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, 2023

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)

Adv. Tamar Fishman Jutkowitz, Vice President & General Counsel
7 Golda Meir St., Weizmann Science Park, Ness Ziona, 7403650, Israel
Tel: 972-8-9313429; email: tami.fishman@sol-gel.com

(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: 27,857,620 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 ☒

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer", "accelerated filer" and "emerging growth company" 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 NIS3.627, NIS 3.519 and NIS 3.11 to $1.00, based on the exchange rates reported by the Bank of Israel on December 31, 2023, December 31, 2022, and December 31, 2021, respectively.

References to the terms below in this Annual Report have the meanings referred to below:

- "SGT-610" - SGT-610 (patidegib), an investigational topical treatment designed to prevent new Basel Cell Carcinomas (BCCs) formation in adults with Gorlin Syndrome;
- "SGT-210" - SGT-210 (erlotinib), an investigational topical ointment for the treatment of rare hyperkeratinization disorders; "erlotinib" refers to an epidermal growth factor receptor inhibitor;
- "Twyneo" - our novel, once-daily, non-antibiotic topical cream that has been approved by the Food and Drug Administration for the treatment of acne vulgaris, or acne;
- "Epsolay" - our novel, once-daily topical cream containing encapsulated benzoyl peroxide that has been approved by the Food and Drug Administration for the treatment of papulopustular (subtype II) rosacea;
- "investigational product candidates" - include SGT-610 and SGT-210;
- "approved products" - Twyneo and Epsolay;
- "generic product candidate" - a generic program developed in collaboration with Padagis Israel Pharmaceuticals Ltd ("Padagis");
- "product candidates" - both investigational product candidates and generic product candidates; and
- "our products" - both approved products and 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 these 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 successfully integrate SGT-610 into our product candidate pipeline, and the benefits of and projections of our future financial performance as a result of our acquisition of SGT-610;
- our ability to enroll patients in our clinical trials and the possibility that patients would discontinue their participation in our clinical trials.
- our ability to complete the development of our product candidates;
- our ability to obtain the benefits associated with orphan drug designation, such as orphan drug exclusivity and, even if we do, that exclusivity may not prevent the U.S. Food and Drug Administration, or FDA, or other comparable foreign regulatory authorities from approving competing products;
- the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their product candidates;
- our dependence on the success of Galderma Holding SA (“Galderma”) and Searchlight Pharma Inc. (“Searchlight”) in commercializing our approved products in the U.S. and in Canada, respectively;
- the ability of Sol-Gel and Searchlight to obtain and maintain the regulatory approval of Twyneo and Epsolay in Canada;
- 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 find suitable co-development, contract manufacturing and marketing partners to our products;
- our ability to commercialize and launch our investigational 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;
- acceptance of our products by healthcare professionals and patients;
- the possibility that we may face third-party claims of intellectual property infringement;
- 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 the current global macroeconomic climate on our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of Twyneo, Epsolay and our product candidates; 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

Not applicable.

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, 2023, 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 dermatology 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 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 products.
- All of our product candidates are in development stage; therefore, we have not yet obtained regulatory approval for our product candidates in the United States or any other country.
- We are largely dependent on the success of Twyneo, Epsolay and our product candidates for the treatment of topical dermatological conditions.
- Our business is highly dependent on market perception of us and the safety and quality of Twyneo, Epsolay and our product candidates, if approved. Our business or products could be subject to negative publicity, which could have a material adverse effect on our business.
- Although we have entered into exclusive license agreements with Galderma and Searchlight for all U.S. and Canadian commercial activities for Twyneo and Epsolay, 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.
- Twyneo, Epsolay and our product candidates, even if they receive regulatory approval, may fail to achieve the broad degree of physician adoption and market acceptance necessary for commercial success.
- 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.
- We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in our or our collaborators' clinical trials, which could delay or prevent clinical trials for our product candidates.
- Twyneo and Epsolay, and our product candidates, if approved, will face, significant competition and our failure to compete effectively may prevent us and our commercial partners from achieving significant market penetration and expansion.
- We rely on Galderma to commercialize Twyneo and Epsolay in the U.S., on Searchlight to commercialize Twyneo and Epsolay in Canada and on Padagis to develop and commercialize our generic product candidates and may depend on other parties for commercialization of Twyneo and Epsolay outside of the U.S. and Canada, and the development and commercialization of our investigational product candidates, if approved. We also rely on Galderma to provide us with accurate reports in order for us to accurately report our royalty revenues and sales based milestone payments. Any collaborative arrangements that we have (including our agreements with Galderma, Searchlight and Padagis) or may establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations.
- We and our partners 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, our partners, or any of our third-party manufacturers encounter any difficulties, our ability to provide product candidates for clinical trials or our approved products to patients, 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 dermatology 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 dermatology company with a limited operating history. We have incurred net losses since our formation in 1997. In particular, we incurred a loss of $14.9 million in 2022 and a loss of $ 27.2 million in 2023. As of December 31, 2023, we had an accumulated deficit of $220.3 million. Our losses have resulted principally from expenses incurred in research and development of Twyneo, Epsolay, SGT-610 and our investigational 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. Recently, based on lower than expected future revenue streams from Twyneo and Epsolay and a delay in the development of SGT-210, we adopted cost-saving measures, including a headcount reduction of about 25 employees, to maintain the cash runway for at least 12 months from the filing date of this annual report.

We anticipate that our expenses will increase substantially as we:

- complete Phase III clinical study of SGT-610;

- conduct Phase I clinical studies of SGT-210 and continue the research and development of other future investigational 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 our approved products;

- continue the development, bioequivalence and other studies required for abbreviated new drug application, or ANDA, submissions for our generic product candidates;

- seek new drug candidates and expand our disease portfolio;

- maintain, expand and protect our intellectual property portfolio;

- seek to enhance our technology platform;

- 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 our products. Although we have received approval from the FDA with respect to our marketing applications for Twyneo in 2021 and Epsolay in 2022, to succeed we must successfully develop and eventually commercialize product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including successfully commercializing our approved products, completing 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.

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 of our product candidates. We expect to continue to incur significant expenses and operating losses over the next several years as we conduct Phase III clinical studies for SGT-610 and conduct Phase I clinical studies of SGT-210. In addition, Twyneo and Epsolay, and our product candidates, if approved, may not achieve commercial success. Substantial revenue, if any, will be derived from sales of Twyneo and Epsolay, and other product candidates, if approved. 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. Recently, based on lower than expected future revenue streams from Twyneo and Epsolay and a delay in the development of SGT-210, we adopted cost-saving measures, including a headcount reduction of about 25 employees, to maintain the cash runway for at least 12 months from the filing date of this annual report.

Our future capital requirements will depend on many factors, including:

- the progress and results of our development activities for SGT-610 and SGT-210;
- the cost of manufacturing clinical supplies and exhibition batches of our investigational product candidates;
- the timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue received from commercial sales of Twyneo, Epsolay and, if any, from our product candidates for which we may receive marketing approval;
- the scope, progress, results and costs of development, laboratory testing and clinical trials for our generic product candidates;
- the costs, timing and outcome of regulatory reviews of any of our product candidates;
- 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; 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 investigational 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.

All of our product candidates are in development stage; therefore we have not yet obtained regulatory approval for our product candidates in the United States or any other country.

Although we have obtained regulatory approvals in the United States for Twyneo and Epsolay and our collaborator obtained regulatory approvals for two generic products, the rights to such generic products we have since sold, none of our current product candidates, has obtained regulatory approval for sale in the United States or any other country, and we cannot guarantee that our current or future 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 or our partners cannot commercialize our product candidates in the United States without first obtaining regulatory approval to market each product candidate from the FDA. Similarly, we or our partners 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 or our partners 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 or our partners are required to submit and obtain the FDA's approval of a new drug application, or NDA, before marketing any product candidate. 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, we or our partners may 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 or our partners 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 or our partners 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 or our partners clinical protocols.

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 or our partners conduct additional clinical trials or pre-clinical studies or take other actions before it will reconsider our or our partners' application. If the FDA requires us or our partners 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.

To date, we have submitted two NDAs that were accepted for filing by the FDA, one for Twyneo, and one for Epsolay, both of which were subsequently approved by the FDA. We have also submitted five ANDAs with our partner Padagis, out of which two have been approved by the FDA.

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 our product candidates 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.

We are largely dependent on the success of Twyneo, Epsolay and our product candidates, if approved, 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 and Epsolay. In June 2021, we entered into two five-year exclusive license agreements with Galderma pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo and Epsolay. In June 2023, we also entered into exclusive license agreements with Searchlight, pursuant to which Searchlight has the exclusive right to, and is responsible for, all Canadian commercial activities for Twyneo and Epsolay over a fifteen-year term that is renewable for subsequent five-year periods. The success of our business depends largely on Galderma and Searchlight's success in commercializing Twyneo and Epsolay and our ability to fund, execute and complete the development of, obtain regulatory approval for and successfully commercialize our product candidates in a timely manner.

Our business is highly dependent on market perception of us and the safety and quality of Twyneo, Epsolay and our product candidates, if approved. 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 products. If Twyneo, Epsolay any of our product candidates, or similar products that other companies distribute, or third-party products from which our investigational 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 products 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.

