



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

November 11, 2021

- Sol-Gel attains a profitable quarter, reporting total revenues of \$8.8 million, net income of \$1.3 million and EPS of \$0.06
- Recently obtained FDA approval of TWYNEO® triggers a \$3.5 million milestone payment from Galderma, and, together with the \$4.0 million down payment from Galderma, a total of \$7.5 million was recognized in Q3
- Sol-Gel to receive \$21 million over 24 months in exchange for the transfer of its rights to two marketed generic drugs and eight unapproved generic programs based on a new agreement with Padagis; Sol-Gel to retain collaboration rights on two programs related to four high-value candidates
- Sol-Gel's cash runway expected to extend through the end of 2023
- Sol-Gel's focus remains on supporting Galderma to launch TWYNEO, and EPSOLAY®, subject to the approval of the latter, along with advancing its innovative new drug candidates

NESS ZIONA, Israel, Nov. 11, 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 third quarter ended September 30, 2021 and provided an overview of recent corporate developments.

Third Quarter Corporate Highlights and Recent Developments

- Sol-Gel reported a profitable quarter. The company recognized total revenues of \$8.8 million, the majority of which was attributed to licensing revenue of \$3.5 million related to TWYNEO approval milestones, and a \$4.0 million TWYNEO upfront payment from partner Galderma. As a result of this recognized revenue, net income was \$1.3 million, and the company reported EPS of \$0.06.
- On July 27, 2021, Sol-Gel announced that the U.S. Food and Drug Administration (FDA) approved its first proprietary drug product, TWYNEO, indicated for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older.
- On November 4, 2021, Sol-Gel announced a new agreement with Padagis (formerly a division of Perrigo Company plc) effective November 1, 2021 (the "Agreement"), which replaces prior collaborative agreements for the development and commercialization of certain generic drugs for skin diseases. Under this Agreement, Sol-Gel is to unconditionally receive \$21 million over 24 months, in lieu of its share in future gross profits for acyclovir cream and ivermectin cream and its potential gross profits for eight unapproved generic programs. In addition, Sol-Gel will cease paying any outstanding and future operational costs related to the earlier collaborative agreements. Importantly, Sol-Gel has retained collaboration rights to two generic programs related to four generic drug candidates that it believes to have the most value-generating potential.
- On April 26, 2021, Sol-Gel received confirmation from the FDA that action on 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.
- During the third quarter, Sol-Gel raised net proceeds of \$505,413 in an at-the-market (ATM) offering of 41,153 shares at an average price of \$12.66.
- 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 continue to support Galderma in their launch preparations for TWYNEO and EPSOLAY, pending the approval of the latter."
- Dr. Seri-Levy continued, "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, along with revenue from our recent sale of certain generics assets to Padagis, allows us to focus on advancing our innovative, early-stage pipeline into clinical development, in line with our vision to establish Sol-Gel as a leading dermatology company, while reducing future cash needs for our company."

Financial Results for the Third Quarter Ended September 30, 2021

Total revenue for the third quarter of 2021 was \$8.8 million, \$7.5 million of which consisted of licensing revenue and \$1.3 million consisting of collaboration revenue, compared to revenues of \$2.1 million of collaboration revenues for the same period in 2020.

Research and development expenses were \$6.0 million in 2021 compared to \$7.9 million during the same period in 2020. The decrease of \$1.9 million was mainly attributed to a decrease of \$3.6 million in regulatory expenses associated with the PDUFA fee for TWYNEO during the same period in 2020, offset by an increase of \$1.6 million in manufacturing expenses and an increase of \$0.3 million in clinical trial expenses.

General and administrative expenses were \$2.1 million in 2021 compared to \$3.0 million in 2020. The decrease of \$0.9 million was mainly attributed to a decrease in commercialization expenses.

Sol-Gel reported a profit of \$1.3 million for the third quarter of 2021 and earnings of \$0.06 per basic share, compared to loss of \$8.6 million and loss of \$0.37 per basic share for the same period in 2020.

