
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 April 2021

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):

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(7):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On April 27, 2021, Sol-Gel Technologies Ltd. (the "Company") issued a press release providing an update on FDA review of EPSOLAY®.

Attached hereto is the following exhibit:

[Exhibit 99.1: Registrant's press release entitled: "Sol-Gel Technologies Provides Update on FDA Review of EPSOLAY®".](#)

Exhibit 99.1 is hereby incorporated by reference into the Company's Registration Statement on Form S-8 (Registration No. 333-223915) and its Registration Statement on Form F-3 (Registration No. 333-230564).

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: April 27, 2021

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

Sol-Gel Technologies Provides Update on FDA Review of EPSOLAY®

NESS ZIONA, Israel, April 27, 2021 – Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, today announced an update regarding the U.S. Food and Drug Administration (FDA) approval process for EPSOLAY® (benzoyl peroxide) 5% topical cream for the treatment of Inflammatory lesions of rosacea in adults.

In September of 2020, Sol-Gel was informed by the FDA that the PDUFA goal date for EPSOLAY is April 26, 2021. Subsequently, the COVID-19 pandemic restricted the FDA's ability to conduct pre-approval inspections. In our most recent written communication with the FDA regarding EPSOLAY, the final content of the labeling was discussed and agreed to. As of today, Sol-Gel has received no notification from the FDA, but did receive email confirmation that that action on the NDA for EPSOLAY could not be taken since a pre-approval inspection of the production site of EPSOLAY still needs to be conducted.

The Company continues to follow-up with the FDA on the scheduling of this inspection.

About Sol-Gel Technologies

Sol-Gel is a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel leverages its proprietary microencapsulation technology platform for the development of TWYNEO, under investigation for the treatment of acne vulgaris, and EPSOLAY, under investigation for the treatment of papulopustular rosacea. The Company's pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, under investigation for the treatment of palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. For additional information, please visit 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, statements regarding the timing of the PDUFA action date for EPSOLAY and the potential to be the first FDA-approved single-agent benzoyl peroxide prescription drug product. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. 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 expectation 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, the risk that the safety, tolerability and efficacy profile of EPSOLAY observed to date may change adversely subsequent to commercialization; the risk that we may not execute an agreement for the commercialization of EPSOLAY, the risk that we may encounter delays in manufacturing or supplying EPSOLAY or that EPSOLAY will not otherwise be available to as many clinicians and patients as anticipated, and 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 and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; (v) our ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our 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. These 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 4, 2021 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. Any such forward-looking statements represent management’s estimates as of the date of this press release. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements.

For further information, please contact:

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Source: Sol-Gel Technologies Ltd.