Although we have entered into exclusive license agreements with Galderma and Searchlight for all U.S. and Canadian commercial activities for Twyneo and Epsolay, 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 product candidates, rather than commercialization. In June 2021, we entered into two five-year exclusive license agreements with Galderma pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo, and Epsolay. In June 2023, we also entered into exclusive license agreements with Searchlight, pursuant to which Searchlight has the exclusive right, and is responsible for all commercial activities for Twyneo and Epsolay in Canada, over a fifteen-year term that is renewable for subsequent five-year periods. We also expect to collaborate with third parties that have sales and marketing experience in order to commercialize Twyneo and Epsolay in other territories, and our other investigational product candidates, if approved, in lieu of our own sales force and distribution systems. We cannot provide any assurances as to when, if ever, we will obtain approvals from governmental authorities outside of the U.S. or generate sufficient revenues to achieve sustained profitability. Our and our partners' ability to successfully commercialize our approved products and product candidates, if approved, and become profitable is subject to a number of challenges, including, among others, that:

- we may not have adequate financial or other resources;
- we or our partners may not be able to manufacture our products in commercial quantities, in an adequate quality or at an acceptable cost;
- we or our partners may not be able to establish adequate sales, marketing and distribution channels for our products;

- we or our partners may not be able to find suitable co-development, contract manufacturing or marketing partners;
- healthcare professionals and patients may not accept our products;
- we may not be aware of possible complications from the continued use of our investigational product candidates since we have limited clinical experience with respect to the actual use of our investigational product candidates;
- changes in the market, new alliances between existing market participants and the entrance of new market participants may interfere with our or our partners market penetration efforts;
- third-party payors may not agree to reimburse patients for any or all of the purchase price of our products, which may adversely affect patients' willingness to purchase our approved products or product candidates, once approved;
- uncertainty as to market demand may result in inefficient pricing of our approved products and product candidates, once approved;
- we may face third-party claims of intellectual property infringement;
- we or our partners 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;
- we may become involved in lawsuits pertaining to our clinical trials; and
- we may experience delays due to shortages in supply and human resources resulting from geopolitical instability (for more information, see "Item 3. Key Information – D. Risk Factors – Risks Related to Our Operations in Israel").

The occurrence of any one or more of these events may limit our or our partners' ability to successfully commercialize our approved products and product candidates, once approved, 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 products.

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 our products 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 our products that we would otherwise prefer to develop and market ourselves.

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 NDAs and ANDAs to the FDA 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 or comparable foreign regulatory authorities 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 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 and our partners' 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 product candidates.

We or our partners 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, or similar foreign requirements (where applicable), 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 or our partners anticipate;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our or our partners 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, we may 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 or our partners 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 or our partners' clinical trials may occur, as a result of which we or our partners may need to amend clinical trial protocols. Amendments may require us or our partners 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 or our partners experience delays in the completion of, or if we or our partners 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.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

Any delays in completing our or our partners' clinical trials will increase our costs, slow down our product candidates' development and regulatory review and approval process and jeopardize our or our partners 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.

We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in our or our collaborators' 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 or our partners can recruit patients to participate in testing our product candidates. Some of the indications we are pursuing include orphan diseases (including Gorlin syndrome) for which the patient population is significantly small. If we or our partners are unable to locate qualified patients or if patients are unwilling to participate in our or our partners' 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 product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidates development, or termination of the clinical trials altogether.

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; and
- ability to monitor patients adequately during and after treatment.

We or our partners 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. 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.

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. Although the FDA has approved Twyneo and Epsolay for marketing, it is possible that Twyneo and Epsolay will not receive approval by comparable foreign authorities, and 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 cannot be certain that Twyneo and Epsolay will receive approval by foreign authorities or 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 development operations. 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, even if approved by the FDA or by comparable foreign authorities.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend, discontinue clinical trials or abandon product candidates. Adverse side effects or other safety risks associated with our approved products , could limit their commercial profile.

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. Results of our clinical trials for product candidates 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 or our partners elect or are required to delay, suspend or terminate any clinical trial for any product candidates, 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, with respect to our approved products and any one or more of our products, for which we obtain regulatory approval, if 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 our products, and could significantly harm our business, results of operations and prospects.

There is a substantial risk of product liability claims in our business, and a product liability claim against us could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of pharmaceutical products. Product liability claims could delay or prevent completion of our development and commercialization programs. Such claims could result in a recall of our products or a change in the approved indications for which they may be used. While we maintain product liability insurance that we believe is adequate for our operations, 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.

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and we have never obtained approval of a product from the FDA through the 505(b)(1) NDA pathway. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our investigational product candidates, we will not be able to commercialize, or will be delayed in commercializing, these product candidates, and our ability to generate revenue from these products will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of our investigational product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Our current investigational product candidate SGT-610 is a new chemical entity that has never been approved by the FDA and we believe we will be required to seek approval for such product candidates through the FDA's 505(b)(1) NDA pathway, which requires full reports of investigations of safety and effectiveness without reliance on the FDA's prior approval of another product candidate.

We have never obtained approval of a product through the 505(b)(1) NDA pathway and may never succeed in doing so. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. If we are unable to submit and obtain regulatory approval for our investigational product candidates, we will not be able to commercialize or obtain revenue in connection with these product candidates.

For our product candidates that we may seek to develop through the Section 505(b)(2) NDA or ANDA pathways, if the FDA does not conclude that our product candidates satisfy the requirements of the applicable regulatory approval pathway, or if the requirements for approval of our product candidates are not as we expect, the approval pathway for such 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.

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, or a Section 505(b)(1) NDA; (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, or a Section 505(b)(2) NDA; 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, or a Section 505(j) ANDA. We are developing product candidates for which we are seeking or intend to seek FDA approval through each of these regulatory pathways. Both Twyneo and Epsolay were submitted for approval in Section 505(b)(2) NDAs, and we may develop and seek approval for our product candidates through this regulatory pathway in the future.

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, the pharmaceutical industry is highly competitive, and both ANDAs 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 an ANDA or Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our applications 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.

We may not be able to obtain the benefits associated with orphan drug designation, such as orphan drug exclusivity and, even if we do, that exclusivity may not prevent the FDA or other comparable foreign regulatory authorities from approving competing products.

Our product candidate, SGT-610, has obtained orphan drug designation in Gorlin syndrome by both the FDA and the European Commission, or EC. Regulatory authorities in these jurisdictions may designate drugs for relatively small patient populations as orphan drugs, but there is no guarantee we will maintain the benefits of such designations.

In the United States, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales in the United States. Orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan designation subsequently receives the first FDA approval for a particular active ingredient for the rare disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same rare disease or condition for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the rare disease or condition for which the product was designated.

In the EU, the EC grants orphan designation on the basis of the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products scientific opinion. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment, of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan, or PIP.

Even though our SGT-610 product candidate has obtained orphan drug designation, we may not be able to obtain or maintain orphan drug exclusivity for this or any other future orphan designated product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained designation in the specific rare disease or condition due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, during the exclusivity period, marketing authorizations may be granted to a similar medicinal product with the same orphan indication if: (i) the applicant can establish that the second medicinal product, although similar to the orphan medicinal product already authorized is safer, more effective or otherwise clinically superior to the orphan medicinal product already authorized; (ii) the marketing authorization holder for the orphan medicinal product grants its consent; or (iii) if the marketing authorization holder of the orphan medicinal product is unable to supply sufficient quantities of product. The European exclusivity period can be reduced to six years, if, at the end of the fifth year a medicine no longer meets the criteria for orphan designation (i.e. the prevalence of the condition has increased above the orphan designation threshold or it is judged that the product is sufficiently profitable so as not to justify maintenance of market exclusivity). Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process.

We may seek and fail to obtain fast track or breakthrough therapy designations for our current or future product candidates. Even if we are successful, these programs may not lead to a faster development or regulatory review process, they do not guarantee we will receive approval for any product candidate and the FDA may later rescind fast track or breakthrough therapy designation if it believes a product candidate no longer meets the conditions for qualification. We may also seek to obtain accelerated approval for one or more of our product candidates, but the FDA may disagree that we have met the requirements for such approval.

If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for fast track designation. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Our product candidate SGT-610 has received breakthrough therapy designation from the FDA, and we may also seek breakthrough therapy designation for other product candidates that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review. Like fast track designation, breakthrough therapy designation is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of breakthrough therapy designation for a product candidate, such as the designation for SGT-610, may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Separate from fast track or breakthrough therapy designation, we may seek accelerated approval for one or more of our product candidates. A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval if it is determined to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-approval clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, or if the sponsor fails to conduct the required studies in a diligent manner, the FDA may withdraw its approval of the drug on an expedited basis. In December 2022, President Biden signed an omnibus appropriations bill that included the Food and Drug Omnibus Reform Act of 2022, which among other things provided the FDA with new statutory authority to mitigate potential risks to patients from continued marketing of ineffective products previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. In addition, the FDA currently requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will agree any of our product candidates has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our product candidates received approval through this pathway, the required post-approval confirmatory clinical trials may fail to verify the predicted clinical benefit of the product, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing.

Twyneo, Epsolay and our product candidates for which we obtain regulatory approval 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 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 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. Similar foreign requirements may also apply in foreign jurisdictions.

