Sol-Gel Technologies Reports Second Quarter 2021 Financial Results and Highlights Recent Corporate Developments

August 4, 2021

- *Recently obtained FDA approval of TWYNEO® triggers milestone payment from Galderma*
- *Exclusive license agreements with Galderma for U.S. commercialization of EPSOLAY® and TWYNEO*
- *Sol-Gel adv*ancing *its early-stage pipeline in plaque psoriasis,* palmoplantar keratoderma *and other high-value dermatologic indications*
- *FDA action on the NDA for EPSOLAY still pending due to COVID-19-related restrictions*
- *Generic ivermectin cream, 1% launched by Sol-Gel's partner Perrigo in June*

NESS ZIONA, Israel, Aug. 04, 2021 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a 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 second quarter ended June 30, 2021 and provided an overview of recent corporate developments.

Second Quarter Corporate Highlights and Recent Developments

- On July 27, 2021, Sol-Gel announced that the U.S. Food and Drug Administration (FDA) approved its first proprietary drug product, TWYNEO® (tretinoin and benzoyl peroxide) cream, 0.1%/3%, indicated for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older. This approval triggers a milestone payment from Galderma.
- On June 28, 2021, Sol-Gel announced that it signed two exclusive, 5-year license agreements with Galderma for the commercialization of EPSOLAY® (benzoyl peroxide) cream, 5%, and TWYNEO in the United States. EPSOLAY is under investigation for the treatment of inflammatory lesions of rosacea in adults. In accordance with the terms of these agreements, Sol-Gel received an $8 million upfront payment in July, $4 million of which is conditional upon FDA approval of EPSOLAY by the end of 2021. In addition, Sol-Gel is entitled to receive additional regulatory milestone payments of up to $7 million, $3.5 million of which is due following the approval of TWYNEO and $3.5 million of which is payable upon approval of EPSOLAY. Sol-Gel is also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentages of net sales as well as up to $9 million in sales milestone payments.
- On June 28, 2021, Sol-Gel also announced that the Company was advancing its early-stage topical drug candidates SGT-210 (erlotinib gel) under investigation for the treatment of palmoplantar keratoderma, SGT-310 (tapinarof cream, 1%) and SGT-510 (roflumilast) under investigation for the treatment of plaque psoriasis and other dermatologic indications.
- On April 26, 2021, Sol-Gel received confirmation from the FDA that action on the New Drug Application (NDA) for EPSOLAY had not yet been taken due to the inability of the FDA to conduct a pre-approval inspection of the production site for EPSOLAY because of COVID-19 travel restrictions. The Company maintains ongoing dialogue with the FDA about advancing this NDA approval.
- A generic product, ivermectin cream, 1% was launched by partner Perrigo in June 2021.

Alon Seri-Levy, Ph.D., Co-Founder and Chief Executive Officer, stated, "The approval of TWYNEO solidifies our Company's reputation as a successful drug developer, and we now look forward to a successful launch of TWYNEO in the U.S. by market leader Galderma. We are extremely proud to have entered into a U.S. partnership with Galderma on attractive terms which permit us to regain our products after a five-year period. This partnership creates a maximum growth opportunity for our products while minimizing future cash needs for our company. It also allows us to focus on our innovative early-stage pipeline and is in line with our vision to establish Sol-Gel as a leading topical dermatology company".

Financial Results for the Second Quarter Ended June 30, 2021

Revenue for the second quarter of 2021 was $0.9 million. The revenue was mainly due to sales of generic products from collaboration arrangements with Perrigo, compared to $1.1 million for the same period in 2020.

Research and development expenses were $6.9 million in 2021 compared to $6.5 million during the same period in 2020. The increase of $0.4 million was mainly attributed to an increase of $0.9 million in manufacturing expenses offset by a decrease of $0.3 million in R&D expenses and a decrease of $0.2 million in other expenses.

General and administrative expenses were $2.0 million in 2021 compared to $2.2 million in 2020. The decrease of $0.2 million was mainly attributed to a decrease in commercialization expenses.

Sol-Gel reported a loss of $8.0 million for the second quarter of 2021 compared to loss of $7.1 million for the same period in 2020.

As of June 30, 2021, Sol-Gel had $32.1 million in cash, cash equivalents and deposits, and $6.8 million in marketable securities for a total balance of $38.9 million. Based on Galderma's expected upfront and milestone payments in accordance with the Galderma agreement, the Company expects that its cash resources will enable funding of operational and capital expenditure requirements into the first quarter of 2023 (assuming timely approval of EPSOLAY in 2021)

About Acne Vulgaris
Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects up to 50 million people in the U.S. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne vulgaris 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 vulgaris 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.

About TWYNEO
TWYNEO (tretinoin and benzoyl peroxide) cream, 0.1%/3%, is indicated for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older. TWYNEO is the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin. Tretinoin and benzoyl peroxide are widely prescribed separately for acne vulgaris; 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 formulation of TWYNEO uses silica (silicon dioxide) core shell structures to separately micro-encapsulate tretinoin crystals and benzoyl peroxide crystals enabling inclusion of the two active ingredients in the cream.

