## 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

# SOL-GEL TECHNOLOGIES LTD.

(Translation of registrant's name into English)

For the month of August 2022

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
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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, 2022, Sol-Gel Technologies Ltd. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 30, 2022. In addition, the Company is submitting with this Form 6-K its unaudited condensed consolidated financial statements as of June 30, 2022 and for the three and six months then ended.

Attached hereto are the following exhibits:

Exhibit 99.1 Press release dated August 4, 2022

Exhibit 99.2 Unaudited condensed consolidated financial statements as of June 30, 2022 and for the three and six months then ended

Exhibits 99.1 (other than the two paragraphs immediately preceding the heading "Second Quarter 2022 and Recent Corporate Developments") and 99.2 are hereby incorporated by reference into the Company's Registration Statement on Form S-8 (Registration No. 333-223915) and its Registration Statements on Form F-3 (Registration Nos. 333-230564 and 333-264190).

#### 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, 2022

By: /s/ Gilad Mamlok

Gilad Mamlok Chief Financial Officer

## <u>Exhibit 99.1</u>

# Sol-Gel Technologies Reports Second Quarter 2022 Financial Results and Provides Corporate Update

- Prescription volumes to date indicate strong uptake, similar to successful dermatology launches
- Sol-Gel receives \$3.5 million milestone payment from commercial partner Galderma Holding SA ("Galderma") for FDA approval of EPSOLAY
- Sol-Gel's cash runway expected to extend through the end of 2023
- SGT-510 to enter clinical trial later this year

NESS ZIONA, Israel, August 4, 2022-- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a dermatology company focused on identifying, developing, commercializing or partnering branded and generic topical drug products for the treatment of skin diseases, announced today financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"We and our partner Galderma are very pleased to report that the launches in the U.S. of EPSOLAY® and TWYNEO are going well and prescriber reception has been strong," stated Alon Seri-Levy, PhD, Chief Executive Officer of Sol-Gel. "Prescription volume data<sup>1</sup> also support our confidence in a strong dermatology launch trajectory. Galderma has an unparalleled track record of commercializing innovative drugs for acne and rosacea in the U.S. and has been using a mix of commercial strategies to drive adoption. Going forward, as they secure managed care access over the course of the year, we expect net sales and royalty income in line with volume growth."

Dr. Seri-Levy added, "Our next areas of focus are to advance our innovative pipeline assets into clinical trials, with SGT-510 planned to enter a clinical trial later this year, and to explore opportunities to extract additional value from our TWYNEO and EPSOLAY products."

## Second Quarter 2022 and Recent Corporate Developments

• On June 2, 2022, Galderma announced the availability in the U.S of EPSOLAY (benzoyl peroxide cream, 5%) for the treatment of inflammatory lesions of rosacea in adults. EPSOLAY is the first and only benzoyl peroxide topical treatment proven to relieve the bumps and blemishes of rosacea and provides rapid, significant and sustained relief.

<sup>1</sup> IQVIA data, July 2022

- On April 25, 2022, Sol-Gel announced FDA approval of EPSOLAY. Sol-Gel has granted to Galderma the exclusive rights to commercialize EPSOLAY in the U.S. A \$3.5 million milestone payment was received by Sol-Gel from Galderma related to the approval, in accordance with the U.S. commercialization agreement between the two companies and recorded as license revenue.
- Following the introduction of TWYNEO by Galderma at the Annual Meeting of the American Academy of Dermatology, March 25-29 in Boston, MA, Sol-Gel announced TYWNEO was made commercially available to the U.S. market.
- Both the launch of TWYNEO and the approval of EPSOLAY were covered by various trade media outlets in print, video and audio by major beauty, personal care and industry publications and media outlets including <u>Allure magazine</u>, <u>Practical Dermatology</u>, <u>The Dermatologist</u>, <u>Medpagetoday.com</u>, <u>Healio.com</u>, <u>Personal Care Insights</u>, <u>Monthly Prescribing Reference (MPR)</u> and <u>Drug Topics</u>.
- Sol-Gel plans to progress SGT-510 into a clinical trial later this year and to progress other proprietary assets into clinical studies in the first half of next year.

## **Second Quarter Financial Results**

Revenue was \$3.5 million for the quarter ending June 30, 2022, received from the Company's commercial partner, Galderma, resulting from the FDA approval of EPSOLAY and recorded as license revenue, compared to \$0.9 million of revenue for the same period in 2021 which was recorded as collaborative revenue and primarily related to sales of generic products by its partner Padagis.