The FDA or comparable foreign regulatory authorities also may approve our 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, Twyneo Epsolay, and any other product candidate for which we obtain approval 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 or our partners conduct post-approval. Similar foreign requirements may also apply in other jurisdictions. 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 or our partners fail to comply with the regulatory requirements of the FDA or comparable foreign regulatory authorities 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 or comparable foreign regulatory authorities could suspend or impose restrictions on operations, including costly new manufacturing requirements;
- the FDA or comparable foreign regulatory authorities could refuse to approve pending applications or supplements to applications;
- the FDA or comparable foreign regulatory authorities could suspend any ongoing clinical trials;
- the FDA or comparable foreign regulatory authorities could suspend or withdraw marketing approval;
- the FDA or comparable foreign regulatory authorities could seek an injunction or impose civil or criminal penalties or monetary fines;
- the FDA or comparable foreign regulatory authorities could ban or restrict imports and exports;
- the FDA or comparable foreign regulatory authorities could issue warning letters or untitled letters or similar enforcement actions alleging noncompliance with regulatory requirements; or
- the FDA or other governmental authorities including comparable foreign regulatory 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, our or our partners' product labeling, advertising and promotional materials for our approved products, if approved by the FDA, 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 drug 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. Similar requirements may apply in foreign jurisdictions. Physicians may nevertheless prescribe 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 foreign 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 or 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 of our investigational product candidates, and the sale and promotion of Twyneo, Epsolay and our product candidates, once 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 instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the biopharmaceutical industry in the long term. 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 Covid-19 and 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 and foreign regulatory authorities 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 or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. 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. 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, such as the EMA following its relocation to Amsterdam and resulting in staff changes, may 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.

Separately, in response to the COVID-19 pandemic the FDA postponed most inspections of both foreign and domestic manufacturing facilities and clinical trial sites at various points. Even though the FDA has since resumed standard inspection operations, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates. Regulatory authorities outside the United States adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. 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.

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

The commercial success of Twyneo Epsolay and our product candidates, if approved, will depend significantly on their broad adoption by dermatologists, pediatricians and other physicians for approved indications and other therapeutic or aesthetic indications for which we may seek approval from the FDA and other regulatory authorities.

The degree and rate of physician and patient adoption of Twyneo Epsolay and our 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 covered and reimbursed by third-party payors, and patients' willingness to pay for our products and product candidates, if approved; 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 similar foreign requirements enforced by foreign regulatory authorities. We spent approximately $20.4 million, $12.7 million and $23.5million on research and development activities during the years ended December 31, 2021, 2022 and 2023, respectively. We are required to obtain FDA and other regulatory authority approvals before marketing our product candidates in the United States or in other jurisdictions. The regulatory authority approval process is costly, time consuming and inherently risky, as is that applicable in other jurisdictions.

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 efficacy clinical trials for Twyneo, Epsolay and our 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 efficacy clinical trials for Twyneo, Epsolay and our 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 investigational 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 Twyneo and Epsolay, 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 Twyneo, Epsolay and our product candidates for which we obtain approval.

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

Twyneo, Epsolay and certain of our product candidates may be manufactured, warehoused and/or tested at third-party facilities located in territories outside of Israel, 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.

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 January 2023, we purchased assets related to our SGT-610 product candidate, which included certain intellectual property rights owned by PellePharm and licensed to PellePharm by Royalty Security LLC. In the future, we may acquire or in-license additional potential products and technologies. Any potential product or technology 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 potential products are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the potential product, 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 potential products or technologies, we in-license or our own know-how is not adequate, we may not be able to commercialize the affected potential products even after expending resources on their development. In addition, we may not be able to manufacture economically or successfully commercialize any potential product that we develop based on acquired or in-licensed technology that is granted regulatory approval, and such potential products may not gain wide acceptance or be competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed potential products could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed. Lastly, our license with Royalty Security LLC requires us, and future in-license agreements will likely require us, to make payments and satisfy various performance obligations in order to maintain our rights to our SGT-610 product candidate or other future product candidate, as the case may be. If we do not satisfy our obligations under our agreement with Royalty Security LLC or under future in-license agreements, or if other events occur that are not within our control, we could lose the rights to develop and commercialize our SGT-610 product candidate and other future product candidate covered by such future in-license agreements.

The time necessary to develop generic API or generic 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 or foreign regulatory authorities 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 or foreign regulatory authorities, 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 or foreign regulatory authorities 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 and the EU 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 ACA, 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 ACA also included a number of changes which may impact our products and product candidates, once approved:

- 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how other healthcare reform measures enacted by Congress or implemented by the Biden administration, if any, will impact our business.

Moreover, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions to Medicare payments to providers, which went into effect on April 1, 2013, and will remain in effect through the first six months of fiscal year 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. 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. More recently, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate beginning January 1, 2024. Previously, the Medicaid rebate was capped at 100% of a drug's average manufacturer price, or AMP.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion. There have been several Congressional inquiries, as well as proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026) with prices that can be negotiated subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). In part because the IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance for the initial years, as opposed to regulation, it is currently unclear how the IRA will be effectuated. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined, but is likely to be significant. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In response to the executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

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 Twyneo, Epsolay and our other product candidates, once approved, or additional pricing pressure.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for Health Technology Assessment (HTA) in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the U.S. and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Risks Related to Commercialization

Our continued growth is dependent on our ability to successfully develop new product candidates and commercialize our approved products and new product candidates, if approved, 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 innovative products increases following launch and then following patent or exclusivity expiry, declines over time, as new competitors enter the market. Our growth is therefore dependent upon our and our partners' ability to successfully commercialize our approved products and successfully introduce and commercialize our product candidates, if approved.

The FDA and other foreign regulatory authorities may not approve marketing applications at all or in a timely fashion for our product candidates under development. Additionally, we or our partners 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 or another foreign regulatory authority approves marketing applications for our product candidates, we or our partners may not be able to market our products successfully or profitably. Our future results of operations will depend significantly upon our or our partners' ability to timely develop, receive FDA or foreign regulatory authority approval for, and market our products or otherwise develop new product candidates or acquire the rights to other products.

Twyneo, Epsolay face, and 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. Twyneo and Epsolay face significant competition from other approved products, including topical anti-acne drugs such as Acanya, Ziana, Epiduo, Epiduo Forte, Benzaclin, Aczone, Onexton, Differin, Arazlo, Aklief and Amzeeq, Winlevi and topical drugs for the treatment of rosacea such as Metrogel, Finacea, Soolantraand Zilxi, oral drugs such as Solodyn, Doryx, Dynacin, Oracea and Minocin. Twyneo and Epsolay also competes with non-prescription anti-acne products as well as unapproved and off-label treatments. In addition, Twyneo competes with drug products utilizing other technologies that can separate two drug substances, such as dual chamber tubes, dual pouches or dual sachets. Competing in the facial aesthetic market could result in price-cutting, reduced profit margins and loss of market share, any of which has and would harm our business, financial condition and results of operations.

There are 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, we may not be able to price Twyneo, Epsolay, and our product candidates, if approved, 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 investigational product candidates, once approved, successfully.

We believe that our principal competitors are Bausch Health Companies, Inc., Galderma S.A. (other than with respect to Twyneo and Epsolay, which it commercializes in the United States), Almirall, LLC and Sun Pharmaceutical Industries Ltd. 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.

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. 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 commercial 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 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 505(b)(2) applications and ANDAs or reduce 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 505(b)(2) and generic products, developing new versions of their products to obtain FDA market exclusivity, filing citizen petitions contesting FDA approvals of 505(b)(2) and generic products such as on alleged health and safety grounds, developing "next generation" versions of products that reduce demand for the 505(b)(2) and 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 period of exclusivity. Recent litigation against the FDA has affirmed the FDA's interpretation of the scope of 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 exclusivity.

Other pharmaceutical companies may develop competing products for acne, rosacea, Gorlin syndrome 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, Gorlin syndrome, 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.

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

Sales of Twyneo, Epsolay, or our product candidates, once 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 for which indications 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 (typically 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 products or product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of Twyneo, Epsolay depend, and our product candidates, once approved, will depend, substantially on the extent to which the costs of Twyneo, Epsolay and our product candidates will be paid by third-party payors. Additionally, the market for Twyneo, Epsolay and our product candidates, once approved, 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. If our products and our product candidates, once approved, are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, this could have a material adverse effect on our business, financial condition, cash flows and results of operations or result in additional pricing pressure on our products and product candidates. 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 products and 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. Additionally, policy efforts designed to reduce patient out-of-pocket costs for medicines could result in new mandatory rebates and discounts or other pricing restrictions. If third-party payors do not consider Twyneo, Epsolay or our product candidates to be medically necessary or cost-effective compared to other therapies, they may not cover Twyneo, Epsolay or 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 or our partners to sell our products or our product candidates once approved on a profitable basis. Decreases in third-party reimbursement for our products or our product candidates, once approved, or a decision by a third-party payor to not cover our products or product candidates could reduce or eliminate utilization of our products or product candidates, once approved, 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, and could result in reduced demand for products and 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 and product candidates once approved, 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 and our product candidates once approved. Accordingly, in markets outside the United States, the reimbursement for our products and our product candidates once approved 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 are 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 and our commercial partners operate, including how we or our partners research, market, sell and distribute our products and product candidates, once approved, for which we or our partners 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;

- 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 non-physician practitioners (nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, anesthesiology assistants and certified nurse midwives), 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 licensing or reporting of sales representatives; and 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;

- similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

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.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and regulations implemented thereunder, or collectively, HIPAA imposes obligations, including certain mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires certain businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States.

