UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

Commission file number 001-38367

Sol-Gel Technologies Ltd.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

Israel

(Jurisdiction of incorporation or organization)

7 Golda Meir St., Weizmann Science Park, Ness Ziona, 7403650, Israel

(Address of principal executive offices)

Gilad Mamlok, Chief Financial Officer
7 Golda Meir St., Weizmann Science Park, Ness Ziona, 7403650, Israel
Tel: 972-8-9313429; Fax: 972-153-523044444

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value NIS 0.1 per share	SLGL	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 23,000,782 Ordinary Shares, par value NIS 0.1 per share,

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has fi led a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒

International Financing Reporting Standards as issued by the International Accounting Standards Board ☐ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

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INTRODUCTION

All references to "Sol-Gel," "Sol-Gel Technologies," "we," "us," "our," "the Company" and similar designations refer to Sol-Gel Technologies Ltd. The terms "shekels," "Israeli shekels" and "NIS" refer to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar," "US$" or "$" refer to U.S. dollars, the lawful currency of the United States. Unless derived from our financial statements or otherwise indicated, U.S. dollar translations of NIS amounts presented in this annual report are translated using the rate of NIS 3.215, NIS 3.456 and NIS 3.748 to $1.00, based on the exchange rates reported by the Bank of Israel on December 31, 2020, December 31, 2019 and December 31, 2018, respectively.

All references to the term "branded product candidates" refers to Twyneo®, a novel, once-daily, non-antibiotic topical cream that we are developing for the treatment of acne vulgaris, or acne; Epsolay®, a novel, once-daily topical cream containing encapsulated benzoyl peroxide that we are developing for the treatment of papulopustular (subtype II) rosacea; SGT-210 (erlotinib gel) that we are developing for the treatment of palmoplantar keratoderma, or PPK; erlotinib, an epidermal growth factor receptor inhibitor; tapinarof, an investigational aryl hydrocarbon receptor modulator; and roflumilast, an investigational phosphodiesterase 4 inhibitor. Erlotinib, tapinarof, and roflumilast are each a potential treatment of various pharmaceutical indications. All references to the term "product candidates" include both branded product candidate and generic product candidates.

Solely for convenience, the trademarks, service marks, and trade names referred to in this annual report are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This annual report contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this annual report are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

This annual report includes statistics and other data relating to markets, market sizes and other industry data pertaining to our business that we have obtained from industry publications and surveys and other information available to us. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Market data and statistics are inherently predictive and speculative and are not necessarily reflective of actual market conditions. Such statistics are based on market research, which itself is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market. In addition, the value of comparisons of statistics for different markets is limited by many factors, including that (i) the markets are defined differently, (ii) the underlying information was gathered by different methods, and (iii) different assumptions were applied in compiling the data. Accordingly, the market statistics included in this annual report should be viewed with caution. We believe that information from these industry publications included in this annual report is reliable.

We make forward-looking statements in this annual report that are subject to risks and uncertainties. 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 good faith belief as of that time with respect to future events, 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 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;
- our ability to complete the development of, and obtain market approval for, our product candidates;
- our ability to find suitable co-development, contract manufacturing and marketing partners;
- our ability to obtain and maintain regulatory approvals for our product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained;
- our ability to commercialize and launch our pharmaceutical product candidates;
- our ability to obtain and maintain adequate protection of our intellectual property;
- our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost;
- our ability to establish adequate sales, marketing and distribution channels;
- acceptance of our product candidates by healthcare professionals and patients;
- the possibility that we may face third-party claims of intellectual property infringement;
- 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;
- 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;
- potential product liability claims;
- potential adverse federal, state and local government regulation in the United States, Europe or Israel;
- the impact of pandemics such as Novel Coronavirus Disease 2019, or COVID-19, on our business and financial condition; and
- loss or retirement of key executives and research scientists.

You should review carefully the risks and uncertainties described under the heading “Risk Factors” in this annual report for a discussion of these and other risks that relate to our business and investing in our ordinary shares. The forward-looking statements contained in this annual report are expressly qualified in their entirety by this cautionary statement. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this annual report to conform these statements to actual results or to changes in our expectations.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected historical financial data, which is derived from our audited financial statements, which have been prepared in accordance with U.S. GAAP. The selected consolidated balance sheet data as of December 31, 2019 and 2020 and our selected statement of operations data for the years ended December 31, 2018, 2019 and 2020 is derived from our audited consolidated financial statements included elsewhere in this annual report. The selected balance sheet data as of December 31, 2016, December 31, 2017 and December 31, 2018 and our selected statement of operations data for the years ended December 31, 2016 and December 31, 2017 have been derived from our audited financial statements not included in this annual report. Our historical results are not necessarily indicative of the results that should be expected in the future. You should read this selected financial data in conjunction with, and it is qualified in its entirety by, our historical financial information and other information provided in this annual report including "Item 5. Operating and Financial Review and Prospects" and our audited consolidated financial statements and related notes appearing elsewhere in this annual report.

	Year Ended December 31,				
	2016	2017	2018	2019	2020
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Collaboration Revenues	$ -	$ 174	$ 129	$ 22,904	$ 8,771
Research and development expenses	17,023	25,805	28,146	40,578	27,913
General and administrative expenses	3,773	6,002	5,504	8,276	11,091
Total operating loss	20,756	31,633	33,521	25,950	30,233
Financial expenses (income), net	15	(65)	(1,318)	(1,374)	(943)
Loss before income taxes	20,771	31,568	32,203	24,576	29,290
Income taxes				33	
Loss for the year	$ 20,771	$ 31,568	$ 32,203	$ 24,609	$ 29,290
Basic and diluted loss per ordinary share*	$ 3.30	$ 5.02	$ 1.80	$ 1.26	$ 1.3
Weighted average number of ordinary shares outstanding – basic and diluted*	3,494,579	6,290,244	17,867,589	19,534,562	22,574,688

* On January 19, 2018, we effected a 1-for-1.8 share split of our ordinary shares by way of an issuance of bonus shares. Unless otherwise indicated, except for our authorized capital, all information in this annual report relating to the number of our ordinary shares and loss per ordinary share in this annual report have been adjusted, on a retroactive basis, to reflect this 1-for-1.8 share split.

	As of December 31,				
	2016	2017	2018	2019	2020
Balance Sheet Data:			(in thousands)		
Cash and cash equivalents	$ 7,001	$ 5,024	$ 5,325	$ 9,412	$ 7,122
Total Assets	10,985	15,315	69,682	61,301	59,161
Total liabilities	42,322	68,014	5,773	8,836	8,312
Accumulated deficit	(63,693)	(95,261)	(127,464)	(152,073)	(181,363)
Total shareholders' equity (capital deficiency)	(31,337)	(52,699)	63,909	52,465	50,849

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this annual report, including our financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares, or the "Ordinary Shares. The risks and uncertainties described below in this annual report on Form/ 20-F for the year ended December 31, 2020 are not the only risks facing us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below or incorporated by reference in this Form 20-F, and any such additional risks, could materially adversely affect our business, financial condition or results of operations. In such case, you may lose all or part of your investment.

Summary of Risk Factors

The following is a summary of some of the principal risks we face. The list below is not exhaustive, and investors should read this "Risk factors" section in full.

- We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history in the dermatological prescription drug space which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We may need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy. If we are successful in raising additional capital, this may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are largely dependent on the success of our branded product candidates for the treatment of topical dermatological conditions.
- We currently have limited marketing capabilities. If we are unable to establish adequate sales and marketing capabilities through third parties we may be required to establish sales and marketing capabilities on our own, or we may be unable to successfully commercialize Twyneo®, Epsolay® or any other of our other product candidates, if approved, or generate product revenues. In addition, establishing our own sales and marketing capabilities would significantly increase our expenses and require us to raise additional capital sooner that an anticipated.

- We have not obtained regulatory approval for most of our product candidates in the United States or any other country.
- Our continued growth is dependent on our ability to successfully develop and commercialize new product candidates in a timely manner. We expend a significant amount of resources on research and development efforts that may not lead to successful product candidate introductions or the recovery of our research and development expenditures.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and clinical trials may not be predictive of future trial results, which could result in development delays or a failure to obtain marketing approval.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, such as the risk of product liability claims.
- Even if our branded product candidates or our other product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and market acceptance necessary for commercial success.
- Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration and expansion.
- The ongoing COVID-19 pandemic may adversely affect our business, revenues, results of operations and financial condition.
- Any collaborative arrangements that we have or may establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations.
- We rely on third parties and consultants to assist us in conducting our clinical trials. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- The manufacture of pharmaceutical products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any difficulties, our ability to provide product candidates for clinical trials or our product candidates to patients, once approved, and the development or commercialization of our product candidates could be delayed or stopped.
- We depend on our intellectual property, and our future success is dependent on our ability to protect our intellectual property and not infringe on the rights of others.
- If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.
- If we are not able to retain our key management, or attract and retain qualified scientific, technical and business personnel, our ability to implement our business plan may be adversely affected.

Risks Related to Our Business and Industry

We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage dermatology company with a limited operating history. We have incurred net losses since our formation in 1997. In particular, we incurred net losses of $32.2 million in 2018, $24.6 million in 2019, and $29.3 million in 2020. As of December 31, 2020, we had an accumulated deficit of $181.4 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur net losses for the foreseeable future as we continue to invest in research and development and seek to obtain regulatory approval and commercialization of our product candidates. The extent of our future operating losses and the timing of generating revenues and becoming profitable are highly uncertain, and we may never achieve or sustain profitability. We anticipate that our expenses will increase substantially as we:

- seek marketing approval and conduct pre-commercialization and launch activities for Twyneo® and Epsolay®;
- conduct Phase I proof of concept clinical studies of SGT-210, and continue the research and development of erlotinib, an epidermal growth factor receptor inhibitor, tapinarof, an investigational aryl hydrocarbon receptor modulator, and roflumilast, an investigational phosphodiesterase 4 inhibitor, and other future branded product candidates;
- seek regulatory approvals for any product candidate that successfully completes clinical development;
- establish commercial manufacturing capabilities through one or more contract manufacturing organizations to commercialize any product candidates for which we may obtain regulatory approval;
- continue the development, bioequivalence and other studies required for abbreviated new drug application, or ANDA, submissions for our generic product candidates;
- seek to enhance our technology platform;
- maintain, expand and protect our intellectual property portfolio;
- seek new drug candidates and expand our disease portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

We have financed our operations primarily through public offerings in the U.S., private placements of equity securities and investments and loans from our controlling shareholder. To date, we have devoted a significant portion of our financial resources and efforts to developing the first generic version of Zovirax® (acyclovir) cream, 5%, developing our product candidates and conducting pre-clinical studies and our clinical trials for Twyneo®, Epsolay®, ivermectin cream, 1% and 5-fluorouracil cream, 5%. Although we are anticipating decisions from the U.S. Food and Drug Administration, or FDA, with respect to our marketing applications for Twyneo®, Epsolay® in 2021, and we are expected to launch an additional generic product in 2021 in addition to the first generic version of Zovirax® (acyclovir) cream . To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical studies and clinical trials for our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any product candidates for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical products, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials, our expenses could increase and revenue could be further delayed.

Even if we do generate revenue from product sales or product royalties, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our ordinary shares also could cause you to lose all or a part of your investment.

We may need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we seek marketing approval and conduct pre-commercialization and launch activities for Twyneo® and Epsolay®, conduct Phase I proof of concept clinical studies of SGT-210 and advance erlotinib, tapinarof, roflumilast and our other product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Substantial revenue, if any, will be derived from sales of products that are not yet, and may never be, commercially available. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the timing and success for obtaining marketing approval for Twyneo® and Epsolay®;
- the progress and results of our development activities for SGT-210, erlotinib, tapinarof and roflumilast;
- the scope, progress, results and costs of development, laboratory testing and clinical trials for our generic product candidates;
- the cost of manufacturing clinical supplies and exhibition batches of our product candidates;
- the costs, timing and outcome of regulatory reviews of any of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims by third parties that we are infringing upon their intellectual property rights;

- the amount of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the extent to which we acquire or invest in businesses, product candidates and technologies, including entering into licensing or collaboration arrangements for any of our product candidates.

In order to continue our future operations, we will need to raise additional capital until becoming profitable. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

We are largely dependent on the success of our branded product candidates for the treatment of topical dermatological conditions.

We have invested a majority of our efforts and financial resources in the research and development of Twyneo® for the treatment of acne and Epsolay® for the treatment of papulopustular (subtype II) rosacea. If Twyneo® and Epsolay® receive regulatory approval from the FDA, we intend to market them in the United States through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. We are currently engaged in the conduct of pre-commercialization and launch activities for Twyneo® and Epsolay®. The success of our business depends largely on our ability to fund, execute and complete the development of, obtain regulatory approval for and successfully commercialize our branded product candidates in the United States in a timely manner.

We have not obtained regulatory approval for most of our product candidates in the United States or any other country.

Other than the first generic version of Zovirax® (acyclovir) cream, 5% for which Perrigo UK Finco Limited Partnership, or Perrigo, our collaborator, received final FDA approval in February 2019, we do not currently have any product candidates that have obtained regulatory approval for sale in the United States or any other country. Although we are expected to launch an additional generic product in 2021, we cannot guarantee that our other product candidates will ever obtain such approvals. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining regulatory approval to market each product candidate from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate in pre-clinical studies and well-controlled clinical trials that the product candidate is safe and effective for use for its target indication and that the related manufacturing facilities, processes and controls are adequate. In the United States, we are required to submit and obtain the FDA's approval of a new drug application, or NDA, before marketing our product candidates. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication and, when subject to the requirements of section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, will allow us to rely in part on published scientific literature and/or the FDA's prior findings of safety and efficacy in its approvals of similar products. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. The FDA will also inspect our manufacturing facilities to ensure that the facilities can manufacture each product candidate that is the subject of an NDA, in compliance with current good manufacturing practice, or cGMP requirements, and may inspect our clinical trial sites to ensure that the clinical trials conducted at the inspected site were performed in accordance with good clinical practices, or GCP, and our clinical protocols.

To date, we have submitted two NDAs that were accepted for filing by the FDA, one for Twyneo® with a Prescription Drug User Fee Act, or PDUFA, goal date assigned by the FDA of August 1, 2021 and one for Epsolay® with a PDUFA goal date assigned by the FDA of April 26, 2021. In addition, in July 2020, Perrigo filed first-to-file Paragraph IV Certification for a generic version of Duobrii® (halobetasol propionate and tazarotene) lotion, a product which is the subject of one of our collaboration agreements with Perrigo Israel, an affiliate of Perrigo Company plc. In August 2020, Bausch Health Companies, Inc. initiated a patent infringement action in the U.S. District Court for the District of New Jersey regarding Perrigo's Abbreviated New Drug Application (ANDA) for this generic version of Duobrii® lotion.

Approval to market and distribute drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process is obtained by submitting an ANDA to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include pre-clinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug.

Obtaining approval of an NDA or an ANDA is a lengthy, expensive and uncertain process, and approval is never guaranteed. Upon submission of an NDA or ANDA, the FDA must make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not accepted for review or approved, the FDA may require that we conduct additional clinical trials or pre-clinical studies or take other actions before it will reconsider our application. If the FDA requires us to provide additional studies or data to support such applications, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than anticipated or that we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

Regulatory authorities outside of the United States also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those countries. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing, development, validation and additional administrative review periods. Seeking regulatory approval outside of the United States could require additional chemical manufacturing control data, pre-clinical studies or clinical trials, which could be costly and time consuming. Obtaining regulatory approval outside of the United States may include all of the risks associated with obtaining FDA approval.

Our business will be highly dependent on market perception of us and the safety and quality of our product candidates. Our business or products could be subject to negative publicity, which could have a material adverse effect on our business.

Market perception of our business is very important, especially market perception of the safety and quality of our product candidates. If any of our product candidates, if approved, or similar products that other companies distribute, or third-party products from which our product candidates are derived, are subject to market withdrawal or recall or are proven to be, or are claimed to be, harmful to consumers, it could have a material adverse effect on our business. Negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to result from, our product candidates could have a material adverse impact on our business.

Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which could call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other costly risk management programs such as the need for a patient registry.

We have a limited operating history in the dermatological prescription drug space which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We have a limited operating history in the dermatological prescription drug space and have focused much of our efforts, to date, on the research and development of our branded and generic product candidates, rather than commercialization. If Twyneo® and Epsolay® receive regulatory approval from the FDA, we intend to market them in the United States through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. Due to these uncertainties, we cannot provide you with any assurances as to when, if ever, we will obtain approvals or generate sufficient revenues to achieve sustained profitability. Our ability to successfully commercialize our product candidates and become profitable is subject to a number of challenges, including, among others, that:

- we may not have adequate financial or other resources;
- we may not be able to manufacture our product candidates in commercial quantities, in an adequate quality or at an acceptable cost;
- we may not be able to establish adequate sales, marketing and distribution channels;
- we may not be able to find suitable co-development, contract manufacturing or marketing partners;
- healthcare professionals and patients may not accept our product candidates;
- we may not be aware of possible complications from the continued use of our product candidates since we have limited clinical experience with respect to the actual use of our product candidates;
- changes in the market, new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;
- third-party payors may not agree to reimburse patients for any or all of the purchase price of our product candidates, which may adversely affect patients' willingness to purchase our product candidates;
- uncertainty as to market demand may result in inefficient pricing of our product candidates;
- we may face third-party claims of intellectual property infringement;
- we may fail to obtain and maintain regulatory approvals for our product candidates in our target markets or may face adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained;
- we are dependent upon the results of ongoing clinical trials relating to our product candidates and the products of our competitors; and
- we may become involved in lawsuits pertaining to our clinical trials.

The occurrence of any one or more of these events may limit our ability to successfully commercialize our product candidates, which in turn could have a material adverse effect on our business, financial condition and results of operations. Consequently, there can be no guaranty of the accuracy of any predictions about our future success or viability.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as an ordinary shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Even if we are able to generate revenues from our operations in the future, our revenues and operating income could fluctuate significantly.

Even if we are able to generate future revenues, our operating income, and results may vary significantly from year-to-year and quarter-to-quarter. Variations may result from, among other factors:

- the timing of any FDA or other regulatory authority approvals;
- the timing of process validation for particular product candidates;
- the timing of product launches and market acceptance of such products launched;
- changes in the amount we spend to research, develop, acquire, license or promote new product candidates;
- the outcome of our research, development and clinical trial programs;
- serious or unexpected health or safety concerns related to our product candidates or the branded product candidates we have genericized;
- the introduction of new products by others that render our product candidates obsolete or noncompetitive;
- the ability to maintain selling prices and gross margins on our product candidates;
- the ability to comply with complex governmental regulations applicable to many aspects of our business;
- changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar government healthcare programs;
- increases in the cost of raw materials used to manufacture our product candidates;
- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- timing of revenue recognition related to our collaboration agreements;

- the ability to protect our intellectual property and avoid infringing the intellectual property of others; and
- the outcome and cost of possible litigation over patents with third parties.

Risks Related to Development and Clinical Testing of Our Product Candidates

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and clinical trials may not be predictive of future trial results, which could result in development delays or a failure to obtain marketing approval.

Clinical testing, of both innovative and generic products, and the submission of new drug applications under the Section 505(b)(2) regulatory pathway is expensive, time consuming and has an inherently uncertain outcome. Failure can occur at any time during the clinical trial process, even with active ingredients that have been previously approved by the FDA as safe and effective. Favorable results in pre-clinical studies and early clinical trials for one or more of our product candidates may not be predictive of similar results in future clinical trials for such product candidate. Also, interim results during a clinical trial do not necessarily predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed pre-clinical studies and clinical trials for our product candidates may not be predictive of the results we may obtain in later stage trials for such product candidates. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Clinical trial results may be inconclusive, or contradicted by other clinical trials, particularly larger clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain FDA, or other applicable regulatory agency, approval for their products.

We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- reaching a consensus with regulatory authorities on study design or implementation of clinical trials;
- obtaining regulatory authorization to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- identifying, recruiting and training suitable clinical investigators;
- obtaining institutional review board, or IRB, or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from FDA regulations, including GCPs, or the study protocol, or dropping out of a trial;

- adding new clinical trial sites;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- third parties being unwilling or unable to satisfy their contractual obligations to us;
- manufacturing sufficient quantities of a product candidate for use in clinical trials; and
- damage to clinical supplies of a product candidate caused during storage and/or transportation.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We may also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by any Data Safety Monitoring Board for such trial, by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of any clinical trial for our product candidates or if any clinical trials are terminated, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed.

Moreover, changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, as a result of which we may need to amend clinical trial protocols. Amendments may require us to resubmit our clinical trial protocols for review and approval, which may adversely affect the cost, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, any of our clinical trials, the commercial prospects for our affected product candidates would be harmed and our ability to generate product revenue would be delayed, possibly materially.

Any delays in completing our clinical trials will increase our costs, slow down our product candidates' development and regulatory review and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us, our collaborators, the FDA or other regulatory authorities for a number of reasons. For example, to date, patients treated with Twyneo® and Epsolay® have experienced drug-related side effects including moderate local site irritation such as dryness, erythema, scaling, pruritus, itching, stinging and burning. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. If we elect or are required to delay, suspend or terminate any clinical trial for any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy, or REMS, which may include a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Our future clinical trial results may not be successful.

We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in our clinical trials, which could delay or prevent clinical trials for our product candidates.

Identifying and qualifying patients to participate in clinical trials for our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates. If patients are unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or pharmaceutical industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidates development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

Patient enrollment is a significant factor in the timing of clinical trials. We may not be able to recruit and enroll a sufficient number of patients, which would impact our ability to complete our clinical trials in a timely manner. Patient enrollment may be affected by numerous factors, including:

- severity of the disease under investigation;
- size and nature of the patient population;
- eligibility criteria for the trial;
- design of the trial protocol;
- perceived risks and benefits of the product candidate under study;
- physicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any drugs that may be approved for the same indications we are investigating;
- proximity to and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- ability to monitor patients adequately during and after treatment; and
- the effects of COVID-19

We face intense competition with regard to patient enrollment in clinical trials from other dermatological companies which also seek to enroll subjects from the same patient populations. In addition, patients enrolled in our clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged related to our product candidates under evaluation. For example, 104 patients, or 12.12% of patients enrolled in our Twyneo® Phase 3 clinical trial, did not complete the study protocol. The most common reasons for subjects not completing the study were the withdrawal of informed consent (41 subjects), loss to follow-up (36 subjects) and adverse events (16 subjects). The discontinuation of patients in any one of our trials may cause us to delay or abandon our clinical trial or cause the results from that trial not to be positive or sufficient to support a filing for regulatory approval of the applicable product candidate.

There is a substantial risk of product liability claims in our business. We currently do not maintain product liability insurance and a product liability claim against us would adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of our product candidates. Product liability claims could delay or prevent completion of our development programs. If we succeed in commercializing our product candidates, such claims could result in a recall of our product candidates or a change in the approved indications for which they may be used. While we intend to purchase and maintain product liability insurance that we believe is adequate for our operations upon commercialization of our product candidates, such coverage may not be adequate to cover any incident or all incidents. Furthermore, product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

If the FDA does not conclude that our product candidates for which we are seeking or intend to seek approval under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfy the requirements of the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in all cases may not be successful.

We are developing product candidates for which we are seeking or intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved drugs, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, any inability to pursue the Section 505(b)(2) regulatory pathway may result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, our product candidates may not receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Even if our branded product candidates or our generic product candidates receive marketing approval, we may continue to face future developmental and regulatory difficulties. In addition, we will be subject to ongoing obligations and continued regulatory review.

Even if we complete clinical testing and receive approval of any of our branded or generic product candidates, the FDA may grant approval contingent on the performance of additional post-approval clinical trials, risk mitigation requirements such as the implementation of a or REMS, and/or surveillance requirements to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our product candidates, if any.

The FDA also may approve branded product candidates or any of our generic product candidates for a more limited indication or a narrower patient population than we initially request, or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Furthermore, any such approved product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. These requirements include registration with the FDA, listing of our product candidates, payment of annual fees, as well as continued compliance with GCP requirements for any clinical trials that we conduct post-approval. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements.

If we fail to comply with the regulatory requirements of the FDA or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including the following:

- the FDA could suspend or impose restrictions on operations, including costly new manufacturing requirements;
- the FDA could refuse to approve pending applications or supplements to applications;
- the FDA could suspend any ongoing clinical trials;
- the FDA could suspend or withdraw marketing approval;
- the FDA could seek an injunction or impose civil or criminal penalties or monetary fines;
- the FDA could ban or restrict imports and exports;
- the FDA could issue warning letters or untitled letters or similar enforcement actions alleging noncompliance with regulatory requirements; or
- the FDA or other governmental authorities could take other actions, such as imposition of product seizures or detentions, clinical holds or terminations, refusals to allow the import or export of products, disgorgement, restitution, or exclusion from federal healthcare programs.

In addition, if our branded product candidates or any of our other product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, a practice known as off-label promotion. If we receive marketing approval for any of our branded product candidates or any of our generic product candidates, physicians may nevertheless prescribe the products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

Moreover, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our branded product candidates or any of our other product candidates, if approved. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities and clinical trial sites. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities and trial sites subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if our branded product candidates or our other product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and market acceptance necessary for commercial success.

Even if we obtain FDA approvals for our branded product candidates or any of our generic product candidates, the commercial success of such products will depend significantly on their broad adoption by dermatologists, pediatricians and other physicians for approved indications and other therapeutic or aesthetic indications that we may seek to pursue if approved.

The degree and rate of physician and patient adoption of our branded product candidates and any of our generic product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved;
- the safety and efficacy of our product as compared to existing therapies for those indications;
- the prevalence and severity of adverse side effects;
- patient satisfaction with the results and administration of our product and overall treatment experience, including relative convenience, ease of use and avoidance of, or reduction in, adverse side effects;
- patient demand for the treatment of acne and rosacea or other indications;

- the cost of treatment in relation to alternative treatments, the extent to which these costs are reimbursed by third-party payors, and patients' willingness to pay for our product candidates; and

- the effectiveness of our sales and marketing efforts, including any head-to-head studies, if conducted, especially the success of any targeted marketing efforts directed toward dermatologists, pediatricians, other physicians, clinics and any direct-to-consumer marketing efforts we may initiate.

We expend a significant amount of resources on research and development efforts that may not lead to successful product candidate introductions or the recovery of our research and development expenditures.

We conduct research and development primarily to enable us to manufacture and market topical dermatological creams containing drugs in accordance with FDA regulations as well as other regulatory authorities. We spent approximately $28.1 million, $40.6 million and $27.9 million on research and development activities during the years ended December 31, 2018, 2019 and 2020, respectively. We are required to obtain FDA approval before marketing our product candidates in the United States. The FDA approval process is costly, time consuming and inherently risky.

We cannot be certain that any investment made in developing product candidates will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able to introduce successful new product candidates as a result of those efforts, we will be unable to recover those expenditures.

Our clinical trials for our branded product candidates were not, and will not be, conducted head-to-head with the applicable leading products of our competitors, and the comparison of our results to those of existing drugs, and the conclusions we have drawn from such comparisons, may be inaccurate.

Our clinical trials for branded product candidates were not, and will not be, conducted head-to-head with the drugs considered the applicable standard of care for the relevant indications. This means that none of the patient groups participating in these trials were, and will not in the future be, treated with the applicable standard of care drugs alongside the groups treated with our product candidates. Instead, we have compared and plan to continue comparing the results of our clinical trials with historical data from prior clinical trials conducted by third parties for the applicable standard of care drugs, and which results are presented in their respective product labels.

Direct comparison generally provides more reliable information about how two or more drugs compare, and reliance on indirect comparison for evaluating their relative efficacy or other qualities is problematic due to lack of objective or validated methods to assess trial similarity. For example, the various trials were likely conducted in different countries with different demographic features and in patients with different baseline conditions and different hygiene standards, among other relevant asymmetries. Therefore, the conclusions we have drawn from comparing the results of our clinical trials with those published in the product labels for these current standard of care drugs, including conclusions regarding the relative efficacy and expediency of our branded product candidates, may be distorted by the inaccurate methodology of the comparison. Moreover, the FDA generally requires head-to-head studies to make labeling and advertising claims regarding superiority or comparability, and our failure to collect head-to-head data may limit the types of claims we may make for our product candidates, if approved.

We may be subject to risk as a result of international manufacturing operations.

Certain of our product candidates may be manufactured, warehoused and/or tested at third-party facilities located in the U.S., Canada, New Zealand, and India, in addition to our facility in Israel, and therefore our operations are subject to risks inherent in doing business internationally. Such risks include the adverse effects on operations from corruption, war, public health crises, such as pandemics and epidemics, international terrorism, civil disturbances, political instability, governmental activities, deprivation of contract and property rights and currency valuation changes. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations.

The third-party logistics providers we will rely on may be unable to warehouse, label and/or supply our products in a timely and efficient manner, which can adversely affect our relationship with our customers..

Our ability to timely supply our products will be dependent on the uninterrupted and efficient operations of our third-party logistics, warehousing, labeling and packaging providers in La Vergne, Tennessee. If for any reason such providers fail to securely warehouse, label and supply our products, our relationships with our customers could be disrupted, which could adversely our business, financial condition or results of operations. Further, we will rely on commercial transportation for the distribution of our products which may be negatively impacted by natural disasters or security threats.

The ongoing COVID-19 pandemic may adversely affect our business, revenues, results of operations and financial condition.

Outbreaks of epidemic, pandemic or contagious diseases, such as SARS-CoV-2, may adversely affect our business, financial condition and results of operations. The global spread of the SARS-CoV-2 has resulted in government-imposed quarantines, travel restrictions, stay-at-home-orders and other public health safety measures in the United States, Israel, and other affected countries. These precautionary measures have and may continue to have an adverse effect on the global markets and its economy and demand for pharmaceutical products, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. In addition, conducting clinical trials during the COVID-19 pandemic requires the adoption of special procedures and in general slows down participant enrollment. The spread of this pandemic has caused significant volatility and uncertainty in U.S. and international markets and has resulted in increased risks to our operations.

Specifically, we are monitoring several risks that have or may affect our business related to this pandemic. For example, the COVID-19 pandemic has reduced the revenue from sales of a generic product from the collaboration with Perrigo due to travel restrictions and stay-at-home-orders. In addition, the COVID-19 pandemic has adversely affected and may continue to adversely affect our ability to manufacture Twyneo® and Epsolay® at the times we planned to do so. An extended duration of this pandemic could adversely affect the ability of the FDA to conduct a pre-approval inspection and possibly delay the timely approval of Twyneo® and/or Epsolay®. Moreover, quarantines, shelter-in-place and similar government orders, travel restrictions, stay-at-home-orders and health impacts of the COVID-19 pandemic have and in the future could impact the availability or productivity of personnel at third-party manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in disruptions in our supply chain.

As COVID-19 continues to spread in the United States and elsewhere, we may experience disruptions that could severely impact our preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy and safety data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations, or CROs, and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

Additionally, because our corporate headquarters are in Israel while our CMOs are located in other countries, there is additional risk in our ability as a company to control, assist and supervise such CMOs activities.

The COVID-19 outbreak continues to rapidly evolve, and its ultimate scope, duration and effects are unknown. The extent of the impact of the disruptions to our business, including commercial sales and clinical development, as a result of the pandemic, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. The continuation of the COVID-19 pandemic could materially disrupt our business and operations, hamper our ability to raise additional funds or sell or securities, continue to slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations.

If in the future we acquire or in-license technologies or additional product candidates, we may incur various costs, may have integration difficulties and may experience other risks that could harm our business and results of operations.

In the future, we may acquire or in-license additional product candidates and technologies. Any product candidate or technologies we in-license or acquire will likely require additional development efforts prior to commercial sale, including extensive pre-clinical studies, clinical trials, or both, and approval by the FDA or other applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate, or product developed based on in-licensed technology, will not be shown to be sufficiently safe and effective for approval by regulatory authorities. If intellectual property related to product candidates or technologies we in-license or our own know-how is not adequate, we may not be able to commercialize the affected product candidates even after expending resources on their development. In addition, we may not be able to manufacture economically or successfully commercialize any product candidate that we develop based on acquired or in-licensed technology that is granted regulatory approval, and such product candidates may not gain wide acceptance or be competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed.

The time necessary to develop generic API or drug products may adversely affect whether, and the extent to which, we receive a return on our capital.

The development process, including drug formulation where applicable, testing, and FDA review and approval for generic drug products often takes many years. This process requires that we expend considerable capital to pursue activities that do not yield an immediate or near-term return. Also, because of the significant time necessary to develop a generic product, the actual market for a generic product at the time it is available for sale may be significantly less than the originally projected market for the generic product. If this were to occur, our potential return on our investment in developing the generic product, if approved for marketing by the FDA, would be adversely affected and we may never receive a return on our investment in the generic product. It is also possible for the manufacturer of the brand-name product for which we are developing a generic drug to obtain approvals from the FDA to switch the brand-name drug from the prescription market to the over-the-counter, or OTC market. If this were to occur, we would be prohibited from marketing our generic product other than as an OTC drug, in which case our revenues could be significantly impacted.

Risks Related to Regulatory Matters

Healthcare reform in the United States may harm our future business.

Healthcare costs in the United States have risen significantly over the past decade. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was signed into law, which, among other things, required most individuals to have health insurance, established new regulations on health plans, created insurance exchanges and imposed new requirements and changes in reimbursement or funding for healthcare providers, device manufacturers and pharmaceutical companies. The Affordable Care Act also included a number of changes which may impact our product candidates:

- revisions to the Medicaid rebate program by: (a) increasing the rebate percentage for branded drugs to 23.1% of the average manufacturer price, or AMP, with limited exceptions, (b) increasing the rebate for outpatient generic, multiple source drugs dispensed to 13% of AMP; (c) changing the definition of AMP; and (d) extending the Medicaid rebate program to Medicaid managed care plans, with limited exceptions;

- the imposition of annual fees upon manufacturers or importers of branded prescription drugs, which fees will be in amounts determined by the Secretary of Treasury based upon market share and other data;

- providing a discount on brand-name prescriptions filled in the Medicare Part D coverage gap as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- imposing increased penalties for the violation of fraud and abuse laws and funding for anti-fraud activities; and

- expanding the definition of "covered entities" that purchase certain outpatient drugs in the 340B Drug Pricing Program of Section 340B of the Public Health Service Act.

While the Affordable Care Act may have increased the number of patients who have insurance coverage for our product candidates, if approved by the FDA, the Affordable Care Act also restructured payments to Medicare managed care plans and reduced reimbursement to many institutional providers. Accordingly, the change in the Medicaid rebate levels, the additional fees imposed upon us if we market branded drugs, other compliance obligations, and the reduced reimbursement levels to institutional providers may result in a loss of revenue and could adversely affect our business. In addition, the Affordable Care Act contemplates the promulgation of significant future regulatory action which may also further affect our business.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Cuts and Jobs Act, or the Tax Act, was enacted, which, among other things, removed penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the Affordable Care Act will impact the law, our business or financial condition.

Moreover, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressure.

Risks Related to Commercialization of Our Product Candidates

Our continued growth is dependent on our ability to successfully develop and commercialize new product candidates in a timely manner.

Our financial results depend upon our ability to introduce and commercialize additional product candidates in a timely manner. Generally, revenue from new products is highest immediately following launch and then declines over time, as new competitors enter the market. Furthermore, the greatest revenue is generally experienced by the company that is able to bring its product to the market first. Our growth is therefore dependent upon our ability to successfully introduce and commercialize new product candidates.

The FDA and other regulatory authorities may not approve our product applications at all or in a timely fashion for our product candidates under development. Additionally, we may not successfully complete our development efforts for other reasons, such as poor results in clinical trials or a lack of funding to complete the required trials. Even if the FDA approves our product candidates, we may not be able to market them successfully or profitably. Our future results of operations will depend significantly upon our ability to timely develop, receive FDA approval for, and market new pharmaceutical product candidates or otherwise develop new product candidates or acquire the rights to other products.

Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration and expansion.

The facial aesthetic market in general, and the market for acne and rosacea treatments in particular, are highly competitive and dynamic, and characterized by rapid and substantial technological development and product innovations. These markets are also characterized by competitors obtaining patents to protect what they consider to be their intellectual property. We anticipate that Twyneo® and Epsolay®, if approved, will face significant competition from other approved products, including topical drugs, topical anti-acne drugs such as Acanya, Ziana, Epiduo, Epiduo Forte, Benzaclin, Aczone, Onexton, Differin, Arazlo, Aklief and Amzeeq, and topical drugs for the treatment of rosacea such as Metrogel, Finacea, Soolantra, Finacea and Zilxi, oral drugs such as Solodyn, Doryx, Dynacin, Oracea and Minocin. If approved, Twyneo® and Epsolay® may also compete with non-prescription anti-acne products, as well as unapproved and off-label treatments. In addition, if approved, Twyneo® may compete with drug products utilizing other technologies that can separate two drug substances, such as dual chamber tubes, dual pouches or dual sachets. To compete successfully in the facial aesthetic market, we will have to demonstrate that our product is safe and effective for the respective treatment and has advantages over existing therapies. Competing in the facial aesthetic market could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements in certain jurisdictions outside the United States, there are many more acne products and procedures available for use in those international markets than are approved for use in the United States. There are also fewer limitations on the claims that our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we may face more competition in markets outside of the United States.

In addition, even if we are able to commercialize our product candidates, we may not be able to price them competitively with the current standards of care or other competing products for their respective indications or their price may drop considerably due to factors outside our control. If this happens or the price of materials and the cost to manufacture our product candidates increases dramatically, our ability to continue to operate our business would be materially harmed and we may be unable to commercialize our product candidates successfully.

We believe that our principal competitors are Bausch Health Companies, Inc., Galderma S.A., Almirall, LLC, LEO Pharma A/S, VYNE Therapeutics Inc. (formerly Menlo Therapeutics Inc.), Dermavant Sciences and Mylan N.V. These competitors are large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition, and more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities.

In addition to the above listed competitors, some of our product candidates might face internal competition with other product candidates of ours, for the same markets and patient populations, due to overlap in the required treatment and/or symptoms. For example, Epsolay® may compete with ivermectin cream, 1%, for treatment of rosacea.

With respect to generic pharmaceutical products, the FDA approval process often results in the FDA granting final approval to a number of ANDAs for a given product at the time a relevant patent for a corresponding branded product or other regulatory and/or market exclusivity expires. For example, on December 30, 2016, Actavis Ltd. submitted an ANDA for ivermectin, 1%, cream, and, as a potential “first applicant,” may qualify for 180-day generic marketing exclusivity. The ANDA of Actavis Ltd. was tentatively approved, and as a result the FDA may be prohibited from approving any other generic ivermectin, 1%, cream product for 180 days from the date of the Actavis Ltd. ANDA approval, such that we would not be able to commercialize this product until after Actavis Ltd.’s exclusivity period expires. Thus, we expect, in accordance with the standard practices in the industry, to face immediate competition when we introduce a generic product into the market. As competition from other manufacturers intensifies, selling prices and gross profit margins often decline. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product that we develop is generally related to the number of competitors in that product’s market and the timing of that product’s regulatory approval and launch, in relation to competing approvals and launches. Additionally, ANDA approvals often continue to be granted for a given product subsequent to the initial launch of the first generic product. These circumstances generally result in significantly lower prices and reduced margins for generic products compared to brand products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

In addition to the competition we face from other generic manufacturers, we face competition from brand-name manufacturers related to our generic product candidates. Branded pharmaceutical companies may sell their branded products as "authorized generics," where an approved brand name drug is marketed, either by the brand name drug company or by another company with the brand company's permission, as a generic product without the brand name on its label, and potentially sold at a lower price than the brand name drug. Further, branded pharmaceutical companies may seek to delay FDA approval of our ANDAs or reduce generic competition by, for example, obtaining new patents on drugs whose original patent protection is about to expire, filing patent infringement suits that could delay FDA approval of generics, developing new versions of their products to obtain FDA market exclusivity, filing citizen petitions contesting FDA approvals of generics such as on alleged health and safety grounds, developing "next generation" versions of products that reduce demand for the generic versions we are developing, changing product claims and labeling, and seeking approval to market as OTC branded products.

Moreover, competitors may, upon the approval of an NDA, or an NDA supplement, obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Such exclusivity may prevent the FDA from approving one or more of our product candidates that are being developed, and for which we would seek the FDA's approval under the 505(b)(2) regulatory pathway, if we were to seek approval for the same conditions of approval as that protected by the three-year period of exclusivity. Recent litigation against the FDA has affirmed the FDA's interpretation of the scope of three-year exclusivity as preventing the approval of a 505(b)(2) NDA for the same change to a previously approved drug, regardless of whether or not the 505(b)(2) applicant relies on the competitor's product as a listed drug in its 505(b)(2) application. Exclusivity determinations are highly fact-dependent and are made by the FDA on a case-by-case basis at the end of the review period for a 505(b)(2) NDA. As such, we may not know until very late in the FDA's review of our 505(b)(2) product candidates whether or not approval may be delayed because of a competitor's period of three-year exclusivity.

Other pharmaceutical companies may develop competing products for acne, rosacea and other indications we are pursuing and enter the market ahead of us.

Other pharmaceutical companies are engaged in developing, patenting, manufacturing and marketing healthcare products that compete with those that we are developing. These potential competitors include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities.

Several of these potential competitors are privately-owned companies that are not bound by public disclosure requirements and closely guard their development plans, marketing strategies and other trade secrets. Publicly-traded pharmaceutical companies are also able to maintain a certain degree of confidentiality over their pipeline developments and other sensitive information. As a result, we do not know whether these potential competitors are already developing, or plan to develop other topical treatments for acne, rosacea or other indications we are pursuing, and we will likely be unable to ascertain whether such activities are underway in the future. These potential competitors may therefore introduce competing products without our prior knowledge and without our ability to take preemptive measures in anticipation of their commercial launch.

Furthermore, such potential competitors may enter the market before us, and their products may be designed to circumvent our granted patents and pending patent applications. They may also challenge, narrow or invalidate our granted patents or our patent applications, and such patents and patent applications may fail to provide adequate protection for our product candidates.