Research and development expenses were \$2.4 million for the quarter ending June 30, 2022, compared to \$6.9 million for the same period in 2021. The decrease of \$4.5 million was mainly attributed to a decrease of \$3.0 million in professional expenses related to TWYNEO and EPSOLAY and a decrease of \$1.5 million in research and development expenses related to previously partnered programs of generic product candidates which are now being developed by Padagis, offset by ongoing development of Sol-Gel's proprietary assets.

General and administrative expenses were \$1.6 million for the quarter ending June 30, 2022, compared to \$2.0 million for the same period in 2021. The decrease of \$0.4 million was mainly attributed to winding down of pre-commercialization-related expenses for EPSOLAY and TWYNEO.

Sol-Gel reported a loss of \$0.1 million for the second quarter of 2022 compared to a loss of \$8.0 million for the same period in 2021.

As of June 30, 2022, Sol-Gel had \$26.8 million in cash, cash equivalents and deposits, and \$9.8 million in marketable securities for a total balance of \$36.6 million. As a result of the Company's agreements with Galderma regarding EPSOLAY and TWYNEO and the previously announced generics sale agreement with Padagis, the Company expects that its cash resources will enable funding of operational and capital expenditure requirements through the end of 2023.

## **About EPSOLAY**

EPSOLAY is a topical cream containing benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults. EPSOLAY utilizes a proprietary technology to encapsulate benzoyl peroxide within silica-based microcapsules to create a barrier between the medication and the skin. The silica-based shell is designed to slowly release benzoyl peroxide over time to provide a favorable efficacy and safety profile. EPSOLAY is covered by granted patents until 2040 as well as a pending patent application until 2041.

Visit www.epsolay.com for further information, including full Prescribing Information.

## **About TWYNEO**

TWYNEO is a topical cream containing a fixed-dose combination of tretinoin, 0.1% and benzoyl peroxide, 3% cream for the treatment of acne vulgaris in adults and pediatric patients 9 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. 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. TWYNEO is patent protected until 2038.

Visit www.twyneo.com for further information, including full Prescribing Information.

## **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 leveraged its proprietary microencapsulation technology platform for TWYNEO, which is approved for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older; and EPSOLAY, which is approved for the treatment of inflammatory lesions of rosacea in adults. Both drugs are exclusively licensed to Galderma for U.S. commercialization. Founded in 1981, Galderma is the world's largest independent dermatology company.

The Company's pipeline also includes topical drug candidates SGT-210, SGT-310 and SGT-510 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 forwardlooking statements, including, but not limited to, statements regarding the benefits we expect to receive under our agreement with Galderma; expected net sales and royalty income in line with volume growth of EPSOLAY and/or TWYNEO; and our expected cash runway. 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 expectations 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 we will not receive all of the anticipated benefits under our agreement with Galderma, the risk that EPSOLAY and/or 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 April 4, 2022, as amended, 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. Except as required by law, we undertake no obligation to update any forward-looking statements in this press release.

## For further information, please contact:

## **Investors:**

Irina Koffler Investor relations, LifeSci Advisors <u>ikoffler@lifesciadvisors.com</u> +1 917 734 7387

## **Sol-Gel Technologies**

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

# SOL-GEL TECHNOLOGIES LTD. **CONSOLIDATED BALANCE SHEETS**

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

(Unaudited)

	December 31, 2021		, June 30, 2022	
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	\$	20,085	\$	5,765
Bank deposits		21,448		21,000
Marketable securities		1,709		9,846
Receivables from collaborative arrangements		13,065		10,176
Prepaid expenses and other current assets		800		1,691
FOTAL CURRENT ASSETS		57,107		48,478
NON-CURRENT ASSETS:				
Long-term receivables from collaborative arrangements		7,402		2,499
Restricted long-term deposits and cash		1,298		1,289
Property and equipment, net		1,051		826
Operating lease right-of-use assets		1,501		1,153
Funds in respect of employee rights upon retirement		830		738
FOTAL NON-CURRENT ASSETS		12,082		6,505
FOTAL ASSETS	\$	69,189	\$	54,983
Liabilities and shareholders' equity				
CURRENT LIABILITIES:				
Accounts payable	\$	766	\$	860
Other accounts payable		10,145		1,664
Current maturities of operating leases		781		701
FOTAL CURRENT LIABILITIES		11,692		3,225
LONG-TERM LIABILITIES				
Operating leases liabilities		810		369
Liability for employee rights upon retirement		1,093		1,038
FOTAL LONG-TERM LIABILITIES		1,903		1,407
FOTAL LIABILITIES	\$	13,595	\$	4,632
SHAREHOLDERS' EOUITY:				
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2021 and June 30, 2022; issued and				
butstanding: 23,126,804 and 23,129,469 as of December 31, 2021 and June 30, 2022, respectively.		638		638
Additional paid-in capital		233,098		233,586
Accumulated deficit		(178,142)		(183,873
FOTAL SHAREHOLDERS' EQUITY		55,594	-	50,351
FOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	¢	69,189	\$	54,983