We are also subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions, including the EU General Data Protection Regulation, or GDPR, which went into effect in May 2018 and imposes obligations and restrictions on the processing of personal data of individuals located in the European Economic Area, or EEA, or in the context of our activities within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant undertaking, whichever is greater. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States and other regions that have not been deemed to offer "adequate" privacy protection and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the EC as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the EC adopted its Adequacy Decision in relation to the new EU-U.S. Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, following the United Kingdom's withdrawal from the European Union, we have to comply with the United Kingdom General Data Protection Regulation and Data Protection Act 2018, collectively, the UK GDPR, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant undertaking's global annual turnover, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. 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.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

The illegal distribution and sale by third parties of counterfeit versions of Twyneo, Epsolay or 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 products, which do not meet the rigorous manufacturing and testing standards that our products 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 products or increased levels of counterfeiting such products could materially affect physician and patient confidence in our authentic products. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to our authentic products. 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 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

We rely on Galderma to commercialize Twyneo and Epsolay in the U.S., on Searchlight to commercialize Twyneo and Epsolay in Canada and on Padagis to develop and commercialize our generic product candidates and may depend on other parties for commercialization of Twyneo and Epsolay outside of the U.S. and Canada, and the development and commercialization of our investigational product candidates, if approved. We also rely on Galderma, to provide us with accurate reports in order for us to accurately report our royalty revenues and sales based milestone payments. 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.

In June 2021, we entered into two five-year exclusive license agreements with Galderma pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo and Epsolay. In consideration for the grant of such rights, we received $11 million in upfront payments and regulatory approval milestone payments. We are also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments. We cannot provide any assurance with respect to the success of the license agreements with Galderma, and we may never receive any sales milestone payments pursuant to these agreements. Following the expiration of the initial term of our agreement with Galderma, if the agreement is not renewed all rights related to the Twyneo and Epsolay will revert to us. We will be required upon such expiration to either establish our own marketing and commercialization infrastructure or collaborate with a new partner, and may not be able to do so.

In June 2023, we entered into exclusive license agreements with Searchlight, a private Canadian specialty pharmaceutical company, pursuant to which Searchlight has the exclusive right, and is responsible for all commercial activities for Twyneo and Epsolay in Canada over a fifteen-year term that is renewable for subsequent five-year periods. Searchlight will be responsible for obtaining and maintaining any regulatory approvals required to market and sell the drugs in Canada with support from us. In consideration for the grant of such rights, we will receive up to $11 million in potential upfront payments and regulatory and sales milestones for both drugs, combined. In addition, we will be entitled to royalty percentages of all Canadian net sales ranging from low-double-digits to high teens.

We are currently a party to collaborative arrangements with respect to the development, manufacture, study and commercialization of our generic product candidates with Padagis (formerly a division of Perrigo Company plc, or Perrigo Plc), by assignment from Perrigo Plc.

We cannot and will not control these third party collaborators, but we rely on them to achieve results, which may be significant to us. Relying upon collaborative arrangements to commercialize Twyneo, Epsolay and to develop and, if approved, 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 Twyneo, Epsolay and our product candidates;
- we may not be able to locate third party partners for the commercialization of Twyneo and Epsolay for territories other than the United States and Canada;
- our current or future collaborators' partners may fail to secure adequate commercial supplies of Twyneo, Epsolay and our product candidates, if approved;
- 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 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.

We also currently rely on Galderma, and will rely on Searchlight and Padagis, to provide us with accurate reports in order for us to accurately report our royalty revenues and calculate our rights to receive sales based milestone payments. Royalty payments under our agreements with Galderma and Searchlight are calculated and paid in accordance with reports we receive from Galderma and Searchlight, and we have limited audit rights and information with respect to these reports. In August 2023, we revised previously reported revenue for the first quarter and revenue for the second quarter due to a disruption in Galderma's first quarter wholesaler ordering patterns ahead of Galderma's implementation of a new enterprise resource planning system, which impacted its standard forecasting procedures and its quarterly assessment of rebate accruals. We cannot provide any assurance that future reports provided by Galderma, Searchlight or any other third parties with whom we have or may have collaborative arrangements will be accurate or timely provided. If the reports we receive from them are inaccurate or delayed, our ability to accurately and timely report our royalty revenues and sales based milestone payments may be adversely affected.

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 Twyneo, Epsolay and 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.

It may be 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 with respect to our current of future investigational product candidates. 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 investigational product candidates and increase the costs of development and commercialization of such investigational product candidates.

We currently contract with third-party manufacturers and suppliers for certain compounds and components necessary to produce our investigational product candidates for clinical trials, and for commercial scale of production of our approved products. Our approved products are manufactured by third party manufacturers that were identified and qualified by us. This dependence on third-party manufacturers increases the risk that we or our partners may not have access to sufficient quantities or such quantities at an acceptable cost, which could delay, prevent or impair our and our partners' development or commercialization efforts.

We and our partners currently rely on third parties for the manufacture and supply of certain compounds and components necessary to produce our investigational product candidates for our clinical trials, and to prepare for commercial scale production of such investigational product candidates, including active ingredients and excipients used in the formulation of our investigational product candidates, as well as primary and secondary packaging and labeling materials. We lack the resources and the capability to manufacture our approved products or any of our investigational product candidates on a large clinical or commercial scale, and we expect that we and our partners will continue to rely on third parties to support commercial requirements for our product candidates if 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 are conducted after we or our partners submit our marketing applications to the FDA. As part of the development of Twyneo and Epsolay we qualified CMOs, the facilities of which have been approved by the FDA. Our current and future potential collaborators commercializing Twyneo and Epsolay, engaged and will engage these CMOs for the commercial supply of our approved products. We 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 or our partners may need to find alternative manufacturing facilities, which would significantly impact our or our partners ability to develop, obtain regulatory approval for or market Twyneo, Epsolay or our product candidates.

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 for our product candidates or the manufacture and commercial sale of Twyneo, Epsolay, and 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 Twyneo, Epsolay or any of our product candidates could delay, prevent or impair our clinical development or commercialization efforts.

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

We and our partners do not have the ability to independently perform all aspects of our anticipated pre-clinical studies and clinical trials. We and our partners rely on medical institutions, clinical investigators, CROs, 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 and our partners 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 and our partners 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 and our partners agreement with these third parties may inevitably enable them to terminate such agreements upon reasonable prior written notice under certain circumstances.

Although we and our partners 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 and our partners studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our and our partners reliance on these third parties does not relieve us or our partners of our and our partners 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 and our partners also rely on our consultants to assist us in the execution, including data collection and analysis of our and our partners clinical trials. If we or any of our and our partners third-party contractors fail to comply with applicable GCPs, the clinical data generated in the clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us or our partners 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 or our partners clinical trials complies with GCP regulations. In addition, our and our partners clinical trials must be conducted with product produced under cGMP regulations or similar foreign requirements. Our or our partners 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 and our partners 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 our partners, 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 or our partners 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 or our partners clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we or our partners 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 or our partners efforts to, successfully commercialize these product candidates, if approved.

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, or our partners' ability to provide product candidates for clinical trials or our products or product candidates, once approved, to patients, 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 or our partners' contract manufacturers must comply with cGMP or similar 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 products or in the manufacturing facilities in which our products 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 products will not occur in the future. Additionally, we, our partners 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, our partners, or our third-party manufacturers were to encounter any of these difficulties, our or our partners ability to provide any product candidates to patients in clinical trials and approved products to patients 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 or our partners to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. 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 products 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 products and 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 products and 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 products and 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 products , 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 products , any patents that protect our products 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, other than the licenses granted to Galderma and Searchlight, 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 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 products.

The development, manufacture, use, offer for sale, sale or importation of our products 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 or our partners to cease making, licensing or using products that incorporate the challenged intellectual property; require us or our partners to redesign, reengineer or rebrand our products and product candidates, if feasible; cause us to stop from engaging in normal operations and activities, including developing and marketing our products and 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 or our partners will be able to manufacture, use, offer for sale, sell or import our products in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we or our partners 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 or our partners were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we or our partners 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 or our partners 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 products 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 or our partners' employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our or our partners' 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 or our partners 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 or our partners' 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 and our partners 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 or our partners of the rights to the ideas, developments, discoveries and inventions of our or our partners' employees and consultants while we or our partners 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 products. 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 or our partners 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 under this section. In October 2020, we submitted an NDA for marketing approval for Twyneo, which was granted by the FDA, and in June 2020, we submitted an NDA for marketing approval for Epsolay, which was granted by the FDA. Both of these NDA's were accepted for filing by the FDA. The FDA granted marketing approval for Twyneo in July 2021, and for Epsolay in April, 2022.

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 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 or our partners 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. Further, although the Section 505(b)(1) regulatory pathway is not subject to the same patent certification requirements as Section 505(b)(2) applications or ANDAs and is accordingly not associated with litigation under the Hatch-Waxman Act, we may still face non-Hatch-Waxman patent litigation for products developed through the Section 505(b)(1) pathway.