We currently have limited marketing capabilities. If we are unable to establish adequate sales and marketing capabilities through third parties, we may be required to establish sales and marketing capabilities on our own, or we may be unable to successfully commercialize Twyneo®, Epsolay® or any other of our other product candidates, if approved, or generate product revenues. In addition, establishing our own sales and marketing capabilities would significantly increase our expenses and require us to raise additional capital sooner that an anticipated.

We currently have limited marketing capabilities. In preparation for commercial launch of our proprietary products, we have opened a U.S. headquarters in Whippany, New Jersey. To commercialize Twyneo®, Epsolay® or any other of our other product candidates, if approved, in the United States and other jurisdictions, we expect to establish adequate sales and marketing capabilities through third parties and intend to enter into arrangements with third parties to perform these services and other non-technical services. For instance, if Twyneo® and Epsolay® receive regulatory approval from the FDA we intend to market them in the United States through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. We are in discussions with potential partners regarding the commercialization of Twyneo® and Epsolay®. If we are unable to enter into such arrangements on acceptable terms or at all, we may be required to establish sales and marketing capabilities on our own or we may be unable to successfully commercialize Twyneo®, Epsolay® or any other of our other product candidates or generate product revenues. In addition, establishing our own sales and marketing capabilities would significantly increase our expenses and require us to raise additional capital sooner that an anticipated.

If we are not successful in establishing sufficient sales and marketing capabilities to commercialize Twyneo®, Epsolay® or any of our other product candidates, through collaborations with one or more third parties, our revenues will suffer and we will incur significant additional losses.

Third-party payor coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell them profitably.

Sales of our product candidates, if approved, will depend, in part, on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Sales of our product candidates, and any future product candidates, will therefore depend substantially on the extent to which the costs of our product candidates, and any future product candidates, will be paid by third-party payors. Additionally, the market for our product candidates, and any future product candidates, will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our product candidates to each payor separately and will be a time-consuming process.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls and transparency requirements, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our revenue and operating results. If these third-party payors do not consider our product candidates to be cost-effective compared to other therapies, they may not cover our product candidates once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our product candidates on a profitable basis. Decreases in third-party reimbursement for our product candidates once approved or a decision by a third-party payor to not cover our product candidates could reduce or eliminate utilization of our product candidates and have an adverse effect on our sales, results of operations and financial condition. In addition, state and federal healthcare reform measures have been and may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates once approved or additional pricing pressures.

Outside the United States, sales of any approved products are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products, if any. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties .

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to certain payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Covered manufacturers are required to submit reports to the government by the 90th day of each calendar year;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or that require the reporting of pricing information and marketing expenditures; and state laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation; and

- similar healthcare laws and regulations in the European Union and other non-U.S. jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU (including health data) and the United Kingdom until the end of the transition period on 31 December 2020 provided for in the Withdrawal Agreement between the EU and the U.K.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The illegal distribution and sale by third parties of counterfeit versions of our product candidates or of stolen products could have a negative impact on our reputation and a material adverse effect on our business, results of operations and financial condition.

Third parties could illegally distribute and sell counterfeit versions of our product candidates, which do not meet the rigorous manufacturing and testing standards that our product candidates undergo. Counterfeit products are frequently unsafe or ineffective and can be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient or no active pharmaceutical ingredient at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs similar to our product candidates or increased levels of counterfeiting such products could materially affect physician and patient confidence in our authentic product candidates. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to our authentic product candidates. In addition, thefts of our inventory at warehouses, plant or while in-transit, which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation and our business.

Public loss of confidence in the integrity of our pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial position and results of operations.

Risks Related to Dependence on Third Parties

Any collaborative arrangements that we have or may establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. We do not control third parties with whom we have or may have collaborative arrangements, and we will rely on them to achieve results which may be significant to us. In addition, any current or future collaborative arrangements may place the development and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We are currently party to collaborative arrangements with respect to the development, manufacture, study and commercialization of certain of our product candidates with Perrigo. In addition, if Twyneo® and Epsolay® receive regulatory approval from the FDA, we intend to market them in the United States through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. We are in discussions with potential partners regarding the commercialization of Twyneo® and Epsolay®. Any current or future potential collaborative arrangements may require us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory, intellectual property and sales and marketing. We cannot and will not control these third parties, but we may rely on them to achieve results, which may be significant to us. Relying upon collaborative arrangements to develop and commercialize our product candidates subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our product candidates;

- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our current or future collaborators may fail to comply with local or any foreign health authorities' laws and regulations, and as a result, the receipt of a site manufacturing, export or import license may be delayed or withheld for an undefined period;
- our current or future collaborators may experience financial difficulties or changes in business focus;
- our current or future collaborators' partners may fail to secure adequate commercial supplies of our product candidates upon marketing approval, if at all;
- our current or future collaborators' partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product developed either independently or in collaboration with others, including our competitors;
- our current or future collaborators may utilize our proprietary information in a way that could expose us to competitive harm; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our product candidates.

In addition, if disputes arise between us and our collaborators, it could result in the delay or termination of the development, manufacturing or commercialization of our product candidates, lead to protracted and costly legal proceedings, or cause collaborators to act in their own interest, which may not be in our interest. As a result, there can be no assurance that the collaborative arrangements that we have entered into, or may enter into in the future, will achieve their intended goals.

If any of these scenarios materialize, they could have an adverse effect on our business, financial condition or results of operations.

We also may have other product candidates where it is desirable or essential to enter into agreements with a collaborator who has greater financial resources or different expertise than us, but for which we are unable to find an appropriate collaborator or are unable to do so on favorable terms. If we fail to enter into such collaborative agreements on favorable terms, it could materially delay or impair our ability to develop and commercialize our product candidates and increase the costs of development and commercialization of such product candidates.

We currently contract with third-party manufacturers and suppliers for certain compounds and components necessary to produce our product candidates for clinical trials and expect to continue to do so to support commercial scale production if any of our product candidates is approved. This increases the risk that if any of our product candidates is approved, we may not have access to sufficient quantities or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third parties for the manufacture and supply of certain compounds and components necessary to produce our product candidates for our clinical trials, including API's such as benzoyl peroxide and tretinoin and other active ingredients and excipients used in the formulation of our various product candidates, as well as primary and secondary packaging and labeling materials. We lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale, and we expect to continue to rely on third parties to support our commercial requirements if any of our product candidates is approved for marketing by the FDA or other foreign regulatory authorities.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Reliance on third-party manufacturers and suppliers entails a number of risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing or supply agreement by the third party, the possibility that the supply is inadequate or delayed, the risk that the third party may enter the field and seek to compete and may no longer be willing to continue supplying, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. If any of these risks transpire, we may be unable to timely retain an alternate manufacturer or suppliers on acceptable terms and with sufficient quality standards and production capacity, which may disrupt and delay our clinical trials or the manufacture and commercial sale of our product candidates, if approved.

Our failure or the failure of our third-party manufacturers and suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates that we may develop. Any failure or refusal to supply or any interruption in supply of the components for any of our product candidates could delay, prevent or impair our clinical development or commercialization efforts.

We rely on third parties and consultants to assist us in conducting our clinical trials. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently perform all aspects of our anticipated pre-clinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties to assist us in conducting our clinical trials and studies for our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs.

In addition, the execution of pre-clinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, require coordination among these various third parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another, which may prove difficult to achieve. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. Our agreement with these third parties may inevitably enable them to terminate such agreements upon reasonable prior written notice under certain circumstances.

Although we rely on these third parties to conduct certain aspects of our clinical trials and other studies and clinical trials, we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. Moreover, the FDA and foreign regulatory authorities require us to comply with GCPs, which are the regulations and standards for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We also rely on our consultants to assist us in the execution, including data collection and analysis of our clinical trials. If we or any of our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If the third parties or consultants that assist us in conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, regulatory requirements or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for the product candidates being tested in such trials, and will not be able to, or may be delayed in our efforts to, successfully commercialize these product candidates.

The manufacture of pharmaceutical products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any difficulties, our ability to provide product candidates for clinical trials or our product candidates to patients, once approved, and the development or commercialization of our product candidates could be delayed or stopped.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates will not occur in the future. Additionally, we and our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we or our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the initiation or completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our product candidates and could have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Our Intellectual Property

We depend on our intellectual property, and our future success is dependent on our ability to protect our intellectual property and not infringe on the rights of others.

Our success depends, in part, on our ability to obtain patent protection for our product candidates, maintain the confidentiality of our trade secrets and know how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights. We try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to our product candidates, inventions and improvements that may be important to the continuing development of our product candidates. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. In addition, we cannot assure you that:

- any of our future processes or product candidates will be patentable;
- our processes or product candidates will not infringe upon the patents of third parties; or
- we will have the resources to defend against charges of patent infringement or other violation or misappropriation of intellectual property by third parties or to protect our own intellectual property rights against infringement, misappropriation or violation by third parties.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned by or licensed to us). Our issued patents may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop formulations, processes and technologies or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not be of sufficient scope to provide us with meaningful protection. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford relatively limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and the European Union. Therefore, we cannot assure you that the patents issued, if any, as a result of our foreign patent applications will have the same scope of coverage as our U.S. patents. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

After the completion of development and registration of our patents, third parties may still act to manufacture and/or market products in infringement of our patent protected rights, and we may not have adequate resources to enforce our patents. Any such manufacture and/or market of products in infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our product candidates, thereby reducing our anticipated cash flows and profits, if any.

In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our product candidates, any patents that protect our product candidates may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of competing products into the market and a subsequent decline in market share and profits.

We have granted, and may in the future grant, to third parties licenses to use our intellectual property. Generally, these licenses have granted rights to commercialize products outside the pharmaceutical field or to technology we no longer use or to otherwise use our intellectual property for a limited purpose outside the scope of our business interests. For example, in August 2013 we entered into an assignment agreement with Medicis Pharmaceutical Corporation ("Medicis"), according to which Medicis assigned to us its entire interest in one of the patents upon which we rely for our product candidate Twyneo® for the treatment of acne . As part of this assignment agreement, we granted to Medicis a non-exclusive, transferable, sub-licensable, royalty-free, perpetual, license to practice the inventions claimed under the patent.

However, our business interests may change or our licensees may disagree with the scope of our license grant. In such cases, such licensing arrangements may result in the development, manufacturing, marketing and sale by our licensees of products substantially similar to our products, causing us to face increased competition, which could reduce our market share and significantly harm our business, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

In addition to filing patent applications, we generally try to protect our trade secrets, know-how, technology and other proprietary information by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our development and/or commercialization partners, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, we cannot assure you that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know-how or other proprietary information because these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable, and a court may determine that the right belongs to a third party.

Legal proceedings or third-party claims of intellectual property infringement and other challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our product candidates.

The development, manufacture, use, offer for sale, sale or importation of our product candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Therefore, there is a risk that we could adopt a technology without knowledge of a pending patent application, which technology would infringe a third-party patent once that patent is issued. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Any claims of patent infringement, even those without merit, could: be expensive and time consuming to defend; cause us to cease making, licensing or using products that incorporate the challenged intellectual property; require us to redesign, reengineer or rebrand our product candidates, if feasible; cause us to stop from engaging in normal operations and activities, including developing and marketing product candidates; and divert management's attention and resources. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our product candidates in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly.

In addition, because of our developmental stage, claims that our product candidates infringe on the patent rights of others are more likely to be asserted after commencement of commercial sales incorporating our technology.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our product candidates. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Patent law outside the United States may be different than in the United States. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all. A failure to obtain sufficient intellectual property protection in any foreign country could materially and adversely affect our business, results of operations and future prospects. Moreover, we may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and divert management's resources and attention. Additionally, due to uncertainty in patent protection law, we have not filed applications in many countries where significant markets exist.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

In the United States, we have filed and may in the future file NDAs for our product candidates for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. To date we have filed two NDAs for our products candidates under this section. In October 2020, we submitted an NDA for marketing approval for Twyneo, and in June 2020, we submitted an NDA for marketing approval for Epsolay. Both of these NDA's have been accepted for filing by the FDA.

A 505(b)(2) application enables us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA. Applicants must also notify the holder of the approved NDA for any product referenced in the 505(b)(2) application, along with all patent owners, regarding submission of a paragraph IV certification with respect to applicable patents listed in the Orange Book.

Under the Hatch-Waxman Act, the NDA holder and patent owner(s) may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) application within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical trials or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Companies that produce branded reference drugs routinely bring litigation against ANDA or 505(b)(2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505(b)(2) applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products.

Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved product candidates, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505(b)(2), products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505(b)(2), products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our ordinary shares to decline.

Risks Related to Our Operations in Israel

Our headquarters, manufacturing and other significant operations are located in Israel and, therefore, our business and operations may be adversely affected by political, economic and military conditions in Israel.

Our business and operations will be directly influenced by the political, economic and military conditions affecting Israel at any given time. A change in the security and political situation in Israel and in the economy could impede the raising of the funds required to finance our research and development plans and to create joint ventures with third parties and could otherwise have a material adverse effect on our business, operating results and financial condition. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, including Hezbollah in Lebanon (and Syria) and Hamas in the Gaza Strip, both of which involved missile strikes in various parts of Israel causing the disruption of economic activities. Our principal offices are located within the range of rockets that could be fired from Lebanon, Syria or the Gaza Strip into Israel. In addition, Israel faces many threats from more distant neighbors, in particular, Iran. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could result in damage to our facilities and likewise have a material adverse effect on our business, operating results and financial condition.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in the region continue or intensify. Such restrictions may seriously limit our ability to sell our product candidates to customers in those countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturns in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our revenues to decrease and adversely affect the share price of publicly traded companies having operations in Israel, such as us. Similarly, Israeli corporations are limited in conducting business with entities from several countries.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there can be no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition and results of operations.

Exchange rate fluctuations between the U.S. dollar, the New Israeli Shekel and other foreign currencies, may negatively affect our future revenues.

In the future, we expect that a substantial portion of our revenues will be generated in U.S. dollars, Euros and other foreign currencies, although we currently incur a significant portion of our expenses in currencies other than U.S. dollars, and mainly in NIS. Our financial records are maintained, and will be maintained, in U.S. dollars, which is our functional currency. As a result, our financial results may be affected by fluctuations in the exchange rates of currencies in the countries in which our prospective product candidates may be sold.

Our operations may be affected by negative labor conditions in Israel.

Strikes and work-stoppages occur relatively frequently in Israel. If Israeli trade unions threaten additional strikes or work-stoppages and such strikes or work-stoppages occur, those may, if prolonged, have a material adverse effect on the Israeli economy and on our business, including our ability to deliver products to our customers and to receive raw materials from our suppliers in a timely manner.

Our operations could be disrupted as a result of the obligation of our personnel to perform military service.

Most of our executive officers and key employees reside in Israel and, although most of them are no longer required to perform reserve duty, some may be required to perform annual military reserve duty and may be called for active duty under emergency circumstances at any time. Our operations could be disrupted by the absence for a significant period of time of one or more of these officers or key employees due to military service. Any such disruption could adversely affect our business, results of operations and financial condition.

The termination or reduction of tax and other incentives that the Israeli Government provides to domestic companies may increase the costs involved in operating a company in Israel.

The Israeli government currently provides tax and capital investment incentives to domestic companies, as well as grant and loan programs relating to research and development and marketing and export activities. In recent years, the Israeli Government has reduced the benefits available under these programs and the Israeli Governmental authorities have indicated that the government may in the future further reduce or eliminate the benefits of those programs. We may take advantage of these benefits and programs in the future; however, there is no assurance that such benefits and programs would continue to be available in the future to us. If such benefits and programs were terminated or further reduced, it could have an adverse effect on our business, operating results and financial condition.

The Israeli government grants that we have received require us to meet several conditions and may restrict our ability to manufacture some of our product candidates and transfer relevant know-how outside of Israel and require us to satisfy specified conditions.

We have received royalty-bearing grants from the government of Israel through the National Authority for Technological Innovation, or the Israel Innovation Authority, also known as the IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS), for the financing of a portion of our research and development expenditures in Israel. These IIA grants relate to a peripheral line of product candidates which forms a negligible part of our activities. We are required to pay the IIA royalties from the revenues generated from the sale of products (and related services) or services developed (in all or in part) according to, or as a result of, a research and development program funded by the IIA (at rates which are determined under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, or the Innovation Law, and related rules and regulations), up to the aggregate amount of the total grants received by the IIA, plus annual interest at an annual rate based on LIBOR. When know-how is developed using IIA grants, the Innovation Law, the IIA's rules and guidelines as well as the terms of these grants, restrict our ability to manufacture product candidates and transfer know-how developed as a result of the IIA's funded R&D outside of Israel. Transfer of the IIA funded know-how outside of Israel where the transferring company remains an operating Israeli entity or where the transferring company ceases to exist as an Israeli entity, requires pre-approval by the IIA, which may, at its sole discretion, grant such approval and impose certain conditions, including payment of a redemption fee calculated according to the formulas provided in the IIA's rules and guidelines, or Redemption Fee, which takes into account the consideration for such know-how paid to the transferring company in the transaction in which the know-how is transferred. The IIA's rules and guidelines establish a maximum payment of the Redemption Fee under the formulas provided in the IIA's rules and guidelines and differentiates between certain situations, as further detailed in such rules and guidelines (while in any event the Redemption Fee will not exceed six times the grants received). In addition, the product candidates may be manufactured outside of Israel by us or by another entity only if prior approval is received from the IIA (such approval is not required for the transfer of less than 10% of the manufacturing capacity in the aggregate). In addition to the obligation to receive prior approval to manufacture outside Israel, in general, a company that transfers manufacturing rights abroad will be required to pay royalties at an accelerated rate and will be required to pay increased royalties, as defined under the IIA's rules and guidelines. The total amount of the increased royalties to be repaid to the IIA shall not exceed, in the aggregate, 300% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR, depending on the manufacturing volume that is performed outside Israel less royalties already paid to the IIA.

A company also has the option of declaring in its IIA grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval following the receipt of the grant and avoiding the need to pay increased royalties to the IIA.

The IIA has published certain rules and guidelines with respect to the grant to a foreign entity of the right to use know-how that was developed using the IIA's grants, or Funded Know-How. According to these rules, the grant to a foreign entity of a right to use the Funded Know-How (which does not entirely prevent the IIA funded company from using the Funded Know-How) is subject to receipt of the IIA's prior approval. This approval is subject to payment to the IIA in accordance with the formulas stipulated in these rules.

The abovementioned rules include a mechanism with respect to the grant of a license by a company (which is part of a multinational corporation) that received grants from the IIA to its group entities to use its funded Know-How. Such license is subject to the IIA's prior approval and to the payment of 5% royalties from the income deriving from such license. Such mechanism includes certain restrictions which must be met in order to be able to enjoy such lower royalty payment.

Subject to prior consent of the IIA, we may transfer Funded Know-How to another Israeli company, provided that the acquiring company assumes all of our responsibilities toward the IIA. In addition, such transfer will not be subject to the payment of the Redemption Fee, but there will be an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation.

The restrictions under the IIA's rules and guidelines continue to apply even after payment of the full amount of royalties payable pursuant to the grants. In addition, the government of the State of Israel may from time to time audit sales of products which it claims incorporate Funded Know-How and this may lead to additional royalties being payable on additional product candidates. Following an audit conducted by the IIA, the IIA confirmed to us that products based on encapsulation technology of solid material are exempt from royalty payment obligations to the IIA. Our product candidates Twyneo® and Epsolay® fall within the category of products based on encapsulation technology of solid material. However, there can be no guarantee that the IIA will not in the future attempt to claim royalties with respect to these products, or that future products will not be subject to royalties.

These restrictions may impair our ability to enter into agreements for Funded Know-How product candidates or technologies without the approval of the IIA. We cannot be certain that any approval of the IIA will be obtained on terms that are acceptable to us, or at all. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of Funded Know-How pursuant to a merger or similar transaction, or in the event we undertake a transaction involving the licensing of Funded Know-How, the consideration available to our shareholders may be reduced by the amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the IIA's rules and guidelines and the Innovation Law may subject us to financial sanctions, to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings.

In August 2015, an amendment to the Innovation Law was enacted, or Amendment No. 7, which came into effect on January 1, 2016. Since Amendment No. 7 has entered into force, the IIA was appointed to act as the entity which is responsible for the activity which was previously under the OCS' responsibility. The IIA was granted wide freedom of action, and among other things, the authority to amend the requirements and restrictions which were specified in the Innovation Law before Amendment No. 7 became effective with respect to the ownership of Funded Know-How (including with respect to the restrictions on transfer of the Funded Know-How and manufacturing activities outside of Israel) as well as with respect to royalty payment obligations which apply to companies that received grants from the IIA. The IIA published rules for the most part adopted the principal provisions and restrictions specified in the Innovation Law prior to the effectiveness of Amendment No. 7. See "Item 4. Information on the Company – B. Business Overview — Government Regulation — *IIA*."

Enforcing a U.S. judgment against us and our current executive officers and directors, or asserting U.S. securities law claims in Israel, may be difficult.

We are incorporated in Israel. All of our current executive officers and directors reside in Israel (other than two of our directors and one of our executive officers who reside in the United States) and most of our assets reside outside of the United States. Therefore, a judgment obtained against us or any of these persons in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It may also be difficult to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel.

Even if an Israeli court agrees to hear such a claim, it may determine that Israeli, and not U.S., law is applicable to the claim. Under Israeli law, if U.S. law is found to be applicable to such a claim, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing these matters.

Provisions of our amended and restated articles of association and Israeli law and tax considerations may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and negatively affect the price of our ordinary shares.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and therefore depress the price of our ordinary shares.

Our amended and restated articles of association provide that our directors (other than external directors) are elected on a staggered basis, such that a potential acquirer cannot readily replace our entire board of directors at a single annual general shareholder meeting.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We have entered into assignment of invention agreements with our employees pursuant to which such individuals agree to assign to us all rights to any inventions created during and as a result of their employment or engagement with us. A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patents Law, 5727-1967, or the Patents Law, inventions conceived by an employee during the scope of his or her employment with a company and as a result thereof are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patents Law also provides that if there is no agreement between an employer and an employee with respect to the employee's right to receive compensation for such "service inventions," the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patents Law, shall determine whether the employee is entitled to remuneration for service inventions developed by such employee and the scope and conditions for such remuneration. Although our employees have agreed to assign to us service invention rights and have waived their right to receive remuneration for their service inventions, as a result of uncertainty under Israeli law with respect to the efficacy of waivers of service invention rights, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business.

The government tax benefits that we currently are entitled to receive require us to meet several conditions and may be terminated or reduced in the future.

Some of our operations in Israel may entitle us to certain tax benefits under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, once we begin to produce revenues. If we do not meet the requirements for maintaining these benefits, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is set at 23% in 2020. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we have already received, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current "Benefited Enterprise" is entitled to may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefits programs. See "Item 10. Additional Information — Israeli Tax Considerations and Government Programs — Tax Benefits Under the 2011 Amendment" for additional information concerning these tax benefits.

Your rights and responsibilities as a shareholder will be governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S. corporations. For example, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of these duties or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

Risks Related to Employee Matters

If we are not able to retain our key management, or attract and retain qualified scientific, technical and business personnel, our ability to implement our business plan may be adversely affected.

Our success largely depends on the skill, experience and effort of our senior management. The loss of the service of any of these persons, including the chairman of our board of directors, Mr. Moshe Arkin, and our chief executive officer, Dr. Alon Seri-Levy, would likely result in a significant loss in the knowledge and experience that we possess and could significantly delay or prevent successful product development and other business objectives. There is intense competition from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, seeking to employ qualified individuals in the technical fields in which we operate, and we may not be able to attract and retain the qualified personnel necessary for the successful development and commercialization of our product candidates.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

Our employment agreements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work. For example, Israeli courts have required employers seeking to enforce covenants not to compete to demonstrate that the competitive activities of a former employee will harm one of a limited number of material interests of the employer, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees and our competitiveness may be diminished.

Risks Related to Our Ordinary Shares

The controlling share ownership position of Arkin Dermatology will limit your ability to elect the members of our board of directors, may adversely affect our share price and will result in our non-affiliated investors having very limited, if any, influence on corporate actions.

Arkin Dermatology is currently our controlling shareholder. As of February 26, 2020, Arkin Dermatology beneficially owned approximately 62.75% of the voting power of our outstanding ordinary shares. Therefore, Arkin Dermatology has the ability to substantially influence us and exert significant control through this ownership position. For example, Arkin Dermatology is able to control elections of directors, amendments of our organizational documents, and approval of any merger, amalgamation, sale of assets or other major corporate transaction. Arkin Dermatology's interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as it continues to own a significant amount of our equity, Arkin Dermatology will continue to be able to strongly influence and significantly control our decisions.

We are a "controlled company" within the meaning of Nasdaq listing standards and, as a result, will qualify for, and intend to rely on, exemptions from certain corporate governance requirements.

As a result of the number of shares owned by Arkin Dermatology, we are a "controlled company" under the Nasdaq corporate governance rules. A "controlled company" is a company of which more than 50% of the voting power is held by an individual, group or another company. Pursuant to the "controlled company" exemption, we are not required to, and may not in the future comply with the requirement that a majority of our board of directors consist of independent directors, and we are not required to, and do not intend to comply with the requirement that we have a nominating committee composed entirely of independent directors with a written charter addressing such committee's purpose and responsibilities. A majority of our board of directors currently consists of independent directors. See "Item 16G. Corporate Governance—Controlled Company." Accordingly, you do not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Global Market.

The market price of our ordinary shares could be negatively affected by future sales of our ordinary shares.

As of February 26, 2021, there were 23,000,782 ordinary shares outstanding. Future sales by us or our shareholders of a substantial number of our ordinary shares in the public market, or the perception that these sales might occur, could cause the market price of our ordinary shares to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities. Of our issued and outstanding shares, all of the ordinary shares listed for trading are freely transferable, except for any shares held by our "affiliates," as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, we have filed a registration statement on Form S-8 with the Securities and Exchange Commission, or the SEC, covering all of the ordinary shares issuable under our 2014 Share Incentive Plan, and we intend to filed one or more registration statements on Form S-8 covering all of the ordinary shares issuable under any other equity incentive plans that we may adopt, and such shares will be freely transferable, except for any shares held by "affiliates," as such term is defined in Rule 144 under the Securities Act. The market price of our ordinary shares may drop significantly when the restrictions on resale by our existing shareholders lapse and these shareholders are able to sell our ordinary shares into the market.

Upon the filing of the registration statements and following the expiration of the lock-up restrictions described above, the number of ordinary shares that are potentially available for sale in the open market will increase materially, which could make it harder for the value of our ordinary shares to appreciate unless there is a corresponding increase in demand for our ordinary shares. This increase in available shares could result in the value of your investment in our ordinary shares decreasing.

In addition, a sale by us of additional ordinary shares or similar securities in order to raise capital might have a similar negative impact on the share price of our ordinary shares. A decline in the price of our ordinary shares might impede our ability to raise capital through the issuance of additional ordinary shares or other equity securities and may cause you to lose part or all of your investment in our ordinary shares.

Arkin Dermatology, our controlling shareholder, as holder of 14,432,266 of our ordinary shares as of February 26, 2021, is entitled to require that we register under the Securities Act the resale of these shares into the public markets. All shares sold pursuant to an offering covered by such registration statement will be freely transferable. See "Item 7.B — Related Party Transactions — Registration Rights Agreement".

We have broad discretion as to the use of the net proceeds from our public offerings and may not use them effectively.

We intend to use the remaining net proceeds from our public offerings in August 2019 and February 2020 (and concurrent private placement with our controlling shareholder, Arkin Dermatology) to fund pre-commercialization and launch activities for Epsolay and Twyneo and fund development activities for our other branded product candidates. The remaining proceeds will be used for other research and development activities, including the development of our generic product candidates, as well as for working capital and general corporate purposes. However, our management has broad discretion in the application of the net proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from our initial public offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from our initial public offering in a manner that does not produce income.

We do not intend to pay dividends on our ordinary shares for at least the next several years.

We do not anticipate paying any cash dividends on our ordinary shares for at least the next several years. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our ordinary shares will be the investors' sole source of gain for at least the next several years. In addition, Israeli law limits our ability to declare and pay dividends and may subject us to certain Israeli taxes. For more information, see "Item 8. Financial Information – A. Financial Statements and Other Financial Information – Dividend Policy."

As a foreign private issuer whose shares are listed on The Nasdaq Global Market, we intend to follow certain home country corporate governance practices instead of certain Nasdaq requirements.

As a foreign private issuer whose shares will be listed on The Nasdaq Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the rules of The Nasdaq Global Market. Pursuant to the "foreign private issuer exemption":

- we established a quorum requirement such that the quorum for any meeting of shareholders is two or more shareholders holding at least 33 1⁄3% of our voting rights, which complies with Nasdaq requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of shareholders, instead of 33 1⁄3% of our voting rights;

- we also intend to adopt and approve material changes to equity incentive plans in accordance with Israeli Companies Law, 5759-1999, or with the Companies Law, which does not impose a requirement of shareholder approval for such actions. In addition, we intend to follow Israeli corporate governance practice in lieu of Nasdaq Marketplace Rule 5635(c), which requires shareholder approval prior to an issuance of securities in connection with equity-based compensation of officers, directors, employees or consultants;

- as opposed to making periodic reports to shareholders in the manner specified by the Nasdaq corporate governance rules, the Companies Law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. We will only mail such reports to shareholders upon request; and

- we will follow Israeli corporate governance practice instead of Nasdaq requirements to obtain shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock or assets of another company). Accordingly, our shareholders may not be afforded the same protection as provided under Nasdaq corporate governance rules.

Otherwise, we intend to comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Global Market. However, we may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Global Market may provide less protection than is accorded to investors of domestic issuers. See "Item 16G. Corporate Governance – Controlled Company".

In addition, as a foreign private issuer, we are exempted from the rules and regulations under the United States Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements (including disclosures with respect to executive compensation), and our officers, directors, and principal shareholders are exempted from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our supervisory board.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not "emerging growth companies." Most of such requirements relate to disclosures that we would only be required to make if we also ceased to be a foreign private issuer in the future, for example, the requirement to hold stockholder advisory votes on executive and severance compensation and executive compensation disclosure requirements for U.S. companies. However, as a foreign private issuer, we could still be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We are exempt from such requirement for as long as we remain an emerging growth company, which may be up to five fiscal years after the date of our initial public offering. We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.07 billion; (b) December 31, 2023, the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act. We may choose to take advantage of some or all of the available exemptions. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We may be considered to be a passive foreign investment company for U.S. federal income tax purposes for the current tax year and possibly thereafter, which could result in materially adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares or warrants.

A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will be a passive foreign investment company, or PFIC, for any taxable year if either (i) at least 75% of its gross income for such year is passive income or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets) during such year is attributable to assets that produce passive income or are held for the production of passive income. Starting in the first quarter of 2019, we began generating revenue under our collaboration agreement with Perrigo for the development of the generic version of Zovirax® (acyclovir) cream, 5%. We generated $8.7 million in revenue under this agreement for our 2020 taxable year, but expect to generate substantially less in future years. Though the application of the relevant rules governing the characterization of such revenue for purposes of the PFIC income test is uncertain, we intend to take the position that, based on our involvement and management contributions throughout the development process, such revenue is non-passive for PFIC purposes. As a result, based on the current and anticipated value and composition of our income and assets, we do not expect that we will be treated as a PFIC for U.S. federal income tax purposes for our current taxable year or for foreseeable future years. However, there are substantial factual and legal ambiguities regarding the nature of the revenue and the application of the relevant PFIC rules, and thus, the determination that such revenue is non-passive is not without doubt, and alternative characterizations are possible.

A separate determination has to be made after the close of each taxable year as to whether we were a PFIC for that year. Because the value of our assets for purposes of the PFIC test will generally be determined by reference to the market price of our ordinary shares, our PFIC status may depend in part on the market price of our ordinary shares, which may fluctuate significantly. In addition, there are certain other ambiguities in applying the PFIC test to us. If we are considered a PFIC, material adverse U.S. federal income tax consequences could apply to U.S. Holders (as defined in “Item 10. Additional Information – E. Taxation – U.S. Federal Income Tax Considerations with respect to the Company”) of our ordinary shares or warrants with respect to any “excess distribution” received from us and any gain from a sale or other disposition of our ordinary shares or warrants. Please see “Item 10. Additional Information – E. Taxation – U.S. Federal Income Tax Considerations with respect to the Company.”

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, such person may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any). If our group includes one or more U.S. subsidiaries, under recently-enacted rules, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations regardless of whether we are not treated as a controlled foreign corporation (although there is currently a pending legislative proposal to significantly limit the application of these rules). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax paying obligations. A United States investor should consult its advisors regarding the potential application of these rules to an investment in the ordinary shares.

General Risk Factors

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed.

We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plan.

We have implemented a business continuity plan to prevent the collapse of critical business processes to a large extent or to enable the resumption of critical business processes in case a natural disaster, public health emergency, such as the global pandemic of Novel Coronavirus Disease 2019, or COVID-19, or other serious event occurs. However, depending on the severity of the situation, it may be difficult or in certain cases impossible for us to continue our business for a significant period of time. Our contingency plans for disaster recovery and business continuity may prove inadequate in the event of a serious disaster or similar event and we may incur substantial costs that could have a material adverse effect on our business.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development and manufacturing involve the use of hazardous materials and chemicals and related equipment. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures and the handling of biohazardous materials. We do not maintain insurance for environmental liability claims that may be asserted against us. Moreover, additional foreign and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with such regulations and pay substantial fines or penalties if we violate any of these laws or regulations.

With respect to environmental, safety and health laws and regulations, we cannot accurately predict the outcome or timing of future expenditures that we may be required to make in order to comply with such laws as they apply to our operations and facilities. We are also subject to potential liability for the remediation of contamination associated with both present and past hazardous waste generation, handling, and disposal activities. We will be periodically subject to environmental compliance reviews by environmental, safety, and health regulatory agencies. Environmental laws are subject to change and we may become subject to stricter environmental standards in the future and face larger capital expenditures in order to comply with environmental laws which could have a material adverse effect on our business.

The price of our ordinary shares may be volatile and may fluctuate due to factors beyond our control.

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our ordinary shares may fluctuate significantly due to a variety of factors, including:

- positive or negative results of testing and clinical trials by us, strategic partners and competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ordinary shares and may otherwise negatively affect the liquidity of our ordinary shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares could decline if one or more securities analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

We have been incurring and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company whose ordinary shares are listed in the United States, and particularly after we no longer qualify as an emerging growth company, we have been incurring and will continue to incur accounting, legal and other expenses that we did not incur as a private company, including costs associated with our reporting requirements under the Exchange Act. We also have incurred and anticipate that we will continue to incur costs associated with corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Global Market, and provisions of Israeli corporate law applicable to public companies. These rules and regulations increase our legal and financial compliance costs, introduce new costs such as investor relations and stock exchange listing fees, and makes some activities more time-consuming and costly. Our board and other personnel need to devote a substantial amount of time to these initiatives. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. As an "emerging growth company," as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, starting with the Annual Report for the year ended on December 31, 2019, our management is required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an "emerging growth company" under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above and depending on our status as per Rule 12b-2 of the Exchange Act, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting under Section 404. The process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls requires the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, while our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2020, our internal control over financial reporting was effective, we cannot predict the outcome of this determination in future years and whether we will need to implement remedial actions in order to implement effective controls over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

Changes in the laws and regulations affecting public companies will result in increased costs to us as we respond to their requirements. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. While our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2020, our internal control over financial reporting was effective, we cannot predict the outcome of our testing or any subsequent testing by our auditor in future periods. Any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information and affect our reputation, which could have a negative effect on the trading price of our ordinary shares.

Our management will be required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is Sol-Gel Technologies Ltd. Our company was incorporated on October 28, 1997 and was registered as a private company limited by shares under the laws of the State of Israel. Our principal executive offices are located at 7 Golda Meir St., Weizmann Science Park, Ness Ziona, 7403650 Israel and our telephone number is 972-8-931 3433. Our website address is http://www.sol-gel.com. The information contained therein, or that can be accessed therefrom, does not constitute a part of this annual report and is not incorporated by reference herein. We have included our website address in this annual report solely for informational purposes. Our agent for service of process in the United States is Cogency Global Inc., located at 10 E. 40th Street, 10th Floor, New York, NY 10016, and its telephone number is +1 (800) 221-0102.

In February 2018 we completed our initial public offering on The Nasdaq Global Market, pursuant to which we issued 7,187,500 Ordinary Shares for aggregate gross proceeds of approximately $86.25 million before deducting underwriting discounts and commissions and offering expenses payable by us, including the full exercise by the underwriters of their option to purchase additional shares. Our Ordinary Shares are traded on The Nasdaq Global Market under the symbol "SLGL".

Our capital expenditures for the years ended December 31, 2018, 2019 and 2020 were approximately $1,052, $597 and $449, respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Our current product candidate pipeline consists of late-stage and early-stage branded product candidates, some of which leverage our proprietary, silica-based microencapsulation technology platform, and several generic product candidates across multiple indications.

Our branded product candidate, Twyneo®, is a novel, once-daily, non-antibiotic topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide and encapsulated tretinoin, that we are developing for the treatment of acne vulgaris, or acne.

On December 30, 2019, we announced top-line results from two pivotal Phase 3 clinical trials evaluating Twyneo for the treatment of acne. Twyneo met all co-primary endpoints in both Phase 3 trials. The Phase 3 program enrolled an aggregate of 858 patients aged nine and older in two multicenter, randomized, double-blind, parallel group, vehicle-controlled trials at 63 sites across the United States. Twyneo demonstrated statistically significant improvement in each of the co-primary endpoints of (1) the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale, (2) an absolute change from baseline in inflammatory lesion count at Week 12, and (3) and an absolute change from baseline in non-inflammatory lesion count at Week 12. In addition, Twyneo was found to be well-tolerated. Our NDA for Twyneo® was accepted for filing by the FDA, which assigned a Prescription Drug User Fee Act, or PDUFA, goal date of August 1, 2021.

Our branded product candidate, Epsolay®, is a novel, once-daily topical cream containing encapsulated benzoyl peroxide, that we are developing for the treatment of papulopustular (subtype II) rosacea. On July 8, 2019, we announced positive top-line results from our Phase 3 program evaluating Epsolay. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Epsolay demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving “clear” or “almost clear” in the Investigator Global Assessment (IGA) relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. In addition, Epsolay® was found to be well- tolerated. Our NDA for Epsolay® was accepted for filing by the FDA, which assigned a PDUFA goal date of April 26, 2021.

Another branded product candidate is SGT-210 (erlotinib gel) that we are developing for the treatment of palmoplantar keratoderma (PPK).

We are also pre-clinically testing erlotinib, tapinarof and roflumilast in various new pharmaceutical indications.

We designed our proprietary, silica-based microencapsulation technology platform to enhance the tolerability and stability of topical drugs while maintaining their efficacy. Topical drugs often struggle to balance achieving both high efficacy and high tolerability. Our technology platform entraps active ingredients in an inert, inorganic silica shell, which creates an unnoticeable barrier between the active ingredient and the skin. The resulting microcapsules are designed to allow the entrapped active ingredients to gradually migrate through the pores of the shell and deliver active ingredient doses onto the skin in a controlled manner, resulting in improved tolerability and stability without sacrificing efficacy. By separately encapsulating active ingredients within protective silica shells, our technology platform also enables the production of novel fixed-dose active ingredient combinations that otherwise would not be stable. We believe that our microencapsulation technology has the potential to be used for topical drug products to treat a variety of skin diseases. As a result of the FDA having already approved silica as a safe excipient for topical drug products, we expect the review process for Twyneo® and Epsolay® to be conducted according to the FDA’s 505(b)(2) regulatory pathway, which may provide for a more efficient regulatory process by permitting us to rely, in part, upon the FDA’s previous findings of safety and efficacy of an approved product.

We maintain exclusive, worldwide commercial rights for our branded product candidates, which consist of:

- Twyneo®, a novel, once-daily, non-antibiotic topical cream, which we are developing for the treatment of acne, containing a fixed-dose combination of encapsulated benzoyl peroxide, or E-BPO, and encapsulated tretinoin. Acne is one of the three most prevalent skin diseases in the world and is the most commonly treated skin disease in the United States. According to the American Academy of Dermatology, acne affects approximately 40 to 50 million people in the United States, of which approximately 10% are treated with prescription medications. In July 2017, we reported positive top-line results from a double-blind, dose-ranging active- and placebo-controlled, six-arm, multi-center Phase II clinical trial of Twyneo® in the United States in 726 subjects, 128 of which subjects across six treatment groups did not complete the study. The clinical trial evaluated the efficacy, tolerability and safety of two Twyneo® concentrations, Twyneo® Low and Twyneo® High, each containing a lower or higher concentration, respectively, of encapsulated tretinoin and an identical concentration of encapsulated benzoyl peroxide. Tretinoin and benzoyl peroxide, the two active components in Twyneo®, are both widely-used therapies for the treatment of acne that historically have not been conveniently co-administered due to stability concerns. The trial also evaluated the contribution of encapsulated tretinoin and encapsulated benzoyl peroxide, in the same concentrations as those in the respective Twyneo® treatment groups, to the efficacy of Twyneo® High and Twyneo® Low. In this trial, Twyneo® showed statistically significant improvements in all pre-defined co-primary and secondary efficacy endpoints, as compared to vehicle. In addition, Twyneo® was well tolerated with no treatment-related serious adverse events. Based on the efficacy data we observed in the Phase II trial, we believe Twyneo®, if approved, has the potential to become a preferred treatment for acne. On December 30, 2019, we announced top-line results from two pivotal Phase 3 clinical trials evaluating Twyneo® for the treatment of acne. Twyneo® met all co-primary endpoints in both Phase 3 trials. The Phase 3 program enrolled an aggregate of 858 patients aged nine and older in two multicenter, randomized, double-blind, parallel group, vehicle-controlled trials at 63 sites across the United States. Twyneo® demonstrated statistically significant improvement in each of the co-primary endpoints of (1) the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale, (2) an absolute change from baseline in inflammatory lesion count at Week 12, and (3) and an absolute change from baseline in non-inflammatory lesion count at Week 12. In addition, Twyneo® was found to be well-tolerated. Our NDA for Twyneo® has been accepted for filing by the FDA, which assigned a PDUFA goal date of August 1, 2021.

