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 August 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): ☐

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 August 4, 2021, Sol-Gel Technologies Ltd. (the "Company") issued a press release reporting second quarter 2021 financial results and highlighting recent corporate developments. In addition, the Company is submitting with this Form 6-K its unaudited condensed consolidated financial statements as of June 30, 2021 and for the three and six months then ended.

Attached hereto is the following exhibit:

Exhibit 99.1	Registrant's press release entitled: "Sol-Gel Technologies Reports Second Quarter 2021 Financial Results and Highlights Recent Corporate Developments".
Exhibit 99.2	Unaudited condensed consolidated financial statements as of June 30, 2021 and for the three and six months then ended

Exhibits 99.1 (other than the paragraph immediately preceding the heading "Financial Results for the Second Quarter Ended June 30, 2021") and 99.2 to this Report on Form 6-K are 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: August 4, 2021

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

Exhibit 99.1

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

- *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, August 4, 2021 -- 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
Assets		
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

SOL-GEL TECHNOLOGIES LTD.

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:

Investors:

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Sol-Gel Technologies

Gilad Mamlok
Chief Financial Officer
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Exhibit 99.2

SOL-GEL TECHNOLOGIES LTD.

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF JUNE 30, 2021

SOL-GEL TECHNOLOGIES LTD.

UNAUDITED CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS
AS OF JUNE 30, 2021

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

SOL-GEL TECHNOLOGIES LTD.

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

(Unaudited)

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The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)

(Unaudited)

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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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total
	Number of shares	Amounts	Amounts		
BALANCE AS OF JANUARY 1, 2020	20,402,800	561	203,977	(152,073)	52,465
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2020:					
Loss for the period				(14,180)	(14,180)
Issuance of shares and warrants through public offering, net of issuance costs	2,091,907	61	21,245		21,306
Issuance of shares and warrants through private placement from the controlling shareholder	454,628	13	4,987		5,000
Vesting of restricted shares units	19,166	*	*		*
Exercise of options	28,447	*	151		151
Share-based compensation			779		779
BALANCE AT JUNE 30, 2020	22,996,948	635	231,139	(166,253)	65,521
BALANCE AS OF JANUARY 1, 2021	23,000,782	635	231,577	(181,363)	50,849
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2021:					
Loss for the period				(12,096)	(12,096)
Vesting of restricted shares units	15,333	*	*		
Exercise of options	13,836	*	83		83
Share-based compensation			411		411
BALANCE AT JUNE 30, 2021	23,029,951	635	232,071	(193,459)	39,247

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total
	Number of shares	Amounts	Amounts		
BALANCE AS OF APRIL 1, 2020	22,514,488	$ 622	$ 225,693	$ (159,183)	$ 67,132
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2020:					
Loss for the period				(7,070)	(7,070)
Issuance of shares and warrants through private placement from the controlling shareholder	454,628	13	4,987		5,000
Vesting of restricted shares units	3,833	*	*		*
Exercise of options	23,999	*	144		144
Share-based compensation			315		315
BALANCE AT JUNE 30, 2020	22,996,948	$ 635	$ 231,139	$ (166,253)	$ 65,521
BALANCE AS OF APRIL 1, 2021	23,028,264	635	231,849	(185,426)	47,058
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2021:					
Loss for the period				(8,033)	(8,033)
Exercise of options	1,687	*	9		9
Share-based compensation			213		213
BALANCE AT JUNE 30, 2021	23,029,951	635	232,071	(193,459)	39,247

***** less than $1 thousand.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SOL-GEL TECHNOLOGIES LTD.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Six months ended June 30	
	2020	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss	$ (14,180)	$ (12,096)
Adjustments required to reconcile loss to net cash used in operating activities:		
Depreciation	470	474
Changes in accrued liability for employee rights upon retirement, net	17	3
Share-based compensation	779	411
Financial expenses (income), net	(14)	15
Net changes in operating leases	(30)	(48)
Changes in fair value of marketable securities	76	(59)
Changes in operating asset and liabilities:		
Receivables from collaborative arrangements	2,949	1,197
Prepaid expenses and other current assets	(201)	(482)
Accounts payable, accrued expenses and other	553	(782)
Net cash used in operating activities	(9,581)	(11,367)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(358)	(54)
Investment in marketable securities	(19,640)	(4,065)
Proceeds from sales and maturity of marketable securities	19,852	18,946
Short-term deposits	(19,900)	500
Long-term deposits	(12)	2
Net cash provided by (used in) investing activities	(20,058)	15,329
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceed from exercise of options	151	83
Proceeds from issuance of shares, net of issuance costs	26,306	-
Net cash provided by financing activities	26,457	83
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS	14	(15)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(3,168)	4,030
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE PERIOD	9,762	8,272
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE PERIODS	$ 6,594	$ 12,302
Cash and Cash equivalents	5,444	11,152
Restricted cash	1,150	1,150
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS	6,594	12,302
SUPPLEMENTARY INFORMATION:		
Interest received	628	582

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

NOTE 1 - NATURE OF OPERATIONS

Sol-Gel Technologies Ltd. (collectively with its U.S. subsidiary, the Company) is an Israeli Company incorporated in 1997.