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 or our partners 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 or our partners 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. For products we develop under the Section 505(b)(1) pathway, the FDA may disagree that our clinical data is sufficient for submission through this pathway, which could result in our inability to seek approval for such products candidates. These factors, among others, may limit our or our partners' 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 or our partners would, unless we or our partners 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 and our partners 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 ANDA and, to a lesser extent, 505(b)(2), products, patented branded products generally realize a substantially higher profit margin than ANDA 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 October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against this terrorist organization commenced in parallel to its continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon may escalate in the future into a greater regional conflict. Additionally, Yemeni rebel group, the Houthis, launched series of attacks on global shipping routes in the Red Sea, causing disruptions of supply chain. These geopolitical developments may adversely affect our ability to continue carrying out various administrative, research, operational and commercial functions and activities both in Israel and globally.

We currently do not anticipate any material risk to the Company resulting from the war. Other than SGT-210, which is manufactured in Israel and has not been impacted, all of the drug production for our products and investigational drug products has either been completed or is conducted outside of Israel. In addition, the Phase III clinical trial for SGT-610 is being conducted in the U.S. and Europe and while our Phase 1 clinical study of SGT-210 is expected to be conducted in Israel, we currently do not expect a delay or disruption of this trial as a result of the recent war. A delay or disruption in our Phase 1 trial of SGT-210 could impact the value of our securities and require us to raise additional capital. If we are unable to do so on terms acceptable to us, we may be required to reduce our operating expenses and limit our product development activities. See "- 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. Additionally, we cannot guarantee that the war will not deter potential investors from investing in Israeli companies such as ours, which could in turn affect our business, operating results and financial condition. It is currently not possible to predict the duration or severity of the ongoing conflict or its effect on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among other possible effects.

In addition, as a result of the war, the international rating agency, Moody's, has cut Israel's credit rating from A1 to A2 and has also lowered Israel's outlook from stable to negative, stating that it sees a possible further downgrade in the future. Lowered credit rating of Israel could materially impact our ability to raise capital and ability to secure loans, if needed, in each case on reasonable terms.

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. Furthermore, prior to Hamas attack in October 2023 the Israeli government p extensive changes to Israel's judicial system which sparked extensive political debate and unrest. In response to the foregoing, individuals, organizations and institutions, both within and outside of Israel, voiced concerns that the proposed changes may negatively impact the business environment in Israel. To date, these initiatives have been substantially put on hold. If such changes to Israel's judicial system are again pursued by the government and approved by the parliament, this may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors. 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 Twyneo, Epsolay and our product candidates, if approved, 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 Twyneo, Epsolay or our prospective product candidates, if approved, 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. 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 for research and development expenditures 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) developed (in all or in part), directly or indirectly, using the IIA grants we received as part of a research and development program funded by the IIA, or the Approved Program, (at rates which are determined under the IIA rules), up to the aggregate amount of the total grants received by the IIA, plus Annual Interest for a File (as defined under the IIA's rules). As we received grants from the IIA, we are subject to certain restrictions under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, or the Innovation Law, the regulations promulgated thereunder and the IIA's rules and guidelines. These restrictions may impair our ability to perform or outsource manufacturing of IIA funded products outside of Israel, granting licenses for R&D purposes or otherwise transfer outside of Israel the know-how resulting, directly or indirectly, in whole or in part, in accordance with or as a result of, research and development activities made according to an Approved Program, as well as any rights associated with such know-how (including later developments, which derive from, are based on, or constitute improvements or modifications of such know-how), or the IIA Funded Know-How.

The restrictions under the IIA's rules and guidelines continue to apply even after payment to the IIA of the full amount of royalties payable pursuant to the grants. In addition, the IIA may from time to time audit sales of products which it claims incorporate IIA Funded Know-How and this may lead to additional royalties being payable on additional product candidates, and may subject such products to the restrictions and obligations specified hereunder. 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. 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 perform or outsource manufacturing rights of IIA funded products outside of Israel, or otherwise transfer or license for R&D purpose our IIA Funded Know-How in and outside of Israel without the approval of the IIA, and 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 IIA Funded Know-How pursuant to a merger or similar transaction, or in the event we undertake a transaction involving the licensing of IIA Funded Know-How for R&D purposes to a non-Israeli entity, the consideration available to our shareholders may be reduced by the amount we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with certain 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 may expose us to criminal proceedings.

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 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.

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.

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, has the authority to determine whether the employee is entitled to remuneration for service inventions developed by such employee and the scope and conditions for such remuneration. Case law clarifies that the right to receive consideration for "service inventions" can be waived by the employee and that in certain circumstances, such waiver does not necessarily have to be explicit. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration, but rather uses the criteria specified in the Patents Law. 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 2023. 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 products.

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 M. 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.

M. Arkin Dermatology Ltd. ("Arkin Dermatology) is currently our controlling shareholder. As of March 1, 2024, Arkin Dermatology, and its sole beneficial owner, Mr. Moshe Arkin, collectively beneficially owned approximately 58% 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 do not 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 currently 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. 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 March 1, 2024, there were 27,857,620 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 statements 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 file 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. Upon the filing of the registration statements, 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 16,154,564 of our ordinary shares as of March 1, 2024, 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".

Our Outstanding Warrants are exercisable for our ordinary shares, which will increase the number of ordinary shares eligible for future resale in the public market and result in dilution to our shareholders.

As of March 1, 2024, we had 4,560,000 outstanding warrants to purchase an aggregate of 4,560,000 ordinary shares. All warrants are exercisable at any time before January 27, 2028, subject to certain limitations and exceptions. The exercise price of the warrants is $5.85 per ordinary share, which is above the current market price of our ordinary share, which was $$1.13 per share based on the closing price of the ordinary shares on Nasdaq on March 1, 2024. The likelihood that the holders of our warrants will exercise their warrants, and the amount of any cash proceeds that we would receive upon such exercise, is dependent upon the market price of the ordinary shares. To the extent that our outstanding warrants are exercised, additional shares of the ordinary shares will be issued, which will result in dilution to our shareholders and increase the number of shares of the ordinary shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such outstanding warrants may be exercised could adversely affect the market price of the ordinary shares. However, there is no guarantee that our outstanding warrants will be in the money prior to their respective expirations, and as such, they may expire worthless.

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

We used the net proceeds from our public offering in January 2023 (and concurrent private placement) to fund the acquisition of SGT-610. The remaining proceeds will be used for other research and development activities, 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 such 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 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 are 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 believe that we were a passive foreign investment company for U.S. federal income tax purposes for our 2023 taxable year, 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 generally be a PFIC for U.S. federal income tax purposes for any taxable year if either (i) at least 75% of its gross income for such year is passive income (such as interest 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 cash or other assets that produce passive income or are held for the production of passive income. Because the value of our assets for purposes of the PFIC asset test will generally be determined by reference to the market price of our ordinary shares, based on the value and composition of our assets for our 2023 taxable year (including, in particular, the size of our cash and other passive assets) and the changes in the market price of our ordinary shares during our 2023 taxable year, we expect that we will be treated as a PFIC for U.S. federal income tax purposes for our 2023 taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares or under proposed regulations, our warrants, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements.

For further discussion of the adverse U.S. federal income tax consequences of our classification as a PFIC, see "Item 10. Additional Information — U.S. Federal Income Tax Considerations – Passive Foreign Investment 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, of which there are none at present, 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 or warrants.

General Risk Factors

Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cyber-security.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data and personal information of our employees and contractors, or collectively, Confidential Information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Despite the implementation of security measures, our information technology systems, and those of third parties on which we rely, are vulnerable to attack, damage and interruption from computer viruses, malware (e.g. ransomware), misconfigurations, bugs or other vulnerabilities, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks, hacking, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks and, sophisticated nation-state and nation-state-supported actors.

The risk of a security breach or disruption, particularly through cyberattacks 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. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', CROs' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of our partners and service providers, 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 access to or disclosure of Confidential Information, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material, we could be subject to regulatory investigations and enforcement actions including fines and penalties, we could incur material legal claims and liability (including class actions), we could suffer damage to our reputation, and the further development of our product candidates could be delayed. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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 the commercialization of Twyneo and Epsolay outside the U.S. and Canada or with respect to the 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 products;
- 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, 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 make some activities more time-consuming and costly. Our board and other personnel need to devote a substantial amount of time to these initiatives. Due to developments with respect to these rules from time to time, we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. Due to our current 'public float' we are eligible to take advantage of an exemption from the requirement 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, our management is required to report on the effectiveness of our internal control over financial reporting. In addition, once our public float exceeds $75 million, we will lose the ability to rely on the exemptions related thereto discussed above, and 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, 2023, 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, 2023, 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 so long as we have a 'public float' of less than $75 million on the last trading day of our second fiscal quarter, 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. 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.

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, 2021, 2022 and 2023 were approximately $143, $171 and $134 respectively. Our current capital expenditure involves equipment and leasehold improvements.

B. Business Overview

Our Company

Sol-Gel is an innovative dermatology company with a successful track record of two NDA approvals and an advanced pipeline of product candidates being developed for orphan indications. Sol-Gel successfully developed pioneer topical drugs Twyneo and Epsolay, respectively approved for the treatments of acne and inflammatory lesions of rosacea. Since 2022, both products have been marketed in the U.S. by our U.S. commercial partner, Galderma. In terms of our proprietary assets in development, we are developing topical patidegib (SGT-610) for prevention of BCC in Gorlin syndrome patients and topical erlotinib (SGT-210) for the treatment of rare hyperkeratinization disorders.