- Epsolay®, a topical cream containing 5% encapsulated benzoyl peroxide, which we are developing for the treatment of papulopustular (subtype II) rosacea. Rosacea is a chronic skin disease characterized by facial redness, inflammatory lesions, burning and stinging. According to the U.S. National Rosacea Society, approximately 16 million people in the United States are affected by rosacea. According to a study we commissioned, approximately 4.8 million people in the United States experience subtype II symptoms. Subtype II rosacea is characterized by small, dome-shaped erythematous papules, tiny surmounting pustules on the central aspects of the face, solid facial erythema and edema, and thickening/overgrowth of skin. Subtype II rosacea resembles acne, except that comedowns are absent, and patients may report associated burning and stinging sensations. We evaluated Epsolay® in a double blind, randomized, dose-ranging Phase II clinical trial involving 92 adult subjects at ten centers in the United States. In this trial, Epsolay® showed statistically significant improvements in the Investigator Global Assessment, or IGA, pre-defined co-primary efficacy endpoint and in the percent change in inflammatory lesion count at week 12, as compared to vehicle. Epsolay® was also well tolerated in this trial. Current topical therapies for subtype II rosacea are limited due to tolerability concerns. For example, BPO, a common therapy for acne, is not used for the treatment of subtype II rosacea due to side effects. As encapsulated BPO, Epsolay® is designed to redefine the standard of care for the treatment of subtype II rosacea. If approved, we expect Epsolay® to be the first product containing BPO that is marketed for the treatment of subtype II rosacea. On July 8, 2019, we announced positive top-line results from our Phase 3 program evaluating Epsolay®. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Epsolay® demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving “clear” or “almost clear” in the Investigator Global Assessment (IGA) relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay® demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. In addition, Epsolay® was found to be well-tolerated. On February 12, 2020, we announced positive topline results from our open-label, long-term safety study, evaluating Epsolay® for a treatment duration up to 52 weeks. Our NDA for Epsolay® has been accepted for filing by the FDA, which assigned a PDUFA goal date of April 26, 2021.

- SGT-210 (erlotinib gel) that we are developing for the treatment of palmoplantar keratoderma, or PPK, a group of skin conditions characterized by thickening of the skin on the hands and soles of the feet. SGT-210 is designed to be used alone or in combination for the treatment of hyperproliferation and hyperkeratinization disorders, including PPK. On January 2, 2020, we announced the initiation of a Phase 1 proof of concept clinical study of SGT-210 in patients with palmoplantar keratoderma. The Phase 1 proof of concept study SGT-84-01 is a single-center, single-blinded, vehicle-controlled study designed to evaluate the bioavailability, safety and tolerability of SGT-210 as well as inform on potential efficacy. The study is targeting enrollment of approximately 15 patients to undergo a three-month treatment period, followed by a three-month follow-up period. The enrollment of patients in the Phase 1 proof of concept study with SGT-210 has been slowed by the COVID-19 pandemic. We expect to report top-line data in the third quarter of 2021.

- We are conducting pre-clinical testing to explore the possible activity of erlotinib, tapinarof (an investigational aryl hydrocarbon receptor modulator) and roflumilast (an investigational phosphodiesterase 4 inhibitor) in various new pharmaceutical indications. A total of 25 provisional patent applications for these project candidates have been submitted to date, including patent applications covering the use of tapinarof in ophthalmic disorders such as dry eye, uveitis, and blepharitis with or without demodex involvement.

In addition to our branded product candidates, we have one FDA approved generic topical dermatological product, which is a generic version of Zovirax® (acyclovir) cream, 5%. In February 2019, we announced that Perrigo received final approval from the FDA for this product. The product was developed in a collaboration between us and Perrigo in which we shared development costs with Perrigo and will equally share the gross profits generated from sales of the product. Following receipt by Perrigo of final approval from the FDA, we launched the product in February 2019.

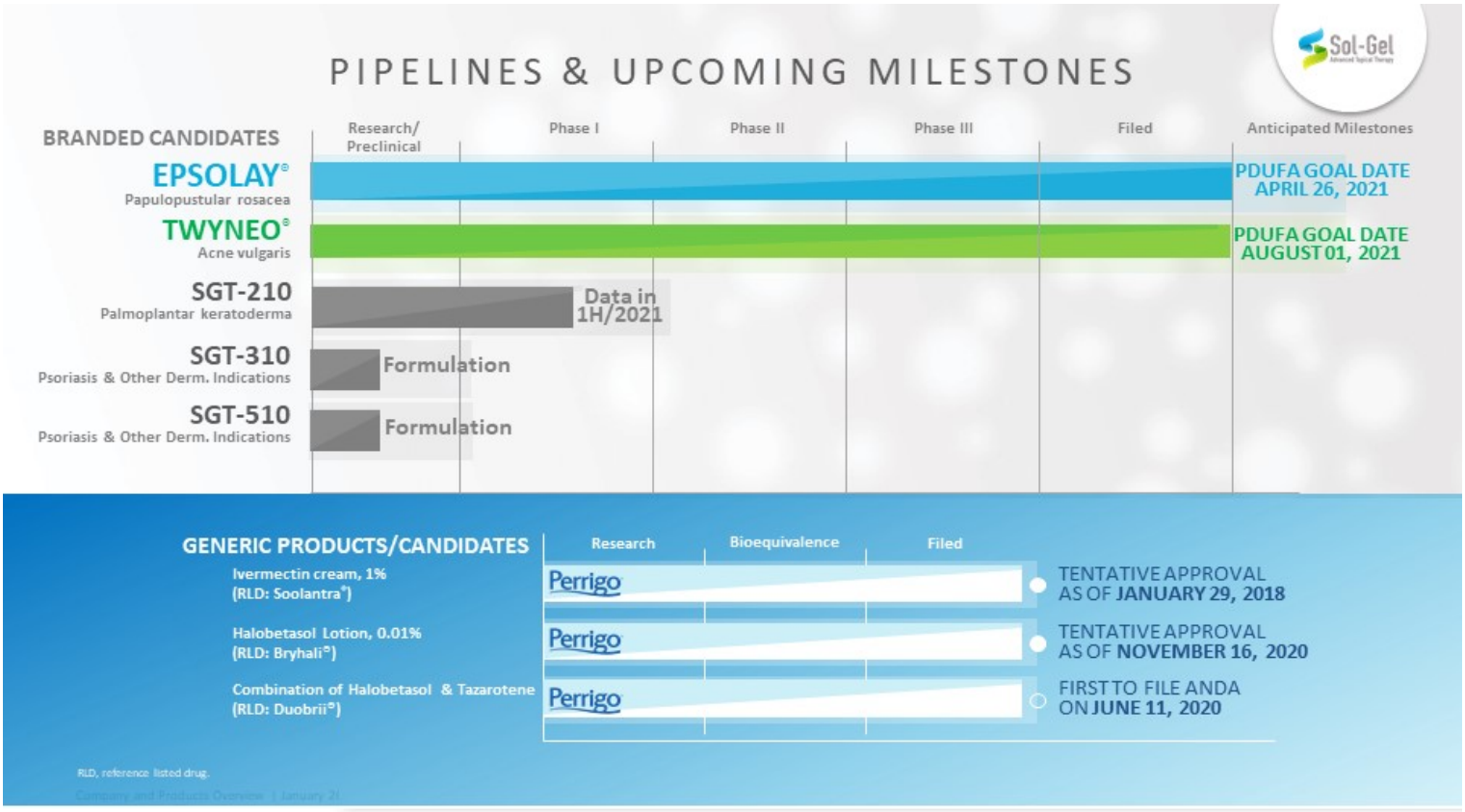
We are also currently developing a portfolio of 11 generic topical dermatological products in collaboration with Perrigo UK Finco Limited Partnership, or Perrigo. Perrigo has significant experience in the development of generic drugs.

Our most advanced generic product candidate is ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which is being developed in collaboration with Perrigo. In March 2017, Perrigo submitted an ANDA with a Paragraph IV certification for ivermectin cream, 1% to the FDA. In January 2018, this ANDA was tentatively approved by the FDA. Final approval from the FDA is subject to a 30-month stay under the Hatch-Waxman Amendments. In addition, because Actavis Ltd. filed an ANDA for ivermectin cream, 1%, before us or any other generic applicants, we may be unable to obtain final approval for our ANDA until the expiration of Actavis Ltd.'s 180-day generic exclusivity. Ivermectin cream, 1% is the active molecule in Soolantra, which is currently marketed in the United States by Galderma Laboratories LP.

Our leadership team has considerable expertise in the identification and development of generic dermatological drug products and our intellectual property and formulation teams continue to seek to identify new opportunities to expand our pipeline of generic product candidates.

In preparation for commercial launch of our proprietary products, we have opened a U.S. headquarters in Whippany, New Jersey. If Twyneo® and Epsolay® receive regulatory approval from the FDA, we intend to market them in the United States through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. We are in discussions with potential partners regarding the commercialization of Twyneo® and Epsolay®.

The following chart represents our current branded and generic product candidate pipeline:



Our Branded Product Candidates

Twyneo® for Acne

Using our proprietary, silica-based microencapsulation technology platform, we are developing Twyneo® to become a preferred treatment for acne by dermatologists and their patients.

Twyneo® is a novel, once-daily, non-antibiotic topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide and encapsulated tretinoin that we are developing for the treatment of acne. Studies have shown that benzoyl peroxide and tretinoin are effective in treating acne as monotherapies; moreover, according to an article in the American Academy of Dermatology (2009), dermatologists recommend combining the two monotherapies as a first-line approach for acne, but a drug-drug interaction that causes the degradation of tretinoin has previously prohibited the development of a combination therapy. By encapsulating the two agents separately through the use of our technology platform, Twyneo® is designed to be a fixed-dose combination that otherwise would not be stable. Similar to other combination drug products, such as clindamycin and benzoyl peroxide, we expect Twyneo® to be kept refrigerated throughout the supply chain and then stored in ambient conditions upon its distribution to patients. Pre-clinical data suggests that Twyneo® may be more tolerable than generic tretinoin gel 0.1% and Epiduo, a branded fixed-dose combination of benzoyl peroxide and adapalene, without a corresponding loss in efficacy. In addition, Epiduo and its successor Epiduo Forte contain adapalene as opposed to tretinoin, which is widely considered to be more effective than adapalene, but generally causes greater irritation. We expect that Twyneo®, if approved, will compete directly with Epiduo and Epiduo Forte. We have utilized the FDA's 505(b)(2) regulatory pathway in seeking approval of Twyneo® in the United States.

In July 2017, we reported the completion of a 726 subject, randomized, multi-center, double-blind, placebo-controlled Phase II clinical trial of Twyneo® in the United States that demonstrated statistically significant improvements compared to vehicle in the co-primary efficacy endpoints of "clear" or "almost clear" with a two-grade reduction in IGA and in reducing absolute inflammatory and non-inflammatory lesion counts at week 12. Of the 726 subjects enrolled in the trial, 128 subjects across six treatment groups did not complete the study. The most common reasons for subjects not completing the study were the withdrawal of informed consent (42 subjects), loss to follow-up (56 subjects) and adverse events (18 subjects).

On December 30, 2019, we announced top-line results from two pivotal Phase 3 clinical trials evaluating Twyneo® for the treatment of acne. Twyneo® met all co-primary endpoints in both Phase 3 trials. The Phase 3 program enrolled an aggregate of 858 patients aged nine and older in two multicenter, randomized, double-blind, parallel group, vehicle-controlled trials at 63 sites across the United States. Twyneo® demonstrated statistically significant improvement in each of the co-primary endpoints of (1) the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale, (2) an absolute change from baseline in inflammatory lesion count at Week 12, and (3) and an absolute change from baseline in non-inflammatory lesion count at Week 12. In addition, Twyneo® was found to be well-tolerated. Our NDA for Twyneo® has been accepted for filing by the FDA, which assigned a PDUFA goal date of August 1, 2021.

Acne Market Opportunity

Acne is a disease characterized by areas of scaly red skin, non-inflammatory blackheads and whiteheads, inflammatory lesions, papules and pustules and occasionally boils and scarring that occur on the face, neck, chest, back, shoulders and upper arms. The development of acne lesions is caused by genetic and environmental factors that arise from the interplay of the following pathogenic factors:

- blockage of hair follicles through abnormal keratinization in the follicle, which narrows pores;
- increase in oils, or sebum production, secreted by the sebaceous gland;
- overgrowth of naturally occurring bacteria caused by the colonization by the anaerobic lipohilic bacterium *Propionibacterium acnes*, or *P. acnes*;
- inflammatory response due to relapse of pro-inflammatory mediators into the skin.

Due to the frequency of recurrence and relapse, acne is characterized as a chronic inflammatory disease, which may require treatment over a prolonged period of time. Acne is one of the three most prevalent skin diseases in the world and is the most commonly treated skin disease in the United States. According to the American Academy of Dermatology, acne affects approximately 40 to 50 million people in the United States and approximately 85% of people between the ages of 12 and 24 experience some form of acne. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Early effective treatment is recommended to lessen the overall long-term impact. For most people, acne diminishes over time and tends to disappear, or at least to decrease, by the age of 25. There is, however, no way to predict how long it will take for symptoms to disappear entirely, and some individuals continue to suffer from acne well into adulthood.

Current Treatment Landscape for Acne

The treatment options for acne depend on the severity of the disease and consist of topical and oral drugs:

- **Mild acne**: characterized by few papules or pustules (both comedonal and inflammatory); treated with an over-the-counter product or topical prescription therapies.
- **Moderate acne**: characterized by multiple papules and pustules with moderate inflammation and seborrhea (scaly red skin); treated with a combination of oral antibiotics and topical therapies.

- **Severe acne**: characterized by substantial papulopustular disease, many nodules and/or cysts and significant inflammation and seborrhea; treated with oral and topical combination therapies and photodynamic therapy as a third-line treatment.

Topical therapies dominate the acne market as physicians and patients often prefer therapies that act locally on the skin, while minimizing side effects. For more pronounced symptoms, patients are typically treated with a combination of topical and oral therapies.

The acne prescription treatment landscape is comprised of four classes of topical products and two classes of oral products:

- **Topical over-the-counter monotherapies** such as adapalene 0.1%, benzoyl peroxide and salicylic acid, in different concentrations, are the most commonly used therapies. These are generally tolerable first-line treatments for mild acne, but less efficacious than prescription therapies.

- **Topical prescription antibiotic monotherapies** such as clindamycin and erythromycin that are most commonly used as topical therapies in cases of mild-to-moderate acne.

- **Topical prescription retinoid monotherapies** such as tretinoin, adapalene 0.3% and tazarotene. Physicians view retinoids as moderately efficacious, but they have high rates of skin irritation.

- **Topical prescription combination products** such as combinations of BPO/adapalene, BPO/clindamycin, BPO/erythromycin and clindamycin/tretinoin. These target multiple components that contribute to the development of acne, though topical side effects are common.

- **Oral prescription antibiotics** such as doxycycline and minocycline. These are typically used as step-up treatments for more severe cases of acne, with risk of systemic side effects.

- **Oral prescription isotretinoin**, which is primarily used for severe cystic acne and acne that has not responded to other treatments. The use of oral prescription isotretinoin is tightly controlled due to tolerability issues.

Twyneo® for Acne

Using our proprietary, silica-based microencapsulation technology platform, we are developing Twyneo® to become a preferred treatment for acne by dermatologists and their patients. Our silica-based proprietary delivery system is designed to enhance the tolerability and stability of topical drugs while maintaining their efficacy. Topical drugs often struggle to balance achieving both high efficacy and high tolerability. Our technology platform entraps active ingredients in an inert silica shell, which creates an unnoticeable barrier between the active ingredient and the skin. The resulting microcapsules are designed to allow the entrapped active ingredients to gradually migrate through the pores of the shell and deliver active ingredient doses into the skin in a controlled manner, resulting in improved tolerability and stability without sacrificing efficacy.

We believe that Twyneo®, a fixed-dose combination of a cream containing encapsulated benzoyl peroxide and encapsulated tretinoin, has the potential to solve the industry-wide challenge of stabilizing tretinoin in the presence of benzoyl peroxide, a combination known to be effective in acne therapy, but not previously conveniently co-administered. While benzoyl peroxide slows the proliferation of P. acnes, tretinoin regulates hyperkeratinization and abnormal desquamation of follicular epithelium. This creates a synergistic combination which has the potential to overcome the challenges faced by currently approved products.

- We designed Twyneo® to protect tretinoin from oxidative decomposition, which occurs when it is combined with benzoyl peroxide, with the goal of enhancing stability without reducing efficacy. We believe this could allow for a suitable clinical and commercial shelf life.

- The silica shell creates a barrier between the two drug substances and the skin. As a result, we believe Twyneo® can reduce irritation typically associated with topical application of benzoyl peroxide and tretinoin, leading to greater tolerability to acne-affected skin.

Our NDA for Twyneo® has been accepted for filing by the FDA, which assigned a PDUFA goal date of August 1, 2021.

Twyneo® Phase 3 Trial Design

The pivotal Phase 3 clinical program evaluating the safety and efficacy of Twyneo® in subjects with acne vulgaris enrolled an aggregate of 858 patients aged nine and older, with moderate-to-severe acne in two multicenter, randomized, double-blind, parallel group, vehicle-controlled trials at 63 sites across the United States. Patients were randomized at a 2:1 ratio to be treated once-daily with either Twyneo (n=571) or vehicle cream (n=287) for 12 weeks.

The primary and secondary efficacy endpoints were assessed at the end of the 12-week treatment period. Three primary efficacy endpoints were defined for this trial:

- the proportion of subjects who achieve at least a two-grade reduction in the IGA score and either “clear” or “almost clear” at week 12;
- the mean absolute change from baseline in the number of inflammatory acne lesions at week 12; and
- the mean absolute change from baseline in the number of non-inflammatory acne lesions at week 12.

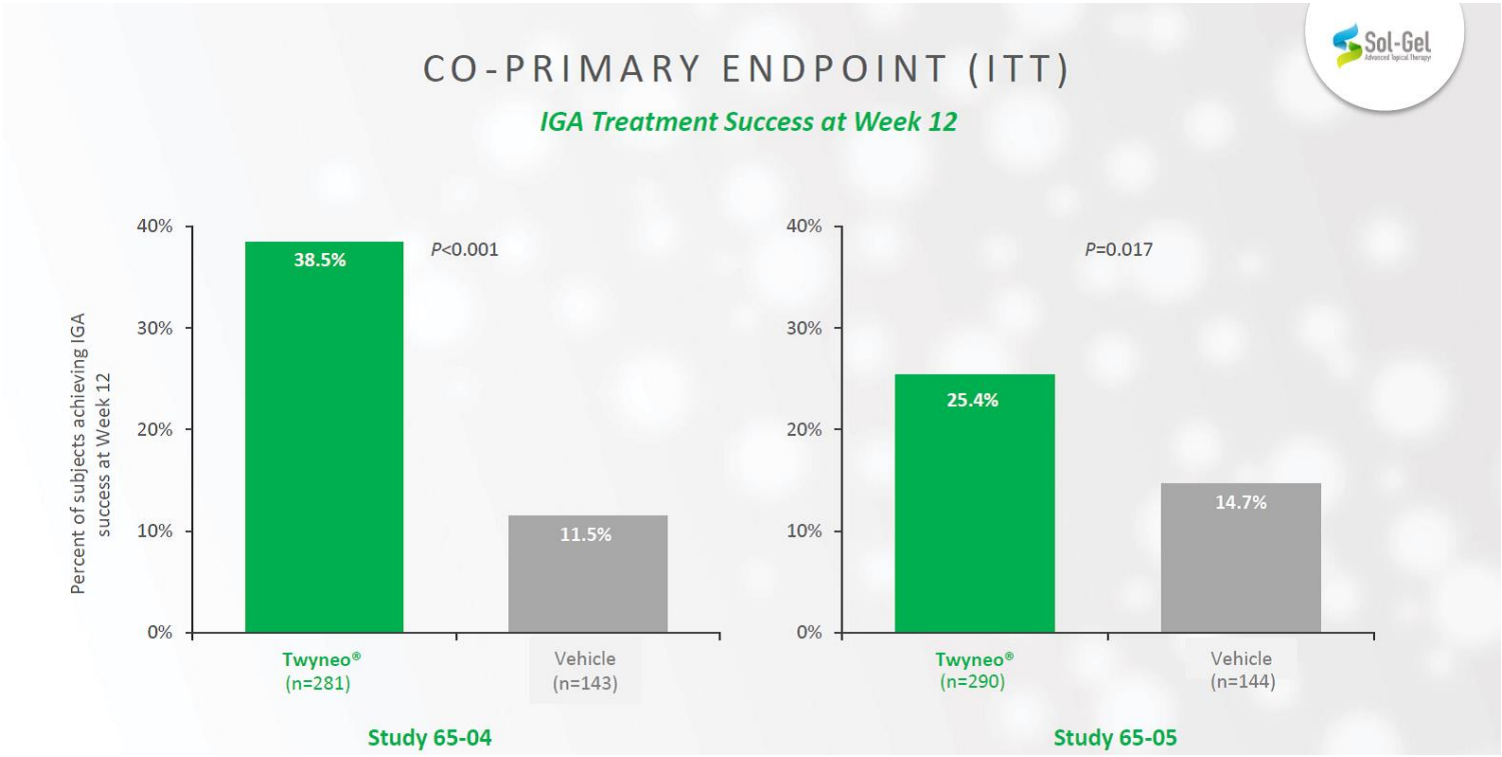
Twyneo® Phase 3 Trial Results

As outlined below Twyneo met all co-primary endpoints in both Phase 3 trials. Twyneo demonstrated statistically significant improvement in each of the co-primary endpoints described above.

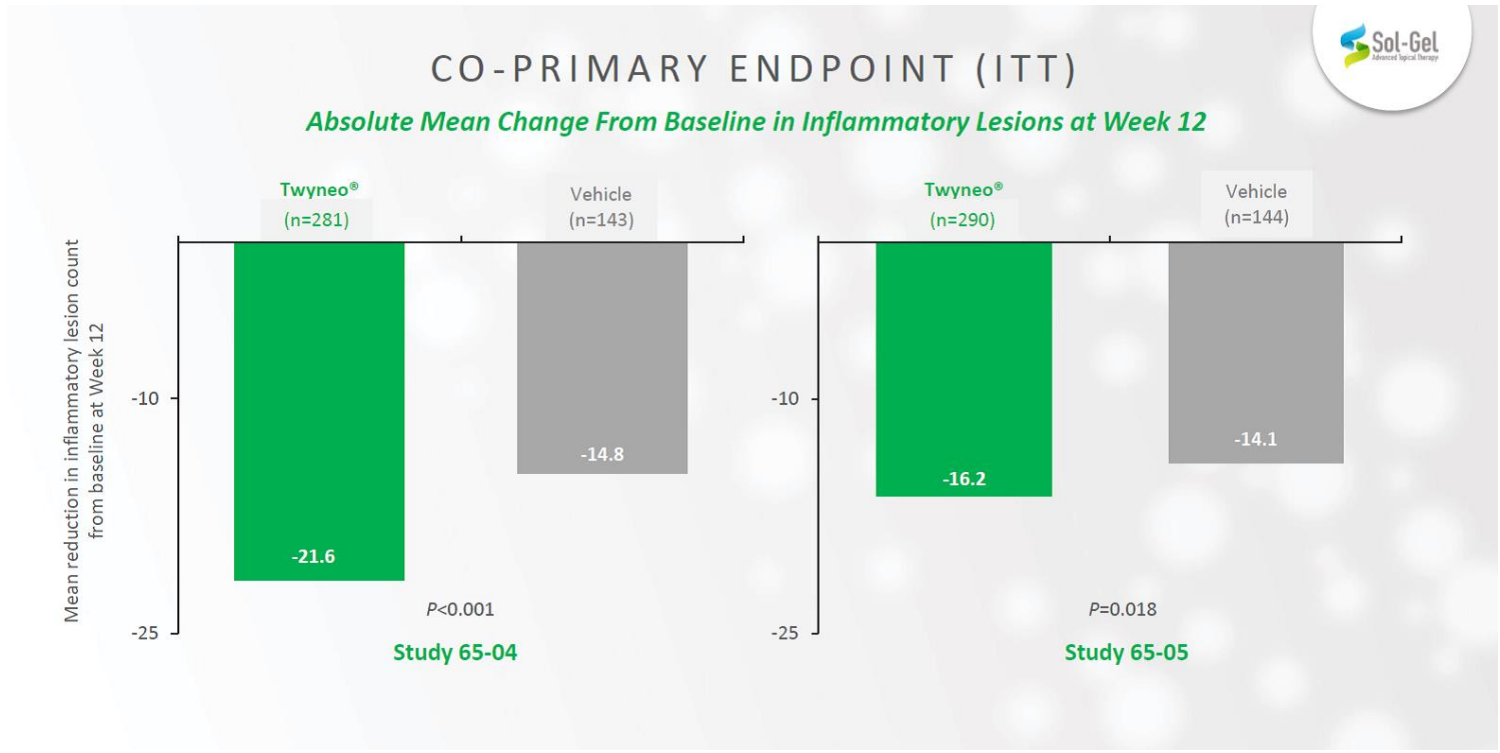
In trial SGT-65-04, 38.5% of patients treated with Twyneo achieved success in IGA versus 11.5% in the vehicle treated group (P<0.001) at week 12. In trial SGT-65-05, 25.4% of patients treated with Twyneo achieved success in IGA versus 14.7% in the vehicle group (P=0.017) at week 12. In trial SGT-65-04, the absolute mean change from baseline of inflammatory lesion count for Twyneo was -21.6 versus -14.8 for the vehicle group (P<0.001) at week 12. In trial SGT-65-05, the absolute change from baseline of inflammatory lesion count for Twyneo was -16.2 versus -14.1 for the vehicle group (P=0.021) at week 12. In trial SGT-65-04, the absolute mean change from baseline of non-inflammatory lesion count for Twyneo was -29.7 versus -19.8 for the vehicle group (P<0.001). In trial SGT-65-05, the absolute mean change from baseline of non-inflammatory lesion count for Twyneo was -24.2 versus -17.4 for the vehicle group (P<0.001) at week 12.

In both trials, Twyneo appeared to be generally safe and well-tolerated and the majority of local skin reactions, when reported, were mild or moderate and improved over time. A total of 18 subjects discontinued treatment in both trials due to treatment emergent adverse events. There were no treatment-related serious adverse events and four unrelated serious adverse events (one Twyneo (depression), three vehicle) were reported across both trials.

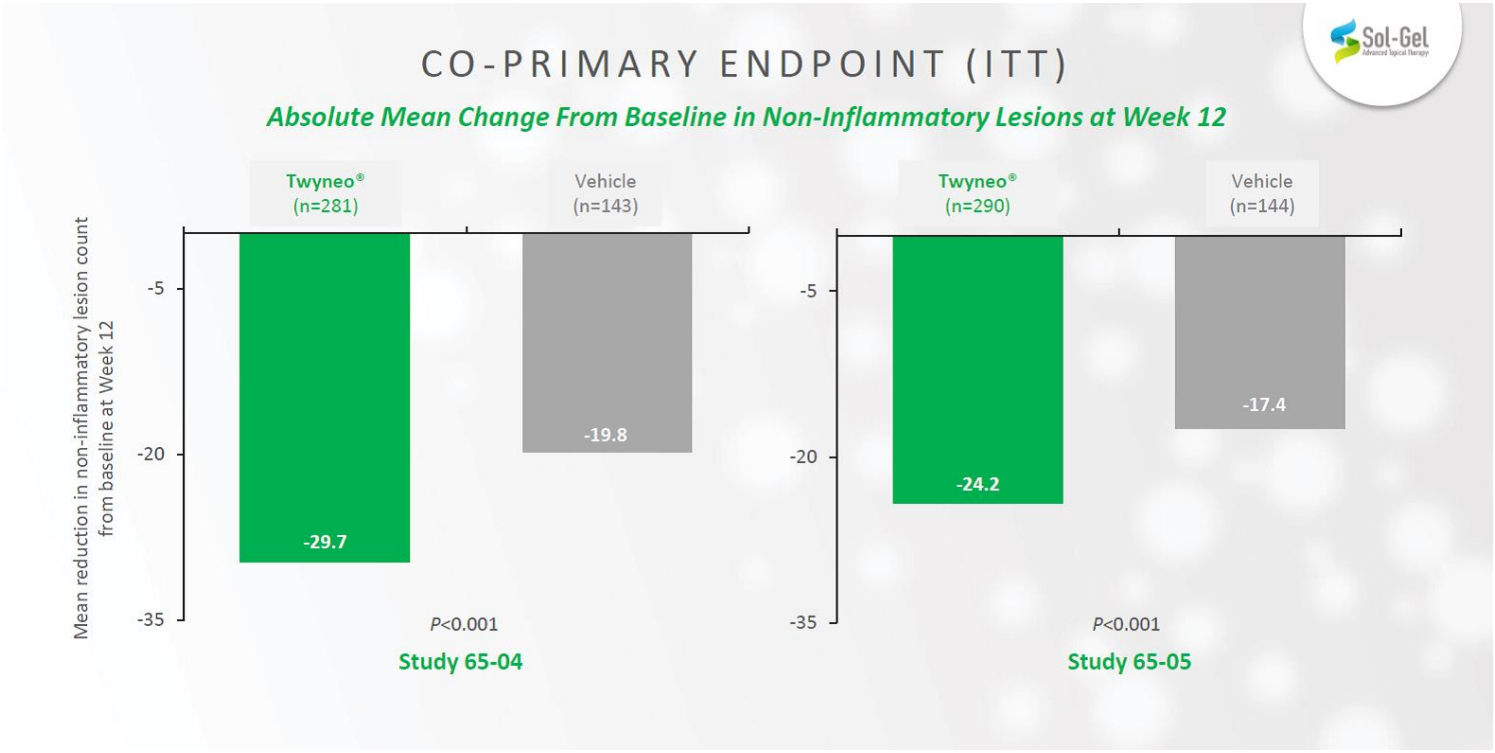
The following chart presents the proportion of subjects in the ITT population in studies SGT 65-04 and SGT 65-05 who achieved a successful improvement in the severity of their disease at week 12, as assessed using the IGA:



The following chart presents the absolute mean change from baseline in the number of inflammatory acne lesions at week 12:



The following chart presents the absolute mean change from baseline in the number of non-inflammatory acne lesions at week 12:



We also assessed cutaneous tolerability by recording the erythema (redness), scaling, pigmentation, dryness, itching, burning and stinging on a four-point scale from 0 to 3 at baseline and at each visit. These measurements are either measured by the physician or reported by the subject. Overall, Twyneo® was generally well tolerated. The majority of cutaneous adverse events were mild.

Out of the 858 subjects who enrolled in both studies, 754 subjects were included in the safety population, and a combined total of 16 subjects discontinued treatment due to an adverse event across both trials. The most common reasons for subjects not completing the study in both groups (active and vehicle) were the withdrawal of informed consent (41 subjects, 4.8%), and loss to follow-up (39 subjects, 4.5%).

Epsolay® for Subtype II Rosacea

Epsolay® *Overview*

Epsolay® is a once-daily topical cream containing 5% encapsulated benzoyl peroxide that we are developing for the treatment of papulopustular (subtype II) rosacea. We believe Epsolay® has the potential to become the first product to contain encapsulated benzoyl peroxide for the treatment of subtype II rosacea and, if approved, has the potential to redefine the standard of care for the treatment of inflammatory lesions associated with subtype II rosacea. Subtype II rosacea is characterized by small, dome-shaped erythematous papules, tiny surmounting pustules on the central aspects of the face, solid facial erythema and edema, and thickening/overgrowth of skin. Subtype II rosacea resembles acne, except that comedones are absent, and patients may report associated burning and stinging sensations. In 2012, we completed a 92 subject, randomized, multi-center, double-blind, vehicle-controlled Phase II trial for Epsolay® in the United States that demonstrated statistically significant improvements compared to vehicle in achieving the IGA success co-primary efficacy endpoint and in reducing papulopustular-lesions based on the percentage change in the inflammatory lesion count from baseline at week 12. In addition, the tolerability profile of Epsolay® was similar to that of vehicle. We expect that Epsolay®, if approved, will compete directly with Soolantra. We expect to utilize the FDA's 505(b)(2) regulatory pathway in seeking approval of Epsolay® in the United States. On July 8, 2019, we announced positive top-line results from our Phase 3 program evaluating Epsolay. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Epsolay demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving "clear" or "almost clear" in the Investigator Global Assessment (IGA) relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. In addition, Epsolay® was found to be well- tolerated. On February 12, 2020, we announced positive topline results from our open-label, long-term safety study, evaluating Epsolay® for a treatment duration up to 52 weeks. Our NDA for Epsolay® has been accepted for filing by the FDA, which assigned a PDUFA goal date of April 26, 2021.

Rosacea is a chronic skin disease characterized by persistent facial erythema (redness) and temporary inflammatory lesions (papules, pustules or both). Often misdiagnosed as acne vulgaris due to similarities between inflammatory acne lesions and rosacea lesions and the potential for disfigurement, rosacea is gradually increasing in visibility as a disease. The most prominent age group affected includes adults age 30 and above, with stronger prevalence across women and adults with fair skin.

Current Treatment Landscape for Subtype II Rosacea

As there is no cure for rosacea, treatment is largely focused on managing the disease. We believe that a significant market opportunity exists for a subtype II rosacea treatment option that can provide both efficacy and higher tolerability than existing treatments. There are currently five approved drugs for the treatment of subtype II rosacea: Soolantra, Metrogel, Oracea, Zilixi and generic metronidazole. In certain cases, dermatologists often prescribe oral antibiotics either as monotherapies or in conjunction with approved medications.

Our Solution for Subtype II Rosacea — Epsolay®

Benzoyl peroxide is approved by the FDA for the treatment of acne and is widely considered to be safe and effective. Currently, there is no approved benzoyl peroxide product in the rosacea treatment landscape as a result of potential tolerability issues, despite clinical studies showing that treatment with benzoyl peroxide could be efficacious. According to a published study, benzoyl peroxide was found to be an effective treatment for rosacea but caused irritation. Using our proprietary, silica-based microencapsulation technology platform, we believe our Epsolay® candidate for the treatment of papulopustular (subtype II) rosacea can improve on current subtype II rosacea treatments in the following ways:

- Epsolay® creates a silica-based barrier between benzoyl peroxide crystals and the skin and, as a result, can reduce irritation typically associated with topical application of benzoyl peroxide, increasing the potential for more tolerable application to rosacea-affected skin.

- Epsolay®'s release of the drug can reduce irritation while maintaining efficacy.

Epsolay® is an innovative topical cream, and if approved, would be the first product containing benzoyl peroxide for the treatment of subtype II rosacea.

Epsolay® Phase 3 Trial Design

In June 2018, we announced dosing of the first subject in our pivotal Phase 3 clinical program of Epsolay® in subjects with papulopustular rosacea. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Patients were randomized at a 2:1 ratio to be treated once-daily with either Epsolay (n=493) or vehicle cream (n=240) for 12 weeks. After the initiation of treatment, clinical and safety evaluations were performed at Weeks 2, 4, 6, 8 and 12.

The primary efficacy endpoints for both trials were success in the IGA defined as two-grade reduction in IGA on a stage of 0 to 4 with a “clear” (0) or “almost clear” (1) at week 12, and a reduction in mean inflammatory lesion count at week 12.

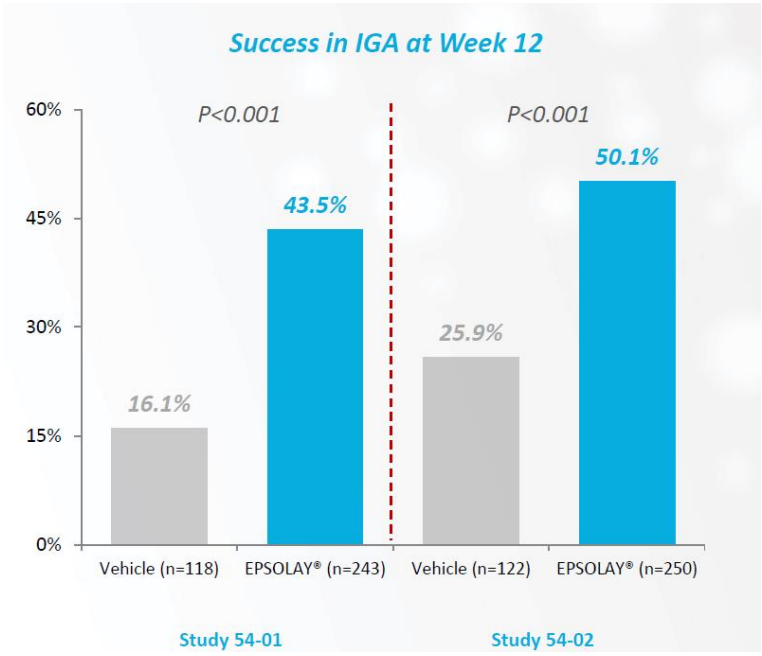
As outlined below, Epsolay demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving "clear" or "almost clear" in the IGA relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. Epsolay demonstrated a favorable safety and tolerability profile similar to vehicle.

In study SGT 54-01, patients in the Epsolay and vehicle treatment groups had a baseline mean inflammatory lesion count of 25.7 and 26.3, respectively. The proportion of patients with "moderate" (3) or "severe" (4) IGA in the Epsolay treatment group was 86.4% and 13.6%, respectively, and 88.1% and 11.9%, respectively, in the vehicle treatment group. In study SGT 54-02, patients in Epsolay and vehicle treatment groups had a baseline mean inflammatory lesion count of 29.8 and 27.5, respectively. The proportion of patients with "moderate" (3) or "severe" (4) IGA in the Epsolay treatment group was 90.8% and 9.2%, respectively, and 91.8% and 8.2%, respectively, in the vehicle treatment group.

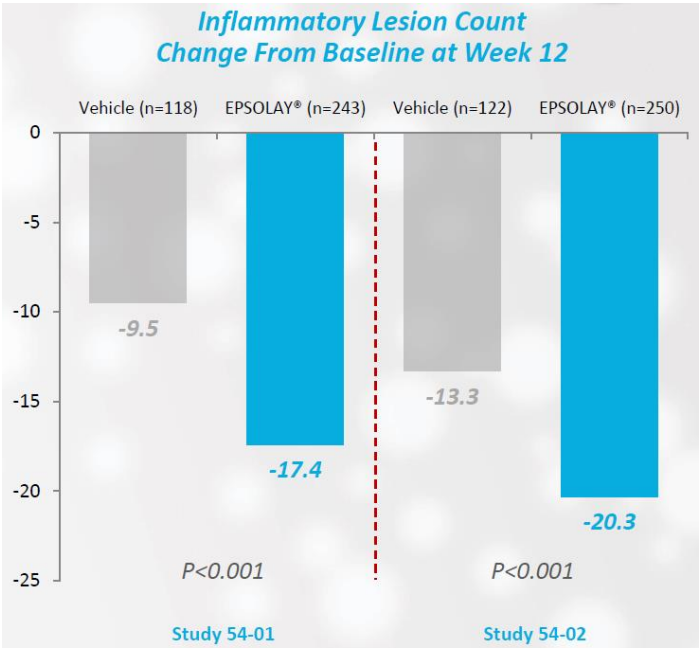
As outlined below, Epsolay met all co-primary endpoints in both Phase 3 trials. Epsolay demonstrated statistically significant improvement in each of the co-primary endpoints described above.

In study SGT 54-01, 43.5% of patients treated with Epsolay achieved success in IGA versus 16.1% in the vehicle treated group (P<0.001) at week 12. In Study 54-02, 50.1% of patients treated with Epsolay achieved success in IGA versus 25.9% in the vehicle group (P<0.001) at week 12. In study SGT 54-01, the absolute change from baseline of inflammatory lesion count for Epsolay was -17.4 versus -9.5 for the vehicle group (P<0.001) at week 12. In study SGT 54-02, the absolute change from baseline of inflammatory lesion count for Epsolay was -20.3 versus -13.3 for the vehicle group (P<0.001) at week 12.

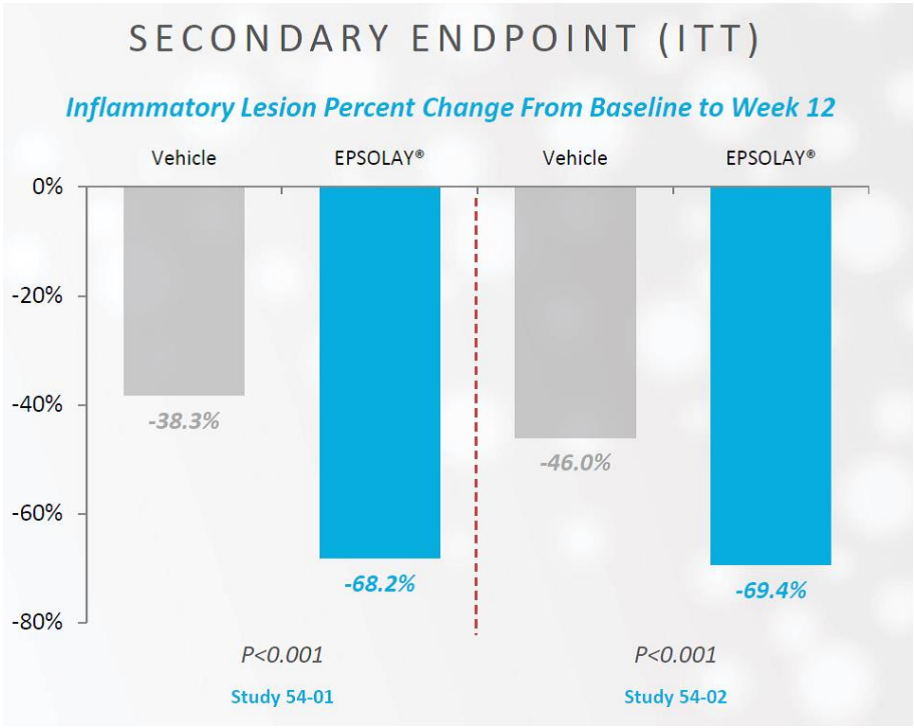
The following chart presents the proportion of subjects in the ITT population in studies SGT 54-01 and SGT 54-02 who achieved a successful improvement in the severity of their disease at week 12, as assessed using the IGA:



The following chart presents the absolute change from baseline in the number of inflammatory acne lesions at week 12:



The following chart presents the percent change from baseline in the number of inflammatory acne lesions at week 12:



In both studies, Epsolay demonstrated a favorable safety and tolerability profile similar to vehicle, with a low rate of cutaneous side effects (e.g., dryness, scaling, itching and burning/stinging) comparable to vehicle. Adverse events were primarily mild to moderate in severity with the most frequently reported adverse events across both studies being application site erythema and application site pain reported by less than 3.4% of subjects. There were no treatment-related serious adverse events, with a combined total of two unrelated serious adverse events (1 Epsolay, 1 vehicle) reported across both trials.

