press release announcing the Full-Year 2023 Financial Results and Corporate Developments.

Attached hereto is the following exhibit:

Exhibit 99.1 Press release dated March 13, 2024

Exhibit 99.1 (other than the paragraph immediately preceding the heading "Financial Results for the Year Ended December 31st, 2023") is hereby incorporated by reference into the Company's Registration Statements on Form S-8 (Registration Nos. 333-223915 and 333-270477) and its Registration Statement on Form F-3 (Registration No 333-264190).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOL-GEL TECHNOLOGIES LTD.

Date: March 13, 2024

By: /s/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer

Exhibit 99.1

Sol-Gel Reports Full-Year 2023 Financial Results and Corporate Developments

- An ongoing phase 3 clinical trial of SGT-610 for Gorlin Syndrome with the first patient screened; Results are expected by the end of 2025
- Sol-Gel maintains a cash runway into the second half of 2025

NESS ZIONA, Israel, March 13, 2024 (GLOBE NEWSWIRE) - Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company with an innovative pipeline and approaches to develop a pioneering treatment for patients with severe skin conditions, is conducting a phase 3 clinical trial of SGT-610 (Patidegib gel, 2%), an Orphan Drug candidate with the potential to be the first therapy for preventing new basal cell carcinomas in Gorlin syndrome and partnered with Galderma to commercialize two approved large-category dermatology products, TWYNEO® and EPSOLAY®, in the U.S, today announced financial results for the full year ended December 31st, 2023 and provided a corporate update.

2023 - Corporate Highlights and Recent Developments

- On November 30, 2023, Sol-Gel announced that it had begun Phase 3 testing of SGT-610 for Gorlin syndrome, with the first patient screened. Sol-Gel acquired Patidegib 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.
- On June 6, 2023, Sol-Gel and Searchlight Pharma Inc. announced licensing agreements to commercialize TWYNEO and EPSOLAY in Canada, according to which Sol-Gel is to receive up to $11 million in upfront payments and regulatory and sales milestones for both drugs, combined plus additional royalties ranging from low double digits to high- teen.
- On January 27, 2023, Sol-Gel announced the acquisition of topically applied patidegib, a hedgehog signaling pathway blocker, for the treatment of Gorlin syndrome for PellePharm Inc., for an upfront payment of $4.7 million, total development and NDA acceptance milestones of up to $6 million and based on the expected market potential up to $64 million in commercial milestones, as well as single digit royalties. Gorlin syndrome is a rare disease with no currently approved therapies by the U.S. Food and Drug Administration (FDA) or European Medical Association (EMA). Investigational compound SGT-610 has the potential to be the first-ever drug for the chronic prevention of BCCs in Gorlin syndrome patients if approved.

- Over the full year of 2023, TWYNEO grew its total prescriptions, with cumulative annual total prescriptions exceeding 106,000 and total prescriptions in the fourth quarter exceeding 27,000, as reported by IQVIA. The number of prescribers also grew quarterly, with a 6% growth of new prescribers for the fourth quarter. The majority of scripts were written by TWYNEO's high base of recurring prescribers, with fourth-quarter patient refills increasing by 12%, driven by a targeted adherence campaign. In addition, TWYNEO increased its broad commercial formulary coverage, with over 6 million additional lives covered between December 2022 and December 2023 per MMIT Analytics. (*)

- Over the full year of 2023, EPSOLAY also grew its total prescriptions every quarter, leading to cumulative annual total prescriptions of approximately 53,000 and total prescriptions in the fourth quarter exceeding 14,000, as reported by IQVIA. EPSOLAY also experienced quarterly growth in terms of the number of prescribers, with unique prescribers growing by 8% in the fourth quarter. Resulting from a targeted patient adherence campaign also for EPSOLAY, there was a significant increase in patient refills of 34% in the quarter. Overall, EPSOLAY grew commercial formulary coverage annually by over 12 million covered or better lives, according to MMIT Analytics.

  (*) MMIT - Managed Markets Insight & Technology

- Based on Sol-Gel's financing and adoption of cost-saving measures during 2023, the company continues to maintain its cash runway into the second half of 2025.

Alon Seri-Levy, Ph.D., Chief Executive Officer of Sol-Gel, stated: "Sol-Gel is advancing the pivotal Phase 3 clinical trial with SGT-610 in accordance with the planned timelines and expects to have the results by the end of 2025. We estimate that the current trial protocol and its defined targets may facilitate the essential outcome, allowing Sol-Gel to provide Gorlin syndrome patients with the first drug that could prevent new BCCs, with a potential market estimated at more than $300 million. Concurrently, we are pursuing additional out-license agreements similar to the agreements signed this year with Searchlight Pharma for Canada. Sol-Gel's current product portfolio, led by SGT-610 and SGT-210, positions us with substantial assets for the future."

