# Sol-Gel Technologies Reports Third Quarter 2020 Financial Results and Corporate Update

November 12, 2020

- *Epsolay® PDUFA goal date set for April 26, 2021*
- *Twyneo® New Drug Application submitted to the U.S. FDA*
- *Top-line generic product revenue of $2.1 million in 3Q 2020*
- *In October 2020, signed an 11th generic product collaboration agreement with Perrigo*

NESS ZIONA, Israel, Nov. 12, 2020 (GLOBE NEWSWIRE) -- 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 financial results for the third quarter ended September 30, 2020 and provided clinical and regulatory updates on its programs.

"The third quarter was highlighted by a major achievement for Sol-Gel, as our first New Drug Application (NDA) for Epsolay for the treatment of inflammatory lesions of rosacea was accepted by the Federal Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) goal date set for April 26, 2021. We now look forward to the NDA acceptance of our second proprietary product, Twyneo, for the treatment of acne vulgaris," commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. "Also, after the close of the third quarter, we expanded our collaboration with Perrigo to develop an eleventh generic product candidate. While we are successfully expanding our partnership with Perrigo, we continue to focus on our own branded product candidates, Epsolay and Twyneo. We are working towards commercializing both treatments, if approved, in 2021, either on our own or with a partner that has a significant U.S. dermatology presence."

**Corporate Highlights and Recent Developments**

- Sol-Gel announced FDA acceptance of NDA for Epsolay (benzoyl peroxide, 5%, cream) with a PDUFA goal date set for April 26, 2021. If approved, Epsolay has the potential to be the first FDA-approved, single-agent benzoyl peroxide prescription drug product for the treatment of inflammatory lesions of rosacea.
- Sol-Gel submitted an NDA for Twyneo (benzoyl peroxide, 3%, and tretinoin, 0.1%, cream) to the FDA in the beginning of October. If approved, Twyneo has the potential to be the first FDA-approved acne treatment that contains fixed-dose combination of benzoyl peroxide and tretinoin.
- Sol-Gel was informed by its collaboration partner that the launch of an FDA-approved generic drug is expected in the second quarter of 2021. Annual sales of the brand name product exceeded $180 million in the United States in 2019.
- Bausch Health Companies, Inc. (NYSE:BHC) initiated patent infringement action in the U.S. District Court for the District of New Jersey on August 31, 2020 regarding Perrigo Company plc's (NYSE; TASE: PRGO) Abbreviated New Drug Application (ANDA) for a generic version of Duobrii® (halobetasol propionate and tazarotene) lotion, a product in which Sol-Gel and Perrigo previously entered into a collaboration agreement. In July 2020, Perrigo filed first-to-file Paragraph IV Certification for Duobrii®.
- In preparation for commercial launch of proprietary products, and as part of Sol-Gel's go-to-market strategy, the Company has opened a US headquarters in Whippany, NJ.
- In October 2020, Sol-Gel signed an additional collaboration agreement with Perrigo for the development, manufacturing and commercialization of a new generic product candidate, the eleventh product collaboration between the companies.
- The enrollment of patients in the Phase 1 proof-of-concept study with SGT-210, a novel, topical, epidermal growth factor receptor inhibitor in patients with punctate palmoplantar keratoderma has been affected by the COVID-19 pandemic. The Company expects to be able to provide an update regarding the timing of top-line results by year-end.
- Pre-clinical testing of tapinarof, an aryl hydrocarbon receptor (AhR) agonist, and roflumilast, a phosphodiesterase 4 (PDE4) inhibitor, is progressing for various, new dermatological indications. The Company is also conducting pre-clinical studies in psoriasis to compare the tapinarof/roflumilast combination to each individual active ingredient. A total of 24 provisional patent applications for these projects have been submitted to date.

**Financial Results for the Three Months ended September 30, 2020**

Revenue in the third quarter of 2020 was $2.1 million. The revenue was mainly due to sales of a generic product from a collaboration arrangement with Perrigo. While revenue increased compared to the previous quarter, it is still adversely affected by the COVID-19 pandemic. In addition, due to the entry of an additional generic version of Zovirax® (acyclovir) cream, 5%, marketed by Amneal Pharmaceuticals Inc., we expect revenue from our generic products to decrease until the expected launch of a second generic drug in the second quarter of 2021 as detailed above.

Research and development expenses were $7.9 million in the third quarter of 2020 compared to $9.9 million during the same period in 2019. The

decrease of $2.0 million was mainly attributed to a decrease of $5.9 million in clinical trial expenses for Epsolay and Twyneo partially offset by an increase of $3.4 million in regulatory expenses mainly related to the PDUFA fee for Twyneo.

General and administrative expenses were $3.0 million in the third quarter of 2020 compared to $2.5 million during the same period in 2019. The increase of $0.5 million was mainly attributed to an increase of $0.4 million in commercialization expenses and of $0.1 million in patent-related expenses.

Sol-Gel reported a loss of $8.6 million for the third quarter of 2020 compared to loss of $7.4 million for the same period in 2019.

As of September 30, 2020, Sol-Gel had $27.4 million in cash, cash equivalents and deposits, and $29.9 million in marketable securities for a total balance of $57.3 million. Sol-Gel expects its existing cash resources will enable funding of operational and capital expenditure requirements into the third quarter of 2021.

**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 inflammatory lesions of 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.