Out of the 733 subjects who enrolled in both studies, 721 subjects were included in the safety population, and a combined total of 10 subjects (9 Epsolay, 1 vehicle) discontinued treatment due to an adverse event across both trials. The most common reasons for subjects not completing the study in both groups (active and vehicle) were the withdrawal of informed consent (25 subjects, 3.4%), and loss to follow-up (17 subjects, 2.3%).

Long-Term Safety Study Results for Epsolay

On February 12, 2020, we announced positive topline results from our open-label, long-term safety study, SGT -54-07, evaluating Epsolay for a treatment duration up to 52 weeks. The study enrolled 547 subjects, all of whom had completed 12 weeks of treatment with Epsolay or vehicle in the preceding double-blind Phase 3 studies. Patients continued onto open-label treatment with Epsolay once-daily for up to an additional 40 weeks. The safety population of 535 subjects received Epsolay therapy for an overall period of at least 28 weeks. Of these 535 subjects, 209 subjects completed 52 weeks of treatment with Epsolay, exceeding the sample size requirements previously defined by the FDA for the Epsolay one-year safety evaluation.

Non-cutaneous adverse events were similar in frequency and type to those observed in the preceding Phase 3 trials. The most common adverse event reported was nasopharyngitis (5.4%). Less than 3% of patients experienced application site adverse events that were considered to be drug-related, and no serious drug-related adverse events were reported.

At every study visit, the investigator conducted Local Tolerability and Cutaneous Safety Assessments. At the end of 52 weeks more than 90% of subjects had “none” or “mild” signs or symptoms (burning or stinging, itching, dryness and scaling) and no “severe” tolerability scores were recorded.

Although the study was designed to evaluate long-term safety, subjects also continued to undergo evaluation according to the Investigator Global Assessment (IGA) 5-point scale. Of the 209 patients treated with Epsolay for 52 weeks, 73.2% reported an IGA score of 0 ("clear") or 1 ("almost clear") at 52 weeks.

Our NDA for Epsolay® has been accepted for filing by the FDA, which assigned a PDUFA goal date of April 26, 2021.

SGT-210 for Palmoplantar Keratoderma

SGT-210 (erlotinib gel) that we are developing for the treatment of palmoplantar keratoderma, or PPK, a group of skin conditions characterized by thickening of the skin on the hands and soles of the feet. SGT-210 is designed to be used alone or in combination for the treatment of hyperproliferation and hyperkeratinization disorders, including PPK. On January 2, 2020, we announced the initiation of a Phase 1 proof of concept clinical study of SGT-210 in patients with palmoplantar keratoderma. The Phase 1 proof of concept study SGT-84-01 is a single-center, single-blinded, vehicle-controlled study designed to evaluate the bioavailability, safety and tolerability of SGT-210 as well as inform on potential efficacy. The study is targeting enrollment of approximately 15 patients to undergo a three-month treatment period, followed by a three-month follow-up period. The enrollment of patients in the Phase 1 proof of concept study with SGT-210 has been slowed by the COVID-19 pandemic. We expect to report top-line data in the third quarter of 2021.

Erlotinib, Tapinarof and roflumilast potentially for psoriasis and other medical conditions

We are conducting pre-clinical testing to explore the possible activity of erlotinib, tapinarof (an investigational aryl hydrocarbon receptor modulator) and roflumilast (an investigational phosphodiesterase 4 inhibitor) in various new pharmaceutical indications. A total of 25 provisional patent applications for these project candidates have been submitted to date, including patent applications covering the use of tapinarof in ophthalmic disorders such as dry eye, uveitis, and blepharitis with or without demodex involvement.

Generic Drug Product Candidates

In addition to our branded product candidates, we have one FDA approved generic topical dermatological product, which is a generic version of Zovirax® (acyclovir) cream, 5%. In February 2019, we announced that Perrigo received final approval from the FDA for this product. The product was developed in a collaboration between us and Perrigo in which we shared development costs with Perrigo and will equally share the gross profits generated from sales of the product. Following receipt by Perrigo of final approval from the FDA, we launched the product in February 2019.

We are also currently developing a portfolio of 11 generic topical dermatological products, including ivermectin cream, 1%, in collaboration with Perrigo. Perrigo has significant experience in the development of generic drugs.

Our most advanced generic product candidate is ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which we are developing in collaboration with Perrigo. In March 2017, Perrigo submitted an ANDA for ivermectin cream, 1% to the FDA, which was tentatively approved. Following notification from Perrigo, Galderma Laboratories, L.P., Galderma S.A., and Nestle Skin Health S.A., filed a patent litigation suit triggering the application of a 30-month stay on approval of the ANDA, under the Hatch-Waxman Amendments. In January 2018, this ANDA was tentatively approved by the FDA. In addition, because Actavis Ltd. filed an ANDA for ivermectin cream, 1%, before us or any other generic applicants, we may be unable to obtain final approval for our ANDA until the expiration of Actavis Ltd.'s 180-day generic exclusivity. Ivermectin cream, 1% is the active molecule in Soolantra which is currently marketed in the United States by Galderma Laboratories LP.

We previously had a collaboration arrangement with Douglas Pharmaceuticals (New Zealand) to develop an additional generic product candidate. We decided not to pursue this collaboration after determining that it would not be economical due to significant market competition.

Our Proprietary Silica-Based Microencapsulation Technology Platform

Encapsulation of a drug substance can be made using a variety of techniques, such as solvent evaporation, coacervation, and interfacial polymerization. Most encapsulations involve organic polymers, such as poly-methyl methacrylate, chitosan and cellulose. The resultant encapsulated drug substance can be an aqueous dispersion of varying payload and volume fraction or a dried powder. Control over the encapsulation process when organic polymers are used is challenging and is mainly limited to shell thickness. Other properties of the organic polymer encapsulating material are hard to control.

In contrast, we use proprietary 'sol-gel' processes to shape silica on site to form microcapsule shells of almost any size and release profile. Sol-gel is a chemical process whereby amorphous silica, or other metal oxides, are made by forming interconnections among colloidal particles (the "sol") under increasing viscosity until a rigid silica shell (the "gel") is formed. The drug substance that is added during the sol-gel reaction is encapsulated, using a patented technique, by which a core-shell structure is formed. The drug substance is in the core and the silica is the capsule shell. At the end of the process, the microcapsules are in the shape of small beads ranging from 1 – 50 micron in size. This process results in an aqueous suspension in which the drug substances are entrapped in silica particles.

Collaboration Agreements with Perrigo

Ivermectin cream, 1%

On April 27, 2015, we entered into a development, manufacturing and commercialization agreement with Perrigo, as amended on October 26, 2015, to work toward the objective of obtaining all FDA approvals necessary for the commercialization of ivermectin cream, 1%, in the United States. Under the agreement, Perrigo will conduct all regulatory, scientific, clinical and technical activities necessary to develop ivermectin cream, 1%, prepare and file an ANDA with the FDA (which received tentative approval in January 2018), and is responsible for other activities to gain regulatory approval to market ivermectin cream, 1%, in the United States. We granted Perrigo the right, title and interest in and to ivermectin cream, 1%, and agreed on each party's portion of the costs associated with performance under the agreement. Perrigo also owns intellectual property created in connection with the development of ivermectin cream, 1%. If approval by the FDA of the ANDA, Perrigo is required to use diligent efforts to commercialize ivermectin cream, 1%, in the United States. Perrigo has the sole and exclusive right to establish and control the prices and all other terms and conditions for the sales of ivermectin cream, 1%, in the United States and is required to do so in good faith. We will be entitled to 50% of Perrigo's gross profits related to the sale of ivermectin cream, 1%, on a quarterly basis, for a period of 20 years following the first commercial sale of the ivermectin cream, 1%, in the United States. The agreement may be terminated if the gross profits relating to the sale of the product do not exceed a certain threshold or if the potential market for the product has been significantly reduced due to regulatory changes.

Each party is responsible for its own costs in relation to performance under the agreement.

We are obligated to finance all out-of-pocket trial expenses (including materials), and Perrigo UK is required to reimburse us for 40% of the out-of-pocket clinical trial expenses as follows (a) if we obtain FDA approval, by financing our share of the out-of-pocket litigation expenses, or (b) if FDA approval is not obtained, by reimbursing us an amount equal to 40% of our out-of-pocket expenses.

Generic version of Zovirax® (acyclovir) cream

In connection with the transfer of the first generic version of Zovirax® (acyclovir) cream, to us by Arkin Dermatology on August 22, 2017, we assumed an agreement with Perrigo for the development, manufacturing and commercialization of the generic version of Zovirax® (acyclovir) cream. Under the terms of the agreement, Perrigo was required to conduct all regulatory, scientific, clinical and technical activities necessary to develop the generic version of Zovirax® (acyclovir) cream, prepare and file an ANDA with the FDA, and gain regulatory approval to market the generic version of Zovirax® (acyclovir) cream. The agreement provides that as soon as reasonably practical after final approval by the FDA of the ANDA, Perrigo is required to use diligent efforts to commercialize the product in the United States. Perrigo has the sole and exclusive right to establish and control the prices and all other terms and conditions for the sales of the product in the United States and is required to do so in good faith . We are responsible for 80% of all out-of-pocket clinical study costs related to the generic version of Zovirax® (acyclovir) cream. We will be entitled to 50% of Perrigo's gross profits related to the sale of the generic version of Zovirax® (acyclovir) cream, on a quarterly basis, for a period of 20 years following the first commercial sale of the generic product. The agreement may be terminated if the gross profits relating to the sale of the generic version of Zovirax® (acyclovir) cream do not exceed a certain threshold or if the potential market for the product has been significantly reduced to regulatory changes.

In February 2019, we announced that Perrigo received final approval from the FDA for the first generic version of Zovirax® (acyclovir) cream, 5%. We launched the product in February 2019.

Generic version of Bryhali® (halobetasol propionate) lotion, 0.01%

We are party to a collaboration agreement with Perrigo Israel, an affiliate of Perrigo Company plc, for the development, manufacturing and commercialization of a generic version of Bryhali® (halobetasol propionate) lotion, 0.01%, for the treatment of plaque psoriasis in adults. On January 30, 2020, Perrigo filed an ANDA for such generic version of Bryhali® (halobetasol propionate) lotion, 0.01%, and on May 1. 2020 Bausch Health Companies, Inc. ("Bausch Health") filed a patent infringement action Perrigo's ANDA in the US District Court for the District of New Jersey for such product.

Generic version of Duobrii® (halobetasol propionate and tazarotene) lotion

We are also a party to a collaboration agreement with Perrigo Israel, an affiliate of Perrigo Company plc, for the development, manufacturing and commercialization of a generic version of Duobrii® (halobetasol propionate and tazarotene) lotion. In July 2020, Perrigo filled first-to-file Paragraph IV Certification for such generic version of Duobrii® lotion asserting that certain U.S. patents, each of which is listed in the FDA's Orange Book for the Duobrii® lotion, are either invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Perrigo's generic lotion, and on August 31, 2020, Bausch Health initiated patent infringement action in the U.S. District Court of New Jersey regarding Perrigo's ANDA for such product.

Other generic products

In addition, we have entered into collaboration agreements with Perrigo Israel, an affiliate of Perrigo Company plc, for the development, manufacturing and commercialization of seven other generic product candidates. Under such agreements and the agreements with respect to a generic version of Bryhali® (halobetasol propionate) lotion, 0.01% and a generic version of Duobrii® (halobetasol propionate and tazarotene) lotion referred to above, Perrigo will conduct the regulatory (if relevant), scientific, clinical and technical activities necessary to develop the generic product candidates and seek regulatory approval with the FDA for the generic product candidates. If approved by the FDA, Perrigo has agreed to commercialize the generic product candidates in the United States. We and Perrigo will share the development costs and the gross profits generated from the sales of the generic product candidates, if approved.

Intellectual Property

Our intellectual property and proprietary technology are directed to the development, manufacture and sale of our branded product candidates, including Twyneo®, Epsolay® and SGT-210. We seek to protect our intellectual property, core technologies and other know-how, through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others.

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business. If any of the below described applications are not approved, or any of the below described patents are invalidated, deemed unenforceable or otherwise successfully challenged, such loss would have a material effect on the commercialization of our product candidates and our future prospects.

Our patent portfolio that is directed to our branded product candidates includes 113 patents and patent applications and claims processes for manufacture (including silica microencapsulation platform and other technologies), formulations, composition of matter, and methods of use. Of these 113 patents and patent applications, 58 are granted patents (10 in the United States and 48 in other countries) and 55 are pending applications (27 in the United States and 28 in other countries).

For our Twyneo® product candidate, we have obtained patent protection for the composition of matter in the United States, Canada, Japan, Mexico (with a term until 2028) and we have a pending application claiming composition of matter in the European Patent Office. There are four patent families protecting the process for the encapsulation of the active agents of our Twyneo® product candidate (one patent family has patents granted in Canada, India, Mexico, Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland and the United Kingdom) and Japan (with a term until 2028) and applications pending in the United States; the second patent family has patents granted in Mexico, Canada and the United States (with a term until 2029) and an application pending in the United States; the third patent family has patents granted in Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland and the United Kingdom), China, India, Japan, Canada, Mexico and the United States (with a term until 2030) and applications pending in the United States); and the fourth patent family has patents granted in Canada, China, Israel, India, Mexico and the United States). We own pending patents for the formulation of our Twyneo® product candidate in the United States (with a term until 2032) and China, and patents granted in Japan, Canada, Mexico and Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland, United Kingdom) (with a term until 2032). We have pending patent applications in the United States for the composition of our Twyneo® product candidate and one patent granted in the United States for the method of treatment of Twyneo® (with a term until 2038). We have five trademarks registered for our Twyneo® product candidate in Israel, Europe, the United States and Canada.

For our Epsolay® product candidate, we have obtained patents in China, Canada, Japan, Europe, Mexico and the United States (with a term until 2032) covering the composition for topical treatment of rosacea. We have further pending applications for this composition in the United States, Canada and China. There are two patent families directed to the process for encapsulation of the active agents of our Epsolay® product candidate (one patent family has granted patents in Canada, India, Mexico, Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland and the United Kingdom) and Japan (with a term until 2028) and pending applications in the United States; and the second patent family has patents granted in Canada, China, Israel, India, Mexico and the United States). We also have 16 patent applications pending covering the methods of use of Epsolay® for the treatment of rosacea. We have four registered trademarks for our Epsolay® product candidate in Israel, Europe, Canada and the United States.

We have one not published application covering the compositions of Epsolay® and Twyneo®, the processes for the encapsulation of the active agents of our Epsolay® and Twyneo® product candidates, and the methods of use.

We have applied for patents covering the use of tapinarof in ophthalmic disorders including dry eye, uveitis, and blepharitis with or without demodex involvement.

We have four registered trademarks in Europe, Canada, the United States and Israel. These registrations cover potential brand names for our Epsolay® product candidate in Israel, Europe, Canada and the United States.

Competition

The pharmaceutical industry is subject to intense competition as well as rapid technological changes. Our ability to compete is based on a variety of factors, including product efficacy, safety, cost-effectiveness, patient compliance, patent position and effective product promotion. Competition is also based upon the ability of a company to offer a broad range of other product offerings, large direct sales forces and long-term customer relationships with target physicians.

There are numerous companies that have branded or generic products or product candidates in the dermatology market. Among them are Aclaris Therapeutics, Inc., Akorn, Inc., Almirall S.A., Aqua Pharmaceuticals LLC, Bayer HealthCare AG, Cassiopea SpA, Dermira, Inc., Vyne Pharmaceuticals Ltd., Galderma Pharma S.A., Glenmark Pharmaceuticals Ltd., G&W Laboratories, Inc., LEO Pharma A/S, Mylan N.V., Novan, Inc., Novartis AG, Novum Pharma, LLC, Perrigo Company plc, Pfizer, Inc., Spear Therapeutics, Ltd., Sun Pharmaceutical Industries Ltd., Teligent, Inc., Teva Pharmaceutical Industries Ltd. and Bausch Health Companies Inc.

In order for our approved product candidates, if any, to compete successfully in the dermatology market, we will have to demonstrate that their efficacy, safety and cost-effectiveness provide an attractive alternative to existing therapies, some of which are widely known and accepted by physicians and patients, as well as to future new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

Many of the companies, academic research institutions, governmental agencies and other organizations involved in the field of dermatology have substantially greater financial, technical and human resources than we do, and may be better equipped to discover, develop, test and obtain regulatory approvals for products that compete with ours. They may also be better equipped to manufacture, market and sell products. These companies, institutions, agencies and organizations may develop and introduce products and drug delivery technologies competitive with or superior to ours which could inhibit our market penetration efforts.

Twyneo® and Epsolay® target the well-established acne and rosacea markets. If approved, we expect them to compete with current standard-of-care treatments, whether branded, generic or over-the-counter, as well as with new treatments to be approved in the future. The current standard-of-care for acne includes topical anti-bacterial drugs such as benzoyl peroxide that are broadly available over-the-counter, prescription drug products that are based on single retinoid drug products such as Differin, Atralin, Retin-A, Retin-A Micro, Tazorac and Altreno, fixed-dose combinations of benzoyl peroxide and adapalene such as Epiduo and Epiduo Forte, fixed-dose combinations of benzoyl peroxide and clindamycin such as Duac, Benzaclin, Onexton and Acanya, fixed-dose combinations of tretinoin and clindamycin such as Ziana and Veltin, and topical antibiotics such as Aczone and Amzeeq. The current standard of care for rosacea includes Metrogel, Finacea, Soolantra and the recently launched Zilxi, as well as oral Oracea (doxycycline embedded in a technology platform). As a fixed-dose combination product candidate, Twyneo® may also compete with drug products utilizing other technologies that can separate two drug substances, such as dual chamber tubes, dual pouches or dual sachets. In addition to these products, our FDA approved generic version of Zovirax® (acyclovir) cream, 5% and our generic drug product candidates, including ivermectin cream, 1%, are expected to face direct competition from branded drugs and authorized generics which are prescription drugs produced by the branded pharmaceutical companies and marketed under a private label, at generic prices. On December 30, 2016, Actavis Ltd. submitted an ANDA for ivermectin, 1%, cream, and therefore we will only be able to commercialize this product after Actavis Ltd.'s six-month exclusivity period expires.

Marketing, Sales and Distribution

We currently have limited sales, marketing and distribution capabilities. In order to commercialize our product candidates, if approved for commercial sale, we expect to collaborate with third parties that have sales and marketing experience. We intend to commercialize our late-stage branded product candidates in the United States, if approved, through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize Twyneo®, Epsolay® or any of our other product candidates. In other markets, we also expect to selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

In preparation for commercial launch of Epsolay and Twyneo, we have opened a U.S. headquarters in Whippany, New Jersey.

Manufacturing

For the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials we rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, or on in-house manufacturing capabilities. As of August 2018, our in-house manufacturing operations have been audited for current good manufacturing, or cGMP, compliance, and were granted a cGMP certification by the Israel Ministry of Health. This certification allowed us to manufacture Twyneo® and its intermediates to support Phase 3 clinical trials. This cGMP certification expired in 2020, and since no other manufacturing for Phase 3 clinical trials is planned at the Company during 2021, the Company and the Israel Ministry of Health have mutually concluded that the cGMP certification will be reassessed and renewed for other products as they reach relevant stages of development. ISO 14001:2015 and OHSAS 18001:2007 certifications continue to be maintained and are due for renewal in May 2021 and March 2021, respectively. For commercial manufacturing of our products, we intend to rely solely on CMOs. It is our policy to have multiple or alternative sources where possible for every service and material we use in our products.

Government Regulation

Regulation by governmental authorities in Israel, the United States and other countries is a significant factor in the development, manufacture and commercialization of our product candidates and in our ongoing research and development activities. Our business is subject to extensive government regulation in Israel for its manufacturing activities involving drug products, drug product intermediates, and drug product active substances to be used in Phase 3 clinical trials and commercial manufacturing.

Product Approval Process in the United States

Review and approval of drugs

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act, or FDCA, and other federal and state statutes and implementing regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions and enforcement actions brought by the FDA, the Department of Justice or other governmental entities. Possible sanctions may include the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

FDA approval of a new drug application is required before any new unapproved drug or dosage form, can be marketed in the United States. Section 505 of the FDCA describes three types of new drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)). Section 505(b)(1) and 505(b)(2) new drug applications are referred to as NDAs, and section 505(j) applications are referred to as ANDAs.

In general, the process required by the FDA prior to marketing and distributing a new drug, as opposed to a generic drug subject to section 505(j), in the United States usually involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practices, or GLP, requirements or other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials in the United States may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- preparation and submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product or components thereof are produced, to assess compliance with current good manufacturing practices, or cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and
- payment of user fees and FDA review and approval of the NDA.

Pre-clinical studies

Pre-clinical studies include laboratory evaluation or product chemistry, formulation and toxicity, as well as animal studies to assess the potential safety and efficacy of the product candidate. Pre-clinical safety tests must be conducted in compliance with the FDA regulations. The results of the pre-clinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an investigational new drug application, or IND, which must become effective before clinical trials may commence. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30- day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. Long-term pre-clinical studies, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

Clinical trials

Clinical trials involve the administration of an investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the local institutional review board, or IRB, and to the FDA as part of the IND.

An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review at least annually. The IRB must review and approve, among other things, the trial protocol information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1*: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- *Phase 2*: The drug is administered to a limited patient population to identify possible short-term adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase 3*: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies, may be conducted after initial marketing approval, and may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

In addition, during the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Unlike NDA products which must be shown to be safe and effective for their intended use, ANDA products must be shown to be the same as, and bioequivalent to, a reference listed drug, or RLD, and superior over the vehicle. A product is considered bioequivalent if there is no significant difference in the rate and extent to which the active ingredient in the generic product and in the RLD becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Accordingly, an applicant typically compares the systemic exposure profile of the generic test drug product to that of the RLD at the same regimen and exposure period as the RLD to demonstrate bioequivalence. For most ANDAs, bioequivalence must be shown in human clinical trials, but in some cases, FDA will accept in vitro data. Specific requirements are typically outlined by FDA in product-specific bioequivalence guidance.

Submission of an NDA to the FDA

Assuming successful completion of all required testing with all applicable regulatory requirements, the results of the pre-clinical studies and clinical trials, together with other detailed information, including information on the manufacture, control and composition of the product, are submitted to the FDA as part of an NDA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, applicants are required to pay fees to the FDA for reviewing an NDA. These application user fees, as well as the annual program fees required for approved products, can be substantial. The NDA application review fee alone can exceed $2.5 million, subject to certain limited deferrals, waivers and reductions that may be available.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. If found complete, the FDA will accept the NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the PDUFA, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. An NDA is eligible for Priority Review if the product candidate is designed to treat serious or life-threatening disease or condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For non-new molecular entities, such as those typically submitted in 505(b)(2) applications, the FDA endeavors to review applications subject to Standard Review within approximately 10 months of receipt, whereas the FDA's goal is to review Priority Review applications within approximately six months of receipt. The FDA, however, may not approve a drug within these established goals, as the review process is often significantly extended by FDA requests for additional information or clarification, and its review goals are subject to change from time to time.

Before approving an NDA, the FDA inspects the facilities at which the product is manufactured or facilities that are significantly involved in the product development and distribution process and will not approve the product unless cGMP compliance is satisfactory. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter indicates that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies or trials be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or impose other limitations. For example, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require manufacturers to develop additional data or conduct additional pre-clinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Any drug products receiving FDA approval will be subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or patient populations that are not described in the drug's approved labeling, known as "off-label use," and other promotional activities, such as those considered to be false or misleading.

Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not encourage, market or promote such off-label uses. As a result, "off-label promotion" has formed the basis for litigation under the Federal False Claims Act, violations of which are subject to significant civil fines and penalties. In addition, manufacturers of prescription products are required to disclose annually to the Center for Medicaid and Medicare any payments made to physicians in the United States under the Sunshine Act of 2012. These payments could be in cash or kind, could be for any reason, and are required to be disclosed even if the payments are not related to the approved product. A failure to fully disclose or not report in time could lead to penalties of up to $1 million per year.

The manufacturing of any drug products must comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. The FDA's cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved NDA, as well as lead to potential market disruptions. These restrictions may include recalls, suspension of a product until the FDA is assured that quality standards can be met, and continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. There also are continuing, annual program user fee requirements for any approved products, as well as new application fees for supplemental applications with clinical data.

The FDA also may require post-marketing testing, or Phase IV testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of our product candidates.

Once approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Pediatric trials and exclusivity

Even when not pursuing a pediatric indication, under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that is adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric trials the applicant plans to conduct, including trial objectives and design, any deferral or waiver requests, and other information required by the statute. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may also, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Separately, in the event the FDA makes a written request for pediatric data relating to a drug product, an NDA sponsor who submits such data may be entitled to pediatric exclusivity. Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing non-patent exclusivity.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Amendments established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by submitting an ANDA to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data, and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include pre-clinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendment, and permits the filing of an NDA where at least some of the information required for approval comes from studies or trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2) typically serves as an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain pre-clinical studies or clinical trials for the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the labeled indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product or method of using the product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the FDA's Publication of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." Any applicant who submits an ANDA seeking approval of a generic equivalent of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (1) that no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) that such patent has expired; (3) the date on which such patent expires; or (4) that such patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding a patented method-of-use rather than certify to a listed method-of-use patent.

If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the ANDA or Section 505(b)(2) NDA until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, an ANDA or Section 505(b)(2) NDA until any non-patent exclusivity, as described in greater detail below, has expired.

If the ANDA or Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the ANDA or Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the ANDA or Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the ANDA or Section 505(b)(2) NDA until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay.

Moreover, in cases where an ANDA or Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five-year NCE exclusivity period, as described more fully below, and the patent holder brings suit within 45 days of notice of the Paragraph IV certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product that has the five-year NCE exclusivity. The court also has the ability to shorten or lengthen either the 30-month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Non-Patent Exclusivity

In addition to patent exclusivity, NDA holders may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a Paragraph IV certification.

Another form of non-patent exclusivity is clinical investigation exclusivity. A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Review and Approval of Drug Products Outside the United States

In addition to regulations in the United States, if we target non-U.S. markets, we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized, decentralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure includes selecting one "reference member state," or RMS, and submitting to more than one-member state at the same time. The RMS National Competent Authority conducts a detailed review and prepares an assessment report, to which concerned member states provide comment. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states post-initial approval. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize the approval.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and other markets, sales of any product candidates for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of Epsolay® and Twyneo®, in addition to the costs required to obtain the FDA approvals. For example, Epsolay® and Twyneo® may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies or trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, there are increasingly high barriers to entry for new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Reform

In March 2010, the President of the United States signed the Affordable Care Act, one of the most significant healthcare reform measures in decades. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The Affordable Care Act contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which impacted existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Additionally, the Affordable Care Act increased the minimum level of rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%, and imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. By way of example, the Tax Act was enacted, which, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court the rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the Affordable Care Act will impact the law or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare initiatives will be adopted in the future, any of which could impact the coverage and reimbursement for drugs, including our product candidates, if approved.

Healthcare Laws and Regulations

Although we do not currently have any product candidates on the market, other than the first generic version of Zovirax® (acyclovir) cream, 5% for which Perrigo, our collaborator, received final FDA approval in February 2019, our current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician and other healthcare provider payment transparency laws. Some of our pre-commercial activities are subject to some of these laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf to knowingly and willfully, directly or indirectly solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to a federal program. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our product candidates, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our product candidates, and the sale and marketing of our product candidates, are subject to scrutiny under this law. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

HIPAA created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The Affordable Care Act imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, as well as certain ownership and investment interests held by physicians as defined by statute and their immediate family members.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that any of our product candidates are sold in a foreign country, we may be subject to similar foreign laws. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices, require reporting of marketing expenditures and pricing information and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations, and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Data Privacy and Security

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the GDPR, which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU members states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information” which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer “adequate” privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or € 20,000,000, whichever is greater. Additionally, following the United Kingdom’s withdrawal from the European Union, we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million/ £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

HIPAA, as amended by HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties. By way of example, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability.

Innovation Authority

We have received royalty-bearing grants from the government of Israel through the IIA, for the financing of a portion of our research and development expenditures in Israel.

Under the Innovation Law and the IIA's rules and guidelines, recipients of grants, or Recipient Company(ies), are subject to certain obligations including, the following:

- In general, the Recipient Company is obligated to pay the IIA royalties from the revenues generated from the sale of products (and related services) developed (in all or in part) as a result of, a research and development program funded by the IIA at rates which are determined under the IIA's rules and guidelines (currently a yearly rate of 1.3% to 5% on sales of products or services developed under the approved programs, depending on the type of the Recipient Company — i.e., whether it is a "Small Company," a "Large Company" or a "Traditional Industrial Company" as such terms are defined in the IIA's rules and guidelines), up to the aggregate amount of the total grants received by the IIA, plus annual interest (as determined in the IIA's rules and guidelines);

- Products developed as a result of the IIA funded R&D must, as a general matter, be manufactured in Israel. The Recipient Company is prohibited from manufacturing products developed using these IIA grants outside of the State of Israel without receiving prior approval from the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate which requires only a notice). If the Recipient Company receives approval to manufacture products developed with government grants outside of Israel, it will be required to pay increased royalties to the IIA, up to 300% of the grant amount plus interest, depending on the manufacturing volume that is performed outside of Israel. The Recipient Company may also be subject to an accelerated royalty repayment rate. A Recipient Company also has the option of declaring in its IIA grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval following the receipt of the grant; and

- Under the IIA's rules and guidelines, a Recipient Company is prohibited from transferring the IIA-financed know-how and related intellectual property rights outside of Israel except under limited circumstances, and only with the approval of the Research Committee and subject to certain payments to the IIA calculated according to formulas provided under the IIA's rules and guidelines (which are capped to amounts specified under such rules and guidelines).

We have received grants from the IIA in connection with our research and development of a peripheral line of product candidates, which forms a negligible part of our activities, and therefore, we are subject to the aforementioned restrictions with respect to such product candidates. Such restrictions continue to apply even after payment of the full amount of royalties payable pursuant to the grants.

Even if our IIA funded know-how is transferred to another Israeli entity, the transfer would require the IIA's approval but will not be subject to the payment of a redemption fee (we note that there will be an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation). In such case, the acquiring company would have to assume all of our responsibilities towards the IIA as a condition to the IIA's approval.

The government of Israel does not own intellectual property rights in technology developed with IIA funding and there is no restriction on the export of products manufactured using technology developed with IIA funding. However, the know-how is subject to transfer of know-how and manufacturing rights restrictions as described above. The IIA's approval is not required for the export of any products resulting from the IIA research or development grants. In addition, the IIA has recently published new rules and guidelines for the granting of licenses to use know-how developed as a result of research financed by the IIA to foreign entities. According to such rules, we will be required to receive the IIA's prior approval for the grant of such use rights, and we will be subject to the IIA in accordance with the formula stipulated under these rules and guidelines.

Pursuant to Amendment No. 7 of the Innovation Law, the IIA is authorized to change the restrictions imposed on the recipients of grants that were stipulated under the Innovation Law prior to the effectiveness of Amendment No. 7 with a new set of arrangements in connection with ownership obligations of know-how (including with respect to restrictions on transfer of know-how and manufacturing activities outside of Israel), as well as royalties obligations associated with approved programs. Amendment No. 7 also includes provisions with respect to sanctions imposed for violations of the Innovation Law. The IIA published rules for the most part adopted the principal provisions and restrictions specified in the Innovation Law prior to the effectiveness of Amendment No. 7.

We may not receive the required approvals for any actual proposed transfer and, if received, we may be required to pay the IIA a portion of the consideration that we receive upon any sale of the IIA funded know-how to a non-Israeli entity. The scope of the support received, the royalties that we have already paid to the IIA, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which the IIA grants were received and the sale price and the form of transaction will be taken into account in calculating the amount of the payment to the IIA.

Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions including Israel. These laws and regulations govern, among other things, (i) the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage and (ii) chemical, air, water and ground contamination, air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations at our Ness Ziona facility use chemicals and produce waste materials and sewage. Our activities require permits from various governmental authorities, including local municipal authorities, the Ministry of Environmental Protection and the Ministry of Health. The Ministry of Environmental Protection and the Ministry of Health, local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations. Our business permit is currently in effect until December 31, 2026.

These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted.

The operations of our subcontractors and suppliers are also subject to various Israeli and foreign laws and regulations relating to environmental, health and safety matters, and their failure to comply with such laws and regulations could have a material adverse effect on our business and reputation, result in an interruption or delay in the development or manufacture of our product candidates, or increase the costs for the development or manufacture of our product candidates.

Properties

Our principal executive offices are located in a leased facility in Weizmann Science Park, Ness Ziona 7403650, Israel. The facility is 2,040 square meters, and houses our offices, warehouse, laboratories and production area. Our lease will expire on December 31, 2023.

We have a U.S. headquarters in Whippany, New Jersey. The facility is 3,361 square feet and houses our U.S. marketing and sales team. Our lease will expire on October 1, 2023.

Legal Proceedings

We are not subject to any material legal proceedings.

C. Organizational Structure

Not applicable.

D. Property, Plant and Equipment

See “Item 4. Information on the Company—B. Business Overview—Properties”.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the consolidated financial statements and the notes thereto included elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this annual report, particularly those in "Item 3. Key Information – D. Risk Factors."

Overview

We are a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Our current product candidate pipeline consists of late-stage and early-stage branded product candidates, some of which leverage our proprietary, silica-based microencapsulation technology platform, and several generic product candidates across multiple indications. Our branded product candidate, Twyneo®, is a novel, once-daily, non-antibiotic topical cream that we are developing for the treatment of acne vulgaris, or acne. We completed a 726 subject, double-blind, placebo-controlled, six-arm, multi-center Phase II clinical trial designed to assess the safety and efficacy of Twyneo® in subjects with facial acne. In this trial, Twyneo® demonstrated statistically significant improvements in all pre-defined co-primary and secondary efficacy endpoints, as compared to vehicle.

On December 30, 2019, we announced top-line results from two pivotal Phase 3 clinical trials evaluating Twyneo® for the treatment of acne. Twyneo® met all co-primary endpoints in both Phase 3 trials. The Phase 3 program enrolled an aggregate of 858 patients aged nine and older in two multicenter, randomized, double-blind, parallel group, vehicle-controlled trials at 63 sites across the United States. Twyneo® demonstrated statistically significant improvement in each of the co-primary endpoints of (1) the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale, (2) an absolute change from baseline in inflammatory lesion count at Week 12, and (3) and an absolute change from baseline in non-inflammatory lesion count at Week 12. In addition, Twyneo® was found to be well-tolerated. Our NDA for Twyneo® has been accepted for filing by the FDA, which assigned a PDUFA goal date of August 1, 2021.

Our branded product candidate, Epsolay®, is a novel, once-daily topical cream containing encapsulated benzoyl peroxide that we are developing for the treatment of papulopustular (subtype II) rosacea. On July 8, 2019, we announced positive top-line results from our Phase 3 program evaluating Epsolay®. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Epsolay® demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving "clear" or "almost clear" in the Investigator Global Assessment, or IGA, relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay® demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. In addition, Epsolay® was found to be well-tolerated.

On February 12, 2020, we announced positive topline results from our open-label, long-term safety study, evaluating Epsolay® for a treatment duration up to 52 weeks. The study enrolled 547 subjects, all of whom had completed 12 weeks of treatment with Epsolay® or vehicle in the preceding double-blind Phase 3 studies. Patients continued onto open-label treatment with Epsolay once-daily for up to an additional 40 weeks. The safety population of 535 subjects received Epsolay® therapy for an overall period of at least 28 weeks. Of these 535 subjects, 209 subjects completed 52 weeks of treatment with Epsolay®, exceeding the sample size requirements previously defined by the FDA for the Epsolay® one-year safety evaluation. Our NDA for Epsolay® has been accepted for filing by the FDA, which assigned a PDUFA goal date of April 26, 2021.

Our other branded product candidates are SGT-210 (erlotinib gel) that we are developing for the treatment of palmoplantar keratoderma (PPK), and erlotinib, tapinarof and roflumilast, each a potential treatment of various pharmaceutical indications.

We designed our proprietary, silica-based microencapsulation technology platform to enhance the tolerability and stability of topical drugs while maintaining their efficacy. Topical drugs often struggle to balance achieving both high efficacy and high tolerability. Our technology platform entraps active ingredients in an inert, inorganic silica shell, which creates an unnoticeable barrier between the active ingredient and the skin. The resulting microcapsules are designed to allow the entrapped active ingredients to gradually migrate through the pores of the shell and deliver active ingredient doses onto the skin in a controlled manner, resulting in improved tolerability and stability without sacrificing efficacy. By separately encapsulating active ingredients within protective silica shells, our technology platform also enables the production of novel fixed-dose active ingredient combinations that otherwise would not be stable. We believe that our microencapsulation technology has the potential to be used for topical drug products to treat a variety of skin diseases. As a result of the FDA having already approved silica as a safe excipient for topical drug products, we have submitted NDAs for Twyneo and Epsolay under the FDA's 505(b)(2) regulatory pathway, which may provide for a more efficient regulatory process by permitting us to rely, in part, upon the FDA's previous findings of safety and efficacy of an approved product.

In order to commercialize our product candidates, if approved for commercial sale, we expect to collaborate with third parties that have sales and marketing experience. We intend to commercialize our late-stage branded product candidates in the United States, if approved, through one or more third party collaborators that have direct sales forces and established distribution systems in lieu of our own sales force and distribution systems. We are in discussions with potential partners regarding the commercialization of Twyneo® and Epsolay®. In other markets, we also expect to selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

Since our inception, we have incurred significant operating losses. We incurred net losses of $32.2 million, $24.6 million and $29.3 million for the years ended December 31, 2018, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of $181.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates from formulation development through pre-clinical development and clinical trials, seek regulatory approval and pursue commercialization of any approved product candidate. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates.

In February 2018 we closed our initial public offering, at which time we sold a total of 7,187,500 ordinary shares in the offering and received net proceeds of approximately $78.8 million, after deducting underwriting discounts and commissions and without deducting other offering expenses.

On August 12, 2019, the Company completed an underwritten public offering, in which it issued 1,437,500 ordinary shares, including the full exercise by the underwriters of their option to purchase 187,500 additional ordinary shares, at a public offering price of $8.00 per ordinary share. The total proceeds received from the offering were approximately $10.8 million net of underwriting discounts and commissions and without deducting other offering expenses.

On February 19, 2020 the Company completed an underwritten public offering in which it issued 2,091,907 ordinary shares together with ordinary share warrants to purchase 1,673,525 ordinary shares. The ordinary shares and warrants were sold together at a combined public offering price of $11.00 per ordinary share and accompanying warrant to purchase 0.80 of an ordinary share. The warrants have an initial exercise price of $14.00 per share, subject to certain adjustments, and will expire on February 19, 2023. The total proceeds received from the offering were approximately $21.6 million net of underwriting discounts and commissions and without deducting other offering expenses.

In addition, following the approval of the Company's shareholders, M. Arkin Dermatology Ltd., the controlling shareholder of the Company, purchased 454,628 ordinary shares and warrants to purchase up to 363,702 ordinary shares in a concurrent private placement, exempt from the registration of the Securities Act of 1933, as amended, at a price equal to the public offering price of the ordinary shares and accompanying warrants in the February 2020 public offering. The private placement, which closed on April 13, 2020, generated proceeds of approximately $5 million.

Collaboration Agreements

For a description of our collaboration agreements, please see "Item 4. Information on the Company—B. Business Overview—Collaboration Agreements with Perrigo."

A. Operating Results

Collaboration Revenues

From 2013 until December 31, 2018, other than revenues of approximately $0.2 million and $0.1 million on royalties generated in 2017 and 2018, respectively, pursuant to sales of products overseas under past collaboration agreements with Merck, we did not recognize any revenue. In 2019, we generated approximately $0.1 million in revenues under such past collaboration agreements with Merck. In addition, in February 2019 we announced that Perrigo had received final approval from the FDA for of the first generic version of Zovirax® (acyclovir) cream, 5% . The product was developed in a collaboration between us and Perrigo in which we shared development costs with Perrigo and are sharing equally the gross profits generated from sales of the product. During the years ended December 31, 2019 and December 31, 2020, the Company recognized revenues from royalties related to sales of this product in the amount of $22.8 million and $8.7 million, respectively.

Operating expenses

Our current operating expenses consist primarily of research and development as well as general and administrative expenses.

Research and development expenses

Research and development expenses consist principally of:

- salaries for research and development staff and related expenses, including employee benefits and share-based compensation expenses;
- expenses paid to suppliers of disposables and raw materials, including drug substances, and related expenses, such as, external laboratory testing and development of analytical methods;
- expenses for production of our product candidates both in-house and by contract manufacturers;
- expenses paid to contract research organizations and other third parties in connection with the performance of pre-clinical studies, clinical trials and related expenses;
- expenses incurred under agreements with other third parties, including subcontractors, suppliers and consultants that conduct formulation development, regulatory activities and pre-clinical studies;
- expenses incurred to acquire, develop and manufacture materials for use in pre-clinical and other studies;
- expenses incurred from the purchase and transfer of product candidates; and
- facilities, depreciation of fixed assets used to develop our product candidates, maintenance of equipment used to develop our product candidates and other expenses, including direct and allocated expenses for rent, maintenance of facilities, insurance and other operating expenses.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development expenses than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect to continue to incur research and development expenses over the next several years as we conduct pre-clinical studies and clinical trials and prepare regulatory filings for our product candidates.

Due to the inherently unpredictable and highly uncertain nature of clinical development processes, we cannot reasonably estimate the nature, timing and expenses of the efforts that will be necessary to complete the remainder of the development of our product candidates, or when, if ever, material net cash inflows may commence from any of our product candidates. Clinical development timelines, the probability of success and development expenses can differ materially from expectations. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- clinical trials and early-stage results;
- the terms and timing of regulatory requirements and approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance of any product candidate that we are developing or may develop in the future.