Financial Results for the Year Ended December 31st, 2023

We generated $1.6 million in revenue in 2023, mainly related to the license agreements with Galderma and Searchlight, comprised of milestone and royalty payments, compared with $3.9 million in total revenues in 2022. The decrease in revenues in 2023 resulted mainly from the milestone payment from Galderma related to the FDA approval of Epsolay in 2022.

Our research and development expenses were $23.5 million for the year ended December 31, 2023, compared to $12.7 million for the year ended December 31, 2022. The increase of $10.9 million was primarily attributed to the $4.7 million upfront payment associated with the acquisition of topically applied patidegib, or SGT-610, $4.2 million related to the pivotal Phase 3 clinical trial for SGT-610, and $2.8 million related to clinical expenses for a generic product.

Our general and administrative expenses were $7.4 million for the year ended December 31, 2023, compared to $7.4 million for the year ended December 31, 2022.

Sol-Gel reported a net loss of $27.2 million and $1.01 or $1.01 per basic share and diluted share, compared to a net loss of $14.9 million in 2022 and a loss of $0.65 per basic and diluted share.

As of December 31, 2023, Sol-Gel had $17.6 million in cash, cash equivalent, and bank deposits and $20.4 million in marketable securities for a total balance of $38.0 in comparison to December 31, 2022, of $24.9 million in cash, cash equivalent, and bank deposit and $8.7 million in marketable securities for a total balance of $33.6 million.

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 is a clinical-stage 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 Searchlight in Canada.

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 potential market of SGT-610, SGT-610 potential as the first therapy for preventing new basal cell carcinomas in Gorlin syndrome, SGT-610 improved safety profile compared to oral hedgehog inhibitors, timing of completing the Phase 3 clinical trial of SGT-610, number of subjects and clinical centers in 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 completitng 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.

Sol-Gel Contact:
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SOL-GEL

Source: Sol-Gel Technologies Ltd.

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

	December 31	
	2022	**2023**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 12,448	$ 7,513
Bank deposits	12,500	10,012
Marketable securities	8,678	20,471
Accounts receivables	62	377
Receivables from collaborative arrangements	7,858	-
Prepaid expenses and other current assets	1,509	2,794
TOTAL CURRENT ASSETS	43,055	41,167
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash equivalents	1,288	1,284
Property and equipment, net	660	434
Operating lease right-of-use assets	876	1,721
Other long-term assets	-	55
Funds in respect of employee rights upon retirement	749	626
TOTAL NON-CURRENT ASSETS	3,573	4,120
TOTAL ASSETS	$ 46,628	$ 45,287
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 251	$ 154
Other accounts payable	2,360	3,921
Current maturities of operating leases	718	447
TOTAL CURRENT LIABILITIES	3,329	4,522
LONG-TERM LIABILITIES:		
Operating leases liabilities	54	1,206
Liability for employee rights upon retirement	1,032	915
TOTAL LONG-TERM LIABILITIES	1,086	2,121
TOTAL LIABILITIES	4,415	6,643
COMMITMENTS (Note 7)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2022 and 2023, respectively; issued and outstanding: 23,129,469 and 27,857,620 as of December 31, 2022 and December 31, 2023, respectively	638	774
Additional paid-in capital	234,640	258,173
Accumulated deficit	(193,065)	(220,303)
TOTAL SHAREHOLDERS' EQUITY	42,213	38,644
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 46,628	$ 45,287

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

	Year ended December 31,		
	2021	**2022**	**2023**
COLLABORATION REVENUES	23,772	-	-
LICENSE REVENUES	7,500	3,883	1,554
TOTAL REVENUES	31,272	3,883	1,554
RESEARCH AND DEVELOPMENT EXPENSES	20,381	12,682	23,541
GENERAL AND ADMINISTRATIVE EXPENSES	8,451	7,445	7,373
OTHER INCOME, net	524	-	55
TOTAL OPERATING INCOME (LOSS)	2,964	(16,244)	(29,305)
FINANCIAL INCOME, net	257	1,321	2,067
NET INCOME (LOSS) FOR THE YEAR	3,221	(14,923)	(27,238)
BASIC EARNINGS (LOSS) PER ORDINARY SHARE	0.14	(0.65)	(1.01)
DILUTED EARNINGS (LOSS) PER ORDINARY SHARE	0.14	(0.65)	(1.01)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:			
BASIC	23,063,493	23,128,722	27,087,081
DILUTED	23,566,182	23,128,722	27,087,081