As of September 30, 2021, Sol-Gel had \$43.3 million in cash, cash equivalents and deposits, and \$2.2 million in marketable securities for a total balance of \$45.6 million. As a result of our agreements with Galderma regarding EPSOLAY and TWYNEO and the Agreement with Padagis, the Company expects that its cash resources will enable funding of operational and capital expenditure requirements through the end of 2023 (assuming EPSOLAY is approved 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 $\geq 1\%$) 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 palmo-plantar 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 that the Company will not have sufficient cash resources to enable funding of operational and capital expenditure requirements into at least the fourth quarter of 2023, 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	September 30, 2021
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 7,122	\$ 43,349
Bank deposits	21,400	-
Marketable securities	21,652	2,239
Receivables from collaborative arrangements	2,153	1,388
Prepaid expenses and other current assets	1,074	1,170
TOTAL CURRENT ASSETS	53,401	48,146
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash	1,293	1,293
Property and equipment, net	1,817	1,211
Operating lease right-of-use assets	1,896	1,424
Funds in respect of employee rights upon retirement	754	752
TOTAL NON-CURRENT ASSETS	5,760	4,680
TOTAL ASSETS	\$ 59,161	\$ 52,826
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,203	\$ 1,291
Other accounts payable	4,088	2,335
Contract Liabilities	-	5,250
Current maturities of operating leases liabilities	673	652
TOTAL CURRENT LIABILITIES	5,964	9,528
LONG-TERM LIABILITIES -		
Operating leases liabilities	1,299	803
Liability for employee rights upon retirement	1,049	1,052
TOTAL LONG-TERM LIABILITIES	2,348	1,855
COMMITMENTS		
TOTAL LIABILITIES	8,312	11,383
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2020 and September 30, 2021; issued and outstanding: 23,000,782 and 23,119,068 as of December 31, 2020 and September 30, 2021, respectively.	635	638
Additional paid-in capital	231,577	232,978
Accumulated deficit	(181,363)	(192,173)
TOTAL SHAREHOLDERS' EQUITY	50,849	41,443
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 59,161	\$ 52,826

SOL-GEL TECHNOLOGIES LTD.

CONDENSED 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	
	2020	2021	2020	2021
COLLABORATION REVENUES	\$ 6,714	\$ 2,965	\$ 2,116	\$ 1,336
LICENSE REVENUES	-	\$ 7,500	-	\$ 7,500
TOTAL REVENUE	6,714	10,465	2,116	8,836
RESEARCH AND DEVELOPMENT EXPENSES	22,248	15,388	7,867	5,989
GENERAL AND ADMINISTRATIVE EXPENSES	8,014	6,625	3,018	2,129
OTHER INCOME, net	-	554	-	554
OPERATING INCOME (LOSS)	(23,548)	(10,994)	(8,769)	1,272
FINANCIAL INCOME, net	746	184	149	14
NET INCOME (LOSS) FOR THE PERIOD	\$ (22,802)	\$ (10,810)	\$ (8,620)	\$ 1,286
BASIC INCOME (LOSS) PER ORDINARY SHARE	(1.02)	(0.47)	(0.37)	0.06
DILUTED INCOME (LOSS) PER ORDINARY SHARE	(1.02)	(0.47)	(0.37)	0.05
WEIGHTED AVERAGE NUMBER OF SHARES				
OUTSTANDING USED IN COMPUTATION OF INCOME (LOSS) PER SHARE :				
BASIC	22,431,096	23,043,701	22,997,708	23,097,379
DILUTED	22,431,096	23,043,701	22,997,708	23,682,601

For further information, please contact:

Investors:

Investor relations
Irina Koffler
LifeSci Advisors
ikoffler@lifesciadvisors.com

+1-917-734-7387

Sol-Gel Technologies

Gilad Mamlok
Chief Financial Officer
gilad.mamlok@sol-gel.com



Source: Sol-Gel Technologies Ltd.