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of the candidates' commercial potential. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for one or more of our product candidates in certain indications in order to focus our resources on more promising product candidates. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and related expenses, including employee benefits and share-based compensation expenses, legal expenses and professional fees for auditors and other expenses not related to research and development activities.

As we are in discussions with potential partners regarding the commercialization of Twyneo® and Epsolay® to occur if the product candidates receive regulatory approval from the FDA, we do not currently anticipate an increase in general and administrative expenses. However, if we are unable to enter into such arrangements on acceptable terms or at all, we may look to directly commercialize Twyneo® and Epsolay® on our own. In such case, our expenses related to product sales, marketing and distribution would increase significantly and we may be forced to raise additional capital sooner than anticipated.

Financial income, net

Our financial income, net consists primarily of income generated on our marketable securities and bank deposits net of expenses related to bank charges and foreign currency exchange transactions.

Results of operations

The following table summarizes our results of operations for the indicated periods:

	Year ended December 31,		
	2018	2019	2020
		(in thousands)	
Collaboration Revenues	$ 129	$ 22,904	$ 8,771
Research and development	28,146	40,578	27,913
General and administrative	5,504	8,276	11,091
Total operating loss	33,521	25,950	30,233
Financial income, net	(1.318)	(1,374)	943
Loss before income taxes	32,203	24,576	29,290
Income taxes		33	
Loss for the year	$ 32,203	$ 24,609	$ 29,290

Year ended December 31, 2019 compared to year ended December 31, 2020

Collaboration Revenues

Revenues are comprised mainly of royalties earned under a collaboration agreement with Perrigo related to the first generic version of Zovirax® (acyclovir) cream, 5%, which generated$8.7 million in 2020, compared with $22.8 million in 2019. The decrease in revenues in 2020 resulted mainly from the entrance of an additional generic version of this product into the market and to a certain extent the impact of COVID-19.

Research and development expenses

The following table describes the breakdown of our research and development expenses for the indicated periods:

	Year Ended December 31,	
	2019	2020
	(in thousands)	
Payroll and related expenses	$ 6,001	$ 6,194
Clinical trial expenses	23,037	5,179
Professional consulting and subcontracted work	7,425	12,855
Other	4,115	3,685
Total research and development expenses	$ 40,578	$ 27,913

Our research and development expenses were $40.6 million for the year ended December 31, 2019, compared to $27.9 million for the year ended December 31, 2020. The decrease of $12.7 million was mainly attributed to a decrease of $17.9 million in clinical trial expenses, mainly related to the completion of the clinical trials of Epsolay and Twyneo, towards the end of 2019, a decrease of $0.4 million in other expenses, mainly purchase of raw material for manufacturing, partially offset by an increase of $5.4 million in manufacturing expenses.

General and administrative expenses

Our general and administrative expenses were $8.3 million for the year ended December 31, 2019, compared to $11.1 million for the year ended December 31, 2020. The increase of $2.8 million was mainly attributed to an increase of $3.0 million in commercialization expenses and an increase of $0.4 million in patent related expenses, partially offset by a decrease of $0.7 million in stock based compensation expenses.

Financial income, net

Our financial income, net, was $1.4 million for the year ended December 31, 2019 compared to $0.9 million for the year ended December 31, 2020.

Year ended December 31, 2018 compared to year ended December 31, 2019

This analysis can be found in Item 5 of the Company's Annual Report on Form 20-F for the year ended December 31, 2019.

Significant Accounting Policies and Estimates

We prepare our consolidated financial statements in conformity with U.S. GAAP. We describe our significant accounting policies and estimates more fully in Note 2 to our consolidated financial statements as of and for the year ended December 31, 2020, included elsewhere in this annual report. We believe that the accounting policies and estimates below are critical in order to fully understand and evaluate our financial condition and results of operations. In preparing these consolidated financial statements, our management has made estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods recognized in our financial statements. Actual results may differ from these estimates. As applicable to the consolidated financial statements included in this annual report, the most significant estimates and assumptions relate to the fair value of share-based compensation.

Share-based Compensation

Share-based compensation reflects the compensation expense of our share option programs granted to employees which compensation expense is measured at the grant date fair value of the options. The grant date fair value of share-based compensation is recognized as an expense over the requisite service period, net of estimated forfeitures. We recognize compensation expense for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach, and classify these amounts in our statement of operations based on the department to which the related employee reports.

Options Valuation

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value of the shared based compensation.

For the purpose of the evaluation of the fair value and the manner of the recognition of share-based compensation, our management is required to estimate, among others, various subjective and complex parameters that are included in the calculation of the fair value of the option. These parameters include the expected volatility of our share price over the expected term of the options, the risk-free interest rate assumption, and the term the that options are expected to remain outstanding.

JOBS Act

On April 5, 2012, the JOBS Act was signed into law. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we elected or may elect to rely on certain exemptions, including without limitation, not (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply until the earliest of (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.07 billion; (b) December 31, 2023, the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act.

B. Liquidity and Capital Resources

Overview

Since our inception, we have devoted substantially all of our resources to developing our product candidates, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing for general and administrative support for these operations. Although we are expected to launch an additional generic product in 2021, we do not currently have any approved products other than the first generic version of Zovirax® (acyclovir) cream, 5% for which Perrigo, our collaborator, received final FDA approval in February 2019.

From inception through December 31, 2020, we have funded our operations primarily through proceeds from our public offerings, the issuance of equity securities to and loans and investments from our controlling shareholder, funding received from the IIA and from amounts received pursuant to past and current collaboration agreements. We automatically converted our outstanding promissory note between us and our controlling shareholder into an aggregate of 5,444,825 ordinary shares immediately prior to the closing of our initial public offering. For a description of the conversion of our shareholder loan agreement, see "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions — Loan Agreements with Our Controlling Shareholder." As of December 31, 2020, our cash and cash equivalents, bank deposits and marketable securities were $50.2 million.

On February 5, 2018, we announced the closing of our initial public offering of 7,187,500 ordinary shares at a public offering price of $12.00 per ordinary share, which included the exercise in full by the underwriters of their option to purchase up to 937,500 additional shares. The aggregate net proceeds to us from the offering were approximately $78.8 million, after deducting underwriting discounts and commissions and before deducting other offering expenses.

On August 12, 2019, the Company completed an underwritten public offering in which it issued 1,437,500 ordinary shares, including the full exercise by the underwriters of their option to purchase 187,500 additional ordinary shares, at a public offering price of $8.00 per ordinary share. The total proceeds received from the offering were approximately $10.8 million net of underwriting discounts and commissions and without deducting other offering expenses.

On February 19, 2020 the Company completed an underwritten public offering in which it issued 2,091,907 ordinary shares together with ordinary share warrants to purchase 1,673,525 ordinary shares. The ordinary shares and accompanying warrants were sold together at a combined public offering price of $11.00 per ordinary share and accompanying warrant. Each warrant sold in the underwritten public offering is exercisable for 0.80 of an ordinary share and has an initial exercise price of $14.00 per share, subject to certain adjustments. The warrants are immediately exercisable and will expire on February 19, 2023. The total proceeds received from the offering were approximately $21.6 million net of underwriting discounts and commissions and without deducting other offering expenses.

In addition M. Arkin Dermatology Ltd., the controlling shareholder of the Company, has purchased 454,628 ordinary shares and warrants to purchase up to 363,702 ordinary shares in a concurrent private placement, exempt from the registration of the Securities Act of 1933, as amended, at a price equal to the public offering price of the ordinary shares and accompanying warrants in the underwritten public offering. The private placement has generated proceeds of approximately $5 million.

The Company was informed by its collaboration partner that the launch of an FDA-approved generic drug is expected in the second quarter of 2021. Annual sales of the brand name exceed $180 million in the United States in 2019.

The table below summarizes our cash flow activities for the indicated periods:

	Year Ended December 31,		
	2018	2019	2020
	(in thousands)		
Net cash used in operating activities	$ (23,467)	$ (22,500)	$ (25,241)
Net cash provided by (used in) investing activities	(54,735)	16,024	(2,694)
Net cash provided by financing activities	78,819	10,613	26,457
Increase (decrease) in cash and cash equivalents	$ 617	$ 4,137	$ (1,478)

Operating Activities

Net cash used in operating activities was $22.5 million during the year ended December 31, 2019, compared to $25.2 million during the year ended December 31, 2020.

Net cash used in operating activities in the year ended December 31, 2020 primarily resulted from our loss of $29.3 million during the period, $1.6 million of net changes in working capital and non-cash expenses of $1.2 million share-based compensation expenses and $0.9 million of depreciation of property and equipment.

Net cash used in operating activities in the year ended December 31, 2019 primarily resulted from our loss of $24.6 million during the period, a net increase of $1.5 million in working capital, net of non-cash expenses of $2.6 million share-based compensation expenses and $0.9 million of depreciation of property and equipment.

Net cash used in operating activities was $23.5 million during the year ended December 31, 2018, compared to $22.5 million during the year ended December 31, 2019.

Net cash used in operating activities in the year ended December 31, 2018 primarily resulted from our loss of $32.2 million during the period, $3.2 million of net changes in working capital and non- cash expenses of $4.7 million share-based compensation expenses and $0.8 million of depreciation of property and equipment.

Investing Activities

Net cash provided by investing activities was $16.0 million during the year ended December 31, 2019, compared to net cash used in investing activities of $2.7 million during the year ended December 31, 2020. The 2019 net cash provided by investing activities resulted mainly from $15.6 million proceeds from marketable securities, net, and $1.0 million proceeds from bank deposits offset by investment of $0.6 million in property and equipment. The 2020 net cash used in investing activities resulted mainly from $19.2 million proceeds from marketable securities, net, offset by investment of $0.5 million in property and equipment and investment of $21.4 million in bank deposits.

Net cash used in investing activities was $54.7 million during the year ended December 31, 2018, compared to net cash provided by investing activities of $16.0 million during the year ended December 31, 2019. The 2018 net cash used in investing activities resulted mainly from $56.7 million investment in marketable securities, net, and investment of $1.0 million in property and equipment offset by $3.0 million proceeds from bank deposits.

Financing Activities

Net cash from financing activities was $10.6 million during the year ended December 31, 2019, compared to $26.4 million during the year ended December 31, 2020. The increase was principally due to our underwritten public offering in 2019, net of issuance cost, of $10.6 million, compared to our underwritten public offering and private placement in 2020, net of issuance cost, of $26.3 million.

Net cash from financing activities was $78.8 million during the year ended December 31, 2018, compared to $10.6 million during the year ended December 31, 2019. The decrease was due to our initial public offering in 2018, net of issuance cost, of $78.9 million, compared to our underwritten public offering in 2019, net of issuance cost, of $10.6 million.

Funding Requirements

Our primary uses of cash have been to fund working capital requirements and research and development. We expect to continue to incur net losses for the foreseeable future as we continue to invest in research and development and seek to obtain regulatory approval for and commercialize our product candidates. We believe that our existing cash resources will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our ability to continue as a going concern will depend on our ability to generate positive cash flow from operations and obtain additional financing, both of which are uncertain.

Developing drugs, conducting clinical trials, obtaining commercial manufacturing capabilities and commercializing products is expensive and we will need to raise substantial additional funds to achieve our strategic objectives. We will require significant additional financing in the future to fund our operations, including if and when we progress into additional clinical trials for our product candidates, obtain regulatory approval for one or more of our product candidates, obtain commercial manufacturing capabilities and commercialize one or more of our product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress and expenses of our pre-clinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the expenses and timing of obtaining regulatory approval, if any, for our product candidates;
- the expenses of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the expenses of, and timing for, expanding our manufacturing agreements for production of sufficient clinical and commercial quantities of our product candidates; and
- the potential expenses of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally.

Other than revenue that we expect to generate from a collaboration between us and Perrigo with respect to the first generic version of Zovirax® (acyclovir) cream, 5% and from a second partnered generic dermatology product with an anticipated launched date in the second quarter of 2021, until we can generate recurring revenues, we expect to satisfy our future cash needs through existing cash resources, additional debt or equity financings or by entering into collaborations with third parties in connection with one or more of our product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. In addition, the terms of any securities we issue in future financings may be more favorable to new investors and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding. If we raise additional funds through collaborations with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to obtain adequate funds on reasonable terms, we will need to curtail operations significantly, including possibly postponing anticipated clinical trials or entering into financing agreements with unattractive terms.

C. Research and Development, Patents and Licenses

For a description of our research and development programs and the amounts that we have incurred over the last two years pursuant to those programs, please see “Item 5. Operating and Financial Review and Prospects — A. Operating Results — Research and Development Expenses”; and “Item 5. Operating and Financial Review and Prospects — A. Operating Results — Year Ended December 31, 2019 compared to Year ended December 31, 2020 - Research and Development Expenses.”; and “Item 5. Operating and Financial Review and Prospects — A. Operating Results — Year Ended December 31, 2018 compared to Year ended December 31, 2019 - Research and Development Expenses.”

D. Trend Information

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events for the period from January 1, 2020 to December 31, 2020 that are reasonably likely to have a material adverse effect on our revenue, income, profitability, liquidity or capital resources, or that caused that disclosed financial information to be not necessarily indicative of future operating results or financial condition.

E. Off-Balance Sheet Arrangements

We do not have any, and during the periods presented we did not have any, off-balance sheet arrangements as defined in the rules and regulations of the SEC.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020:

	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
			(in thousands)		
Operating lease obligations (1)	$ 2,140	$ 778	$ 1,362	-	-
Total	$ 2,140	$ 778	$ 1,362	-	-

(1) Operating lease obligations consist of payments pursuant to several lease agreements that are scheduled to expire on December 31, 2023.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information concerning our directors and senior management, which includes members of our administrative, supervisory and management bodies, including their ages, as of the date of this annual report:

Name	Age	Position
Moshe Arkin	68	Chairman of the Board of Directors
Alon Seri-Levy	59	Chief Executive Officer and Director
Gilad Mamlok	52	Chief Financial Officer
Ofer Toledano	55	Vice President Research and Development
Ofra Levy-Hacham	54	Vice President Clinical and Regulatory Affairs
Karine Neimann	49	Vice President Projects and Planning, Chief Chemist
Itzik Yosef	44	Vice President Operations
Dov Zamir	67	Vice President Special Projects
Nissim Bilman	59	Vice President Quality
John Vieira	51	U.S. Head of Commercialization
Itai Arkin	32	Director
Shmuel Ben Zvi	60	Director
Hani Lerman	48	Director
Yaffa Krindel-Sieradzki	66	Director
Jonathan B. Siegel	47	Director
Ran Gottfried	76	External Director
Jerrold S. Gattegno	68	External Director

Mr. Moshe Arkin has served as chairman of our board of directors since 2014. Mr. Moshe Arkin currently sits on the board of directors of several private pharmaceutical and medical device companies including Exalenz Bioscience Ltd., a developer of advanced systems for gastrointestinal and liver disorders since 2006, SoniVie Ltd., a company developing systems for the treatment of pulmonary arterial hypertension, Digma Medical, a company developing systems to treat insulin resistance present in type 2 diabetes and other metabolic syndrome diseases, and Valcare Medical, a company developing heart valve devices. From 2005 to 2008, Mr. Moshe Arkin served as the head of generics at Perrigo Company and from 2005 until 2011 as the vice chairman of its board of directors. Prior to joining us, Mr. Moshe Arkin served as a director of cCAM Biotherapeutics Ltd., a company focused on the discovery and development of novel immunotherapies to treat cancer from 2012 until its acquisition in 2015 by Merck & Co., Inc. Mr. Moshe Arkin served as chairman of Agis Industries Ltd. from its inception in 1972 until its acquisition by Perrigo Company in 2005. Mr. Moshe Arkin holds a B.A. in psychology from the Tel Aviv University, Israel.

Dr. Alon Seri-Levy co-founded Sol-Gel and has served as our chief executive officer since our inception in 1997 and as a member of our board of directors until 2014. Prior to founding Sol-Gel, Dr. Seri-Levy established the computer-aided drug design department at Peptor Ltd., an Israeli research and development company that specialized in the development of peptide-based drug products. Dr. Seri-Levy holds a Ph.D. in Chemistry (summa cum laude) from The Hebrew University of Jerusalem, Israel, and conducted his post-doctoral studies at Oxford University, United Kingdom. Dr. Seri-Levy was appointed to our board of directors immediately following the pricing of our initial public offering.

Mr. Gilad Mamlok has served as our chief financial officer since February 2017. From August 2015 to January 2017, Mr. Mamlok served as the chief financial officer for Medigus Ltd., a medical device company dual listed on Nasdaq and the Tel Aviv Stock Exchange, or the TASE. From September 2005 to March 2015, Mr. Mamlok served as senior vice president, global finance and accounting of Given Imaging Ltd., a medical device company dual listed on Nasdaq and TASE, acquired by Covidien plc in February 2014. From January 2002 to September 2005, Mr. Mamlok served as chief financial officer of two other medical device companies. Mr. Mamlok holds a Master’s degree in business economics from Tel-Aviv University and a B.A. in economics (magna cum laude) from Tel-Aviv University, Israel.

Dr. Ofer Toledano has served as our vice president of research and development since 2004. Prior to joining Sol-Gel, Dr. Toledano served as manager of the formulation department at ADAMA Agricultural Solutions Ltd. (formerly known as Makhteshim Agan Industries Ltd.), an Israeli manufacturer and distributor of crop protection products from 1998 until 2004. Dr. Toledano holds a Ph.D. in chemistry from The Hebrew University of Jerusalem, Israel.

Dr. Ofra Levy-Hacham has served as our vice president of clinical and regulatory affairs since 2018, and as our vice president of quality and regulatory affairs from 2011 to 2018. Prior to joining Sol-Gel, Dr. Levy-Hacham served as a scientific specialist and project manager at Biotechnology General Ltd., a wholly owned subsidiary of Ferring Pharmaceuticals Ltd., and a fully integrated biopharmaceutical services private company from 2010 until 2011. From 2005 until 2010, Dr. Levy-Hacham served as vice president chemistry, manufacturing and controls at HealOr Ltd., a private company engaging in the development of therapeutics for the treatment of various skin disorders. Dr. Levy-Hacham holds a Ph.D. in chemistry from The Technion – Israel Institute of Technology, Israel.

Dr. Karine Neimann has served as our vice president of projects and planning and chief chemist since September 2016. Since joining us in 2008, Dr. Neimann held various positions, including as chief chemist and laboratory manager. Dr. Neimann holds a Ph.D. in chemistry from The Hebrew University of Jerusalem, Israel.

Dr. Itzik Yosef has served as our vice president of operations since August 2016. Since joining us in 2010, Dr. Yosef held various positions including as head of operations. Dr. Yosef holds a Ph.D. in chemistry from The Hebrew University of Jerusalem, Israel.

Dr. Dubi Zamir has served as our vice president special projects since August 2016. Prior to joining us, Dr. Zamir lead the R&D group in Cima NanoTech Ltd., a private company developing sophisticated nanotechnology-based coating formulations from 2007 until 2016. From 2004 to 2007, Dr. Zamir was VP of Pharma and Analytical R&D at Taro Pharmaceutical Industries in Haifa, and for three years prior to that he managed its Analytical R&D lab. Dr. Zamir holds a Ph.D. in organic chemistry from Tel-Aviv University, Israel.

Mr. Nissim Bilman became Vice President Quality of Sol-Gel on the August 15, 2018. From 2004 until 2018, Mr. Bilman served as CEO of QPRO Pharma, a project management and consulting company offering services related to the pharmaceutical industry. From 2011 until 2018, he served as the Vice President Drug Development of Exalenz Bioscience. From 2007 until 2010, Mr. Bilman served as VP R&D and Manufacturing and Site Manager for Gelesis Inc./Gelesis R&D Ltd. Mr. Bilman holds a Bachelor Degree in Chemistry and Meteorology, as well as a Master of Science in Applied Chemistry, both from the Hebrew University in Israel.

Mr. John Vieira has served as our U.S. head of commercialization since January 2019. Prior to joining Sol-Gel, Mr. Vieira served in U.S. and Global Marketing roles at Leo Pharmaceuticals. Prior to Leo Pharmaceuticals, Mr. Vieira was Executive Director, Thrombosis, at Daiichi Sankyo, where he led the global launch of a major anti-coagulant, following various senior leadership roles in the U.S. commercial operations. Prior to Daiichi Sankyo, Mr. Vieira held leadership positions at several healthcare companies, including Organon Biopharmaceuticals and GlaxoSmithKline, successfully launching over six new global and U.S. products in diverse therapeutic areas. Mr. Vieira holds an M.B.A. degree from Rutgers University and a B.A. degree from York University in Toronto, Canada.

Mr. Itai Arkin became a member of our board of directors immediately following the pricing of our initial public offering. Mr. Itai Arkin currently serves as Investment Manager at Arkin Holdings Ltd. and as an investment committee member of Accelmed, a leading Israeli MedTech investment firm since March 2014. Mr. Itai Arkin holds a B.A. in business administration (cum laude) from Interdisciplinary Center, Herzliya, Israel, and an MBA (cum laude) from Tel Aviv University. Mr. Itai Arkin is the son of Mr. Moshe Arkin, the chairman of our board of directors and sole beneficial owner of Arkin Dermatology, our controlling shareholder.

Dr. Shmuel (Muli) Ben Zvi became a member of our board of directors immediately following pricing of our initial public offering. Dr. Ben Zvi is currently a board member and member of the risk management, technology, investment and strategy committees at Bank Leumi, and a board member and member of the audit committee and compensation committee of VBL Therapeutics. From 2004 to 2014, Dr. Ben Zvi held various managerial positions at Teva Pharmaceuticals Industries Ltd., including Vice President of Finance and Vice President of Strategy. From 2000 to 2004, Dr. Ben Zvi was the financial advisor to the Chief of General Staff of the Israel Defense Forces and head of the Defense Ministry budget department. Dr. Ben Zvi holds a Ph.D. in economics from Tel-Aviv University, Israel and participated in the Harvard Business School Advanced Management Program (AMP).

Ms. Hani Lerman became a member of our board of directors immediately following pricing of our initial public offering. Ms. Lerman has served as chief financial officer at Arkin Holdings since 2015. From 2010 until 2014, Ms. Lerman served as chief financial officer of Sansa Security (f/k/a Discretix Technologies), and from 2006 until 2010, she served as chief financial officer of Storwize, which was acquired by IBM in 2010. She holds a Master's degree in business administration with a major in finance from Tel-Aviv University, Israel, and a B.A. in economics and accounting from Tel-Aviv University, Israel.

Ms. Yaffa Krindel-Sieradzki became a member of our board of directors on February 23, 2018. Ms. Krindel-Sieradzki currently serves on the board of Itamar Medical Ltd., a medical device company publicly traded on both Nasdaq and the Tel Aviv Stock Exchange ("TASE"), BGN Technologies Ltd., the technology transfer company of Ben Gurion University, and three private medical device companies, as follows: EZbra Advanced Wound Care Ltd., Theranica Bio Electronics Ltd. and Trisol Medical Ltd. Ms. Krindel-Sieradzki has served on the board of directors of numerous companies publicly traded on Nasdaq. From 1997 until 2007, Ms. Krindel-Sieradzki served as Partner and Managing Partner of Star Ventures, a private venture capital fund headquartered in Munich, Germany. Before joining Star Ventures, Ms. Krindel served from 1992 to 1996 as CFO and VP Finance of Lannet Data Communications Ltd., an Israeli telecommunications company publicly traded on Nasdaq which is now part of Avaya Inc. From 1993 to 1997, she served as CFO and later as director of BreezeCOM Ltd., an Israeli telecommunications company which traded on Nasdaq and TASE. Ms. Krindel-Sieradzki has earned an M.B.A. from Tel Aviv University and a B.A. in Economics and Japanese Studies from the Hebrew University in Jerusalem, both with honors.

Jonathan B. Siegel became a member of our board of directors on September 13, 2018. Mr. Siegel is the founder and CEO of JBS Healthcare Ventures since formation in 2017. Previously, he was a partner and healthcare sector head at Kingdon Capital Management from 2011 until 2017. Prior to joining Kingdon, Mr. Siegel was a healthcare portfolio manager at SAC Capital Advisors from 2005 until 2011; an associate director of pharmaceutical and specialty pharmaceutical research at Bear, Stearns & Co.; a pharmaceuticals research associate at Dresdner Kleinwort Wasserstein; and a consultant to the Life Sciences Division of Computer Sciences Corporation. Mr. Siegel has worked as a research associate at the Novartis Center for Immunobiology at Harvard Medical School and as a research assistant at Tufts University School of Medicine. He is also a director at Jaguar Health, Inc., a Nasdaq listed company, and has served on the board of advisors of Vitalis LLC, a private pharmaceutical company, since March 2019. Mr. Siegel received a BS in Psychology from Tufts University in 1995 and an MBA from Columbia Business School in 1999.

Mr. Ran Gottfried became a member of our board of directors immediately following the pricing of our initial public offering and serves as an external director under the Companies Law. Since 1975, Mr. Gottfried has served as a chief executive officer, consultant and director of private companies in Israel and Europe in the areas of retail and distribution of pharmaceuticals, consumer and household products. Mr. Gottfried served as a director of Perrigo Company from 2006 until 2015. From 2006 until 2008, Mr. Gottfried served as chairman and chief executive officer of Powerpaper Ltd., a leading developer and manufacturer of micro electrical cosmetic and pharmaceutical patches. From 2005 until 2010, Mr. Gottfried served as a director of Bezeq, Israel’s leading telecommunications provider and from 2003 until its acquisition by Perrigo Company in 2005, Mr. Gottfried served as a director of Agis Industries Ltd. He is currently a board member and member of the audit and investment, technology and innovation and risk management committees at Shufersal Ltd.

Mr. Jerrold S. Gattegno became a member of our board of directors immediately following the pricing of our initial public offering and serves as an external director under the Companies Law. Mr. Gattegno worked in the New York, Washington D.C. and London offices of Deloitte Touche Tohmatsu Limited, a public accounting firm, from 1973 until 2015, where he served in various senior positions, including as the partner-in-charge and founding partner of Deloitte's multistate tax practice and as a managing partner in Deloitte's Washington National Tax Office, and as managing director and principal of Deloitte Tax Overseas Services LLC. Mr. Gattegno served as a governing board member of the Hispanic Association of Colleges and Universities and a member of its finance and audit committee, from 2012 until 2015. Mr. Gattegno is a certified public accountant and holds a B.S. in accounting (cum laude) from the City University of New York and an M.B.A. in taxation (with honors) from Pace University, New York.

B. Compensation

The aggregate compensation paid by us to our executive officers and directors for the year ended December 31, 2020 was approximately $3.2 million. This amount includes approximately $0.4 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to officers, and other benefits commonly reimbursed or paid by companies in Israel.

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2020. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2020.

Name and Position of director or officer	Base Salary or Other Payment (1)	Value of Social Benefits (2)	Value of Equity Based Compensation Granted (3)	All Other Compensation (4)	Total
(Amounts in U.S. dollars are based on 2020 monthly average representative U.S. dollar – NIS rate of exchange)					
Alon Seri-Levy / CEO	314	61	239	22	636
Gilad Mamlok / CFO	262	54	137	48	501
John Vieira / U.S. Head of Commercialization	241	17	113	26	398
Ofer Toledano / VP R&D	206	57	79	24	366
Ofra Levy-Hacham / VP Clinical & RA	152	45	63	21	280

(1) "Base Salary or Other Payment" means the aggregate yearly gross monthly salaries or other payments with respect to the Company's Executive Officers and members of the board of directors for the year 2020.

(2) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law.

(3) Consists of the fair value of the equity-based compensation granted during 2020 in exchange for the directors and officers services recognized as an expense in profit or loss and is carried to the accumulated deficit under equity. The total amount recognized as an expense over the vesting period of the options.

(4) "All Other Compensation" includes, among other things, car-related expenses, communication expenses, basic health insurance, holiday presents, and 2018, 2019 and 2020 special bonuses that officers received.

In addition, all of our directors and executive officers are covered under our directors' and executive officers' liability insurance policies and were granted letters of indemnification by us.

Employment Agreements

We have entered into written employment agreements with each of our executive officers. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. See “Item 3. Key Information – D. Risk Factors — Risks Related to Employee Matters — Under applicable employment laws, we may not be able to enforce covenants not to compete” for a further description of the enforceability of non-competition clauses.

For information on exemption and indemnification letters granted to our directors and officers, please see “ – C. Board Practices – Exculpation, Insurance and Indemnification of Directors and Officers”.

Director Compensation

We currently pay our external directors and our other independent directors: (i) $35,000 annually in cash; (ii) $5,000 annually in cash for service on each of the Audit Committee and/or Compensation Committee (as the case may be) and (iii) $10,000 annually in cash for service as chairman of the Audit Committee and/or Compensation Committee (as the case may be), which includes amounts payable under clause (ii) (all cash amounts to be paid quarterly).

There shall be no limit regarding the number and/or hours of meetings, and it includes all meetings of the Board and any Board’s committees.

In addition, each of our external directors and our other independent directors has received 11,500 Restricted Share Units ("RSU's") for the first three years of their service as a director, with a three-year vesting, one-third of the RSU's to vest after each year (if they continue to serve as directors), and otherwise in accordance with the Company's 2014 Share Incentive Plan.

We do not pay compensation to the other directors of the Company in their capacity as directors.

Compensation Policy

Our compensation policy, which became effective immediately after the pricing of our initial public offering, is designed to promote retention and motivation of directors and executive officers, incentivize superior individual excellence, align the interests of our directors and executive officers with our long-term performance and provide a risk management tool. To that end, a portion of an executive officer compensation package is targeted to reflect our short and long-term goals, as well as the executive officer’s individual performance. On the other hand, our compensation policy includes measures designed to reduce the executive officer’s incentives to take excessive risks that may harm us in the long-term, such as limits on the value of cash bonuses and equity-based compensation, limitations on the ratio between the variable and the total compensation of an executive officer and minimum vesting periods for equity-based compensation.

Our compensation policy also addresses our executive officer’s individual characteristics (such as his or her respective position, education, scope of responsibilities and contribution to the attainment of our goals) as the basis for compensation variation among our executive officers, and considers the internal ratios between compensation of our executive officers and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, annual bonuses and other cash bonuses (such as a signing bonus and special bonuses with respect to any special achievements, such as outstanding personal achievement, outstanding personal effort or outstanding company performance), equity-based compensation, benefits and retirement and termination of service arrangements. All cash bonuses are limited to a maximum amount linked to the executive officer’s base salary. In addition, the total variable compensation components (cash bonuses and equity-based compensation) may not exceed 85% of each executive officer’s total compensation package with respect to any given calendar year.

An annual cash bonus may be awarded to executive officers upon the attainment of pre-set periodic objectives and individual targets. The annual cash bonus that may be granted to our executive officers other than our chief executive officer will be based on performance objectives and a discretionary evaluation of the executive officer's overall performance by our chief executive officer and subject to minimum thresholds. The annual cash bonus that may be granted to executive officers other than our chief executive officer may be based entirely on a discretionary evaluation. Furthermore, our chief executive officer will be entitled to recommend performance objectives, and such performance objectives will be approved by our compensation committee (and, if required by law, by our board of directors).

The performance measurable objectives of our chief executive officer will be determined annually by our compensation committee and board of directors, will include the weight to be assigned to each achievement in the overall evaluation. A less significant portion of the chief executive officer's annual cash bonus may be based on a discretionary evaluation of the chief executive officer's overall performance by the compensation committee and the board of directors based on quantitative and qualitative criteria.

The equity-based compensation under our compensation policy for our executive officers (including members of our board of directors) is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the executive officers' interests with our long-term interests and those of our shareholders and to strengthen the retention and the motivation of executive officers in the long term. Our compensation policy provides for executive officer compensation in the form of share options or other equity-based awards, such as restricted shares and restricted share units, in accordance with our share incentive plan then in place. All equity-based incentives granted to executive officers shall be subject to vesting periods in order to promote long-term retention of the awarded executive officers. The equity-based compensation shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the executive officer.

In addition, our compensation policy contains compensation recovery provisions which allows us under certain conditions to recover bonuses paid in excess, enables our chief executive officer to approve an immaterial change in the terms of employment of an executive officer (provided that the changes of the terms of employment are in accordance our compensation policy) and allows us to exculpate, indemnify and insure our executive officers and directors subject to certain limitations set forth thereto.

Our compensation policy also provides for compensation to the members of our board of directors either (i) in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director) of 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel) of 2000, as such regulations may be amended from time to time, or (ii) in accordance with the amounts determined in our compensation policy.

Our compensation policy, which was approved by our board of directors and our controlling shareholder on October 2, 2017, became effective upon the pricing of our initial public offering.

C. Board Practices

Appointment of Directors and Terms of Officers

Our board of directors consists of eight directors, including two external directors, and appointment fulfills the requirements of the Companies Law for the company to have two external directors (see " – External Directors"). These two directors, as well as three additional directors, qualify as independent directors under the corporate governance standards of the Nasdaq corporate governance rules and the independence requirements of Rule 10A-3 of the Exchange Act.

Under our amended and restated articles of association, the number of directors on our board of directors will be no less than five (5) and no more than nine (9), including any external directors required to be appointed under the Companies Law. The minimum and maximum number of directors may be changed, at any time and from time to time, by a special 66 2⁄3% majority shareholder vote.

Other than external directors, for whom special election requirements apply under the Companies Law, as detailed below, our directors are divided into three classes with staggered three-year terms. Each class of directors consists, as nearly as possible, of one-third of the total number of directors constituting the entire board of directors (other than the external directors). At each annual general meeting of our shareholders, the election or re-election of directors following the expiration of the term of office of the directors of that class of directors will be for a term of office that expires on the third annual general meeting following such election or re-election, such that from 2019 and after, at each annual general meeting the term of office of only one class of directors will expire. Each director holds office until the third annual general meeting of our shareholders and until his or her successor is duly appointed, unless the tenure of such director expires earlier pursuant to the Companies Law or unless removed from office as described below, except that our external directors have a term of office of three years under Israeli law. See "— External directors — Election and Dismissal of External Directors".

Our directors who are not external directors are divided among the three classes as follows:

- Class I directors consist of Ms. Yaffa Krindel-Sieradzki, Dr. Shmuel Ben Zvi and Mr. Jonathan B. Siegel, who are all independent directors, and their term will expire at our annual general meeting of our shareholders to be held in 2022;
- Class II directors consist of Ms. Hani Lerman and Dr. Alon Seri-Levy, and their term will expire at our annual general meeting of our shareholders to be held in 2023; and
- Class III directors consist of Mr. Itai Arkin and Mr. Moshe Arkin, and their term will expire at our annual general meeting of our shareholders to be held in 2021.

Mr. Ran Gattegno and Mr. Jerrold S. Gottfried serve as our external directors and will each have a term of three years.

Under our amended and restated articles of association, our board of directors may elect new directors if the number of directors is below the maximum provided therein. External directors are elected for an initial term of three years and may be elected for up to two additional three-year terms (or more) under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Companies Law. See "— External Directors— Election and Dismissal of External Directors" for a description of the procedure for the election of external directors.

Under Israeli law, the chief executive officer of a public company may not serve as the chairman of the board of directors of the company unless approved by a special majority of our shareholders as required under the Companies Law.

In addition, under the Companies Law, our board of directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. See "— External Directors — Qualifications of External Directors." He or she must be able to thoroughly comprehend the financial statements of the company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that we require at least one director with the requisite financial and accounting expertise and that has such expertise.

There are no family relationships among any of our office holders (including directors), other than Mr. Itai Arkin who is the son of Mr. Moshe Arkin.

Alternate Directors

Our amended and restated articles of association provide, as allowed by the Companies Law, that any director may, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director. The alternate director will be regarded as a director. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors as long as he or she is not already serving as a member of such committee, and if the alternate director is to replace an external director, he or she is required to be an external director and to have either "financial and accounting expertise" or "professional expertise," depending on the qualifications of the external director he or she is replacing. The term of appointment of an alternate director may be for one meeting of the board of directors or until notice is given of the cancellation of the appointment. A person who does not have the requisite "financial and accounting experience" or the "professional expertise," depending on the qualifications of the external director he or she is replacing, may not be appointed as an alternate director for an external director.

External Directors

Qualifications of External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," including companies with shares listed on The Nasdaq Global Market, are generally required to appoint at least two external directors who meet the qualification requirements set forth in the Companies Law.

A person may not be appointed as an external director if the person is a relative of a controlling shareholder or if on the date of the person's appointment or within the preceding two years the person or his or her relatives, partners, employers or anyone to whom that person is subordinate, whether directly or indirectly, or entities under the person's control have or had any affiliation with any of (each an "Affiliated Party"): (1) us; (2) any person or entity controlling us on the date of such appointment; (3) any relative of a controlling shareholder; or (4) any entity controlled, on the date of such appointment or within the preceding two years, by us or by a controlling shareholder. If there is no controlling shareholder or any shareholder holding 25% or more of voting rights in the company, a person may not be appointed as an external director if the person has any affiliation to the chairman of the board of directors, the general manager (chief executive officer), any shareholder holding 5% or more of the company's shares or voting rights or the senior financial officer as of the date of the person's appointment.

The term "controlling shareholder" means a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to have "control" of the company and thus to be a controlling shareholder of the company if the shareholder holds 50% or more of the "means of control" of the company. "Means of control" is defined as (1) the right to vote at a general meeting of a company or a corresponding body of another corporation; or (2) the right to appoint directors of the corporation or its general manager. For the purpose of approving related-party transactions, the term also includes any shareholder that holds 25% or more of the voting rights of the company if the company has no shareholder that owns more than 50% of its voting rights. For the purpose of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company's approval are deemed as joint holders.

The term affiliation includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

The term "relative" is defined as a spouse, sibling, parent, grandparent, descendant, spouse's descendant, sibling and parent and the spouse of each of the foregoing.

The term "office holder" is defined as a general manager, chief business manager, deputy general manager, vice general manager, director or manager directly subordinate to the general manager or any other person assuming the responsibilities of any of the foregoing positions, without regard to such person's title.

A person may not serve as an external director if that person or that person's relative, partner, employer, a person to whom such person is subordinate (directly or indirectly) or any entity under the person's control has a business or professional relationship with any entity that has an affiliation with any Affiliated Party, even if such relationship is intermittent (excluding insignificant relationships). Additionally, any person who has received compensation intermittently (excluding insignificant relationships) other than compensation permitted under the Companies Law may not continue to serve as an external director.

No person can serve as an external director if the person's position or other affairs create, or may create, a conflict of interest with the person's responsibilities as a director or may otherwise interfere with the person's ability to serve as a director or if such a person is an employee of the Israeli Securities Authority or of an Israeli stock exchange. If at the time an external director is appointed all current members of the board of directors, who are not controlling shareholders or relatives of controlling shareholders, are of the same gender, then the external director to be appointed must be of the other gender. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

The Companies Law provides that an external director must meet certain professional qualifications or have financial and accounting expertise and that at least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the Nasdaq corporate governance rules for membership on the audit committee and (3) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. The determination of whether a director possesses financial and accounting expertise is made by the board of directors. A director with financial and accounting expertise is a director who by virtue of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements so that he or she is able to fully understand our financial statements and initiate debate regarding the manner in which the financial information is presented.

The regulations promulgated under the Companies Law define an external director with requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration, (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company's primary field of business or in an area which is relevant to his or her office as an external director in the company, or (3) the director has at least five years of experience serving in any one of the following, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a substantial scope of business, (b) a senior position in the company's primary field of business or (c) a senior position in public administration.

Until the lapse of a two-year period from the date that an external director of a company ceases to act in such capacity, the company in which such external director served, and its controlling shareholder or any entity under control of such controlling shareholder may not, directly or indirectly, grant such former external director, or his or her spouse or child, any benefit, including via (i) the appointment of such former director or his or her spouse or his child as an officer in the company or in an entity controlled by the company's controlling shareholder, (ii) the employment of such former director, and (iii) the engagement, directly or indirectly, of such former director as a provider of professional services for compensation, directly or indirectly, including via an entity under his or her control. With respect to a relative who is not a spouse or a child, such limitations shall only apply for one year from the date such external director ceased to be engaged in such capacity.

Election and Dismissal of External Directors

Under Israeli law, external directors are elected by a majority vote at a shareholders' meeting, provided that either:

- the majority of the shares that are voted at the meeting in favor of the election of the external director, excluding abstentions, include at least a majority of the votes of shareholders who are not controlling shareholders and do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder); or

- the total number of shares held by non-controlling shareholders or any one on their behalf that are voted against the election of the external director does not exceed two percent of the aggregate voting rights in the company.

Under Israeli law, the initial term of an external director of an Israeli public company is three years. The external director may be re-elected, subject to certain circumstances and conditions, for up to two additional terms of three years each, and thereafter, subject to conditions set out in the regulations promulgated under the Companies Law, to further three year terms, each re-election subject to one of the following:

- his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved at a shareholders meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company and subject to additional restrictions set forth in the Companies Law with respect to the affiliation of the external director nominee;

- the external director proposed his or her own nomination, and such nomination was approved in accordance with the requirements described in the paragraph above; or

- his or her service for each such additional term is recommended by the board of directors and is approved at a meeting of shareholders by the same majority required for the initial election of an external director (as described above).

An external director may be removed by the same special majority of the shareholders required for his or her election, if he or she ceases to meet the statutory qualifications for appointment or if he or she violates his or her fiduciary duty to the company. An external director may also be removed by order of an Israeli court if the court finds that the external director is permanently unable to exercise his or her office, has ceased to meet the statutory qualifications for his or her appointment, has violated his or her fiduciary duty to the company, or has been convicted by a court outside Israel of certain offenses detailed in the Companies Law.

If the vacancy of an external directorship causes a company to have fewer than two external directors, the company's board of directors is required under the Companies Law to call a special general meeting of the company's shareholders as soon as possible to appoint such number of new external directors so that the company thereafter has two external directors.

Additional Provisions

Under the Companies Law, each committee authorized to exercise any of the powers of the board of directors is required to include at least one external director and its audit and compensation committees are required to include all of the external directors.

An external director is entitled to compensation and reimbursement of expenses in accordance with regulations promulgated under the Companies Law and is prohibited from receiving any other compensation, directly or indirectly, in connection with serving as a director except for certain exculpation, indemnification and insurance provided by the company, as specifically allowed by the Companies Law.