Indications and Usage
TWYNEO is a combination of tretinoin, a retinoid, and benzoyl peroxide indicated for the topical treatment of acne vulgaris in adults and pediatric patients nine years of age and older.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS: History of serious hypersensitivity reaction to benzoyl peroxide or any component of TWYNEO.

WARNINGS AND PRECAUTIONS

- Hypersensitivity: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with use of benzoyl peroxide products.
- Skin Irritation: Pain, dryness, exfoliation, erythema, and irritation may occur with use of TWYNEO. Avoid application of TWYNEO to cuts, abrasions, eczematous or sunburned skin.
- Photosensitivity: Minimize unprotected exposure to sunlight and sunlamps. Use sunscreen and protective clothing when sun exposure cannot be avoided.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 1%) are pain, dryness, exfoliation, erythema, dermatitis, pruritus and irritation (all at the application site).
Please see full Prescribing Information here.

About EPSOLAY
EPSOLAY is an investigational topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea, also known as papulopustular rosacea, in adults. If approved, EPSOLAY has the potential to be the first FDA-approved single-active benzoyl peroxide prescription drug product. The benzoyl peroxide in EPSOLAY is in a solid form that is incorporated into silica-based microcapsules. EPSOLAY is not approved by the FDA and the safety and efficacy have not been established.

About Sol-Gel Technologies
Sol-Gel is a 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 TWYNEO, which is FDA approved for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, under investigation for the treatment of inflammatory lesions of rosacea with an NDA filed with the FDA and a PDUFA goal date that was set for April 26, 2021. Action on the NDA for EPSOLAY has not yet been taken due to the inability of the FDA to conduct a pre-approval inspection of the production site of EPSOLAY as a result of COVID-19 travel restrictions. Both product candidates are exclusively licensed for U.S. commercialization with Galderma

The Company's pipeline also includes early-stage topical drug candidates SGT-210 (erlotinib gel) under investigation for the treatment of palmoplantar keratoderma, SGT-310 (tapinarof cream, 1%) and SGT-510 (roflumilast) under investigation for the treatment of plaque psoriasis and other dermatologic indications.

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 FDA approval of EPSOLAY and statements regarding the progress on our innovative earlier stage programs. 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 of a further delay in receipt of approval, if any, of the NDA for EPSOLAY, the risk that we don't progress on our innovative earlier stage programs, the risk that we will not receive all the financial benefits under the agreements with Galderma, the risk of a delay in the commercial availability of EPSOLAY and/or TWYNEO, the risk that EPSOLAY and TWYNEO will not provide treatment to the number of patients anticipated, 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 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.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	December 31, 2020	June 30, 2021
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,122	$ 11,152
Bank deposits	21,400	20,900
Marketable securities	21,652	6,830
Receivables from collaborative arrangements	2,153	956
Prepaid expenses and other current assets	1,074	1,556
TOTAL CURRENT ASSETS	53,401	41,394
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash	1,293	1,291
Property and equipment, net	1,817	1,397
Operating lease right-of-use assets	1,896	1,579
Funds in respect of employee rights upon retirement	754	744
TOTAL NON-CURRENT ASSETS	5,760	5,011
TOTAL ASSETS	$ 59,161	$ 46,405
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 1,203	$ 1,345
Other accounts payable	4,088	3,164
Current maturities of operating leases liabilities	673	649
TOTAL CURRENT LIABILITIES	5,964	5,158
LONG-TERM LIABILITIES -		
Operating leases liabilities	1,299	958
Liability for employee rights upon retirement	1,049	1,042
TOTAL LONG-TERM LIABILITIES	2,348	2,000
COMMITMENTS		
TOTAL LIABILITIES	8,312	7,158
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2020 and June 30, 2021; issued and outstanding: 23,000,782 and 23,029,951 as of December 31, 2020 and June 30, 2021, respectively.	635	635
Additional paid-in capital	231,577	232,071
Accumulated deficit	(181,363)	(193,459)
TOTAL SHAREHOLDERS' EQUITY	50,849	39,247
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 59,161	$ 46,405

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Six months ended June 30		Three months ended June 30	
	2020	2021	2020	2021
COLLABORATION REVENUES	$ 4,598	$ 1,629	$ 1,133	$ 928
RESEARCH AND DEVELOPMENT EXPENSES	14,381	9,399	6,451	6,933
GENERAL AND ADMINISTRATIVE EXPENSES	4,994	4,496	2,233	2,037
TOTAL OPERATING LOSS	14,777	12,266	7,551	8,042
FINANCIAL INCOME, net	(597)	(170)	(481)	(9)
LOSS FOR THE PERIOD	$ 14,180	$ 12,096	$ 7,070	$ 8,033
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 0.64	$ 0.53	$ 0.31	$ 0.35
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	22,143,099	23,016,104	22,920,557	23,028,508

For further information, please contact:

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Sol-Gel Technologies

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