Products and Pipeline

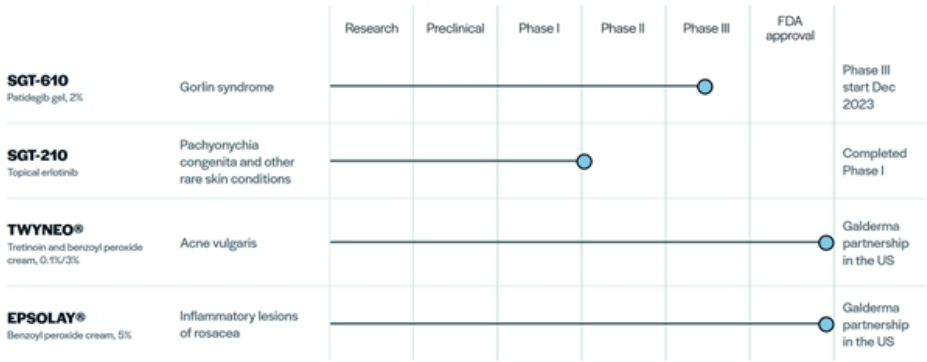
We are a dermatology company leveraging innovative approaches to develop pioneering treatments for patients with severe skin conditions, conducting a Phase 3 clinical trial of SGT-610 (patidegib gel, 2%) for Gorlin syndrome, and with two approved large-category dermatology products, Twyneo and Epsolay.

Our current product candidate pipeline includes SGT-610 (Patidegib Topical Gel), a new chemical entity hedgehog signaling pathway blocker, for the chronic use and prevention of new BCC in Gorlin syndrome patients, and the topical drug candidate SGT-210 for the treatment of rare hyperkeratinization disorders such as Darier ,PC , PPK, Olmsted, etc..

Our FDA-approved product, Twyneo, is a novel, once-daily, non-antibiotic topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide, or BPO, and encapsulated tretinoin, developed for the treatment of acne vulgaris, or acne. Our FDA-approved product, Epsolay, is a novel, once-daily topical cream containing encapsulated BPO that we have developed for the treatment of inflammatory lesions of rosacea.

In June 2021, we entered into two five-year exclusive license agreements with Galderma pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo, and, Epsolay. In June 2023, we entered into two exclusive license agreements with Searchlight pursuant to which Searchlight has the exclusive right, and is responsible for, all regulatory and commercial activities for Twyneo and Epsolay in Canada, over a fifteen-year term that is renewable for subsequent five-year periods.

The following chart represents our current approved products and candidate pipeline.



We are developing the new chemical entity SGT-610 (Patidegib Topical Gel), a hedgehog signaling pathway blocker, for the chronic use and prevention of new BCC in Gorlin syndrome patients. Gorlin syndrome is a rare disease with no therapies approved by the FDA or the EC for this disease. SGT-610 is aimed to prevent new BCCs in adults with Gorlin syndrome without systemic adverse events. We believe it has the potential to be the first drug approved for the treatment of Gorlin syndrome patients. SGT-610 has been granted Orphan Drug Designation by the FDA and the EC as well as Breakthrough Designation by the FDA. If approved by the FDA, SGT-610 has the potential to generate, at peak, annual net sales in excess of $300 million (based in part on independent sources and also based on our good faith estimates). Although we believe such data and estimate to be reliable, it involves a number of assumptions and limitations, including without limitations the number of patients, the penetration level of the treatment, and the expected treatment annual price.

On November 30, 2023 we announced that we have begun screening patients for our Phase 3 study. In the patidegib's seller, PellePharm Inc. ("PellePharm") study the SGT-610 arm was found to be as tolerable as the vehicle and the significant adverse events commonly seen with oral hedgehog inhibitors were not observed. Our clinical study includes essential modifications to the former Phase 3 study conducted by PellePharm. We have refined screening criteria in order to enroll subjects with more severe disease at baseline reflected in a higher baseline number of facial BCC lesions. This refinement may help to better demonstrate the preventive effect of our medication candidate. We are also pre-screening patients for a specific genetic mutation associated with Gorlin syndrome that is considered relevant for HH inhibitors. In an effort to increase patient study compliance we reduced the number of study visits over the 12 months of treatment. We plan to conduct the Phase 3 study to investigate SGT-610 in approximately 140 subjects at approximately 40 experienced clinical centers in North America, United Kingdom and Europe. We currently expect results of our Phase 3 study by the end of 2025.

The rights to SGT-610 were purchased on January 30, 2023, pursuant to an asset purchase agreement with PellePharm, dated January 23, 2023.

Under the terms of the agreement upon closing of the transaction, we paid an upfront payment of $4 million to PellePharm, and the remaining principal amount outstanding of $0.7 million has not been transferred as of the issuance date of this report. We are also required to pay:

- up to $6 million in total development and NDA acceptance milestone payments;
- up to $64 million in commercial milestone payments, which amount increases to $89 million when sales exceed $500 million; and
- single digit royalties, which increase to double digit royalties when sales exceed $500 million.

SGT-210 (erlotinib) is a topical drug candidate for the treatment of rare hyperkeratinization disorders. Erlotinib is a tyrosine kinase receptor inhibitor which acts on the epidermal growth factor receptor, a protein expressed on the surface of cells, whose job is to help cells grow and divide. Published clinical research has shown that orally administered erlotinib improved the quality of life of pachyonychia congenita patients but was associated with significant adverse events, while topically applied erlotinib, 0.2%, failed to display significant improvement1. Sol-Gel's scientists have developed a topical product with a significantly higher concentration of erlotinib than that which was reported to be inefficient. SGT-210 is expected to treat rare hyperkeratinization disorders with limited adverse events caused by oral erlotinib. Our Phase-1 study has been completed, with results supporting further development of this product candidate. We expect to initiate a phase 1 clinical trial for an indication within the hyperkeratinization disorders during H1 2024.

Twyneo, is a once-daily, non-antibiotic topical cream, containing a fixed-dose combination of encapsulated benzoyl peroxide, or E-BPO, and encapsulated tretinoin for the treatment of acne. 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. 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. Twyneo was approved for marketing by the FDA in July 2021 in the United States and was licensed in the United States exclusively to Galderma in June 2021, and in Canada exclusively to Searchlight in June 2023.

Epsolay, is a once-daily topical cream containing 5% encapsulated benzoyl peroxide, that we have developed for the treatment of inflammatory lesions of rosacea in adults. 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. 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. 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. Epsolay, is the first product containing BPO that is marketed for the treatment of subtype II rosacea. Epsolay was approved for marketing by the FDA in April 2022 and was licensed in the United States exclusively to Galderma in June 2021 and in Canada exclusively to Searchlight in June 2023.

We are also currently developing a generic program in collaboration with Padagis, by assignment from Perrigo. Under the terms of the agreement with Padagis, we received $21.5 million over 24 months, in lieu of our share in ten generic programs, two of which were approved by the FDA and eight of which remain unapproved.

In June 2021, we entered into two exclusive license agreements with Galderma, pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo and Epsolay, including promotion and distribution, and we were responsible for obtaining all regulatory approvals of the products in the United States, which we completed in July 2021 and April 2022, respectively. Each of the license agreements has a term of five years from the date of Galderma's first commercial sale of the applicable product in the United States. The license agreements provide that Galderma is responsible for all filings and communications with regulatory authorities in the U.S. until expiration of the applicable license agreement. In connection with the licenses, we and Galderma have entered into a three-party supply agreement with Douglas Manufacturing Limited, which will supply Galderma the Twyneo product, and Galderma entered into a supply agreement with a third party for the supply of the Epsolay product. In consideration for the grant of such rights, Galderma has paid us $11 million in upfront payments and regulatory approval milestone payments. We are also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments.

In June 2023, we entered into exclusive license agreements with Searchlight, a private Canadian specialty pharmaceutical company, pursuant to which Searchlight has the exclusive right, and is responsible for all commercial activities for Twyneo and Epsolay in Canada, over a fifteen-year term that is renewable for subsequent five-year periods. Searchlight will be responsible for obtaining and maintaining ay regulatory approvals required to market and sell the drugs in Canada with support from us. In consideration for the grant of such rights, we will receive up to $11 million in potential upfront payments and regulatory and sales milestones for both drugs, combined. In addition, we will be entitled to royalty percentages of all Canadian net sales ranging from low-double-digits to high teens.

Our Products

SGT-610 for Gorlin Syndrome

We are developing SGT-610 for chronic use in Gorlin syndrome patients to reduce the significant tumor burden of persistently developing basal cell carcinomas (BCCs) with a minimum systemic tolerability side effects seen with and approved oral formulations of Hedgehog (HH) pathway inhibitors. SGT-610 has been granted Orphan Drug Designation by the FDA and the EC, as well as Breakthrough Therapy Designation by the FDA. Both FDA and the European Medicines Agency (EMA) have agreed that a single pivotal Phase 3 study may be used for the approval of this investigational drug. If approved by the FDA, SGT-610 has the potential to generate, at peak, annual net sales in excess of $300 million (based on good faith estimates derived from our knowledge and based in part on independent sources). Although we believe such data and estimate it to be reliable, it involves a number of assumptions and limitations, including without limitation the number of patients, the penetration level of the treatment, and the expected treatment annual price.

On November 30, 2023, we announced that we began screening patients for our Phase 3 study. In PellePharm's study the SGT-610 arm was found to be as tolerable as the vehicle and the significant adverse events commonly seen with oral hedgehog inhibitors were rarely observed.