Audit Committee

Companies Law Requirements

Under the Companies Law, the board of directors of any public company must also appoint an audit committee comprised of at least three directors, including all of the external directors. The audit committee may not include:

- the chairman of the board of directors;
- a controlling shareholder or a relative of a controlling shareholder;
- any director employed by us or by one of our controlling shareholders or by an entity controlled by our controlling shareholders (other than as a member of the board of directors); or
- any director who regularly provides services to us, to one of our controlling shareholders or to an entity controlled by our controlling shareholders.

According to the Companies Law, the majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, will be required to be "independent" (as defined below) and the chairman of the audit committee will be required to be an external director. Any persons disqualified from serving as a member of the audit committee may not be present at the audit committee meetings, unless the chairman of the audit committee has determined that such person is required to be present at the meeting or if such person qualifies under one of the exemptions of the Companies Law.

The term "independent director" is defined under the Companies Law as an external director or a director who meets the following conditions and who is appointed or classified as such according to the Companies Law: (1) the conditions for his or her appointment as an external director (as described above) are satisfied and the audit committee approves the director having met such conditions and (2) he or she has not served as a director of the company for over nine consecutive years with any interruption of up to two years of his or her service not being deemed a disruption to the continuity of his or her service.

Nasdaq Listing Requirements

Under the Nasdaq corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

Our audit committee consists of Ran Gottfried, Jerrold S. Gattegno, Shmuel Ben Zvi and Yaffa Krindel-Sieradzki. Jerrold S. Gattegno serves as Chairman of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq corporate governance rules. Our board of directors has determined that Jerrold S. Gattegno is an audit committee financial expert as defined by SEC rules and has the requisite financial experience as defined by the Nasdaq corporate governance rules.

Each of the members of the audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

Approval of Transactions with Related Parties

The approval of the audit committee is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. See "— Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law – Fiduciary Duties of Office Holders." The audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless at the time of approval the audit committee meets the composition requirements under the Companies Law.

Audit Committee Role

Our board of directors has adopted an audit committee charter effective immediately after the pricing of our initial public offering setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq corporate governance rules, which include:

- retaining and terminating our independent auditors, subject to board of directors and shareholder ratification;
- overseeing the independence, compensation and performance of the Company's independent auditors;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approval of audit and non-audit services to be provided by the independent auditors;
- reviewing with management and our independent directors our financial statements prior to their submission to the SEC; and
- approval of certain transactions with office holders and controlling shareholders, as described below, and other related party transactions.

Additionally, under the Companies Law, the role of the audit committee includes the identification of irregularities in our business management, among other things, by consulting with the internal auditor or our independent auditors and suggesting an appropriate course of action to the board of directors. In addition, the audit committee or the board of directors, as set forth in the articles of association of the company, is required to approve the yearly or periodic work plan proposed by the internal auditor. The audit committee is required to assess the company's internal audit system and the performance of its internal auditor. The Companies Law also requires that the audit committee assess the scope of the work and compensation of the company's external auditor. In addition, the audit committee is required to determine whether certain related party actions and transactions are "material" or "extraordinary" for the purpose of the requisite approval procedures under the Companies Law and whether certain transactions with a controlling shareholder will be subject to a competitive procedure. The audit committee charter states that in fulfilling its role the committee is empowered to conduct or authorize investigations into any matters within its scope of responsibilities. A company whose audit committee's composition also meets the requirements set for the composition of a compensation committee (as further detailed below) may have one committee acting as both audit and compensation committees.

Compensation Committee

Under the Companies Law, public companies are required to appoint a compensation committee in accordance with the guidelines set forth thereunder.

The compensation committee must consist of at least three members. All of the external directors must serve on the committee and constitute a majority of its members. The chairman of the compensation committee must be an external director. The remaining members are not required to be external directors, but must be directors who qualify to serve as members of the audit committee (as described above).

The compensation committee, which consists of Ran Gottfried, Jerrold S. Gattegno, Shmuel Ben Zvi and Jonathan B. Siegel, assists the board of directors in determining compensation for our directors and officers. Ran Gottfried serves as Chairman of the committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard supervisory board member fees. Although foreign private issuers are not required to meet this heightened standard, our board of directors has determined that all of our expected compensation committee members meet this heightened standard.

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

(1) to recommend to the board of directors the compensation policy for directors and officers, and to recommend to the board of directors once every three years whether the compensation policy that had been approved should be extended for a period of more than three years;

(2) to recommend to the board of directors updates to the compensation policy, from time to time, and examine its implementation;

(3) to decide whether to approve the terms of office and employment of directors and officers that require approval of the compensation committee; and

(4) to decide whether the compensation terms of the chief executive officer, which were determined pursuant to the compensation policy, will be exempted from approval by the shareholders because such approval would harm the ability to engage the chief executive officer.

In addition to the roles mentioned above our compensation committee also makes recommendations to our board of directors regarding the awarding of employee equity grants.

In general, under the Companies Law, a public company must have a compensation policy approved by the board of directors after receiving and considering the recommendations of the compensation committee. In addition, the compensation policy requires the approval of the general meeting of the shareholders. In public companies such as our company, shareholder approval requires one of the following: (i) the majority of shareholder votes counted at a general meeting including the majority of all of the votes of those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who vote at the meeting (excluding abstentions) or (ii) the total number of votes against the proposal among the shareholders mentioned in paragraph (i) does exceed two percent (2%) of the voting rights in the company. Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed arguments and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the meeting of shareholders, is for the benefit of the company.

If a company initially offer its securities to the public, like we recently did, adopts a compensation policy in advance of its initial public offering, and describes it in its prospectus, then such compensation policy shall be deemed a validly adopted policy in accordance with the Companies Law requirements described above. Furthermore, if the compensation policy is set in accordance with the aforementioned relief, then it will remain in effect for term of five years from the date such company has become a public company.

The compensation policy must be based on certain considerations, include certain provisions and needs to reference certain matters as set forth in the Companies Law.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, business plan and long-term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the education, skills, experience, expertise and accomplishments of the relevant office holder;
- the office holder's position, responsibilities and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the employment of other employees of the company, including employees employed through contractors who provide services to the company, in particular the ratio between such cost, the average and median salary of the employees of the company, as well as the impact of such disparities on the work relationships in the company;
- if the terms of employment include variable components — the possibility of reducing variable components at the discretion of the board of directors and the possibility of setting a limit on the value of non-cash variable equity-based components; and
- if the terms of employment include severance compensation — the term of employment or office of the office holder, the terms of his or her compensation during such period, the company's performance during the such period, his or her individual contribution to the achievement of the company goals and the maximization of its profits and the circumstances under which he or she is leaving the company.

The compensation policy must also include, among others:

- with regards to variable components:
  - with the exception of office holders who report directly to the chief executive officer, determining the variable components on long-term performance basis and on measurable criteria; however, the company may determine that an immaterial part of the variable components of the compensation package of an office holder's shall be awarded based on non-measurable criteria, if such amount is not higher than three monthly salaries per annum, while taking into account such office holder contribution to the company;
  - the ratio between variable and fixed components, as well as the limit of the values of variable components at the time of their grant.
- a condition under which the office holder will return to the company, according to conditions to be set forth in the compensation policy, any amounts paid as part of his or her terms of employment, if such amounts were paid based on information later to be discovered to be wrong, and such information was restated in the company's financial statements;
- the minimum holding or vesting period of variable equity-based components to be set in the terms of office or employment, as applicable, while taking into consideration long-term incentives; and
- a limit to retirement grants.

Corporate Governance Practices

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor may not be an interested party or an office holder or a relative of an interested party or of an office holder, nor may the internal auditor be the company's independent auditor or the representative of the same.

An "interested party" is defined in the Companies Law as (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. As of the date of this annual report, we have not yet appointed our internal auditor.

Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law

Fiduciary Duties of Office Holders

The Companies Law imposes a duty of care and a fiduciary duty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the business advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to such action.

The fiduciary duty incumbent on an office holder requires him or her to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above which would otherwise constitute a breach of the office holder's fiduciary duty, provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest a sufficient time before the approval of such act. Any such approval is subject to the terms of the Companies Law, setting forth, among other things, the appropriate bodies of the company entitled to provide such approval, and the methods of obtaining such approval.

Disclosure of Personal Interests of an Office Holder and Approval of Transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, once an office holder has complied with the above disclosure requirement, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest. However, a company may not approve a transaction or action that is not to the company's benefit.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, which is not an extraordinary transaction, requires approval by the board of directors. Our amended and restated articles of association provide that such a transaction, which is not an extraordinary transaction, shall be approved by the board of directors or a committee of the board of directors or any other body or person (which has no personal interest in the transaction) authorized by the board of directors. If the transaction considered is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and executive officers, see " – Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law – Fiduciary Duties of Office Holders."

Any persons who have a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting or vote on the matter. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of an office holder with a personal interest is required, such office holder may be present at the meeting for the purpose of presenting the matter. Notwithstanding the foregoing, a director who has a personal interest may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee have a personal interest in the approval of such transaction. If a majority of the directors at a board of directors meeting have a personal interest in the transaction, such transaction also requires approval of the shareholders of the company.

A "personal interest" is defined under the Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or the interest of any other corporate body in which the person and/or such person's relative is a director or general manager, a 5% shareholder or holds 5% or more of the voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest also includes (1) a personal interest of a person who votes according to a proxy of another person, including in the event that the other person has no personal interest, and (2) a personal interest of a person who gave a proxy to another person to vote on his or her behalf regardless of whether or not the discretion of how to vote lies with the person voting.

An "extraordinary transaction" is defined under the Companies Law as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions

The Companies Law also requires that a controlling shareholder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. A controlling shareholder's disclosure must be made promptly and, in any event, no later than the first meeting of the board of directors at which the transaction is considered. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder or employee of the company, regarding his or her terms of employment, require the approval of each of (i) the audit committee or the compensation committee with respect to the terms of the engagement of the company, (ii) the board of directors and (iii) the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than two percent (2%) of the voting rights in the company.

In addition, an extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest, and an engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder or employee of the company, regarding his or her terms of employment, in each case with a term of more than three years requires the abovementioned approval every three years, however, transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances. In addition, transactions with a controlling shareholder or a controlling shareholder's relative who serves as an officer in a company, directly or indirectly (including through a corporation under his control), involving the receipt of services by a company or their compensation can have a term of five years from the company's initial public offering under certain circumstances.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote.

Disclosure of Compensation of Executive Officers

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our chief executive officer and other two most highly compensated executive officers on an individual, rather than an aggregate, basis. Nevertheless, regulations promulgated under the Companies Law will require us, after we became a public company, to disclose the annual compensation of our five most highly compensated office holders on an individual basis, rather than on an aggregate basis. This disclosure will not be as extensive as that required of a U.S. domestic issuer.

Compensation of Directors and Executive Officers

Directors. Under the Companies Law, the compensation of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under regulations promulgated under the Companies Law, the approval of the shareholders at a general meeting. If the compensation of our directors is inconsistent with our stated compensation policy, then, those provisions that must be included in the compensation policy according to the Companies Law must have been considered by the compensation committee and board of directors, and shareholder approval will also be required, provided that:

- at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such matter, present and voting at such meeting, are voted in favor of the compensation package, excluding abstentions; or

- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed two percent (2%) of the aggregate voting rights in the company.

Executive officers other than the chief executive officer. The Companies Law requires the approval of the compensation of a public company's executive officers (other than the chief executive officer) in the following order: (i) the compensation committee, (ii) the company's board of directors, and (iii) if such compensation arrangement is inconsistent with the company's stated compensation policy, the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision.

Chief executive officer. Under the Companies Law, the compensation of a public company's chief executive officer is required to be approved by: (i) the company's compensation committee; (ii) the company's board of directors, and (iii) the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide a detailed report for their decision. The approval of each of the compensation committee and the board of directors should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Companies Law and that shareholder approval was obtained (by a special majority vote as discussed above with respect to the approval of director compensation). In addition, the compensation committee may waive the shareholder approval requirement with regards to the approval of the engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at meetings of shareholders on the following matters:

- an amendment to the articles of association;

- an increase in the company's authorized share capital;

- a merger; and

- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the shareholder duties mentioned above, and in the event of discrimination against other shareholders, additional remedies may be available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or any other power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.

Approval of Private Placements

Under the Companies Law and the regulations promulgated thereunder, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in special circumstances, such as a private placement which is intended to obviate the need to conduct a special tender offer (see "Item 10. Additional Information— Memorandum of Association – Acquisitions under Israeli Law") or a private placement which qualifies as a related party transaction (see "— Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law – Fiduciary Duties of Office Holders"), approval at a general meeting of the shareholders of a company is required.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the fiduciary duty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association include such a provision. The company may not exculpate in advance a director from liability arising due to the breach of his or her duty of care in the event of a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Israeli Securities Law, 5728-1968, or the Securities Law, a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed by him or her as an office holder, either in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or imposed on the office holder in favor of another person pursuant to a court judgment, including pursuant to a settlement confirmed as judgment or arbitrator's decision approved by a competent court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;

- reasonable litigation expenses, including reasonable attorneys' fees, which were incurred by the office holder as a result of an investigation or proceeding filed against the office holder by an authority authorized to conduct such investigation or proceeding, provided that such investigation or proceeding was either (i) concluded without the filing of an indictment against such office holder and without the imposition on him of any monetary obligation in lieu of a criminal proceeding; (ii) concluded without the filing of an indictment against the office holder but with the imposition of a monetary obligation on the office holder in lieu of criminal proceedings for an offense that does not require proof of criminal intent; or (iii) in connection with a monetary sanction;

- a monetary liability imposed on the office holder in favor of a payment for a breach offended at an Administrative Procedure (as defined below) as set forth in Section 52(54)(a)(1)(a) to the Securities Law;

- expenses expended by the office holder with respect to an Administrative Procedure under the Securities Law, including reasonable litigation expenses and reasonable attorneys' fees;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or which were imposed on the office holder by a court (i) in a proceeding instituted against him or her by the company, on its behalf, or by a third party, (ii) in connection with criminal indictment of which the office holder was acquitted, or (iii) in a criminal indictment which the office holder was convicted of an offense that does not require proof of criminal intent; and

- any other obligation or expense in respect of which it is permitted or will be permitted under applicable law to indemnify an office holder, including, without limitation, matters referenced in Section 56H(b)(1) of the Securities Law.

An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the fiduciary duty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;

- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;

- a monetary liability imposed on the office holder in favor of a third party;

- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and

- expenses incurred by an office holder in connection with an Administrative Procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the fiduciary duty, except for indemnification and insurance for a breach of the fiduciary duty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;

- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;

- an act or omission committed with intent to derive illegal personal benefit; or
- a fine or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the compensation committee and the board of directors and, with respect to directors or controlling shareholders, their relatives and third parties in which controlling shareholders have a personal interest, also by the shareholders.

Our amended and restated articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by law. Our office holders are currently covered by a directors' and officers' liability insurance policy. As of the date of this annual report, no claims for directors' and officers' liability insurance have been filed under this policy and we are not aware of any pending or threatened litigation or proceeding involving any of our office holders, including our directors, in which indemnification is sought.

See "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions - Directors and Officers Insurance Policy and Indemnification Agreements" for information regarding letters of indemnification to directors and officers of the Company.

D. Employees

As of December 31, 2020, we had 65 employees, all of whom except 3 are located in Israel.

	As of December 31,					
	2018		2019		2020	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management	8		9		9	
Research and development and other	48		52		56	

While none of our employees are party to a collective bargaining agreement, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by order of the Israel Ministry of Labor. These provisions primarily concern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, please see "Item 7.A. Major Shareholders."

Award Plans

2014 Share Incentive Plan

On December 2, 2014, we adopted the 2014 Share Incentive Plan, or the Plan, and, in connection with our initial public offering, we amended and restated the Plan which became effective immediately after the pricing of our initial public offering. The Plan is intended to afford an incentive to our and any of our affiliate's employees, directors, officers, consultants, advisors and any other person or entity who provides services to the Company, to continue as service providers, to increase their efforts on our and our affiliates behalf and to promote our success, by providing such persons with opportunities to acquire a proprietary interest in us.

The number of shares that may be issued under the Plan is subject to adjustment if particular capital changes affect our share capital or such other number as our board of directors may determine from time to time. Ordinary shares subject to outstanding awards under the Plan that subsequently expire, are cancelled, forfeited or terminated for any reason before being exercised will be automatically, and without any further action, returned to the "pool" of reserved shares and will again be available for grant under the Plan. As of February 26, 2021, we had an aggregate of 929,415 ordinary shares available for issuance under the Plan (including ordinary shares underlying outstanding options and restricted share units).

A share option is the right to purchase a specified number of ordinary shares in the future at a specified exercise price and subject to the other terms and conditions specified in the option agreement and the Plan. The exercise price of each share option granted under the Plan will be determined in accordance with the limitations set forth under the Plan. The exercise price of any share options granted under the Plan may be paid in cash, through the surrender of ordinary shares by the option holder or any other method that may be approved by our compensation committee, which may include procedures for cashless exercise.

Our compensation committee may also grant, or recommend that our board of directors grant, other forms of equity incentive awards under the Plan, such as restricted shares, restricted share units, and other forms of share-based compensation.

Israeli participants in the Plan may be granted options subject to Section 102 of the Israeli Income Tax Ordinance (New Version), 1961, or the Israeli Tax Ordinance. Section 102 of the Israeli Tax Ordinance allows employees, directors and officers who are not controlling shareholders (as defined for those purposes under the Israeli Tax Ordinance) and are considered Israeli residents to receive favorable tax treatment for compensation in the form of shares or options. Our non-employee service providers and controlling shareholders may only be granted options under another section of the Israeli Tax Ordinance, which does not provide for similar tax benefits. Section 102 includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. The most favorable tax treatment for the grantees is under Section 102(b)(2) of the Israeli Tax Ordinance, the issuance to a trustee under the "capital gain track." However, under this track we are not allowed to deduct an expense with respect to the issuance of the options or shares.

In addition, any options granted under the Plan to participants in the United States will be either "incentive stock options," which may be eligible for special tax treatment under the Code, or options other than incentive stock options (referred to as "nonqualified stock options" under the Plan). The type of option granted under the Plan and specific terms and conditions are, in each case, determined by our compensation committee or our board of directors and set forth in the applicable option agreement.

Our compensation committee will administer the Plan, or if determined otherwise by our board of directors, the Plan will be administered by our board of directors or other designated committee on its behalf. Even if the compensation committee or any other committee was appointed by our board of directors in order to administrate the Plan, our board of directors may, subject to any legal limitations, exercise any powers or duties of the compensation committee or any other committee concerning the Plan. The compensation committee will, among others, select which eligible persons will receive options or other awards under the Plan and will determine, or recommend to our board of directors, the number of ordinary shares covered by those options or other awards, the terms under which such options or other awards may be exercised (however, options generally may not be exercised later than ten years from the grant date of an option) or may be settled or paid, and the other terms and conditions of such options and other awards under the Plan. All awards granted under the Plan shall not be transferable other than by will or by the laws of descent and distribution, unless otherwise determined by our compensation committee.

To the extent permitted under applicable law, our compensation committee will have the authority to accelerate the vesting of any outstanding awards at such time and under such circumstances as it, in its sole discretion, deems appropriate. In the event of a change of control, as defined in the Plan, any award then outstanding shall be assumed or an equivalent award shall be substituted by the successor corporation of the merger or sale or any parent or affiliate thereof as determined by our board of directors. In the event that the awards are not assumed or substituted, our compensation committee may, in its discretion, accelerate the vesting, exercisability of the outstanding award, or provide for the cancellation of such award and payment of cash, as determined to be fair in the circumstances.

Subject to particular limitations specified in the Plan and under applicable law, our board of directors may amend or terminate the Plan, and the compensation committee may amend awards outstanding under the Plan. In addition, an amendment to the Plan that requires shareholder approval under applicable law will not be effective unless approved by the requisite vote of shareholders. In addition, in general, no suspension, termination, modification or amendment of the Plan may adversely affect any award previously granted without the written consent of grantees holding a majority in interest of the awards so affected. The Plan will continue in effect until all ordinary shares available under the Plan are delivered and all restrictions on those shares have lapsed, unless the Plan is terminated earlier by our board of directors. No awards may be granted under the Plan on or after the tenth anniversary of the date of adoption of the plan unless our board of directors chooses to extend the term.

Any equity award to an office holder, director or controlling shareholder, whether under the Plan or otherwise, may be subject to further approvals in addition to the approval of the compensation committee as described above. As of December 31, 2020, options to purchase 1,199,469 ordinary shares, at a weighted average exercise price of $5.08 per share, were outstanding under our Plan.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 26, 2021 by:

- each person or entity known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors, executive officers and director nominees; and
- all of our executive officers, directors and director nominees as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days as of February 26, 2021, if any, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ordinary shares beneficially owned is based on 23,000,782 ordinary shares outstanding as of February 26, 2021.

Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares.

None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Unless otherwise noted below, the address for each beneficial owner is c/o Sol-Gel Technologies Ltd., 7 Golda Meir St., Weizmann Science Park, Ness Ziona, 7403650 Israel.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percentage**
5% or greater shareholders		
M. Arkin Dermatology Ltd. (1)	14,432,266	62.75%
The Phoenix Holding Ltd. (2)	2,672,944	11.62%
Directors, director nominees and executive officers		
Moshe Arkin (1)	14,518,266	63.12%
Alon Seri-Levy (3)	285,188	1.23%
Gilad Mamlok	*	*
Ofer Toledano	*	*
Ofra Levy-Hacham	*	*
Karine Neimann	*	*
Itzik Yosef	*	*
Dubi Zamir	*	*
Nissim Bilman	*	*
John Vieira	*	*
Itai Arkin	*	*
Ran Gottfried	*	*
Jerrold S. Gattegno	*	*
Shmuel Ben Zvi	*	*
Hani Lerman	*	*
Yaffa Krindel Sieradzki	*	*
Jonathan Siegel	*	*
All directors, director nominees and executive officers as a group (17 persons) (1)	15,292,379	64.49%

* Less than 1%.

(1) Based on the Schedule 13D/A filed with the SEC on April 20, 2020, Arkin Dermatology directly owns 14,432,266 ordinary shares. Mr. Moshe Arkin, the chairman of our board of directors, is the sole shareholder and sole director of Arkin Dermatology and may therefore be deemed to be the indirect beneficial owner of the ordinary shares owned directly by Arkin Dermatology. In addition, Mr. Moshe Arkin directly owns 86,000 ordinary shares.

(2) Based on the Schedule 13G/A filed with the SEC on February 11, 2021, the ordinary shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holding Ltd., or the Subsidiaries. The Subsidiaries manage their own funds and/or the funds of others, including for holders of exchange-traded notes or various insurance policies, members of pension or provident funds, unit holders of mutual funds, and portfolio management clients. Each of the Subsidiaries operates under independent management and makes its own independent voting and investment decisions.

(3) Consists of options to purchase 285,188 ordinary shares exercisable within 60 days of February 26, 2021. The exercise price of these options ranges between $1.59 and $11.21 per share and the options expire between March 2025 and May 2028.

Record Holders

As of February 26, 2021, we had one holder of record of our ordinary shares in the United States, consisting of Cede & Co., the nominee of The Depository Trust Company. That shareholder held, in the aggregate, 10,811,084 ordinary shares, representing 47.0% of the outstanding ordinary shares as of February 26, 2021. The number of record holders in the United States is not representative of the number of beneficial holders nor is it representative of where such beneficial holders are resident since many of these ordinary shares were held by brokers or other nominees.

B. Related Party Transactions

Private Placement with Our Controlling Shareholder

On April 13, 2020, we closed a $5.0 million private placement with our controlling shareholder, Arkin Dermatology, which agreed to make this private investment concurrently with the February 2020 public offering. In the private placement, we issued to Arkin Dermatology 454,628 ordinary shares and warrants to purchase up to 363,702 ordinary shares at a combined price of $11.00 per ordinary share and accompanying warrant to purchase 0.80 of an ordinary share, which is the same price as the public offering price of the ordinary shares and accompanying warrants issued in the Company's February 2020 public offering. The warrants issued to Arkin Dermatology have an initial exercise price of $14.00 per share, subject to certain adjustments, and will expire on February 19, 2023, which are on the same terms as the warrants issued in the February 2020 public offering.

Participation in Our Initial Public Offering

According to Form 13D filed by it on February 12, 2018, our controlling shareholder, Arkin Dermatology, which is wholly-owned by the chairman of our board of directors, purchased 1,833,333 of our ordinary shares in our initial public offering in consideration for $22.0 million, on the same terms as the other purchasers in the offering.

Directors and Officers Insurance Policy and Indemnification Agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and officers to the fullest extent permitted by the Companies Law. We have obtained Directors and Officers insurance for each of our executive officers and directors. For further information, see
"Item 6 C. – Board Practices – Exculpation, Insurance and Indemnification of Directors and Officers".

We entered into agreements with each of our current directors and officers exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, subject to limited exceptions, including, with respect to liabilities resulting from our initial public offering, to the extent that these liabilities are not covered by insurance. This indemnification is limited, with respect to any monetary liability imposed in favor of a third party, to events determined as foreseeable by the board of directors based on our activities. The maximum aggregate amount of indemnification that we may pay to our directors and officers based on such indemnification agreement is the greater of (1) 25% of our shareholders' equity pursuant to our audited financial statements for the year preceding the year in which the event in connection of which indemnification is sought occurred, and (2) $40 million (as may be increased from time to time by shareholders' approval). Such indemnification amounts are in addition to any insurance amounts. Each director or officer who agrees to receive this letter of indemnification also gives his approval to the termination of all previous letters of indemnification that we have provided to him or her in the past, if any.

Registration Rights Agreement

We entered into a registration rights agreement, pursuant to which we granted demand registration rights, short-form registration rights and piggyback registration rights to Arkin Dermatology, our controlling shareholder. All fees, costs and expenses of underwritten registrations are expected to be borne by us. No registration rights to be granted pursuant to this registration rights agreement shall be exercisable until expiration of the 180-day lock-up agreement entered into by Arkin Dermatology with the underwriters in connection with our initial public offering.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Financial Statements and Other Financial Information

The financial statements required by this item are found at the end of this annual report, beginning on page F-2.

Legal Proceedings

We are not currently a party to any material legal proceedings.

Dividend Policy

We have never declared or paid any cash dividends on our ordinary shares and we anticipate that, for the foreseeable future, we will retain any future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends for at least the next several years.

The distribution of dividends may also be limited by the Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due. Our amended and restated articles of association provide that dividends will be paid at the discretion of, and upon resolution by, our board of directors, subject to the provisions of the Companies Law.

B. Significant Changes

Except as otherwise disclosed in this annual report, no significant change has occurred since December 31, 2020.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares have been trading on The Nasdaq Global Market under the symbol “SLGL” since February 1, 2018. Prior to that date, there was no public trading market for our Ordinary Shares. Our initial public offering was priced at $12.00 per share on January 31, 2018.

On February 26, 2021, the last reported closing price of our Ordinary Shares on The Nasdaq Global Market was $8.90 per share.

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed and traded on The Nasdaq Global Market under the symbol “SLGL”.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Registration Number and Purposes of the Company

Our registration number with the Israeli Registrar of Companies is 51-254469-3. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity.

Voting Rights and Conversion

All ordinary shares will have identical voting and other rights in all respects.

Transfer of Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our amended and restated articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Liability to Further Capital Calls

Our board of directors may make, from time to time, such calls as it may deem fit upon shareholders with respect to any sum unpaid with respect to shares held by such shareholders which is not payable at a fixed time. Such shareholder shall pay the amount of every call so made upon him. Unless otherwise stipulated by the board of directors, each payment in response to a call shall be deemed to constitute a pro rata payment on account of all shares with respect to which such call was made. A shareholder shall not be entitled to his rights as shareholder, including the right to dividends, unless such shareholder has fully paid all the notices of call delivered to him, or which according to our amended and restated articles of association are deemed to have been delivered to him, together with interest, linkage and expenses, if any, unless otherwise determined by the board of directors.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors under the Companies Law described under "Management — External Directors."

Under our amended and restated articles of association, our board of directors must consist of not less than five (5) but no more than nine (9) directors, including any external directors required to be appointed by the Companies Law. Pursuant to our amended and restated articles of association, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares participating and voting at the relevant meeting. In addition, our amended and restated articles of association allow our board of directors to appoint new directors to fill vacancies on the board of directors if the number of directors is below the maximum number provided in our amended and restated articles. Furthermore, under our amended and restated articles of association our directors other than external directors are divided into three classes with staggered three-year terms. For a more detailed description on the composition of our board of election procedures of our directors, other than our external directors, see "Item 6. Directors, Senior Management and Employees — C. Board Practices — Appointment of Directors and Terms of Officers." External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Companies Law. For further information on the election and removal of external directors, see "Item 6. Directors, Senior Management and Employees — C. Board Practices — External Directors — Election and Dismissal of External Directors."

Dividend and Liquidation Rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All general meetings other than the annual meeting of shareholders are referred to in our amended and restated articles of association as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law provides that our board of directors is required to convene a special meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power. This is different from the Delaware General Corporation Law, or the DGCL, which allows such right of shareholders to be denied by a provision in a company's certificate of incorporation.

Under Israeli law, one or more shareholders holding at least 1% of the voting rights at the general meeting may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our amended and restated articles of association;
- appointment or termination of our auditors;
- appointment of external directors;
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- mergers; and
- the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

Under our amended and restated articles of association, we are not required to give notice to our registered shareholders pursuant to the Companies Law, unless otherwise required by law. The Companies Law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, or as otherwise required under applicable law, notice must be provided at least 35 days prior to the meeting. Under the Companies Law, shareholders are not permitted to take action by written consent in lieu of a meeting. Our amended and restated articles of association provide that a notice of general meeting shall be published by us on Form 6-K at a date prior to the meeting as required by law.

Voting Rights

Quorum Requirements

Pursuant to our amended and restated articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. Under our amended and restated articles of association, the quorum required for general meetings of shareholders must consist of at least two shareholders present in person or by proxy (including by voting deed) holding 33 1⁄3% or more of the voting rights in the Company, which complies with the quorum requirements for general meetings under the Nasdaq Marketplace Rules. A meeting adjourned for lack of a quorum will generally be adjourned to the same day of the following week at the same time and place, or to such other day, time or place as indicated by our board of directors if so specified in the notice of the meeting. At the reconvened meeting, any number of shareholders present in person or by proxy shall constitute a lawful quorum, instead of 33 1⁄3% of the issued share capital as required under the Nasdaq Marketplace Rules.

Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our amended and restated articles of association. Pursuant to our amended and restated articles of association, an amendment to our amended and restated articles of association regarding any change of the composition or election procedures of our directors will require a special majority vote (662⁄3%). Under the Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary) requires the approval described above under "Management — Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions." Certain transactions with respect to remuneration of our office holders and directors require further approvals described above under "Management — Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law — Compensation of Directors and Executive Officers." Under our amended and restated articles of association, any change to the rights and privileges of the holders of any class of our shares requires a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. Another exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Access to Corporate Records

Under the Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our amended and restated articles of association, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting, as set forth in our amended and restated articles of association.

Registration Rights

For a discussion of registration rights we granted to our controlling shareholder in connection with the closing of our initial public offering, please see "Item 7. Major Shareholders and Related Party Transactions – Related Party Transactions — Registration Rights Agreement."

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (a) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser and its controlling shareholder, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any other person acting on their behalf, including relatives and entities under such person's control). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under the DGCL there are no provisions relating to mandatory tender offers.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described under "Management — Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions").

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value to the parties to the merger and the consideration offered to the shareholders of the company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Anti-Takeover Measures under Israeli Law

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. As of the date of this annual report, no preferred shares are authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "— Voting Rights."

As an Israeli company we are not subject to the provisions of Section 203 of the DGCL, which in general prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior did own, 15% or more of the voting stock of a corporation.

Borrowing Powers

Pursuant to the Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Capital

Our amended and restated articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly adopted by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company, LLC.

C. Material Contracts

For a description of other material agreements, please see "Item 4. Information on the Company – B. Business Overview."

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of certain countries that are considered to be in a state of war with Israel at such time.

E. Taxation

Israeli Tax Considerations and Government Programs

General

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax at the rate of 23% in 2020. However, the effective tax rate payable by a company that derives income from a Benefited Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate.

Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as a company resident in Israel and which was incorporated in Israel of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it and which is located in Israel. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise;
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

Although as of the date of this annual report, we do not have industrial production activities, we may qualify as an Industrial Company in the future and may be eligible for the benefits described above.

Tax Benefits and Grants for Research and Development

Israeli tax law allows, under certain conditions, a tax deduction for expenditures, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research;
- The research and development must be for the promotion of the company; and
- The research and development are carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the financing of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Israeli Tax Ordinance, 1961. Expenditures not so approved are deductible in equal amounts over three years.

From time to time we may apply to the IIA for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets) by "Industrial Enterprises" (as defined under the Investment Law).

Tax Benefits Prior to the 2005 Amendment

An investment program that is implemented in accordance with the provisions of the Investment Law prior to an amendment that became effective in April 2005, or the 2005 Amendment, referred to as an "Approved Enterprise," is entitled to certain benefits. A company that wished to receive benefits as an Approved Enterprise must have received approval from the Investment Center of the Israeli Ministry of Economy and Industry, or the Investment Center. Each certificate of approval for an Approved Enterprise relates to a specific investment program in the Approved Enterprise, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

In general, an Approved Enterprise is entitled to receive a grant from the Government of Israel or an alternative package of tax benefits, known as the alternative benefits track. The tax benefits from any certificate of approval relate only to taxable profits attributable to the specific Approved Enterprise. Income derived from activity that is not integral to the activity of the Approved Enterprise does not enjoy tax benefits.

In addition, a company that has an Approved Enterprise program is eligible for further tax benefits if it qualifies as a Foreign Investors' Company, or FIC, which is a company with a level of foreign investment, as defined in the Investment Law, of more than 25%. The level of foreign investment is measured as the percentage of rights in the company (in terms of shares, rights to profits, voting and appointment of directors), and of combined share and loan capital, that are owned, directly or indirectly, by persons who are not residents of Israel. The determination as to whether a company qualifies as an FIC is made on an annual basis. We are currently not entitled to tax benefits for Approved Enterprise.

Tax Benefits Subsequent to the 2005 Amendment

The 2005 Amendment applies to new investment programs and investment programs commencing after 2004, but does not apply to investment programs approved prior to April 1, 2005. The 2005 Amendment provides that terms and benefits included in any certificate of approval that was granted before the 2005 Amendment became effective (April 1, 2005) will remain subject to the provisions of the Investment Law as in effect on the date of such approval. Pursuant to the 2005 Amendment, the Investment Center will continue to grant Approved Enterprise status to qualifying investments. The 2005 Amendment, however, limits the scope of enterprises that may be approved by the Investment Center by setting criteria for the approval of a facility as an Approved Enterprise, such as provisions generally requiring that at least 25% of the Approved Enterprise's income be derived from exports.

The 2005 Amendment provides that Approved Enterprise status will only be necessary for receiving cash grants. As a result, it was no longer necessary for a company to obtain Approved Enterprise status in order to receive the tax benefits previously available under the alternative benefits track. Rather, a company may claim the tax benefits offered by the Investment Law directly in its tax returns, provided that its facilities meet the criteria for tax benefits set forth in the amendment. Companies are entitled to approach the Israeli Tax Authority for a pre-ruling regarding their eligibility for benefits under the Investment Law, as amended.

In order to receive the tax benefits, the 2005 Amendment states that a company must make an investment which meets all of the conditions, including exceeding a minimum investment amount specified in the Investment Law. Such investment allows a company to receive "Benefited Enterprise" status, and may be made over a period of no more than three years from the end of the year in which the company requested to have the tax benefits apply to its Benefited Enterprise. Where the company requests to apply the tax benefits to an expansion of existing facilities, only the expansion will be considered to be a Benefited Enterprise and the company's effective tax rate will be the weighted average of the applicable rates. In this case, the minimum investment required in order to qualify as a Benefited Enterprise is required to exceed a certain percentage of the value of the company's production assets before the expansion.

The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Benefited Enterprise depend on, among other things, the geographic location in Israel of the Benefited Enterprise. The location will also determine the period for which tax benefits are available. Such tax benefits include an exemption from corporate tax on undistributed income for a period of between two to 10 years, depending on the geographic location of the Benefited Enterprise in Israel, and a reduced corporate tax rate of between 10% and the applicable corporate tax for the remainder of the benefits period, depending on the level of foreign investment in the company in each year. A company qualifying for tax benefits under the 2005 Amendment which pays a dividend out of income derived by its Benefited Enterprise during the tax exemption period will be subject to corporate tax in respect of the gross amount of the dividend at the otherwise applicable corporate tax rate or a lower rate in the case of a qualified FIC which is at least 49% owned by non-Israeli residents. Dividends paid out of income attributed to a Benefited Enterprise are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty.

The benefits available to a Benefited Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations. If a company does not meet these conditions, it may be required to refund the amount of tax benefits, as adjusted by the Israeli consumer price index, and interest, or other monetary penalties.

We applied for tax benefits as a “Benefited Enterprise” with 2012 as a “Year of Election.” We may be entitled to tax benefits under this regime once we are profitable for tax purposes and subject to the fulfillment of all the relevant conditions. If we do not meet these conditions, the tax benefits may not be applicable which would result in adverse tax consequences to us. Alternatively, and subject to the fulfillment of all the relevant conditions, we may elect in the future to irrevocably waive the tax benefits available for Benefited Enterprise and claim the tax benefits available to Preferred Enterprise under the 2011 Amendment (as detailed below).

Tax Benefits Under the 2011 Amendment

The Investment Law was significantly amended as of January 1, 2011, or the 2011 Amendment. The 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment.

The 2011 Amendment introduced new tax benefits for income generated by a “Preferred Company” through its “Preferred Enterprise,” in accordance with the definition of such term in the Investment Law, which generally means that a “Preferred Company” is an industrial company meeting certain conditions (including a minimum threshold of 25% export).

A Preferred Company is entitled to a reduced flat tax rate with respect to the income attributed to the Preferred Enterprise, at the following rates:

Tax Year	Development Region “A”	Other Areas within Israel
2011 – 2012	10%	15%
2013	7%	12.5%
2014 – 2016	9%	16%
2017 and thereafter	7.5%	16%

Dividends distributed from income which is attributed to a “Preferred Enterprise” will be subject to withholding tax at source at the following rates: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 20% in 2020 (iii) non-Israeli residents — may be reduced down to 4% in 2020, subject to certain conditions under the Investment Law and to a reduced tax rate under the provisions of an applicable double tax treaty.

Under the 2011 Amendment, a company located in Development Region "A" may be entitled to cash grants and the provision of loans under certain conditions, if approved. The rates for grants and loans shall not be fixed, but up to 20% of the amount of the approved investment (may be increased by an additional 4%). In addition, a company owning a Preferred Enterprise under the Grant Track may be entitled also to the tax benefits which are prescribed for a Preferred Company.

The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

We are currently not entitled to tax benefits for a Preferred Enterprise.

Taxation of Our Shareholders

Capital Gains

Capital gain tax is imposed on the disposition of capital assets by an Israeli resident, and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Israeli Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli consumer price index between the date of purchase and the date of disposition. Inflationary Surplus is not currently subject to tax in Israel.

Real Gain accrued by individuals on the sale of our ordinary shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%.

Real Gain derived by corporations will be generally subject to the corporate tax rate of 23% in 2020.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income —23% for corporations in 2020, and a marginal tax rate of up to 50% for individuals, including an excess tax.

Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares by a non-Israeli shareholder may be exempt under the Israeli Tax Ordinance from Israeli capital gain tax provided that the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed. However, non-Israeli corporations will not be entitled to the foregoing exemption if more than 25% of its means of control are held, directly and indirectly, by Israeli residents, and Israeli residents are entitled to 25% or more of the revenues or profits of the corporation, directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the U.S.-Israel Double Tax Treaty exempts U.S. residents from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding of Israeli tax at source at a rate of 25% if the seller is an individual and at the corporate tax rate (23% in 2020) if the seller is a corporation. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and July 31 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Tax Ordinance and regulations promulgated thereunder, the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

We have never paid cash dividends. A distribution of a dividend by our company from income attributed to a Benefited Enterprise will generally be subject to withholding tax in Israel at a rate of 20% unless a reduced tax rate is provided under an applicable tax treaty. A distribution of a dividend by our company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals — 20%; Israeli resident companies — 0% for a Preferred Enterprise; Non-Israeli residents — 20%, subject to a reduced rate under the provisions of any applicable double tax treaty. A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to withholding tax at a rate of 25%, or 30% if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will not be subject to Israeli tax provided the income from which such dividend is distributed was derived or accrued within Israel.

The Israeli Tax Ordinance provides that a non-Israeli resident (either individual or corporation) is generally subject to Israeli withholding tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12-month period); those rates may be subject to a reduced rate under the provisions of an applicable double tax treaty. Under the U.S.-Israel Double Tax Treaty, the following withholding rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting share capital of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends — the rate is 12.5%, (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate applicable to an Approved Enterprise — the rate is 15% and (iii) in all other cases, the rate is 25%. The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from a business conducted in Israel by the taxpayer, and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Dividends are generally subject to Israeli withholding tax at a rate of 25% so long as the shares are registered with a nominee company (whether or not the recipient is a "Controlling Shareholder," as defined above), unless relief is provided in a treaty between Israel and the shareholder's country of residence and provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% on annual income exceeding NIS 651,600 for 2020, linked to the annual change in the Israeli consumer price index, including, but not limited to income derived from, dividends, interest and capital gains.

Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated and may be restored at any time by administrative action.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Considerations with respect to the Company

The following discussion describes certain material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in our ordinary shares or warrants. This discussion applies only to U.S. Holders that hold our ordinary shares or warrants as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or (the Code, and that have the U.S. dollar as their functional currency.