The Company is a clinical stage specialty pharmaceutical company focused on developing and commercializing topical dermatological drug products. The Company's lead product candidates are based upon its proprietary microencapsulation delivery system, consisting of microcapsules made of precipitated silica. The most advanced investigational drugs in the Company's product pipeline are: (i) Twyneo®, which is developed for the treatment of acne vulgaris and (ii) Epsolay®, a potential treatment for subtype II rosacea. The New Drug Application ("NDA") for Twyneo® was accepted by the U.S. Food and Drug Administration (the "FDA"), which assigned a Prescription Drug User Fee Act ("PDUFA") goal date of August 1, 2021. The NDA for Epsolay® was accepted by the FDA, which assigned a PDUFA goal date of April 26, 2021. On such PDUFA goal date, the Company received confirmation from the FDA that action on the NDA could not be taken since a pre-approval inspection of the production site of Epsolay® still needs to be conducted. In June 2021, the Company entered into two exclusive license agreements with a third party for the commercialization of Twyneo® and Epsolay®, in the United States, see note 5. On July 27, 2021, the Company announced that the FDA approved the drug product, Twyneo®, see note 9. In addition to the novel product candidates, the Company's products include the generic products Acyclovir, Ivermectin and other generic product candidates.

Risk and Uncertainties

Since incorporation through June 30, 2021, the Company has an accumulated deficit of $193,459 and its activities have been funded mainly by its shareholders and collaboration revenues, see also Notes 4 and 5. The Company expects to continue to incur significant research and development and other costs related to its ongoing operations. In June 2021, the Company entered into two exclusive license agreements with a third party for the commercialization of two of the Company's most advanced investigational drug products in the United States including upfront and milestone payments and related royalties, see note 5.

In addition, management is continuing to analyze cash resources and considering raising additional funding from different sources, such as corporate collaborations, public or private equity offerings and/or debt financings, and/or selling shares under the Company's Open Market Sale Agreement with Jefferies LLC. Management expects that the Company's cash and cash equivalents, deposits and marketable securities as of June 30, 2021 will allow the Company to fund its operating plan through at least the next 12 months from the condensed financial statement issuance date.

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenues from collaboration arrangements, expenses, reserves and allowances, manufacturing, supply, regulatory approvals, clinical trials, commercial launch of branded and generic product candidates, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain and cannot be predicted. The Company continues to monitor and assess new information related to the COVID-19 pandemic, the actions taken to contain or treat COVID-19, as well as the economic impact on various markets.

Furthermore, the estimation process required to prepare the Company's consolidated financial statements requires assumptions to be made about future events and conditions and the impact of COVID-19 on its financial results, and while management believes such assumptions are reasonable, they are inherently subjective and uncertain. The Company's actual results could differ materially from those estimates.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial statements. Accordingly, they do not include all of the information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company’s consolidated financial position as of June 30, 2021, the consolidated results of operations and the statements of changes in shareholders' equity for the six month and three month periods ended June 30, 2020 and 2021 and the statements of cash flows for the six month period ended June 30, 2020 and 2021.

The consolidated results for the six month period ended June 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2020. The comparative balance sheet at December 31, 2020 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP.

b. Loss per share

Basic loss per share is computed on the basis of the net loss for the period divided by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is based upon the weighted average number of ordinary shares and of potential ordinary shares outstanding when dilutive. Potential ordinary shares equivalents include outstanding stock options, restricted shares and warrants, which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include 3,437,843 and 3,463,710 options, restricted shares and warrants for the six and three months ended June 30, 2021 and 1,244,731 and 1,197,028 options and restricted shares for the six and the three months ended June 30, 2020, respectively, because the effect would be anti-dilutive.

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

NOTE 3 - MARKETABLE SECURITIES:

The following table sets forth the Company's marketable securities for the indicated periods:

	December 31, 2020	June 30, 2021
Level 2 securities:		
U.S government and agency bonds	$ 4,192	$ 2,716
Canada government bonds	-	-
Other foreign government bonds	2,006	-
Corporate bonds*	15,454	4,114
Total	$ 21,652	$ 6,830

* Investments in Corporate bonds rated A or higher.

The Company's debt securities are classified within Level 2 because it uses quoted market prices or alternative pricing sources and models utilizing market observable inputs to determine their fair value.

The table below sets forth a summary of the changes in the fair value of the Company's marketable securities for the indicated periods:

	Marketable securities	
	For the year ended December 31, 2020	For the Six Months ended June 30, 2021
Balance at beginning of the period	$ 40,966	$ 21,652
Additions	32,322	4,065
Sale or maturity	(51,498)	(18,946)
Changes in fair value during the period	(138)	59
Balance at end of the period	$ 21,652	$ 6,830

As of June 30, 2021, the Company's debt securities had the following maturity dates:

	Market value June 30, 2021
Due within one year	6,830

The carrying amount of the cash and cash equivalents, bank deposits, restricted cash, restricted long term deposits, accrued expenses and other liabilities approximates their fair value.