# 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				
		2021		2022		2021		2022
COLLABORATION REVENUES	\$	1,629		-	\$	928		-
LICENSE REVENUES		-		3,521		-		3,518
TOTAL REVENUES	\$	1,629	\$	3,521	\$	928	\$	3,518
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>		9,399		6,422		6,933		2,380
GENERAL AND ADMINISTRATIVE EXPENSES		4,496		3,512		2,037		1,601
TOTAL OPERATING LOSS		12,266		6,413		8,042		463
FINANCIAL INCOME, net		(170)		(682)		(9)		(329)
LOSS FOR THE PERIOD	\$	12,096	\$	5,731	\$	8,033	\$	134
BASIC AND DILUTED LOSS PER ORDINARY SHARE	\$	0.53	\$	0.25	\$	0.35	\$	0.01
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE		23,016,104		23,127,958		23,028,508	_	23,128,429

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF JUNE 30, 2022

#### UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF JUNE 30, 2022

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

# CONDENSED CONSOLIDATED BALANCE SHEETS (U.S. dollars in thousands, except share and per share data)

(Unaudited)

	De	December 31, 2021		June 30, 2022
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	\$	20,085	\$	5,765
Bank deposits		21,448		21,000
Marketable securities		1,709		9,846
Receivables from collaborative arrangements		13,065		10,176
Prepaid expenses and other current assets		800		1,691
TOTAL CURRENT ASSETS		57,107		48,478
NON-CURRENT ASSETS:				
Long-term receivables from collaborative arrangements		7,402		2,499
Restricted long-term deposits and cash		1,298		1,289
Property and equipment, net		1,051		826
Operating lease right-of-use assets		1,501		1,153
Funds in respect of employee rights upon retirement		830		738
TOTAL NON-CURRENT ASSETS		12,082		6,505
TOTAL ASSETS	\$	69,189	\$	54,983
Liabilities and shareholders' equity				
CURRENT LIABILITIES:				
Accounts payable	\$	766	\$	860
Other accounts payable		10,145		1,664
Current maturities of operating leases		781		701
TOTAL CURRENT LIABILITIES		11,692		3,225
LONG-TERM LIABILITIES				
Operating leases liabilities		810		369
Liability for employee rights upon retirement		1,093		1,038
TOTAL LONG-TERM LIABILITIES		1,903		1,407
TOTAL LIABILITIES	\$	13,595	\$	4,632
SHAREHOLDERS' EQUITY:				
Ordinary Shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2021 and June 30, 2022; issued				
and outstanding: 23,126,804 and 23,129,469 as of December 31, 2021 and June 30, 2022, respectively.		638		638
Additional paid-in capital		233,098		233,586
Accumulated deficit		(178,142)		(183,873)
TOTAL SHAREHOLDERS' EQUITY	_	55,594		50,351
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	69,189	\$	54,983

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

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

(Unaudited)

	Six months ended June 30			Three months endec June 30				
		2021		2022		2021		2022
COLLABORATION REVENUES	\$	1,629		-	\$	928	_	-
LICENSE REVENUES		-		3,521		-		3,518
TOTAL REVENUES	\$	1,629	\$	3,521	\$	928	\$	3,518
RESEARCH AND DEVELOPMENT EXPENSES		9,399		6,422		6,933		2,380
GENERAL AND ADMINISTRATIVE EXPENSES		4,496		3,512		2,037		1,601
TOTAL OPERATING LOSS		12,266		6,413		8,042		463
FINANCIAL INCOME, net		(170)		(682)		(9)		(329)
LOSS FOR THE PERIOD	\$	12,096	\$	5,731	\$	8,033	\$	134
BASIC AND DILUTED LOSS PER ORDINARY SHARE	\$	0.53	\$	0.25	\$	0.35	\$	0.01
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE		23,016,104		23,127,958		23,028,508		23,128,429

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

## 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, 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
BALANCE AS OF JANUARY 1, 2022	23,126,804	638	233,098	(178,142)	55,594
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2022:					
Loss for the period				(5,731)	(5,731)
Exercise of options	2,665	*	15		15
Share-based compensation			473		473
BALANCE AT JUNE 30, 2022	23,129,469	638	233,586	(183,873)	50,351
	F - 4				

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

(Unaudited)

			Additional paid-	Accumulated	T. (.)
	Ordinary	snares	in capital	deficit	Total
	Number of				
	shares	Amounts		Amounts	
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
BALANCE AS OF APRIL 1, 2022	23,127,669	638	233,224	(183,739)	50,123
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2022:					
Loss for the period				(134)	(134)
Exercise of options	1,800	*	10		10
Share-based compensation			352		352
BALANCE AT JUNE 30, 2022	23,129,469	638	233,586	(183,873)	50,351

\* less than \$1 thousand.