This discussion is based on the tax laws of the United States, including the Code, as in effect on the date hereof and on U.S. Treasury regulations as in effect or, in some cases, as proposed, on the date hereof, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below. This summary does not address any estate or gift tax consequences, the alternative minimum tax, the Medicare tax on net investment income or any state, local, or non-U.S. tax consequences. The following discussion neither deals with the tax consequences to any particular investor nor describes all of the tax consequences applicable to persons in special tax situations such as:

- banks;
- certain financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;
- traders that elect to mark to market;
- U.S. expatriates;
- tax-exempt entities;
- persons holding our ordinary shares or warrants as part of a straddle, hedging, constructive sale, conversion or integrated transaction;
- persons that actually or constructively (including through the ownership of our warrants) own 10% or more of our share capital (by vote or value);
- persons that are resident or ordinarily resident in or have a permanent establishment in a jurisdiction outside the United States;
- persons who acquired our ordinary shares or warrants pursuant to the exercise of any employee share option or otherwise as compensation;

- persons subject to special tax accounting rules as a result of any item of gross income with respect to our ordinary shares or warrants being taken into account in an applicable financial statement; or

- pass-through entities, or persons holding our ordinary shares or warrants through pass-through entities.

INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF AN INVESTMENT IN OUR ORDINARY SHARES OR WARRANTS.

The discussion below of the U.S. federal income tax consequences to "U.S. Holders" will apply to you if you are the beneficial owner of our ordinary shares or warrants and you are, for U.S. federal income tax purposes,

- an individual who is a citizen or resident of the United States;

- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia;

- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

- a trust that (i) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity or other arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or warrants, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. A person that would be a U.S. Holder if it held our ordinary shares or warrants directly and that is a partner of a partnership holding our ordinary shares or warrants is urged to consult its own tax advisor.

Passive Foreign Investment Company

A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will generally be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for any taxable year if either:

- at least 75% of its gross income for such year is passive income (such as interest income); or

- at least 50% of the value of its assets (based on an average of the quarterly values of the assets) during such year is attributable to assets that produce passive income or are held for the production of passive income.

For this purpose, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other entity treated as a corporation for U.S. federal income tax purposes in which we own, directly or indirectly, 25% or more (by value) of the stock.

Starting in the first quarter of 2019, we began generating revenue under a collaboration agreement with Perrigo for the development of the generic version of Zovirax® (acyclovir) cream, 5%. We generated $8.7 in revenue under such agreement for our 2020 taxable year, but expect to generate substantially less in future years. Though the application of the relevant rules governing the characterization of such revenue for purposes of the PFIC income test is uncertain, we intend to take the position that, based on our involvement and management contributions throughout the development process, such revenue is non-passive for PFIC purposes. As a result, assuming we continue to earn substantial revenue from such agreement as anticipated and based on the current and anticipated value and composition of our income and assets, we do not expect that we will be treated as a PFIC for U.S. federal income tax purposes for our current taxable year or for foreseeable future years. However, there are substantial factual and legal ambiguities regarding the nature of the revenue and the application of the relevant PFIC rules, and thus, the determination that such revenue is non-passive is not without doubt, and alternative characterizations are possible.

A separate determination must be made after the close of each taxable year as to whether we were a PFIC for that year. Because the value of our assets for purposes of the PFIC test will generally be determined by reference to the market price of our ordinary shares, our PFIC status may depend in part on the market price of our ordinary shares, which may fluctuate significantly. In addition, there may be certain other ambiguities in applying the PFIC test to us. No rulings from the U.S. Internal Revenue Service, or the IRS, however, have been or will be sought with respect to our status as a PFIC. If the IRS were to assert that, contrary to our expectation, we are a PFIC in the current taxable year or a future year, there would be adverse tax consequences to investors, including those described below. Potential investors are strongly advised to consult their own advisors regarding the consequences to them if we were to be considered a PFIC.

If we are a PFIC for any taxable year during your holding period for our ordinary shares (or under proposed Regulations, our warrants), we generally will continue to be treated as a PFIC with respect to your investment in our ordinary shares or warrants for all succeeding years during which you hold our ordinary shares or warrants, and, although subject to uncertainty, potentially our ordinary shares received upon exercise of such warrants. Certain elections (such as a deemed sale election) may be available under certain circumstances.

For each taxable year that we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any "excess distribution" (as defined below) you receive and any gain you realize from a sale or other disposition (including a pledge) of our ordinary shares or warrants, unless you make a valid "mark-to-market" election as discussed below, which may not be available for the warrants. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period;
- the amount allocated to the current taxable year, and any taxable years in your holding period prior to the first taxable year in which we were a PFIC, will be treated as ordinary income; and
- the amount allocated to each other taxable year will be subject to the highest tax rate in effect for individuals or corporations, as applicable, for each such year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to taxable years prior to the year of disposition or excess distribution cannot be offset by any net operating losses, and gains (but not losses) realized on the sale of our ordinary shares or warrants cannot be treated as capital gains, even if you hold our ordinary shares or warrants as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you may be deemed to own a proportionate interest in such lower-tier PFICs that are directly or indirectly owned by us, and you may be subject to the adverse tax consequences described above with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any excess distribution described above if we receive a distribution from our lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

A U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the tax treatment discussed above. If you make a valid mark-to-market election for our ordinary shares, you will include in income for each year that we are treated as a PFIC with respect to you an amount equal to the excess, if any, of the fair market value of our ordinary shares as of the close of your taxable year over your adjusted basis in such ordinary shares. You will be allowed a deduction for the excess, if any, of the adjusted basis of our ordinary shares over their fair market value as of the close of the taxable year. However, deductions will be allowable only to the extent of any net mark-to-market gains on our ordinary shares included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of our ordinary shares, will be treated as ordinary income. Ordinary loss treatment will also apply to the deductible portion of any mark-to-market loss on our ordinary shares, as well as to any loss realized on the actual sale or disposition of our ordinary shares, to the extent the amount of such loss does not exceed the net mark-to-market gains for such ordinary shares previously included in income. Your basis in our ordinary shares will be adjusted to reflect any such income or loss amounts. If you make a mark-to-market election, any distributions we make would generally be subject to the rules discussed below under "— Taxation of Dividends and Other Distributions on our Ordinary Shares," except the lower rates applicable to qualified dividend income would not apply.

The mark-to-market election is available only for "marketable stock," which is stock that is regularly traded on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations, and may not include our warrants. Our ordinary shares are listed on the Nasdaq Global Market. Because a mark-to-market election cannot be made for equity interests in any lower-tier PFICs we own, you generally will continue to be subject to the PFIC rules with respect to your indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. The Nasdaq Global Market is a qualified exchange, but there can be no assurance that the trading in our ordinary shares will be sufficiently regular to qualify our ordinary shares as marketable stock. You should consult your tax advisor as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Alternatively, if a non-U.S. entity treated as a corporation is a PFIC, a holder of shares in that entity may avoid taxation under the PFIC rules described above regarding excess distributions and recognized gains by making a "qualified electing fund" election to include in income its share of the entity's income on a current basis. However, you may make a qualified electing fund election with respect to your ordinary shares only if we furnish you annually with certain tax information, and we currently do not intend to prepare or provide such information. A qualified electing fund election may not be available for our warrants regardless of whether we provide such information.

A U.S. Holder of a PFIC may be required to file an IRS Form 8621. If we are a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you. You are urged to consult your tax advisor regarding the application of the PFIC rules to an investment in ordinary shares or warrants.

YOU ARE STRONGLY URGED TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT ON YOUR INVESTMENT IN OUR ORDINARY SHARES OR WARRANTS IF WE WERE TO BE CONSIDERED A PFIC AS WELL AS THE APPLICATION OF THE PFIC RULES AND THE POSSIBILITY OF MAKING A MARK-TO-MARKET ELECTION.

Taxation of Dividends and Other Distributions on our Ordinary Shares

Subject to the PFIC rules discussed above, the gross amount of any distributions we make to you (including the amount of any tax withheld) with respect to our ordinary shares generally will be includible in your gross income as dividend income on the date of receipt by the holder, but only to the extent the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). The dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations. To the extent the amount of the distribution exceeds our current and accumulated earnings and profits (as determined under U.S. federal income tax principles), such excess amount will be treated first as a tax-free return of your tax basis in your ordinary shares, and then, to the extent such excess amount exceeds your tax basis in your ordinary shares, as capital gain. We currently do not, and we do not intend to, calculate our earnings and profits under U.S. federal income tax principles. Therefore, you should expect that a distribution will generally be reported as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may be taxed at the lower capital gain rates applicable to "qualified dividend income," provided (i) our ordinary shares are readily tradable on an established securities market in the United States (such as the Nasdaq Global Market), (ii) we are neither a PFIC nor treated as such with respect to you (as discussed above) for either the taxable year in which the dividend was paid or the preceding taxable year, (iii) certain holding period requirements are met and (iv) you are not under an obligation to make related payments with respect to positions in substantially similar or related property.

The amount of any distribution paid in a currency other than U.S. dollars will be equal to the U.S. dollar value of such currency on the date such distribution is includible in your income, regardless of whether the payment is in fact converted into U.S. dollars at that time. The amount of any distribution of property other than cash will be the fair market value of such property on the date of distribution.

Any dividends will constitute foreign source income for foreign tax credit limitation purposes. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by the reduced tax rate applicable to qualified dividend income and divided by the highest tax rate normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to our ordinary shares will generally constitute "passive category income."

If Israeli withholding taxes apply to any dividends paid to you with respect to our ordinary shares, subject to certain conditions and limitations, such withholding taxes may be treated as foreign taxes eligible for credit against your U.S. federal income tax liability. Instead of claiming a credit, you may elect to deduct such taxes in computing taxable income, subject to applicable limitations. If a refund of the tax withheld is available under the applicable laws of Israel or under the Israel-U.S. income tax treaty, or the Treaty, the amount of tax withheld that is refundable will not be eligible for such credit against your U.S. federal income tax liability (and will not be eligible for the deduction against your U.S. federal taxable income). The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor regarding the availability of a foreign tax credit in your particular circumstances, including the effects of the Treaty.

Constructive Dividends on our Ordinary Shares or Warrants

If the exercise price of our warrants is adjusted in certain circumstances (or in certain circumstances, there is a failure to make adjustments or a failure to make adequate adjustments), that adjustment (or failure to adjust) may result in the deemed payment of a taxable dividend to a U.S. Holder of the warrants or our ordinary shares. Any such constructive dividend will be taxable generally as described above under "Taxation of Dividends and Other Distributions on our Ordinary Shares." Generally, a U.S. Holder's tax basis in our ordinary shares or the warrants will be increased to the extent of any such constructive dividend. It is not entirely clear whether a constructive dividend deemed paid to a non-corporate U.S. Holder could be "qualified dividend income" as discussed above under "Taxation of Dividends and Other Distributions on our Ordinary Shares." U.S. Holders should consult their tax advisers regarding the proper U.S. federal income tax treatment of any adjustments to (or failure to adjust or adjust adequately) the exercise price of the warrants.

We are currently required to report the amount of any constructive dividends on our website or to the IRS and to holders not exempt from reporting. The IRS has proposed regulations addressing the amount and timing of constructive dividends, as well as, obligations of withholding agents and filing and notice obligations of issuers in respect of such constructive dividends. If adopted as proposed, the regulations would generally provide that (i) the amount of a constructive dividend is the excess of the fair market value of the right to acquire stock immediately after the exercise price adjustment over the fair market value of the right to acquire stock (after the exercise price adjustment) without the adjustment, (ii) the constructive dividend occurs at the earlier of the date the adjustment occurs under the terms of the instrument and the date of the actual distribution of cash or property that results in the constructive dividend and (iii) we are required to report the amount of any constructive dividends on our website or to the IRS and to all holders (including holders that would otherwise be exempt from reporting). The final regulations will be effective for constructive dividends occurring on or after the date of adoption, but holders and withholding agents may rely on them prior to that date under certain circumstances.

Taxation of Disposition of our Ordinary Shares or Warrants

Subject to the PFIC rules discussed above, upon a sale or other disposition of our ordinary shares or warrants, you will generally recognize capital gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized (including the amount of any tax withheld) and your tax basis in such ordinary shares or warrants. If the consideration you receive for our ordinary shares or warrants is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if our ordinary shares or warrants are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Any gain or loss on the sale or other disposition of our ordinary shares or warrants will generally be treated as U.S. source income or loss and treated as long-term capital gain or loss if your holding period in our ordinary shares or warrants at the time of the disposition exceeds one year. Accordingly, in the event any Israeli tax (including withholding tax) is imposed upon the sale or other disposition, you may not be able to utilize foreign tax credit unless you have foreign source income or gain in the same category from other sources. Long-term capital gain of non-corporate U.S. Holders generally will be subject to U.S. federal income tax at reduced tax rates. The deductibility of capital losses is subject to significant limitations.

Taxation of Exercise or Expiration of our Warrants

In general, you will not be required to recognize income, gain or loss upon exercise of our warrants by payment of the exercise price. Your tax basis in our ordinary shares received upon exercise of our warrants will be equal to the sum of (1) your tax basis in the warrants exchanged therefor and (2) the exercise price of the warrants. Your holding period in our ordinary shares received upon exercise will commence on the day after you exercise the warrants.

If the warrants expire without being exercised, you will recognize a capital loss in an amount equal to your tax basis in the warrants. Such loss will be long-term capital loss if, at the time of the expiration, your holding period in the warrants is more than one year. The deductibility of capital losses is subject to limitations.

Information Reporting and Backup Withholding

Dividend payments (including constructive dividends) with respect to our ordinary shares or warrants and proceeds from the sale, exchange or redemption of our ordinary shares or warrants may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and makes any other required certification or that is otherwise exempt from backup withholding. U.S. Holders that are required to establish their exempt status generally must provide such certification on IRS Form W-9. You should consult your tax advisor regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Information with respect to Foreign Financial Assets

Certain U.S. Holders may be required to report information relating to an interest in our ordinary shares or warrants, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain financial institutions). Penalties can apply if U.S. Holders fail to satisfy such reporting requirements. You should consult your tax advisor regarding the effect, if any, of this requirement on your ownership and disposition of our ordinary shares.

THE SUMMARY OF U.S. FEDERAL INCOME TAX CONSEQUENCES SET OUT ABOVE IS FOR GENERAL INFORMATIONAL PURPOSES ONLY. INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF AN INVESTMENT IN OUR ORDINARY SHARES OR WARRANTS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers, and under those requirements, we file reports with the SEC. Our filings with the SEC are available to the public through the SEC's website at *http://www.sec.gov*.

As a foreign private issuer, we are exempt from the rules under the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act, to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to comply with the informational requirements of the Exchange Act, and, accordingly, file current reports on Form 6-K, annual reports on Form 20-F and other information with the SEC.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail below.

Interest Rate Risk

We do not anticipate undertaking any significant long-term borrowings.

At present, our investments consist primarily of marketable securities and bank deposits. We may be exposed to market price risk because of investments in tradable securities, mainly corporate bonds, held by us and classified in our financial statements as financial assets at fair value through profit or loss. To manage the price risk arising from investments in tradable securities, we invest in marketable securities with high ratings and diversify our investment portfolio. Our investments may also be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. Although a substantial portion of our expenses (mainly salaries and related costs) are denominated in NIS, accounting for almost half of our expenses in the year ended December 31, 2020, all of our financing has been in U.S. dollars and the vast majority of our liquid assets are held in U.S. dollars. Furthermore, while we anticipate that a portion of our expenses, principally salaries and related personnel expenses in Israel, will continue to be denominated in NIS, we expect to incur an increasing amount of expenses in U.S. dollars as we progress in the development and the regulatory processes of our product candidates. Changes of 5% in the U.S. dollar/NIS exchange rate would have increased/decreased operating expenses by approximately 2% during the fiscal year ended on December 31, 2020. We also have expenses, although to a much lesser extent, in other non-U.S. dollar currencies, in particular the Euro.

Moreover, for the next few years we expect that the substantial majority of our revenues from the sale of our products in the United States, if any, will be denominated in U.S. dollars. Since a portion of our expenses is denominated in NIS and other non-U.S. currencies, we are exposed to risk associated with exchange rate fluctuations vis-à-vis the non-U.S. currencies. See "Item 3 – D. Risk Factors — Exchange rate fluctuations between the U.S. dollar, the New Israeli Shekel and other foreign currencies, may negatively affect our future revenues." If the NIS fluctuates significantly against the U.S. dollar it may have a negative impact on our results of operations. As of the date of this annual report and for the periods under review, fluctuations in the currencies exchange rates have not materially affected our results of operations or financial condition.

The Company carries out transactions involving foreign currency exchange derivative financial instruments. The transactions are designed to hedge the Company's exposure in currencies other than the U.S. dollar. The derivative does not meet the definition of a cash flow accounting hedge, and therefore the changes in the fair value are included in financial expense (income), net.

Inflation-related risks

We do not believe that the rate of inflation in Israel has had a material impact on our business to date, however, our costs in Israel will increase if the inflation rate in Israel exceeds the devaluation of the NIS against the U.S. dollar or if the timing of such devaluation lags behind inflation in Israel.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Not applicable.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

All proceeds have been applied from our initial public offering on Nasdaq on February 5, 2018.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed and filed with the SEC is recorded, processed, summarized and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report are effective at such reasonable assurance level.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act of 1934, as amended. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors (as appropriate); and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013).

Based on our assessment and this framework, our management concluded that the Company's internal control over financial reporting was effective as of December 31, 2020.

(c) Attestation Report of Registered Public Accounting Firm

Not applicable.

(d) Changes in Internal Controls Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2020 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

ITEM16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Mr. Jerrold S. Gattegno is an audit committee financial expert. Mr. Gattegno is an independent director for the purposes of the Nasdaq Listing Rules.

ITEM 16B. CODE OF ETHICS

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, http://ir.sol-gel.com/corporate-governance/governance-overview.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the aggregate fees billed by our independent registered public accounting firm for professional services.

	Year Ended December 31,	
Services Rendered	**2020**	**2019**
	(U.S. dollars in thousands)	
Audit Fees (1)	187	164
Tax (2)	29	37
Total	216	201

(1) Audit Fees consist of professional services rendered in connection with the audit of our consolidated financial statements, review of our consolidated quarterly financial statements, issuance of comfort letters, consents and assistance with review of documents filed with the SEC.
(2) Tax fees relate to tax compliance, planning and advice.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee approves in advance the particular services or categories of services to be provided to the Company during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq Stock Listing Rules and Home Country Practices

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Also, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information. However, we intend to file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and we intend to submit to the SEC from time to time, on Form 6-K, reports of information that would likely be material to an investment decision in our securities.

As a foreign private issuer, we are permitted to follow certain Israeli corporate governance practices instead of the Nasdaq corporate governance rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. Pursuant to the "foreign private issuer exemption":

- the quorum for any meeting of shareholders is two or more shareholders holding at least 33-1⁄3% of our voting rights, which complies with Nasdaq requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of shareholders, instead of 33-1⁄3% of our voting rights;

- we adopt and approve material changes to equity incentive plans in accordance with the Companies Law, which does not impose a requirement of shareholder approval for such actions. In addition, we intend to follow Israeli corporate governance practice in lieu of Nasdaq Marketplace Rule 5635(c), which requires shareholder approval prior to an issuance of securities in connection with equity based compensation of officers, directors, employees or consultants;

- as opposed to making periodic reports to shareholders and proxy solicitation materials available to shareholders in the manner specified by the Nasdaq corporate governance rules, the Companies Law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. We only mail such reports to shareholders upon request; and

- we follow Israeli corporate governance practice instead of Nasdaq requirements to obtain shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock or assets of another company).

Otherwise, we intend to comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Global Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. We also intend to comply with Israeli corporate governance requirements under the Companies Law applicable to public companies.

Controlled Company

As a result of the number of shares owned by Arkin Dermatology, as of the date of this annual report, we are a "controlled company" under the Nasdaq corporate governance rules. A "controlled company" is a company of which more than 50% of the voting power is held by an individual, group or another company. Pursuant to the "controlled company" exemption, we are not required to, and may not in the future comply with the requirement that a majority of our board of directors consist of independent directors, and we are not required to, and do not intend to comply with the requirement that we have a nominating committee composed entirely of independent directors with a written charter addressing such committee's purpose and responsibilities. A majority of our board of directors currently consists of independent directors. See "Item 6. Directors, Senior Management and Employees — C. Board Practices."

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The financial statements required by this item are found at the end of this annual report, beginning on page F-1.

ITEM 19. EXHIBITS

See Exhibit Index on page [___].

EXHIBIT INDEX

The exhibits filed with or incorporated into this Registration Statement are listed in the index of exhibits below.

Exhibit Number	Exhibit Description
1.1	Amended and Restated Memorandum of Association (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on January 23, 2018).
1.2	Amended and Restated Articles of Association (incorporated by reference to Exhibit 99.1 of Form 6-K/A filed with the Securities and Exchange Commission on August 20, 2018).
2.1	Form of Specimen Share Certificate (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on September 20, 2017).
2.2	Description of Share Capital (incorporated by reference to Exhibit 2.2 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 24, 2020).
4.1†	Development, Manufacturing and Commercialization Agreement between Perrigo UK Finco Limited Partnership and Sol-Gel Technologies Ltd., dated as of April 27, 2015 (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on September 20, 2017).
4.2†	Amendment to the Development, Manufacturing and Commercialization Agreement between the Registrant and Perrigo UK Finco Limited Partnership, dated as of October 26, 2015 (incorporated by reference to Exhibit 10.4 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on September 6, 2017).
4.3	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.5 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on September 20, 2017).
4.4	2014 Share Incentive Plan (incorporated by reference to Exhibit 4.4 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 24, 2020).
4.5	Compensation Policy.
4.6	Registration Rights Agreement (incorporated by reference to Exhibit 99.2 of Form 6-K filed with the Securities and Exchange Commission on February 6, 2018).
4.7∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of October 10, 2007 (incorporated by reference to Exhibit 10.7 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.8∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 29, 2014 (incorporated by reference to Exhibit 10.8 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.9∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of March 30, 2016 (incorporated by reference to Exhibit 10.9 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).

4.10∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 20, 2016 (incorporated by reference to Exhibit 10.10 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.11∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of January 30, 2017 (incorporated by reference to Exhibit 10.11 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.12∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 25, 2017 (incorporated by reference to Exhibit 4.12 of the Annual on Form 20-F filed with the Securities and Exchange Commission on March 21, 2019).
4.13∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of July 3, 2018 (incorporated by reference to Exhibit 4.13 of the Annual on Form 20-F filed with the Securities and Exchange Commission on March 21, 2019).
4.14∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of August 14, 2018 (incorporated by reference to Exhibit 4.14 of the Annual on Form 20-F filed with the Securities and Exchange Commission on March 21, 2019).
4.15∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of November 12, 2019 (incorporated by reference to Exhibit 4.15 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 24, 2020).
4.16	Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 2, 2016 (incorporated by reference to Exhibit 10.12 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.17	Schedule A, as amended, of Promissory Note by and between the Registrant and Moshe Arkin, dated as of June 28, 2017 (incorporated by reference to Exhibit 10.13 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.18	Instrument of Conversion of Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 22, 2017 (incorporated by reference to Exhibit 10.14 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.19	Assignment Agreement between the Registrant and Medicis Pharmaceutical Corporation, dated August 16, 2013 (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.20∞	Asset Transfer Agreement and Assignment Deed between Sol-Gel Technologies Ltd. and M. Arkin Dermatology Ltd., dated August 22, 2017 (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on January 30, 2017).
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13	Certification by Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Independent Registered Public Accounting Firm
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2020 formatted in XBRL: (i) Consolidated Statements of Comprehensive Loss, (ii) Consolidated Statements of Financial Position, (iii) Consolidated Statements of Changes in Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.
†	Confidential treatment granted with respect to certain portions of this Exhibit.
∞	Informal translation of the original Hebrew document.

SIGNATURE

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

SOL-GEL TECHNOLOGIES LTD.

By: /s/ Alon Seri-Levy
Name: Alon Seri-Levy
Title: Chief Executive Officer and Director

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

Date: March 4, 2021

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2020

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2020

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Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of Sol-Gel Technologies Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sol-Gel Technologies Ltd**.** and its subsidiary (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, of changes in shareholders' equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2(o) to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Tel-Aviv, Israel
March 4, 2021

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

We have served as the Company's auditor since 2000.

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	December 31	
	2019	2020
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,412	$ 7,122
Bank deposits	-	21,400
Marketable securities	40,966	21,652
Receivables from collaborative arrangements	4,120	2,153
Prepaid expenses and other current assets	1,293	1,074
TOTAL CURRENT ASSETS	55,791	53,401
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash	472	1,293
Property and equipment, net	2,314	1,817
Operating lease right-of-use assets	2,040	1,896
Funds in respect of employee rights upon retirement	684	754
TOTAL NON-CURRENT ASSETS	5,510	5,760
TOTAL ASSETS	$ 61,301	$ 59,161
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 1,710	$ 1,203
Other accounts payable	4,123	4,088
Current maturities of operating leases	672	673
TOTAL CURRENT LIABILITIES	6,505	5,964
LONG-TERM LIABILITIES:		
Operating leases liabilities	1,373	1,299
Liability for employee rights upon retirement	958	1,049
TOTAL LONG-TERM LIABILITIES	2,331	2,348
COMMITMENTS		
TOTAL LIABILITIES	8,836	8,312
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2019 and 2020, respectively; issued and outstanding: 20,402,800 and 23,000,782 as of December 31, 2019 and December 31, 2020, respectively	561	635
Additional paid-in capital	203,977	231,577
Accumulated deficit	(152,073)	(181,363)
TOTAL SHAREHOLDERS' EQUITY	52,465	50,849
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 61,301	$ 59,161

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

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

	Year ended December 31,		
	2018	**2019**	**2020**
COLLABORATION REVENUES	$ 129	$ 22,904	$ 8,771
OPERATING EXPENSES			
Research and Development	28,146	40,578	27,913
General and Administrative	5,504	8,276	11,091
TOTAL OPERATING LOSS	33,521	25,950	30,233
FINANCIAL INCOME, net	(1,318)	(1,374)	(943)
LOSS BEFORE INCOME TAXES	32,203	24,576	29,290
INCOME TAXES	-	33	-
LOSS FOR THE YEAR	$ 32,203	$ 24,609	$ 29,290
BASIC AND DILUTED LOSS PER ORDINARY SHARE	$ 1.80	$ 1.26	$ 1.30
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	17,867,589	19,534,562	22,574,688

The accompanying notes are an integral part of these consolidated financial statement.

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share data)

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total
	Number of shares	Amounts	Amounts		
BALANCE AS OF JANUARY 1, 2018	6,290,244	82	42,480	(95,261)	(52,699)
CHANGES DURING 2018:					
Loss for the year				(32,203)	(32,203)
Stock split	*	66	(66)		-
Conversion of loans from the Controlling shareholder	5,444,825	160	65,178		65,338
Issuance of shares through an initial public offering, net of issuance costs	7,187,500	211	78,564		78,775
Exercise of options granted to employee	27,399	1	43		44
Share-based compensation			4,654		4,654
BALANCE AS OF DECEMBER 31, 2018	18,949,968	520	190,853	(127,464)	63,909
CHANGES DURING 2019:					
Loss for the year				(24,609)	(24,609)
Vesting of restricted share units	15,332	*	*		-
Issuance of shares through public offering, net of issuance costs	1,437,500	41	10,572		10,613
Share-based compensation			2,552		2,552
BALANCE AS OF DECEMBER 31, 2019	20,402,800	561	203,977	(152,073)	52,465
CHANGES DURING 2020:					
Loss for the year				(29,290)	(29,290)
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 share units	23,000	*			
Exercise of options	28,447	*	151		151
Share-based compensation			1,217		1,217
BALANCE AS OF DECEMBER 31, 2020	23,000,782	635	231,577	(181,363)	50,849

* Less than 1,000.

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

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,		
	2018	**2019**	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Loss	$ (32,203)	$ (24,609)	$ (29,290)
Adjustments required to reconcile loss to net cash used in operating activities:			
Depreciation	762	887	946
Changes in accrued liability for employee rights upon retirement	106	38	21
Share-based compensation expenses	4,654	2,552	1,217
Net changes in operating leases	-	5	71
Changes in fair value of marketable securities	29	65	138
Finance expenses, net	(34)	50	12
Changes in operating asset and liabilities:			
Receivables from collaborative arrangements	-	(4,120)	1,967
Prepaid expenses and other current assets	(1,463)	1,694	219
Accounts payable, accrued expenses and other	3,029	938	(542)
Long term receivables	1,653	-	-
Net cash used in operating activities	(23,467)	(22,500)	(25,241)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(1,052)	(597)	(449)
Bank deposits	3,000	1,000	(21,400)
Restricted long-term deposits	8	(10)	(21)
Investments in marketable securities	(71,783)	(38,702)	(32,322)
Proceeds from sales and maturity of marketable securities	15,092	54,333	51,498
Net cash provided by (used in) investing activities	(54,735)	16,024	(2,694)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of options granted to employees	44	-	151
Proceeds from issuance of shares and warrants through public offering, net of issuance costs	78,775	10,613	21,306
Net proceeds from issuance of shares and warrants to the controlling shareholder through private placement			5,000
Net cash provided by financing activities	78,819	10,613	26,457
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS	34	(50)	(12)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	651	4,087	(1,490)
CASH AND CASH EQUIVALENTS AND RESRICTED CASH AT BEGINNING OF THE YEAR	5,024	5,675	9,762
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE YEAR	$ 5,675	$ 9,762	$ 8,272
Cash and Cash equivalents	5,325	9,412	7,122
Restricted cash	350	350	1,150
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS	$ 5,675	$ 9,762	$ 8,272
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Recognition of new operating lease ROU and liabilities	$ -	$ 1,329	$ 378
Conversion of loans from the controlling shareholder	$ 65,338	$ -	$ -
SUPPLEMENTARY INFORMATION:			
Income taxes paid	$ -	$ -	$ 7
Interest received	$ 1,477	$ 1,600	$ 770

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

NOTE 1 — NATURE OF OPERATIONS

Sol-Gel Technologies Ltd. (collectively with its 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. 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; and (ii) Epsolay®, a potential treatment for subtype II rosacea. The NDA for Epsolay® was accepted by the FDA, which assigned a PDUFA goal date of April 26, 2021. In addition to the novel product candidates, the Company's products include the generic product Acyclovir and other generic product candidates.

The Company has a wholly owned U.S. subsidiary - Sol-Gel Technologies Inc. (the "Subsidiary"). The Subsidiary supports the Company with regard to marketing, regulatory affairs and business development relating to its products and technology in the U.S.

Since incorporation through December 31, 2020, the Company has an accumulated deficit of approximately $181,363 thousand and its activities have been funded mainly by its shareholders and collaboration revenues. The Company expects to continue to incur significant research and development and other costs related to its ongoing operations and in order to continue its future operations, the Company will need to obtain additional funding until becoming profitable.

NOTE 1 - NATURE OF OPERATIONS (continued)

Management is considering raising additional funding from different sources, such as corporate collaborations, licensing of its branded products or similar arrangements, 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 December 31, 2020 will allow the Company to fund its operating plan through at least the next 12 months from the financial statement issuance date.

In December 2019, COVID-19 was identified in Wuhan, China. This virus continues to spread globally and, as of December 2020, has spread to over 50 countries, including the United States and Israel. The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic.

As of December 31, 2020, the main impact on the Company's operations resulting from COVID-19 was the decline in revenues of Acyclovir in the second quarter. Management believes that such decline was mainly attributed to travel restrictions and stay-at-home-orders.

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 the different 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

Basis of presentation

The Company’s financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”).

a. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results may differ from those estimates.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation and the incremental borrowing rate for leases.

b. Functional and presentation currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of the Company and its subsidiary are conducted. The Company's financing has been provided in dollars, revenues are primarily in dollars and a significant part of expenses are incurred in dollars. The financial statements are presented in dollars, which is the Company's functional and presentation currency.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (I) for transactions — exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation) — historical exchange rates. Currency transaction gains and losses are presented in financial income or expenses, as appropriate.

c. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

d. **Bank deposits**

Bank deposits with original maturity dates of more than three months but less than one year are included in short-term deposits. Such short-term deposits bear interest at an average annual rate of approximately 0.71%-1.87% in 2020. Interest accrued on bank deposits was recorded as interest receivable as part of "Prepaid expenses and other current assets" in the company's balance sheet.

Bank deposits with maturity of more than one year are considered long-term.

e. Marketable securities

Marketable securities consist of debt securities. The Company elected the fair value option to measure and recognize its investments in debt securities in accordance with ASC 825, Financial Instruments as the Company manages its portfolio and evaluates the performance on a fair value basis. Changes in fair value, realized gains and losses on sales of marketable securities, are reflected in the statements of operation as finance expense (income), net.

f. Derivatives and hedging

The Company carries out transactions involving foreign currency exchange derivative financial instruments. The transactions are designed to hedge the Company's exposure in currencies other than the U.S. dollar. The derivative does not meet the definition of a cash flow accounting hedge, therefore the changes in the fair value are included in financial expense (income), net.

The currency hedged items are denominated in New Israeli Shekel (NIS). The counterparties to the derivatives are major banks in Israel.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

As of December 31, 2020, the Company has $1,150 on the Company's bank account that is restricted in order to secure the hedging transactions. This amount is presented among Restricted long-term deposits and cash.

g. Trade receivables:

Trade receivables are initially recognized at the transaction price and subsequently measured at amortized cost less any allowance for expected credit losses.

Starting from January 1, 2020, the Company applies ASU 2016-13 "Financial Instruments Credit Losses Measurement of Credit Losses on Financial Instruments" ("the Standard").

h. Property and equipment:

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company's property and equipment are depreciated utilizing the straight-line method on the basis of their estimated useful life.

Annual rates of depreciation are as follows:

	%
Laboratory equipment	10 – 33 (mainly 15 – 25)
Office equipment and furniture	7 – 15
Computers and related equipment	33

Leasehold improvements are amortized utilizing the straight-line method over the shorter of the expected lease term or the estimated useful life of the improvements.

i. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would then be written down to their estimated fair values.

For the three years ended December 31, 2020, the Company did not recognize an impairment loss for its long-lived assets.

j. Share-based compensation

The Company accounts for employees' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach.

On January 1, 2019 the Company adopted ASU 2018-07 (Topic 718) that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Under the provision of the amendment, the Company measures share-based compensation to non-employees in the same manner (except for certain exceptions) as share-based compensation to employees.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

Prior to January 1, 2019, when options were granted as consideration for services provided by consultants and other non-employees, the grant was accounted for based on the fair value of the consideration received or the fair value of the options issued, whichever is more reliably measurable. The fair value of the options granted was measured on a final basis at the end of the related service period and recognized over the related service period using the graded vesting schedule method.

The Company has elected to recognize forfeitures as they occur.

k. Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

Acquisitions of in-process research and development product candidate, which are not part of business combination, are recognized as an expense as research and development expenses as incurred.

Grants received from Israel Innovation Authority (hereafter — "IIA"), formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred. See note 6a(1).

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources its clinical trial activities utilizing external entities such as clinical research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical trials. Clinical trial costs are expensed as incurred.

l. Revenue recognition

The Company applies ASC 606, Revenue from Contracts with Customers. According to the standard, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied.

An entity only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer, after considering any price concession expected to be provided to the customer, when applicable. At contract inception, the entity assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The entity then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

Collaborative Arrangements

The Company entered into collaborative arrangements with partners that fall under the scope of Topic 808, Collaborative Arrangements ("ASC 808"). While these arrangements are in the scope of ASC 808, the Company may analogize to ASC 606 for some aspects of the arrangements. The Company analogizes to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of its ongoing major or central operations. Revenue recognized by analogizing to ASC 606 is recorded as "collaboration revenues".

The terms of the Company's collaborative arrangements typically include one or more of the following: (i) royalties on net sales of licensed products; (ii) reimbursements or cost-sharing of R&D expenses. Each of these payments results in collaboration revenues or an offset against R&D expense.

Royalties: For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes collaboration revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Under certain collaborative arrangements, the Company has been reimbursed for a portion of its R&D expenses or participates in the cost-sharing of such R&D expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of R&D expense in the Company's consolidated statements of operations, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations.

m. Income taxes:

1) Deferred taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"). ASC 740 prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value if it is more likely than not that a portion or all of the deferred tax assets will not be realized, based on the weight of available positive and negative evidence. Deferred tax liabilities and assets are classified as non-current.

Uncertainty in income taxes

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

n. Leases

As of January 1, 2019, the Company adopted ASU No. 2016-02, “Leases (Topic 842)". The Company adopted the standard using the modified retrospective approach with an effective date as of the beginning of the Company's fiscal year, January 1, 2019. The Company elected the package of transition provisions available for expired or existing contracts, which allowed it to carryforward its historical assessments of (1) whether contracts are or contain leases, (2) lease classification and (3) initial direct costs.

Right of Use ("ROU") assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

The Company uses the implicit rate when readily determinable. As the Company’s leases do not provide an implicit rate, the Company uses its estimated incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company elected to not separate lease and non-lease components for the leases. The Company elected the practical expedient of the short-term lease recognition exemption for all leases with a term shorter than 12 months.

Additionally, the company applies the portfolio approach to account for operating lease ROU asset and liabilities for certain car leases and incremental borrowing rates.

Upon adoption, the standard resulted in an increase of $1,200 in operating lease ROU assets and corresponding liabilities on the Company’s consolidated balance sheet and did not have a material impact on the Company’s consolidated statements of operations or consolidated statements of cash flows. See also note 6b.

o. 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 1,119,310, 1,260,984 and 3,271,507 options, restricted shares and warrants for the years ended December 31, 2018, 2019 and 2020, respectively, because their effect would be anti-dilutive.

p. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The carrying amount of the cash and cash equivalents, bank deposits, restricted cash, receivables from collaborative arrangements, restricted long-term deposits, accrued expenses (under other account payable), operating leases liabilities and other liabilities approximates their fair value.

q. Concentration of credit risks

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, bank deposits and marketable securities and certain receivables. The Company deposits cash and cash equivalents with highly rated financial institutions (Israeli banks). In addition, all marketable securities carry a high rating or are government insured. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

r. Newly issued and recently adopted accounting pronouncements

Recently adopted accounting pronouncements:

In June 2016, the FASB issued ASU 2016-13 “Financial Instruments Credit Losses Measurement of Credit Losses on Financial Instruments”. This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance became effective for the fiscal year beginning on January 1, 2020, including interim periods within that year. This guidance did not have significant impact on the Company’s financial statements.

NOTE 3 — MARKETABLE SECURITIES

The following table sets forth the Company’s marketable securities for the indicated period:

	December 31,	
	2019	2020
Level 2 securities:		
U.S government and agency bonds	$ 2,499	$ 4,192
Canada government bonds	999	-
Other foreign government bonds	3,521	2,006
Corporate bonds*	33,947	15,454
Total	$ 40,966	$ 21,652

* Investments in Corporate bonds rated A or higher.

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

NOTE 3 — MARKETABLE SECURITIES (continued)**:**

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 years ended December 31, 2019 and 2020:

	December 31,	
	2019	2020
Balance at beginning of the year	$ 56,662	$ 40,966
Additions	38,702	32,322
Sale or maturity	(54,333)	(51,498)
Changes in fair value during the year	(65)	(138)
Balance at end of the year	$ 40,966	$ 21,652

As of December 31, 2020, the Company's debt securities had the following maturity dates:

	Market value December 31, 2020
Due within one year	21,652
1 to 2 years	-
Total	21,652

NOTE 4 — PROPERTY AND EQUIPMENT

	December 31	
	2019	**2020**
Cost:		
Laboratory equipment	$ 3,242	$ 3,644
Office equipment and furniture	265	265
Computers and software	490	530
Leasehold improvements	1,946	1,953
	5,943	6,392
Less:		
Accumulated depreciation and amortization	(3,629)	(4,575)
Property and equipment, net	$ 2,314	$ 1,817

Depreciation and amortization expense totaled $762, $887 and 946$ for the years ended December 31, 2018, 2019 and 2020, respectively.

NOTE 5 — EMPLOYEE SEVERANCE BENEFITS

The Company is required to make severance payments upon dismissal of an employee or upon termination of employment in certain circumstances. The severance payment liability to the employees (based upon length of service and the latest monthly salary — one month's salary for each year employed) is recorded on the Company's balance sheet under "Liability for employee rights upon retirement." The liability is recorded as if it was payable at each balance sheet date on an undiscounted basis.

NOTE 5 — EMPLOYEE SEVERANCE BENEFITS (continued)**:**

In accordance with the current employment terms starting in August 2014 with all of its employees (Section 14 of the Israeli Severance Pay Law, 1963), the Company makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's retirement benefit obligation. The Company is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the Company balance sheet, as the amounts funded are not under the control and management of the Company and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plan").

With regard to the period before August 2014, the liability is funded in part from the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the balance sheets under "Funds in respect of employee rights upon retirement." These policies are the Company's assets.

The amounts of severance payment expenses were $431, $402 and $428 for the years ended December 31, 2018, 2019 and 2020, respectively, of which $292, $363 and $408 in the years ended December 2018, 2019 and 2020, respectively, were in respect of the Contribution Plan.

The Company expects to contribute approximately $408 in the year ending December 31, 2021 to insurance companies in connection with its expected severance liabilities for that year.

NOTE 6 — COMMITMENTS:

a. **Royalty Commitments:**

1) The Company is obligated to pay royalties to the IIA on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from the IIA.

Under the specific terms of the funding arrangements with the IIA, royalties of 3.5% to 25% are payable on the sale of products developed with funding received from the IIA, which payments shall not exceed, in the aggregate, 300% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR.

Up to December 31, 2020, the Company had recognized and received grants from the IIA in the aggregate amount of $1,431 (no grants were received in the last three years.). Through December 31, 2020, the Company recorded an accumulated royalty expense of $2,086 as royalties to the IIA with respect to revenue recognized through December 31, 2020 ($32, $32 and $25 were recorded in 2018, 2019 and 2020 accordingly, as an expense in the consolidated statements of operations).

The Company did not receive any grants from the IIA for the years ended December 31, 2018, 2019 and 2020.

2) The Company has an agreement, that was amended several times (hereafter — the agreements) with Yissum Research Development Company (hereafter — "Yissum"), the technology-licensing arm of the Hebrew University of Jerusalem.

NOTE 6 — COMMITMENTS (continued):

According to the agreements, the Company received from Yissum an exclusive and a non-exclusive license for the commercialization of certain Yissum patents. According to the agreements the Company shall pay Yissum:

Royalties of 1.5% of net sales related to certain patents.

i. 1.5% – 8% of proceeds received by the Company for the sub-license or license of certain patents.