Our clinical study includes essential modifications to the former Phase 3 study conducted by patidegib's seller, PellePharm. We refined screening criteria in order to enroll subjects with a more severe disease at baseline reflected in a higher baseline number of facial BCC lesions. This refinement may help to better demonstrate the preventive effect of our medication candidate. We are also screening patients for a specific genetic mutation associated with Gorlin syndrome that is considered relevant for HH signaling pathway. In an effort to increase patient study compliance we reduced the number of study on site visits over the 12 months of treatment. We will conduct the Phase 3 study to investigate SGT-610 in approximately 140 subjects at approximately 40 experienced clinical centers in North America, United Kingdom and Europe. We currently expect results of our Phase 3 study by the end of 2025.

Basal Cell Carcinomas

Basal cell carcinomas, BCCs are the most common of human cancers, occurring in an estimated 2 to 3 million Americans each year. The overwhelming majority of BCCs occur at a low tempo with a strong predilection for sun exposed skin sites in persons of Northern European descent who have had excessive sun exposure. They are most commonly seen starting in the fourth decade of life. Some patients develop BCCs at a higher tempo and often at a younger age. They are referred to as having High Frequency BCC (HF-BCC). These include patients with rare genetic BCC syndromes that have been well characterized along a spectrum of severity and frequency of BCC formation. Gorlin syndrome is the most common of these rare conditions. More recently, a subset of patients with HF-BCC has been identified who develop multiple BCCs throughout life at an unusually high frequency, but who do not qualify for a diagnosis of Gorlin syndrome. This patient population is referred to as non Gorlin high frequency basal cell carcinoma.

Gorlin Syndrome

Gorlin syndrome is a rare disease with no therapies currently approved by the FDA or the EC for this disease. Gorlin syndrome affects approximately 1 in 31,000 people and is an autosomal dominant genetic disorder, mostly caused by inheritance of one defective copy of the tumor suppressor gene PTCH1. The PTCH1 gene blocks the SMO gene, turning off the hedgehog signaling pathway when it is not needed. However, mutations in PTCH1 may cause loss of PTCH1 function, release of SMO, and may allow BCC tumor cells to divide uncontrollably. Gorlin syndrome is also called nevoid BCC syndrome because approximately 90% of individuals with this syndrome develop multiple BCCs, ranging from a few to many thousands of lesions during a patient's lifetime. Gorlin syndrome patients are also susceptible to many abnormalities, including, most frequently, palmar and plantar pits and jaw cysts, and, most devastatingly, medulloblastomas. We estimate that there are approximately 17,000 Gorlin syndrome patients with multiple BCCs worldwide. Painful surgical excision is currently the treatment of choice for BCCs. However, as multiple BCCs continue to evolve, repeated surgical intervention becomes practically impossible, which makes the prevention of the development of new BCCs a critical treatment consideration. Patidegib, the active substance in SGT-610, is designed to block the SMO signal, thus allowing cells to function normally and reduce production of new tumors.

Current Treatment Options for Gorlin Syndrome

In general, patients with Gorlin syndrome have their BCCs treated as they become problematic, such as when the BCCs present a risk of invasion of vital structures on the face such as eyes, nose, or ears, or become large enough off the face that they are uncomfortable, bleed, etc. Patients with Gorlin syndrome are typically never free of BCCs. Although currently available oral drug treatments can produce partial or complete clinical clearing, once the drug is stopped the BCCs recur.

Topical Treatment: Several topically-applied drugs are used in the treatment of BCCs, in particular imiquimod and 5-fluorouracil. Based on clinical trials performed both of these topical products can cure approximately 80% of the superficial subtype of BCCs, most of which generally occur off the face. However, clinical trials demonstrate that these treatments generally are not useful against nodular BCCs, which are the more prevalent subtype, especially on the face. In addition, clinical trials show that both typically cause significant inflammation at sites of application, which render them inadequate for the long-term management of a chronic condition.

Retinoid Treatment: Oral retinoid treatment of patients with Gorlin syndrome can reduce the rate of development of BCCs, but based on clinical trials is does so only at a dose that usually produces intolerable side effects.

Oral HH Inhibitors: With identification of uncontrolled HH signaling as the driving molecular abnormality in all BCCs, several anti-HH drugs have been developed for oral treatment of BCCs, and two of these - vismodegib and sonidegib - have been approved for systemic treatment of advanced BCCs defined as BCCs whose surgical excision likely would produce unsatisfactory results (i.e. "locally advanced") or those which have become metastatic. Clinical trials demonstrate that approximately 50% of such advanced BCCs fail to respond initially, frequently due to mutations in the SMOOTHENED (SMO) gene, which encodes the protein to which these HH inhibitor drugs bind. Clinical trials further evidence that of those that do respond, a significant proportion develop secondary resistance, often due to mutations in the drug binding pocket of the SMO protein.

Vismodegib has been studied for efficacy against BCCs in patients with Gorlin syndrome and has demonstrated a combined result of shrinkage of existing BCCs and prevention of the development of new BCCs as long as patients continue to take vismodegib. However, clinical trials show that most patients discontinue vismodegib because of class-specific side effects that affect their quality of life. Clinical trials demonstrate that oral HH inhibitors have a poor long-term safety and tolerability record for a chronic condition due to unacceptable side effects such as loss of hair, sense of taste, and weight; fatigue; and intense muscle cramps. The severity of the adverse events (AEs) associated with vismodegib is illustrated by the fact that 54% of patients with Gorlin syndrome in an oral vismodegib clinical trial discontinued treatment because of adverse effects despite clear efficacy against their BCCs.

Surgical Treatment of BCCs: Given the lack of alternate treatment options, patients who develop a high rate of BCCs often need surgery for their chronic tumors. However, studies show that surgery has significant morbidity (e.g., scarring, disfigurement, functional loss of eyelid, nose, ear) and multiple surgeries may lead to psychological distress of the patient. The number of surgically eligible BCCs and specifically, the chronic surgical intervention, constitutes a significant burden of disease in patients with Gorlin syndrome.

Twyneo for Acne

Using our proprietary, silica-based microencapsulation technology platform, we developed 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 developed 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, Twyneo is required 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. In the U.S. Twyneo competes directly with Winlevi, Aklief, Epiduo, Epiduo Forte and Cabtreo. 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. Twyneo was approved for marketing by the FDA in July 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/adapalene/clinidamycin, 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.

Epsolay for Subtype II Rosacea

Epsolay *Overview*

Epsolay is a once-daily investigational topical cream containing 5% encapsulated benzoyl peroxide that we have developed for the treatment of papulopustular (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 the U.S. Epsolay competes directly with Soolantra. We utilized 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. Epsolay was approved by the FDA in April 2022.

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. Previously, there was no benzoyl peroxide product approved for the treatment of rosacea 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 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 the first FDA approved product containing benzoyl peroxide for the treatment of subtype II rosacea.

SGT-210 for Hyperkeratinization Disorders

We are developing SGT-210 for the treatment of rare hyperkeratinization disorders, such as Darier, PC, PPK, Olmsted, etc. a group of skin conditions characterized by thickening of the skin. SGT-210 is designed to be used alone or in combination for the treatment of hyperproliferation and hyperkeratinization disorders. On January 2, 2020, we announced the initiation of a Phase 1 clinical study of SGT-210 in patients with palmoplantar keratoderma. The Phase 1 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. During the third quarter of 2021, we reported that the study with respect to six (6) palmoplantar keratoderma (PPK) patients has been completed and indicated modest improvement and a favorable safety results. Two elevated concentrations of topical erlotinib were investigated in MUSE –PK Phase I study on healthy volunteers initiated in December 2022. The study was finalized by second quarter of 2023, where topical erlotinib was generally safe and well tolerated and minimal absorbance regardless of its concretion was observed. We believe these results support further development of this product candidate. We expect to initiate a phase 1 clinical trial for an indication within the hyperkeratinization disorders during H1 2024.

Generic Drug Product Candidate

In addition to our investigational product candidates, we are also currently developing a generic topical dermatological product candidate in collaboration with Padagis by assignment from Perrigo. Padagis has significant experience in the development of generic drugs.

We previously had collaboration arrangements with Perrigo to develop a portfolio of 11 generic topical dermatological product candidates. In November 2021, we announced that we had signed an agreement with Padagis, pursuant to which we sold our rights related to 10 generic collaborative agreements between the parties. Under the terms of this agreement with Padagis, effective as of we received $21.5 million over 24 months, in lieu of our share in the ten generic programs, two of which were approved by the FDA, and eight of which are unapproved. Pursuant to the agreement, effective as of November 1, 2021, we ceased paying any outstanding and future operational costs related to these 10 collaborative agreements.

We currently have one active collaboration agreement with Padagis for the development, manufacturing and commercialization of a generic program. Under this agreement, Padagis will conduct the regulatory (if relevant), scientific, clinical and technical activities necessary to develop the generic product candidate and seek regulatory approval with the FDA for this generic product candidate. If approved by the FDA, Padagis has agreed to commercialize the generic product candidate in the United States. We and Padagis will share the development costs and the gross profits generated from the sales of the generic product candidate, if approved by the FDA.

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.

Intellectual Property

Our intellectual property and proprietary technology are directed to the development, manufacture and sale of our products. 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 Twyneo, Epsolay, our investigational product candidates (once approved), if approved, and our future prospects.