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

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

## (Unaudited)

	Six months ended June 30		
		2021	2022
CASH FLOWS FROM OPERATING ACTIVITIES:			
Loss for the period	\$	(12,096)	\$ (5,731)
Adjustments required to reconcile loss to net cash used in operating activities:			
Depreciation		474	327
Changes in accrued liability for employee rights upon retirement, net		3	37
Share-based compensation expenses		411	473
Financial expenses (income), net		15	(126)
Net changes in operating leases		(48)	(173)
Changes in fair value of marketable securities		(59)	135
Changes in operating asset and liabilities:			
Receivables from collaborative arrangements (including long-term)		1,197	7,792
Prepaid expenses and other current assets		(482)	(891)
Accounts payable, accrued expenses and other		(782)	(8,387)
Net cash used in operating activities		(11,367)	(6,544)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment		(54)	(102)
Investment in marketable securities		(4,065)	(10,006)
Proceeds from sales and maturity of marketable securities		18,946	1,734
Proceeds from short-term deposits		500	448
Proceeds from long-term deposits		2	9
Net cash provided by (used in) investing activities		15,329	(7,917)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of options		83	15
Net cash provided by financing activities		83	15
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS		(15)	126
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH		4,030	(14,320)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE PERIOD		8,272	21,235
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE PERIODS	\$	12,302	\$ 6,915
Cash and Cash equivalents		11,152	5,765
Restricted cash	_	1,150	1,150
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH			
FLOWS		12,302	6,915
SUPPLEMENTARY INFORMATION:			
Interest received		582	153
	-		

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

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

#### 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 products candidates are based upon its proprietary microencapsulation delivery system, consisting of microcapsules made of precipitated silica. The Company has two approved drugs: (i) Twyneo®, which was developed for the treatment of acne vulgaris and received marketing authourization by the U.S. Food and Durg Administration (the "FDA") on July 27, 2021 and (ii) Epsolay®, a treatment for subtype II rosacea that received marketing authourization by the FDA on April 25, 2022. In June 2021, the Company entered into two exclusive license agreements with Galderma for the commercialization of Twyneo® and Epsolay®, in the United States, see note 5. On April 14, 2022, the Company announced that Twyneo® is available for purchase by consumers who obtain a prescription from their physician. On June 2, 2022, the Company announced that Epsolay® is available for purchase by consumers who obtain a prescription from their physician. In addition to the novel products, the Company's products included the approved generic products Acyclovir, Ivermectin and other generic product candidates. In November 2021, the company entered into an agreement with Padagis, to sell its rights in relation to ten generic collaborative agreements between the parties, including the agreements for the two aforementioned approved generic drug products. Under the new agreement, the company has retained collaboration rights to two generic programs related to four generic drug candidates, see note 4b.

#### **Risk and Uncertainties**

Since incorporation through June 30, 2022, the Company has an accumulated deficit of \$183,873 and its activities have been funded mainly by its shareholders, collaboration revenues and license agreements, 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 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, 2022 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. To date, the impact of COVID-19 pandemic has been limited and resulted in delays with respect to pre-approval inspections.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

#### NOTE 1 - NATURE OF OPERATIONS (continued):

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, 2022, the consolidated results of operations for the six month and three month periods ended June 30, 2021 and 2022 and statements of changes in shareholders' equity and cash flows for the six month period ended June 30, 2021.

The consolidated results for the six month period ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022.

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, 2021. The comparative balance sheet at December 31, 2021 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 ordinary shares equivalents outstanding when dilutive. Ordinary share 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 3,713,296 and 4,085,416 options, restricted shares and warrants for the six and three months ended June 30, 2022 and 3,437,843 and 3,463,710 options and restricted shares for the six and the three months ended June 30, 2021, respectively, because the effect would be anti-dilutive.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

#### (Unaudited)

#### NOTE 3 – MARKETABLE SECURITIES:

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

	December 31,	June 30,
	2021	2022
Level 2 securities:		
U.S government and agency bonds	275	1,174
Other foreign government bonds	-	1,507
Corporate bonds*	1,434	7,165
Total	1,709	9,846

\* 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				
		-		e Six Months June 30, 2022	
Balance at beginning of the period	\$	21,652	\$	1,709	
Additions		6,716		10,006	
Sale or maturity		(26,784)		(1,734)	
Changes in fair value during the period		125		(135)	
Balance at end of the period	\$	1,709	\$	9,846	

As of June 30, 2022, the Company's debt securities had the following maturity dates:

	Market value
	June 30, 2022
Due within one year	9,041
Between 1-2 years	805

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



#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

#### 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 2020, the Company entered into several collaboration agreements mainly with one Partner for the development, manufacturing and commercialization of several generic product candidates. Under the agreements, the Partner is 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 Partner has exclusive rights and is 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 a share of the Partner's gross profits related to the sale of the products, as such term is defined in each of the agreements.