Royalty expenses in immaterial amounts were recorded in 2018, 2019 and 2020 in respect of these agreements

According to the agreements, the Company may continue commercial use of certain Yissum's patents in connection with the products and subject to the obligation to pay Yissum the royalties and the sub-license fees.

The Company granted rights to a third party for use and commercialization of certain Yissum patents.

b. **Lease Agreements**

The Company leases offices and vehicles under operating leases. For leases with terms greater than 12 months, the Company records right of use assets and lease liabilities at the present value of lease payments over the leases term.

Offices
The Company leases office spaces and research and development facilities under several agreements. These agreements are linked to the change in the Israeli consumer price index and expire in December 2023. These agreements are considered as operating leases and presented under operating lease right-of-use assets and operating leases liabilities. A restricted deposit of $143 has been made in order to secure the agreement.

Vehicles
The Company has entered into operating lease agreements for vehicles used by its employees for a period of 3 years. These contracts are considered as operating leases and presented under operating lease right-of-use assets and operating leases liabilities.

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

NOTE 6 — COMMITMENTS (continued):

Lease Position

The table below presents the lease-related assets and liabilities recorded on the consolidated balance sheet:

	As of December 31,	
	2019	**2020**
Assets		
Operating Leases		
Operating lease right-of-use assets	$ 2,040	$ 1,896
Liabilities		
Current liabilities		
Current maturities of operating leases	$ 672	$ 673
Long-term liabilities		
Non-current operating leases	$ 1,373	$ 1,299
Weighted Average Remaining Lease Term		
Operating leases	1.66	1.29
Weighted Average Discount Rate		
Operating leases	7.44%	6.25%

Lease Costs

The table below present certain information related to lease costs of operating leases the year ended December 31, 2020:

	Year Ended December 31,	
	2019	**2020**
Operating lease cost:	$ 643	$ 685

The table below presents supplemental cash flow information related to leases for the year ended December 31, 2020:

	Year Ended December 31,	
	2019	**2020**
Cash paid for amounts included in the measurement of leases liabilities:		
Operating cash flows from operating leases	$ 807	$ 735

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

NOTE 6 — COMMITMENTS (continued):

Undiscounted Cash Flows

The table below reconciles the undiscounted cash flows for each of the first five years and total of the remaining years to the operating lease liabilities recorded on the consolidated balance sheet:

	Operating Leases
For the year ended December 31, 2020	
2021	$ 778
2022	714
2023	648
Total minimum lease payments	2,140
Less: amount of lease payments representing interest	(168)
Present value of future minimum lease payments	1,972
Less: Current maturities of operating leases	673
Long-term operating leases liabilities	1,299
	$ 1,972

c. In June 2008, the Company entered into a Master Clinical Trial Services Agreement with a third party, which was later amended in April 2017, to retain its services as a clinical research organization for certain product candidate subject to task work orders to be issued by the Company. During 2018, the Company entered into six additional task orders. As consideration for its services the Company will pay a total amount of approximately $14,425 during the term of the engagement and based on achievement of certain milestones, out of which $14,354 were recognized as an expense until December 31, 2020.

d. In 2016 through 2020, the Company entered into twelve collaboration agreements with two third parties for the development, manufacturing and commercialization of ten product candidates (including an agreement assumed by the Company in August 2018, following the transfer of an in-process research and development product candidate from a related party). See detailed information in note 7b.

e. In October 2017, the Company entered into a Clinical Development Master Services Agreement with a third party, to retain it as clinical research organization for certain product candidate, subject to task work orders to be issued by the Company. As consideration for its services the Company will pay a total amount of approximately $13,955 during the term of the engagement and based on achievement of certain milestones, out of which $13,801 were recognized as an expense until December 31, 2020.

NOTE 6 — COMMITMENTS (continued):

f. In July 2018, the Company signed on a Master Services Agreement to receive certain clinical research services for certain product candidate subject to task work orders to be issued by the Company. As consideration for the services in the first work order the Company will pay a total amount of approximately $2,234 during the term of the engagement and based on achievement of certain milestones, out of which $2,099 were recognized as an expense until December 31, 2020.

NOTE 7 — 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 with two third parties for the development, manufacturing and commercialization of several generic 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.

As of December 31, 2020, the Company decided not to pursue one of the agreements with one of the third parties collaborators.

In February 2019, the Company announced that a third party has received final approval from the FDA for the first generic version of a drug product. During the years ended December 31, 2019 and 2020, the Company recognized collaboration revenues related to sales of products in the U.S. under this agreement in the amounts of $22,775 and $8,673, respectively.

This Agreement is 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 revenues when the related sales occur.

NOTE 8— SHARE CAPITAL

a. Ordinary shares

1) **Rights of the Company's ordinary shares**

Each ordinary share is entitled to one vote. The holder of the ordinary shares is also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

NOTE 8 — SHARE CAPITAL (continued):

2) On January 19, 2018, the Company executed a 1-for-1.8 share split of the Company's shares by way of an issuance of bonus shares for each share. Upon the effectiveness of the share split, (i) 0.8 bonus shares were issued for each outstanding share, (ii) the number of ordinary shares into which each outstanding option to purchase ordinary shares is exercisable was proportionally increased, and (iii) the exercise price of each outstanding option to purchase ordinary shares was proportionately decreased. Unless otherwise indicated, and except for authorized capital, all of the share numbers, loss per share amounts, share prices and option exercise prices in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-1.8 share split.

3) In January 2018, the Company completed an Initial Public Offering ("IPO") on the NASDAQ Stock Market, in which it issued 6,250,000 Ordinary shares at a price per share of $12. During February 2018 the underwriters exercised their green shoe option and purchased additional 937,500 ordinary shares at the same price per share. The total proceeds received from the IPO, net of issuance costs, were $78,775.

   Immediately prior to the closing of the IPO, the outstanding promissory note received from its current controlling shareholder (the "Controlling Shareholder") were automatically converted into 5,444,825 Ordinary shares of the Company based on the IPO price of $12 per ordinary share.

4) On August 12, 2019, the Company completed an underwritten follow-on public offering, in which it issued 1,437,500 ordinary shares, including the full exercise by the underwriters of their option to purchase 187,500 additional ordinary shares, at a public offering price of $8.00 per ordinary share.
   The total proceeds received from the offering, net of issuance costs, were approximately $10,613.

5) 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. The warrants are exercisable over a three-years period from the date of issuance at a per share exercise price of $14, subject to certain adjustments as defined in the agreement. The total proceeds received from the offering, net of issuance costs, were approximately $21,306.

   In addition and in parallel to the public offering, the Company signed an agreement for a 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. The private placement agreement was contingent on certain conditions and was approved by the company's shareholders on April 8, 2020. The total proceeds of $5,000 were received in April 2020.

b. Share-based compensation:

1) **Option plan**

In December, 2014, the Company's Board of Directors approved a Share Incentive Plan (hereafter — the Plan) and reserved a pool of 629,025 ordinary shares, par value NIS 0.1 each, or such other number as the Board may determine, subject to certain terms and conditions as defined in the Plan. According to the Plan, the Company may issue shares or restricted shares, may grant options or restricted share units and other share-based awards (hereafter — the awards) to the Company employees, consultants, directors and other service providers.

The Plan is designed to enable the Company to grant awards to purchase Ordinary Shares under various and different tax regimes including, without limitation: pursuant and subject to Section 102 of the Israeli Tax Ordinance and pursuant and subject to Section 3(i) of the Israeli Tax Ordinance and under Internal revenue Code Section 422.

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

NOTE 8 — SHARE CAPITAL (continued):

The awards may be exercised after vesting and in accordance with vesting schedules which will be determined by the Board of Directors for each grant. The maximum term of the awards is 10 years. The fair value of each option granted under this Plan is estimated using the Black-Scholes option pricing method. Expected volatility is based on the historical volatility of comparable peer companies.

The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms. The expected term of the options is estimated based on the simplified method, as its historical experience for options grants as a public company is insufficient.

In December 2019, the Company's Board of Directors approved an increase of the ordinary shares that may be issued under the Company's Plan by reserving an additional amount of 912,230 ordinary shares.

As of December 31, 2020, 949,415 ordinary shares remain available for future grants under the Plan.

2) **Options grants**

a. Option granted to employees and directors

i. In January 2019, the Company granted a total of 80,000 options to an executive officer to purchase ordinary shares at an exercise price of $5.95 per share.

ii. In May 2019, the Company granted a total of 9,000 options to several employees to purchase ordinary shares at an exercise price of $7.32 per share.

iii. In December 2019, the Company granted a total of 6,300 options to several employees to purchase ordinary shares at an exercise price of $8.32 per share.

The options vest over a period of 4 years; 25% 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 to employees and directors in 2018 and 2019 were $878 and $485 respectively. The underlying data used for computing the fair value of the options are as follows:

	2018	2019
Value of one ordinary share	$6.24-$10.40	$6.08-$8.59
Dividend yield	0%	0%
Expected volatility	70.43 %-73.35%	74.87%-77.83 %
Risk-free interest rate	2.67%-2.83%	1.82%-2.75%
Expected term	5.50-7 years	6.11 years

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

NOTE 8 — SHARE CAPITAL (continued)

The total unrecognized compensation cost of employee options at December 31, 2020 is $271, which is expected to be recognized over a period of 2.96 years.

The following table summarizes the number of options granted to employees under the Plan for the years ended December 31, 2019 and 2020, and related information:

	Year ended December 31					
	2019			2020		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at the beginning of the year	938,090	$ 4.47	7.89	1,031,591	$ 4.74	7.25
Granted	95,300	$ 6.24	9.17	-	-	-
Exercised	-	-	-	(28,447)	$ 5.27	-
Expired	(563)	$ 5.57	-	-	-	-
Forfeited	(1,238)	$ 5.57	-	(2,250)	$ 7.77	-
Options outstanding at the end of the year	1,031,591	$ 4.74	7.25	1,000,894	$ 4.63	6.05
Options exercisable at the end of the year	683,979	$ 3.60	6.56	900,687	$ 4.08	5.67

b. Option granted to non-employees

In March 2018, the Company granted a total of 76,895 options to several consultants to purchase ordinary shares at an exercise price of $11.21 per share.

The options vest over a period of 4 years; 25% 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 to non-employees in 2018 was $648. The underlying data used for computing the fair value of the options are as follows:

	2018
Value of one ordinary share	$ 10.40
Dividend yield	0%
Expected volatility	79.07%
Risk-free interest rate	2.86%
Expected term	10 years

The total unrecognized compensation cost of non-employees' options at December 31, 2020 is $25, which is expected to be recognized over a period of 1.23 years.

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

NOTE 8 — SHARE CAPITAL (continued)

The following table summarizes the number of options granted to non-employees under the Plan for the year ended December 31, 2019 and 2020, and related information:

	Year ended December 31					
	2019			2020		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at the beginning of the year	198,575	$ 7.48	8.81	198,575	$ 7.48	7.84
Granted	-	-	-	-	-	-
Options outstanding at the end of the year	198,575	$ 7.48	7.84	198,575	$ 7.70	6.84
Options exercisable at the end of the year	96,588	$ 6.97	7.78	137,771	7.34	6.8

c. The aggregate intrinsic value of the total outstanding and of total exercisable options as of December 31, 2020 is approximately $482 and $413, respectively.

d. Restricted Share Units (RSUs) granted to Directors

In February 2018 and September 2018, the board of directors approved and recommended the Company shareholders to approve a total grant of 46,000 and 11,500 RSUs, respectively, to its independent and external directors that vest annually in equal portions over a three-year period. The fair value of shares as of the date of grant was $495 and $105 respectively. As of December 31, 2020, 38,332 RSUs were vested.

e. The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31		
	2018	2019	2020
Research and development expenses	$ 2,708	$ 1,028	$ 431
General and administrative expenses	$ 1,946	$ 1,524	$ 786
	$ 4,654	$ 2,552	$ 1,217

NOTE 9 — TAXES ON INCOME

a. Tax rates in Israel

The Company is taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2018, 2019 and 2020 is 23%. Capital gain is subject to capital gain tax according to the corporate tax rate in the year the assets are sold.

b. Tax rates for the U.S Subsidiary

The subsidiary is taxed according to U.S. tax laws. The Company's income is taxed in the United States at the federal rate of 21%.

c. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Investment Law")

Under the Investment Law, including Amendment No. 60 to the Investment Law that was published in April 2005, by virtue of the Benefited Enterprise program for certain of its facilities; the Company may be entitled to various tax benefits.

The main benefit arising from such status is the reduction in tax rates on income derived from a Benefited Enterprise. The extent of such benefits depends on the location of the enterprise. Since the Company's facilities are not located in "national development zone A," income derived from Benefited Enterprises will be tax exempt for a period of two years and then have a reduced tax rate for a period of up to an additional eight years.

The period of tax benefits, as described above, is limited to 12 years from the beginning of the Benefited Enterprise election year (2012). As of December 31, 2020, the period of benefits has not yet commenced.

In the event of distribution of cash dividends from income, which was tax exempt as above, the amount distributed will be subject to the tax rate it was exempted from. The Company is entitled to claim accelerated depreciation in respect of equipment used by the approved enterprises during five tax years.

Entitlement to the above benefits is conditioned upon the Company fulfilling the conditions stipulated by the Investment Law and regulations published thereunder.

In the event of failure to comply with these conditions, the benefits may be canceled and the Company may be required to refund the amount of the benefits, in whole or in part, with the addition of linkage differences to the Israeli consumer price index and interest.

The Investment Law was amended as part of the Economic Policy Law for the years 2011 – 2012 (the "Amendment"), which became effective on January 1, 2011 and was further amended in August 2013 and January 2017.

Under the 2017 Amendment, and provided the conditions stipulated therein are met, income derived by Preferred Companies from 'Preferred Technological Enterprises' ("PTE") (as defined in the 2017 Amendment), would be subject to reduced corporate tax rates of 7.5% in Development Zone "A" and 12% elsewhere, or 6% in case of a 'Special Preferred Technological Enterprise' ("SPTE") as defined in the 2017 Amendment) regardless of the company's geographical location within Israel. A Preferred Company distributing dividends from income derived from its PTE or SPTE, would subject the recipient to a 20% tax (or lower, if so provided under an applicable tax treaty). The 2017 Amendment further provides that, in certain circumstances, a dividend distributed to a corporate shareholder who is not an Israeli resident for tax purposes would be subject to a 4% tax (inter alia, if the amount of foreign investors in the distributing company exceeds 90%). Such taxes would generally be withheld at source by the distributing company.

NOTE 9 — TAXES ON INCOME (continued)

On June 14, 2017, the Encouragement of Capital Investments Regulations (Preferred Technology Income and Capital Profits for a Technological Enterprise), 2017 (the "Regulations") were published, which adopted Action 5 under the base erosion and profit shifting ("BEPS") regulations. The Regulations describe, inter alia, the mechanism used to determine the calculation of the benefits under the PTE and under the SPTE Regime and determine certain requirements relating to documentation of intellectual property for the purpose of the PTE. According to these provisions, a company that complies with the terms under the PTE regime may be entitled to certain tax benefits with respect to income generated during the company's regular course of business and derived from the preferred intangible asset (as determined in the Investments Law), excluding income derived from intangible assets used for marketing and income attributed to production activity. In the event that intangible assets used for marketing purposes generate over 10% of the PTE's income, the relevant portion, calculated using a transfer pricing study, would be subject to regular corporate income tax. If such income does not exceed 10%, the PTE will not be required to exclude the marketing income from the PTE's total income. The Regulations set a presumption of direct production expenses plus 10% with respect to income related to production, which can be countered by the results of a supporting transfer pricing study. Tax rates applicable to such production income expenses will be similar to the tax rates under the Preferred Enterprise regime, to the extent such income would be considered as eligible. In order to calculate the preferred income, the PTE is required to take into account the income and the research and development expenses that are attributed to each single preferred intangible asset. Nevertheless, it should be noted that the transitional provisions allow companies to take into account the income and research and development expenses attributed to all of the preferred intangible assets they have.

Under the transitional provisions of the law, a company is allowed to continue to enjoy the tax benefits available under the law prior to its amendment until the end of the period of benefits, as defined in the law. In each year during the period of benefits as a Benefited Enterprise, the Company will be able to opt for application of the amendment, thereby making available the tax rates discussed above. The Company's election to apply the amendment is irrecoverable.

As of December 31, 2020, the Company's management decided not to adopt the application of the Amendment.

There is no assurance that future taxable income of the Company will qualify as Benefited or Preferred income or that the benefits described above will be available to the Company in the future.

d. Tax assessments

Tax assessments filed by the Company through the year 2015 are considered to be final.

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

NOTE 9 — TAXES ON INCOME (continued)

e. Losses for tax purposes carried forward to future years

As of December 31, 2020, the Company had approximately $151.4 million of net carry forward tax losses which are available to reduce future taxable income with no limited period of use.

f. Deferred income taxes:

	December, 31	
	2019	**2020**
In respect of:		
Net operating loss carry forward	$ 25,879	$ 34,835
Research and development expenses	7,842	7,133
Other	1,226	1,085
Less – valuation allowance	(34,947)	(43,053)
Net deferred tax assets	$ —	$ —

g. Reconciliation of theoretical tax expenses to actual expenses

Actual tax expenses are in respect of the U.S. subsidiary. The primary reconciling items between the statutory tax rate of the Company and the effective rate are the full valuation allowance of deferred tax assets and nondeductible expenses in relation to the operations in Israel.

h. Roll forward of valuation allowance

Balance at January 1, 2018	$ 21,982
Additions	4,184
Balance at December 31, 2018	$ 26,166
Additions	8,781
Balance at December 31, 2019	$ 34,947
Additions	8,106
Balance at December 31, 2020	$ 43,053

i. Provision for uncertain tax positions

As of December 31, 2019, and 2020, the Company does not have a provision for uncertain tax positions.

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

NOTE 10 — SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Other accounts payables and accruals

	December, 31	
	2019	2020
Accrued expenses	$ 3,249	$ 3,250
Employees payables	841	812
Other	33	26
	$ 4,123	$ 4,088

NOTE 11 — 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 and restricted shares granted to directors and executive officers, see note 8b.

c. As to issuance of shares and warranted to the controlling shareholder in a private placement for a total consideration of $5,000, see note 8a (4).

Exhibit 4.5

COMPENSATION POLICY

SOL-GEL TECHNOLOGIES LTD.

Compensation Policy for Executive Officers and Directors

ADOPTED: October 2, 2017

Table of Contents

A. Overview and Objectives

1. **Introduction**

This document sets forth the compensation policy for executive officers (this "**Compensation Policy**" or "**Policy**") of Sol-Gel Technologies Ltd. ("**Sol-Gel**" or the "**Company**" and "**Executive Officers**", accordingly), in accordance with the requirements of the Companies Law 5759-1999 (the "**Companies Law**").

Compensation is a key component of Sol-Gel's overall human capital strategy to attract, retain, reward, and motivate highly skilled individuals that will enhance Sol-Gel's value and otherwise assist Sol-Gel to reach its business and financial short and long term goals. Accordingly, the structure of this Policy was established to tie the compensation of each Executive Officer to Sol-Gel's goals and performance.

For purposes of this Policy, "**Executive Officers**" shall mean "Office Holders" as such term is defined in Section 1 of the Companies Law.

This Compensation Policy shall apply to compensation agreements and arrangements which will be approved after the date on which this Compensation Policy is approved by the general meeting of Sol-Gel's shareholders and shall serve as Sol-Gel's Compensation Policy for the maximum period of time permitted by any applicable law.

The Compensation Committee (upon its appointment in accordance with the applicable law) and the Board of Directors of Sol-Gel (the "**Compensation Committee**" and "**Board**", respectively) shall review and reassess the adequacy of this Policy from time to time, as required by the Companies Law.

It should be clarified, that wherever reference is made to the required approvals in this Compensation Policy, such reference relates to the applicable law as of the date of approval of this Compensation Policy and in any case is subject to the provisions of sections 32 and 34 below.

2. **Objectives**

Sol-Gel's objectives and goals in setting this Compensation Policy are to attract, motivate and retain highly experienced personnel who will provide leadership for Sol-Gel's success and enhance the Company's shareholders' value, while supporting a performance culture that is based on merit, and rewards excellent performance in the short and long term, while recognizing Sol-Gel's core values. To that end, this Policy is designed, among others:

2.1. To closely align the interests of the Executive Officers with those of Sol-Gel's shareholders in order to enhance shareholder value;

2.2. To provide the Executive Officers with a structured compensation package, while creating a balance between the fixed components, *i.e.*, the base salaries and benefits, and the variable compensation, such as bonuses and equity-based compensation in order to minimize potential conflicts between the interests of Executive Officers and those of Sol-Gel;

2.3. To strengthen the retention and the motivation of Executive Officers in the short and long term.

2.4. This Compensation Policy was prepared taking into account the Company's nature, size and business and financial characteristics.

3. **Compensation structure and instruments**

29. Compensation instruments under this Compensation Policy may include the following:

- Base salary;

- Benefits and perquisites;
- Cash bonuses (short-to-medium term incentive);
- Equity based compensation (medium-to-long term incentive); and
- Retirement and termination of service arrangements payments.

For the purpose of this Compensation Policy:

"Base Salary" shall mean: gross salary, before contributions to social benefits ("**Base Salary**"); "Employment Cost" shall mean: any payment for the employment, including contributions to social benefits, car and expenses of the use thereof, bonuses and any other benefit or payment ("**Employment Cost**").

4. **Overall Compensation - Ratio Between Fixed and Variable Compensation**

This Policy aims to balance the mix of "fixed compensation", comprised of base salary and benefits ("**Fixed Compensation**") and "variable compensation", comprised of cash bonuses and equity based compensation[1] (excluding adjustment period/retirement bonuses, granted in accordance with section 21 below) ("**Variable Compensation**") in order to, among other things, appropriately incentivize Executive Officers to meet Sol-Gel's short and long term goals while taking into consideration the Company's need to manage a variety of business risks.

The total Variable Compensation of each Executive Officer shall not exceed 85% of the total compensation package of such an Executive Officer on an annual basis. The Board believes that such range expresses the appropriate compensation mix in the event that all performance objectives are achieved and assumes that all compensation elements are granted with respect to a given year.

It should be clarified, that the Fixed Compensation may constitute 100% of the total compensation package for an Executive Officer in any year (under circumstances in which a variable component will not be approved for that year and/or in the event of a failure to meet the set goals, if and when determined).

5. **Intra-Company Compensation Ratio**

29. In the process of drafting this Policy, Sol-Gel's Board has examined the ratio between employer cost, as such term is defined in the Companies Law, associated with the engagement of the Executive Officers (the "**Executive Officers Cost**") and the average and median employer cost associated with the engagement of the other employees of Sol-Gel (the "**Other Employees Cost**" and the "**Ratio**", respectively). The Board believes that the current Ratio does not adversely impact the work environment in Sol-Gel. The following are the ratios as of the date of the approval of this Compensation Policy:

Position	**Ratio between the Executive Officers Cost and the average Other Employees Cost**	**Ratio between the Executive Officers Cost and the median Other Employees Cost**
CEO	8.12	10.64
Other Executive Officers	3.12	4.16

1 Based on the fair value on the date of grant, calculated annually, on a linear basis.

B. Base Salary and Benefits

6. **Base Salary**

6.1. The Base Salary varies between Executive Officers, is individually determined by the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO, also the Company's general meeting of shareholders) and may be considered and adjusted by the Company (subject to the approvals of the abovementioned organs) on a periodically basis, according to, among others, the educational background, prior vocational experience, expertise and qualifications, role, business authorities and responsibilities, past performance and previous compensation arrangements of such Executive Officer, as well as the Company's financial state and cash position and any requirements or restrictions prescribed by any applicable legislation, from time to time. When determining the Base Salary, the Company may also decide to consider, at the sole discretion of the Compensation Committee and the Board and as required, the prevailing pay levels in the relevant market, Base Salary and the total compensation package of comparable Executive Officers in the Company, the proportion between the Executive Officer's compensation package and the salaries of other employees in the Company and specifically the median and average salaries and the effect of such proportions on the work relations in the Company.

7. **Benefits**

7.1. In addition to the Base Salary, the following benefits may be granted to the Executive Officers (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting pf shareholders), in order, among other things, to comply with legal requirements. It shall be clarified, that the list below is an open list and Sol-Gel (subject to the abovementioned required approvals) may grant to its Executive Officers other similar, comparable or customary benefits, subject to the applicable law. In addition, Executive Officers employed outside of Israel may receive other similar, comparable or customary benefits as applicable in the relevant jurisdiction in which they are employed.

- Vacation days in accordance with market practice and the applicable law, up to a cap of 30 days per annum;
- Sick days in accordance with market practice and the applicable law; However, the Company may decide to cover sick days from the first day;
- Convalescence pay according to the applicable law;
- Medical Insurance in accordance with market practice and the applicable law;
- With respect to Executive Officers employed in Israel: monthly remuneration for a study fund ("Keren Hishtalmut"), as allowed by applicable tax law and with reference to Sol-Gel’s practice and common market practice;
- Pension and savings – according to local market practices and legislation;
- Disability insurance – the Company may purchase disability insurance, according to applicable legislation.

7.2. Sol-Gel may offer additional benefits to its Executive Officers, including but not limited to: communication, company car and travel benefits, insurances and other benefits (such as newspaper subscriptions, academic and professional studies), etc., including their gross up.

7.3. Sol-Gel may reimburse its Executive Officers for reasonable work-related expenses incurred as part of their activities, including without limitations, meeting participation expenses, reimbursement of business travel, including a daily stipend when traveling and accommodation expenses. Sol-Gel may provide advance payments to its Executive Officers in connection with work-related expenses.

8. **Signing Bonus**

At the discretion of the Compensation Committee and the Board (and with respect to the CEO- also the Company's general meeting of shareholders), Sol-Gel may grant a newly recruited Executive Officer a signing bonus. Such bonus may be granted in cash, equity or a combination of both. The signing bonus will not exceed: (1) 50% of such Executive Officer's annual Base Salary, if the signing bonus is granted in cash; (2) 100% of such Executive Officer's annual Base Salary, if the signing bonus is granted by equity; (3) In case the signing bonus is a combination of cash and equity, its ceiling shall be proportional to the cash and equity components, calculated in accordance with the ratios mentioned in sections (1) and (2) above.

C. Cash Bonuses (Excluding Directors)

The Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may grant cash bonuses to its Executive Officers (excluding directors) on a quarterly or annually basis, or on a shorter or longer period basis, in accordance with the principles detailed below.

9. **Annual Bonuses**

9.1. The annual bonus that may be paid to the Executive Officers for any fiscal year shall not exceed twelve (12) monthly Base Salaries to the CEO, and six (6) monthly Base Salaries to any other Executive Officer.

9.2. CEO

The annual bonus to the CEO will be based mainly on measurable criteria, and with respect to its less significant part shall be determined at the discretion of the Compensation Committee and the Board, in accordance with the following:

Position	**Company/Individual Performance Measures**	**Company's Discretion**
CEO	75%-100%	0%-25%

The measurable criteria and their relative weight shall be determined by the Compensation Committee and the Board in respect of each calendar year. These measurable criteria will include, *inter alia*, objectives relating to compliance with the Company's work plans and with various budget objectives, including, *inter alia*, compliance with objectives relating to revenues, expenses, investments, etc., meeting various financial objectives, such as objectives relating to the annual profit (net profit, pre-tax profit, etc.) and the Company's EBITDA, objectives relating to the recruitment and development of professional personnel, objectives relating to raising investments, debt, etc., objectives relating to the Company's business operations and the Company's operations as a company traded on NASDAQ, objectives relating to the realization of the Company's assets, the acquisition of new activities and/or companies and objectives relating to an increase of the return on the Company's assets.

9.3. Other Executive Officers (Excluding CEO and Directors)

The Company may also award (subject to the approvals of the Compensation Committee and the Board) an annual bonus to its Executive Officers, due to their unique contribution to the Company. Such grant will be based, *inter alia*, on measurable criteria, based on the Company's financial results, the scope of the Company's business activity, the CEO's opinion on the contribution of the Executive Officer to the Company, the distribution of the annual bonus over the year, etc. It should be clarified, that the annual bonus may be based in whole or in part on discretion, provided that it does not exceed the ceiling specified in section 9.1 above. The CEO of the Company shall be entitled to determine the abovementioned targets for each such an Executive Officer. Notwithstanding the foregoing, it is hereby clarified, that the grant of annual bonus to an Executive Officer, of up to three Base Salaries, shall be approved by the CEO of the Company.

10. **Special Bonuses**

In addition to the annual bonus, Sol-Gel may grant Executive Officers a special bonus as an award for special achievements (outstanding personal achievement, outstanding personal effort or outstanding Company's performance, such as in connection with mergers and acquisitions, offerings, achieving target budget or business plan under exceptional circumstances and special recognition in case of retirement), at the discretion of the Compensation Committee and the Board (and with respect to the CEO- also the Company's general meeting of shareholders) which shall not exceed six (6) monthly Base Salaries.

11. **Additional Provisions Relating to Cash Bonuses**

11.1. **Pro Rata Payment**

Should the employment or service of the Executive Officer terminate prior to the end of a fiscal year, Sol-Gel may pay the Executive Officer his/her pro-rata share of that fiscal year's bonus, based on the period such Executive Officer was employed by the Company or has served in the Company.

11.2. **Compensation Recovery ("Clawback")**

11.2.2. In the event of an accounting restatement, Sol-Gel shall be entitled to recover from its Executive Officers the bonus compensation in the amount in which such bonus exceeded what would have been paid under the financial statements, as restated ("**Compensation Recovery**"), provided that a claim is made by Sol-Gel prior to the third anniversary of fiscal year end of the restated financial statements.

11.2.3. Notwithstanding the aforesaid, the Compensation Recovery will not be triggered in the following events:

- The financial restatement is required due to changes in the applicable financial reporting standards; or
- The Company (subject to any required approval by the applicable law) has determined that clawback proceedings in the specific case would be impossible, impractical or not commercially or legally efficient; or
- The amount to be paid under the clawback proceedings is less than 10% of the relevant bonus received by the Executive Officer.

11.2.4. It shall be clarified, that Sol-Gel shall not be entitled to Compensation Recovery with respect to equity-based compensation granted to its Executive Officers.

11.3. **Reduction or Postponement**

In the event of the termination of office of an Executive Officer under circumstances in which he/she will not be entitled to severance pay, the Company (subject to the approvals of the Compensation Committee and the Board) may revoke the entitlement of such an Executive Officer to an annual bonus and to all parts of the annual bonus which have not yet been paid to him.

D. Equity-Based Compensation

12. **General and Objectives**

12.1. The Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) may grant from time to time equity-based compensation which will be individually determined and awarded according to, *inter alia*, the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the Executive Officer. Equity-based compensation may also be awarded to the Company's directors, including, for the avoidance of doubt, the Executive Chairman, provided that such directors do not also serve as officers in the Company.

12.2. The main objectives of the equity-based compensation is to enhance the alignment between the Executive Officers' and directors' interests with the long term interests of Sol-Gel and its shareholders, and to strengthen the retention and the motivation of Executive Officers in the medium-to-long term. In addition, since equity-based awards are structured to vest over several years, their incentive value to recipients is aligned with longer-term strategic plans.

12.3. The equity based compensation offered by Sol-Gel is intended to be in a form of options exercisable into shares, restricted shares and/or other equity based awards, such as restricted share units (RSUs), in accordance with the Company's incentive plan in place as may be updated from time to time.[2]

13. **Fair Market Value**

The fair market value of the equity-based compensation for each Executive Officer during a fiscal year, shall not exceed 200% of his/her annual Base Salary, as shall be determined according to acceptable valuation practices at the time of grant.[3]

14. **Taxation Regime**

Subject to any applicable law, Sol-Gel may determine, at the discretion of the Compensation Committee and the Board (and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders), the tax regime under which equity-based compensation may be granted, including a tax regime which will maximize the benefit to the Executive Officers.

15. **Exercise Period**

The exercise price for each option shall not be less than the average closing Company's share price on NASDAQ over the 30 trading days preceding the Board's decision on the grant of the relevant option.

It is hereby clarified, that unless otherwise determined by the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders), and subject to the provisions of any applicable law, the exercise price of restricted shares and restricted share units (RSUs) is zero. In addition, it shall be clarified, that the exercise of restricted shares and RSUs may be subject to the achievement of goals set in advance and approved in accordance with the applicable law.

Options, restricted shares and restricted share units (RSUs) may also be exercised by a method of "Cashless" exercise.

The Board considered the possibility of determining a ceiling for the exercise value of the variable equity components and decided, taking into account the purpose of the equity-based compensation, not to set such a ceiling in this Policy.

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[2] The equity based compensation is based on the fair value on the date of grant, calculated annually, on a linear basis.

[3] Calculated annually, on a linear basis.

16. **Vesting**

All equity-based incentives granted to Executive Officers and directors shall be subject to vesting periods in order to promote long-term retention of such recipients. Grants to Executive Officers (excluding directors) shall vest gradually over a period of at least two years, while grants to directors shall vest over a period of at least one year. Such grants may be vested on a quarterly, semi-annual or an annual basis, or based on other time periods (which may not be necessarily equal), as determined by the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders). The Company (subject to the abovementioned required approvals) may condition the vesting of part or all of the equity-based incentives, for some or all of its Executive Officers, upon the achievement of predetermined performance goals. The Company (subject to the abovementioned required approvals) may also set terms relating to vesting in connection with an Executive Officer leaving the Company (due to a dismissal, resignation, death or disability).

17. For details regarding ceilings with respect to director's equity-based compensation see section 29 below.

18. **General**

All other terms of the equity awards shall be in accordance with Sol-Gel's incentive plans and other related practices and policies. Accordingly, the Company may (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) extend the period of time for which an award is to remain exercisable and make provisions with respect to the acceleration of the vesting period of any Executive Officer's awards, including, without limitation, in connection with a corporate transaction involving a change of control, subject to any additional approval as may be required by the Companies Law.

E. Retirement and Termination of Service Arrangements (Excluding Directors)

19. **Advanced Notice Period**

19.1. Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may provide each Executive Officer (excluding directors), pursuant to an Executive Officer's employment agreement and according to the Company's decision per each case, a prior notice of termination of up to six (6) months, except for the CEO whose prior notice may be of up to twelve (12) months (the "**Advance Notice Period**"). During the Advance Notice Period, the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her options, restricted shares, RSUs and/or any other equity based awards.

19.2. During the Advance Notice Period, an Executive Officer will be required to keep performing his/her duties pursuant to his/her agreement with the Company, unless the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) has waived the Executive Officer’s services to the Company during the Advance Notice Period and pay the amount payable in lieu of notice, plus the value of benefits.

19.3. In the event of a change of control in the Company, the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may decide to extend the Advance Notice Period as provided in section 19.1 above (and the compensation paid for such Advance Notice Period, accordingly) to up to two times the original Advance Notice Period of the Executive Officer, in accordance with the applicable law as of that time.

20. **Adjustment Period/Retirement Bonus**

In addition to the Advance Notice Period, the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may provide an additional adjustment period/retirement payment that will be determined, among other things, taking into consideration the Executive Officer's seniority in the Company, performance during employment, contribution to Sol-Gel achieving its goals and the circumstances of retirement or termination. The maximum adjustment period/retirement bonus that may be paid to each Executive Officer shall be up to six (6) month Base Salaries and may only be granted to Executive Officers who have served in the Company for at least one year.

21. **Additional Retirement and Termination Benefits**

Sol-Gel may provide additional retirement and terminations benefits and payments as may be required by applicable law (e.g., mandatory severance pay under Israeli labor laws- unless employment/term of service was terminated for cause), or which will be comparable to customary market practices.

F. Exemption, Indemnification and Insurance

22. **Exemption**

Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) may exempt in advance and retroactively its Executive Officers, from any liability to the Company, in whole or in part, for damages in consequence of his or her duty of care vis-a-vis the Company, to the fullest extent permitted by law and subject to the provisions of the Company's Articles of Association.

23. **Indemnification**

Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) may indemnify its Executive Officers to the fullest extent permitted by applicable law and the Company's Articles of Association, for any liability and expense that may be imposed on the Executive Officer, as provided in the Indemnity Agreement between such individuals and Sol-Gel, all subject to applicable law and the Company's Articles of Association.

24. **Insurance**

24.1. Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) will provide "Directors' and Officers' Liability Insurance" (the "**Insurance Policy**"), as well as a "run off" insurance policy for its Executive Officers as follows:

- The annual premium to be paid by Sol-Gel shall not exceed $1.5 million of the aggregate coverage of the Insurance Policy;
- The limit of liability of the insurer shall be up to $75 million per event and in the aggregate in the insurance period.
- The deductible amount per each claim shall not exceed $5 million.
- The Insurance Policy, as well as the limit of liability and the premium for each extension or renewal shall be approved by the Company, which shall determine (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) that the sums are reasonable considering Sol-Gel's exposures, the scope of coverage and the market conditions and that the Insurance Policy reflects the current market conditions, and it shall not materially affect the Company's profitability, assets or liabilities.
- The policy will also cover the liability of the controlling shareholders due to their positions as Executive Officers in the Company, from time to time, provided that the coverage terms in this respect do not exceed those of the other Executive Officers in the Company.

G. Arrangements upon Change of Control

25. The following benefits may be granted to the Executive Officers in addition to the benefits applicable in the case of any retirement or termination of service upon a "Change of Control" following of which the employment of the Executive Officer is terminated or adversely adjusted in a material way:

    25.1. Vesting acceleration of outstanding options, restricted shares, restricted share units (RSUs) and/or other equity based awards.

    25.2. Extension of the exercising period of options, restricted shares, restricted share units (RSUs) and/or other equity based awards for Sol-Gel's Executive Officers for a period of up to five (5) years, following the date of termination of employment.

    25.3. An Advance Notice Period, in accordance with section 19.3 above.

    25.4. An Adjustment period/retirement bonus in accordance with section 20 above, of up to twelve (12) months of Employment Cost.

H. Board of Directors Compensation

26. The compensation of the Company's directors shall be in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director) of 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel) of 2000, as such regulations may be amended from time to time, or in accordance with section 27 below, subject to any required approvals by the applicable law.

27. The compensation of the Company's directors (including external directors and independent directors) shall not exceed the following:

    27.1. Base payment of $45,000 per year (the "**Base Payment**");

    27.2. Chairman of the Board- an additional amount of $25,000 per year to the Base Payment;

    27.3. Committee Chairman- an additional amount of $10,000 per year to the Base Payment;

    27.4. Committee member- an additional amount of $5,000 per year to the Base Payment;

28. In addition, the Company may engage with its directors (excluding external and independent directors) for the receipt of consulting services and/or other special services, for a consideration of up to $1,000 per day, plus reasonable expense reimbursement. Such compensation shall be paid for a maximum of 6 days per year for each director.

29. Directors may be granted equity-based compensation in accordance with the applicable principles detailed in section D of this Policy, and subject to the provisions of the Companies Law and the regulations thereunder.[4]

Equity based-compensation granted to the Company's directors, shall not exceed the following amounts (subject to any applicable law):[5]

29.1. Director: $55,000 per year (the "**Equity Compensation**");

29.2. Chairman of the Board- an additional amount of $55,000 per year to the Equity Compensation;

29.3. Committee Chairman- an additional amount of $10,000 per year per year to the Equity Compensation;

29.4. Committee member- an additional amount of $5,000 per year to the Equity Compensation;

30. Sol-Gel's external and independent directors may be entitled to reimbursement of expenses in accordance with the Companies Law and the regulations thereunder.

I. Miscellaneous

31. This Policy is designed solely for the benefit of Sol-Gel. Nothing in this Compensation Policy shall be deemed to grant any of Sol-Gel's Executive Officers or employees or any third party any right or privilege in connection with their employment by the Company and their compensation thereof. Such rights and privileges, to which Executive Officers or employees serving in the Company or that will serve in the Company in the future, are entitled for, shall be governed by the respective personal employment agreements.

32. This Policy is subject to applicable law and is not intended, and should not be interpreted as limiting or derogating from, provisions of applicable law to the extent not permitted, nor should it be interpreted as limiting or derogating from the Company's Articles of Association.

33. This Policy is not intended to affect current agreements nor affect obligating customs (if applicable) between the Company and its Executive Officers as such may exist prior to the approval of this Compensation Policy, subject to any applicable law.

34. In the event of amendments made to the Companies Law or any regulations promulgated thereunder providing relief in connection with Sol-Gel's compensation to its Executive Officers, Sol-Gel may elect to act pursuant to such relief without regard to any contradiction with this Policy.

35. The Company (subject to any required approvals by the applicable law) may determine that none or only part of the payments, benefits and perquisites shall be granted, and is authorized to cancel or suspend a compensation package or part of it.

36. An immaterial change in the terms of office of Executive Officers (excluding directors, a controlling shareholder or a controlling shareholder's relative) during the term of this Compensation Policy, will be subject to the approval of the Company's CEO only (changes in the terms of office of the CEO shall be approved in accordance with the Companies Law). An immaterial change in this matter shall be deemed to be a change that does not exceed 5% of the annual Employment Cost with respect to the employment of such an Executive Officer in the Company, subject to the conditions prescribed in this Compensation Policy.

37. It should be clarified, that the compensation components detailed in this Policy do not relate to various components that the Company may provide to all or part of its employees and/or its Executive Officers, such as: parking spaces, entry permits for its assets, reimbursement for meals and accommodation expenses, vacations, company events, etc.

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[4] The equity based compensation is based on the fair value on the date of grant, calculated annually, on a linear basis.

[5] Based on the fair value on the date of grant, calculated annually, on a linear basis.

Exhibit 12.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alon Seri-Levy, certify that:

1. I have reviewed this annual report on Form 20-F of Sol-Gel Technologies Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 4, 2021

/s/ Alon Seri-Levy
Alon Seri-Levy
Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gilad Mamlok, certify that:

1. I have reviewed this annual report on Form 20-F of Sol-Gel Technologies Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 4, 2021

/s/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUAN TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Sol-Gel Technologies Ltd. (the "Company") on Form 20-F for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 4, 2021

/s/ Alon Seri-Levy
Alon Seri-Levy
Chief Executive Officer

/s/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-223915) and Form F-3 (No. 333-230564) of Sol-Gel Technologies Ltd. of our report dated March 4, 2021 relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
March 4, 2021

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

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