NOTE 4 - COLLABORATION AGREEMENTS:

a. In 2007, the Company granted rights to a third party for use and commercialization of a product for skin protection. Under this agreement, the Company is entitled to royalties during the years 2016 to 2024. Based on current sales, royalties are not material.

b. In 2016 through 2021, the Company entered into several collaboration agreements with two third parties for the development, manufacturing and commercialization of several product candidates. Under the agreements, the third parties are obligated to conduct regulatory, scientific, clinical and technical activities necessary to develop the product and prepare and file ANDA, with the FDA and gain regulatory approval. The Company participates in the development of the product candidates, including participation in joint steering committees and is obligated for sourcing the active pharmaceutical ingredient (API) during the development phase.

Upon FDA approval, the third parties have exclusive rights and are required to use diligent efforts to commercialize these products in territories defined under the agreements, including all required sales, marketing and distributing activities associated with the agreements. The Company is entitled to 50% of the third parties' gross profits related to the sale of these products, as such term is defined in the agreements.

During the six and three months ended June 30, 2021, respectively, the Company recognized revenues from royalties related to sales of two generic products in the U.S. under these agreements in the amount of $1,582 and $904.

The Agreements are considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity.

The Company recognizes collaboration revenue when the related sales occur.

NOTE 5 - LICENSE AGREEMENTS:

In June 2021, the Company entered into two exclusive license agreements with a third party for the commercialization of two of the Company most advanced investigational drug products (Twyneo® and Epsolay®) in the United States. The Company is entitled to up to $7.5 million per product in upfront payments and regulatory approval milestone payments assuming 2021 approval of each respective product. The Company is also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments. According to the agreement, the Company has an option to regain commercialization rights five years following first commercialization. Subsequent to June 30, 2021, the Company received $4 million per product of upfront payments, which are refundable if FDA approval for each respective product is not received by December 31, 2021. As to FDA approval, received subsequent to June 30, 2021, with respect to Twyneo® , see note 9.

NOTE 6 - COMMITMENTS:

In June 2021, the Company entered into a new agreement with a third party for the commercialization of a product candidate. According to the agreement the Company shall receive from the third party an upfront payment of $1,250 and additional milestone payments in the future. In connection with the development of the product candidate, the Company is expected to sign an agreement with another third party. Both third parties are expected to sign a manufacture and supply agreement. In case either the development and/or supply agreements will not be executed during the 3rd quarter of 2021, the Company shall be required to refund the third party with the aforementioned upfront payment. In July 2021, the Company received the upfront payment.

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

NOTE 7 – SHARE CAPITAL:

Options grants

During the six months ended June 30, 2021, the Company granted 248,600 options to employees and directors:

i. In January 2021 and March 2021, the Company granted a total of 20,000 options and 3,600 options, respectively, to several employees to purchase ordinary shares at an exercise price of $10.44 and $9.93 per share, respectively. The options vest over a period of 4 years; one quarter of the options vest on the first anniversary of the vesting commencement date (as described in each agreement) and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of their grant date.

ii. In February 2021, the Company granted a total of 225,000 options to several directors to purchase ordinary shares at an exercise price of $10.02 per share. The options vest over a period of 3 years; one third of the options vest on the first anniversary of the vesting commencement date (as described in each agreement) and the rest vest quarterly over the following two years. The options expire on the tenth anniversary of their grant date.

The fair value of options granted in 2021 was $1,061. The underlying data used for computing the fair value of the options are as follows:

	2021
Value of one ordinary share	$9.56-$10.44
Dividend yield	0%
Expected volatility	59.52%-70.48%
Risk-free interest rate	0.55%-1.14%
Expected term	3.25-7 years

Ordinary shares

On February 19, 2020, the Company completed an underwritten public offering, in which it issued 2,091,907 ordinary shares and 2,091,907 warrants to purchase up to 1,673,525 ordinary shares, at a public offering price of $11.00 per ordinary shares for total proceeds, net of issuance costs of approximately $21,306. The warrants are exercisable over a six-years period from the date of issuance at a per share exercise price of $14, subject to certain adjustments as defined in the agreement.

In addition and in parallel to the public offering, the Company completed private placement with its controlling shareholder for an additional investment of approximately $5,000 in consideration of 454,628 ordinary shares and 454,628 warrants to purchase up to 363,702 ordinary shares, at the same terms of the underwritten public offering mentioned above.

NOTE 8 - RELATED PARTIES:

a. Related parties include the controlling shareholder and companies under his control, the board of directors and the executive officers of the Company.

b. As to the private placement with the controlling shareholder, see note 7.

NOTE 9 – SUBSEQUENT EVENT:

i. On July 27, 2021, the Company announced that the FDA approved the Company's first proprietary drug product, Twyneo® . The Company expects to receive a regulatory milestone payment in conjunction with this approval under the exclusive license executed in June 2021 related to the commercialization of Twyneo® and retains the option to regain U.S. commercialization rights five years following first commercialization in the U.S. FDA approval of Twyneo®.

ii. In July 2021, the Company received the upfront payment related to a new agreement with a third party for the commercialization of a product candidate, see Note 6.