These Agreement 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.

In November 2021, the Company entered into a new agreement (the "New Agreement") with the Partner, to sell its rights in relation to ten generic collaborative agreements between the parties, including the agreements for two approved generic drug products. Under the New Agreement, the Company has retained collaboration rights to two generic programs related to four generic drug candidates. Following the signing of the New Agreement, the Company is no longer entitled to receive its share in profit as detailed above.

Under the terms of the New Agreement, effective as of November 1, 2021, the Company will unconditionally receive \$21,500 over 24 months, in lieu of its share in future gross profits for the two approved generic drug products and its potential gross profits for eight unapproved generic programs. The Company received \$1,250 as an upfront payment and \$20,250 in eight equal quarterly instalments. The New Agreement also provides that effective as of November 1, 2021, the Company will cease paying any outstanding and future operational costs related to these collaborative agreements.

#### NOTE 5 – LICENSE AGREEMENTS:

In June 2021, the Company entered into two exclusive license agreements with Galderma for the commercialization of Twyneo® and Epsolay®, in the United States. According to the agreement, the Company has an option to regain commercialization rights five years following first commercialization. In the third quarter of 2021, the Company received \$7.5 million for Twyneo® and \$4 million for Epsolay® of upfront payments, which are refundable if FDA approval for each respective product is not received by December 31, 2021. On July 27, 2021, the Company announced that the FDA approved the Company's first proprietary drug product, Twyneo®.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

#### NOTE 5 – LICENSE AGREEMENTS (continued):

On April 14, 2022, the Company announced that Twyneo® is available for purchase by consumers who obtain a prescription from their physician, See note 1. In March 2022, the Company has refunded the \$4 million upfront payment to Galderma, since FDA approval for Epsolay® had not been received as of December 31, 2021. On April 25, 2022, the Company announced that the FDA approved the drug product, Epsolay®, which entitled the Company to \$3.5 million milestone payment, according to the license agreement. In May 2022, the Company has received the \$3.5 million payment from Galderma. On June 2, 2022, the Company announced that Epsolay® is available for purchase by consumers who obtain a prescription from their physician, See note 1.

#### NOTE 6 - SHARE CAPITAL:

#### **Options grants**

During the six months ended June 30, 2022, the Company granted 722,488 options to employees and executive officers:

i. In March 2022, the Company granted a total of 148,907 options to several employees to purchase ordinary shares at an exercise price of \$7.38 per share.

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 March 2022, the Company granted a total of 271,517 options to several Executive Officers to purchase ordinary shares at an exercise price of \$10 per share.

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.

iii. In March 2022, the board of directors approved and recommended the Company shareholders to approve a grant of 302,064 options to the Company's CEO to purchase ordinary shares at an exercise price of \$10 per share. The Company's shareholders approved the grant in June 2022.

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.

The fair value of options granted in 2022 was \$3,278. The underlying data used for computing the fair value of the options are as follows:

	 2022
Value of one ordinary share	\$ 7.72
Dividend yield	 0%
Expected volatility	62.6%
Risk-free interest rate	 2.5%
Expected term	 7 years

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

#### NOTE 6 - SHARE CAPITAL (continued):

#### **Ordinary shares**

In July 2021, the Company entered into an ATM sales agreement with Jefferies LLC ("Jefferies"), pursuant to which the Company is entitled, at its sole discretion, to offer and sell through Jefferies, acting as sales agent, Shares having an aggregate offering price of up to \$25.0 million throughout the period during which the ATM facility remains in effect. The Company agreed to pay Jefferies a commission of 3.0% of the gross proceeds from the sale of shares under the facility.

From the effective date of the agreement through its expiration, 41,154 shares were sold under the program for total gross proceeds of approximately \$ 0.5 million.

In April 2022, the Company signed a new ATM agreement with Jefferies for total amount of \$23 million. As of the issuance date of this report, no shares were sold under the new ATM agreement.

#### NOTE 7-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 options granted to executive officers, see note 6.