**About Epsolay®**

Epsolay is an investigational topical cream containing encapsulated benzoyl peroxide, 5%, for the treatment of papulopustular rosacea. Epsolay utilizes a patented technology process to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The slow migration of medication from the microcapsules is designed to deliver an effective dose of benzoyl peroxide onto the skin, while reducing the ability of benzoyl peroxide to induce skin irritation, such as erythema, burning and stinging. If approved, Epsolay has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. Epsolay is not approved by the FDA and the safety and efficacy has not been established.

**About Papulopustular Rosacea**

Papulopustular rosacea is a chronic and recurrent inflammatory skin disorder that affects nearly 5 million Americans. The condition is common, especially in fair-skinned people of Celtic and northern European heritage. Onset is usually after age 30 and typically begins as flushing and subtle redness on the cheeks, nose, chin or forehead. If left untreated, rosacea can slowly worsen over time. As the condition progresses the redness becomes more persistent, blood vessels become visible and pimples often appear. Other symptoms may include burning, stinging, dry skin, plaques and skin thickening.

**About Twyneo®**

Twyneo is an investigational, fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris. If approved, it will be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin, which are separately encapsulated in silica using Sol-Gel's proprietary microencapsulation technology. Tretinoin and benzoyl peroxide are widely prescribed separately as a combination treatment for acne; 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. The silica-based microcapsule is designed to protect tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability of the active drug ingredients. The silica-based shell is also designed to release the ingredients slowly over time to provide a favorable efficacy and safety profile. Twyneo is not approved by the FDA and the safety and efficacy has not been established.

**About Acne Vulgaris**

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

**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 PDUFA goal date for Epsolay (benzoyl peroxide, 5%, cream), the expectation that the FDA will accept the NDA for Twyneo and the timing of commercialization of Epsolay and Twyneo, expectation that revenue from our generic products will continue to decrease until the expected launch of a second FDA-approved generic drug in the second quarter of 2021. 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, risks relating to the effects of COVID-19 (coronavirus) 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 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 24, 2020 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.*

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

| | December 31, 2019 | September 30, 2020 |
|---|---|---|
| **A s s e t s** | | |
| **CURRENT ASSETS**: | | |
| Cash and cash equivalents | $ 9,412 | $ 6,007 |
| Bank deposit | - | 21,400 |
| Marketable securities | 40,966 | 29,875 |
| Receivables from collaborative arrangements | 4,120 | 2,180 |
| Prepaid expenses and other current assets | 1,293 | 1,200 |
| **TOTAL CURRENT ASSETS** | 55,791 | 60,662 |
| **NON-CURRENT ASSETS:** | | |
| Restricted long-term deposits | 472 | 1,285 |
| Property and equipment, net | 2,314 | 2,048 |
| Operating lease right-of-use assets | 2,040 | 1,658 |
| Funds in respect of employee rights upon retirement | 684 | 687 |
| **TOTAL NON-CURRENT ASSETS** | 5,510 | 5,678 |
| **TOTAL ASSETS** | $ 61,301 | $ $66,340 |
| **Liabilities and shareholders' equity** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable | $ 1,710 | $ 1,121 |
| Other accounts payable | 4,123 | 5,469 |
| Current maturities of operating leases | 672 | 508 |
| **TOTAL CURRENT LIABILITIES** | 6,505 | 7,098 |
| **LONG-TERM LIABILITIES** - | | |
| Operating leases liabilities | 1,373 | 1,105 |
| Liability for employee rights upon retirement | 958 | 980 |
| **TOTAL LONG-TERM LIABILITIES** | 2,331 | 2,085 |
| **COMMITMENTS** | | |
| **TOTAL LIABILITIES** | 8,836 | 9,183 |
| **SHAREHOLDERS' EQUITY:** | | |
| Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2019 and September 30, 2020; issued and outstanding: 20,402,800 and 23,000,782 as of December 31, 2019 and September 30, 2020, respectively. | 561 | 635 |
| Additional paid-in capital | 203,977 | 231,397 |
| Accumulated deficit | (152,073) | (174,875) |
| **TOTAL SHAREHOLDERS' EQUITY** | 52,465 | 57,157 |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | $ 61,301 | $ 66,340 |

(The amounts are stated in U.S. dollars in thousands, except share and per share data)

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

| | Nine months ended September 30 | | Three months ended September 30 | |
|---|---|---|---|---|
| | **2019** | **2020** | **2019** | **2020** |
| **COLLABORATION REVENUES** | $ 18,884 | $ 6,714 | $ 4,733 | $ 2,116 |
| **RESEARCH AND DEVELOPMENT EXPENSES** | 32,146 | 22,248 | 9,913 | 7,867 |
| **GENERAL AND ADMINISTRATIVE EXPENSES** | 5,816 | 8,014 | 2,484 | 3,018 |
| **TOTAL OPERATING LOSS** | 19,078 | 23,548 | 7,664 | 8,769 |
| **FINANCIAL INCOME,** NET | (1,071) | (746) | (311) | (149) |
| **LOSS FOR THE PERIOD** | $ 18,007 | $ 22,802 | $ 7,353 | $ 8,620 |
| **BASIC AND DILUTED LOSS PER ORDINARY SHARE** | $ 0.94 | 1.02 | $ 0.37 | 0.37 |
| **WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE** | 19,230,070 | 22,431,096 | 19,787,194 | 22,997,708 |

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