Our patent portfolio that is directed to Twyneo, Epsolay and our other investigational product candidates includes 158 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 158 patents and patent applications, 97 are granted patents (23 in the United States and 74 in other countries) and 61 are pending applications (39 in the United States and 22 in other countries).

For SGT-610, we have one not yet published international application that refers to a method of treatment with SGT-610, and one pending application in the United States that refers to a method of treatment with SGT-610 for a period of more than 12 months; and we purchased from PellePharm 3 granted patents in the US (with a term until 2036), 2 granted patents in South Africa, and granted patents in Israel, Japan, Mexico, Canada, Brazil, and Australia and pending applications in Chile, Europe and Hong Kong. We also licensed from Royalty Security LLC (as part of the asset purchase from PellePharm) 21 granted patents in the US (with terms 2027-2031), 1 granted patent in Canada , 36 granted patents in Europe (Norway and EPO members such as France, Germany, Ireland, Switzerland, United Kingdom, Spain, Italy, etc.) 39 Granted patents in the rest of the world (such as Argentina, Australia, Brazil, Chile, China, Hong-Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Philippines, Russia, Singapore, Thailand, Taiwan, Ukraine, South Africa).

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

We have five trademarks registered for our Twyneo product in Israel, Europe, the United States and Canada. Twyneo was also filed for registration in China, Australia, Mexico, and Brazil. For Epsolay, we have obtained patents in China, Canada, Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland and the United Kingdom), Mexico and the United States (with a term until 2032) covering the composition for topical treatment of rosacea. We have further one pending application for this composition in the United States. There are two patent families directed to the process for encapsulation of the active agents of Epsolay (one patent family has granted patents in Canada, India, Mexico, and Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland and the United Kingdom) (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 7 granted patents in the United States (with a term until 2040) and 4 patent applications pending in the United States covering the methods of use of Epsolay for the treatment of rosacea. We have one published international application and one US application with a term until 2042.

We have pending applications in Australia, Brazil, Chile, Colombia, Korea, Malaysia, New Zealand, Philippines, Thailand, Vietnam and South Africa, and four pending applications in the United States covering the compositions of Epsolay and Twyneo, the processes for the encapsulation of the active agents of our Epsolay and Twyneo, and the methods of use.

We have four registered trademarks in Europe, Canada, the United States and Israel. These registrations cover potential brand names for our Epsolay in Israel, Europe, Canada and the United States. Epsolay was also filed for registration in Brazil, Mexico, and Australia.

For SGT-210, we have seven pending applications in Korea, Mexico and the United States, and one published international application, and one granted patent in the United States that refer to methods and compositions of use in the treatment of psoriasis.

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, Arcutis Biotherapeutics, Bausch Health Companies Inc., Bayer HealthCare AG, Cassiopea SpA, Dermavant Sciences, Galderma Pharma S.A., Glenmark Pharmaceuticals Ltd., G&W Laboratories, Inc., LEO Pharma A/S, Mylan N.V., Novan, Inc., Novartis AG, Palvella Therapeutic, Padagis US LLC, Pfizer, Inc., Spear Therapeutics, Ltd., Sun Pharmaceutical Industries Ltd., Teligent, Inc., Teva Pharmaceutical Industries Ltd. And Vyne Pharmaceuticals Ltd..

In order for Twyneo, Epsolay and our product candidates, if approved, 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 Twyneo, Epsolay and our product candidates and contribute to downward pressure on the pricing of Twyneo, Epsolay and 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.

SGT-610 is expected to be the first, if approved, product for the prevention of new BCCs in Gorlin syndrome patients. We believe that the competition will be limited in the short term after launch.

Twyneo and Epsolay target the well-established acne and rosacea markets. Twyneo and Epsolay 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, and fixed-dose combinations of benzoyl peroxide, clindamycin and adapalene, such as Cabtreo, fixed-dose combinations of tretinoin and clindamycin such as Ziana and Veltin, topical antiandrogen such as Winlevi and topical antibiotics such as Aczone and Amzeeq. The current standard of care for rosacea includes Metrogel, Finacea, Soolantra and 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 generic drug product candidates 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.

Marketing, Sales and Distribution

We currently have limited sales, marketing and distribution capabilities. In June 2021, we entered into two five-year exclusive license agreements with Galderma pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo and Epsolay. Pursuant to the agreements, we received $11 million in upfront payments and regulatory approval milestone payments. We are also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments. In June 2023, we entered into exclusive license agreements with Searchlight, pursuant to which, Searchlight has the exclusive right, and is responsible for all commercial activities for Twyneo and Epsolay in Canada, over a fifteen-year term that is renewable for subsequent five-year periods. In consideration for the grant of such rights, we will receive up to $11 million in potential upfront payments and regulatory and sales milestones for both drugs, combined. In addition, we will be entitled to royalty percentages of all Canadian net sales ranging from low-double-digits to high teens. We expect to collaborate with third parties that have sales and marketing experience in order to commercialize Twyneo and Epsolay outside of the United States and Canada, and our other investigational product candidates, if approved by the FDA for commercial sale, in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements for our product candidates on acceptable terms or at all, we may not be able to successfully commercialize them. 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.

Manufacturing

For the supply of current good manufacturing practice-grade, or cGMP-grade and clinical trial materials we rely on and expect to continue to rely on third-party 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 ISO 45001:2018 certifications continue to be maintained and are due for renewal in May 2024. 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, manufacturing and commercialization of Twyneo, Epsolay and 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 clinical trials.

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.

ANDA products must be shown to be the similar to, and bioequivalent to, a reference listed drug, or RLD. 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 by the FDA, would provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For new molecular entities, or NMEs, such as those typically submitted in 505(b)(1) NDAs, the FDA endeavors to review applications subject to Standard Review within 10 months 60-day filing date, or within 6 months of the 60-day filing date for Priority Review. For non-NMEs, such as those typically submitted in 505(b)(2) NDAs, FDA's goal is to review applications subject to Standard Review within 10 months of receipt, and those subject to Priority Review within 6 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.

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 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 a 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 Amendments 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)(1) and 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.

Further, although applications submitted in a Section 505(b)(1) NDA are not subject to the same patent certification requirements as Section 505(b)(2) applications or ANDAs, and are not associated with litigation under the Hatch-Waxman Act, applicants may still face non-Hatch-Waxman patent litigation for products developed through the Section 505(b)(1) pathway.

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 ANDA or 505(b)(2) 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 investigations (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

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, manufacturing, clinical trials, marketing authorization, commercial sales and distribution of our products. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulation. 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. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. 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, promotion and reimbursement vary greatly from country to country.

Non-clinical Studies and Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the EC through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

  Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops.

Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Orphan designation must be requested before submitting an MAA. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of Twyneo, Epsolay, and 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 or Galderma may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of Epsolay, Twyneo or our product candidates once approved. For example, some third-party payors may not consider Epsolay, Twyneo and other product candidates once approved medically necessary or cost-effective and may decide to impose coverage or other utilization limits on their use. 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 payor 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 international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries operate positive and negative list systems under which products may be marketed only after a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, 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 EU 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. EU member states may approve a specific price or level of reimbursement for a pharmaceutical product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. 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 ACA, one of the most significant healthcare reform measures in decades. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA 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 ACA 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 ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

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, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. 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. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap beginning January 1, 2024.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion. There have been several Congressional inquiries, as well as proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Most significantly, on August 16, 2022, President Biden signed the IRA into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026) with prices that can be negotiated subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In response to the executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. 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 Twyneo Epsolay and our other product candidates, once approved.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Healthcare Laws and Regulations

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, 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 products or product candidates, once approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products and product candidates, once approved, and the sale and marketing of our products and product candidates, once approved, 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 federal Physician Payment Sunshine Act 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 about covered manufacturers for certain payments and other "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, as well as certain ownership and investment interests held by physicians as defined by statute and their immediate family members. Covered manufacturers are required to submit reports to the government by the 90th day of each calendar year.

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 products or product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may also be broader in scope than the provisions described above. These laws and regulations may differ from one another in significant ways, thus further complicating compliance efforts. For instance, in the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of compliance programs, or require reporting of marketing expenditures and pricing information.

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 Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Innovation Authority We have received royalty-bearing grants from 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 and restrictions with respect to the use of their IIA Funded Know-How, including, the following:

- **Royalty Payment Obligation**. In general, the Recipient Company may be obligated to pay the IIA royalties from any income deriving from the products (and related know-how and services), whether received by the grant recipient or any affiliated entity, developed (in all or in part), directly or indirectly, as a result of, an Approved Program, or deriving therefrom, at rates which are determined under the IIA's rules and guidelines (currently a yearly rate of between 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," or a "Large 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 for a File (as such term is defined in the IIA's rules and guidelines).

  Reporting Obligations. The Recipient Company is subject to certain reporting obligations (such as, periodic reports regarding the progress of the research and development activities under the Approved Program and the related research expenses, and regarding the scope of sales of the Recipient Company's products). In addition, any direct change in control of a Recipient Company must be notified to the IIA. In the event that a non-Israeli entity or a non-Israeli citizen or resident person becomes an "Interested Party" (as such term is defined in the Israeli Securities Law, 5728-1968) in the Recipient Company, notification to the IIA is required, accompanied by a written undertaking (in the form available on the IIA's website) by such party to be bound by the Innovation Law and by the terms of the Approved Program;

- **Local Manufacturing Obligation**. Products developed using the IIA grants must, as a general matter, be manufactured in Israel. The transfer of manufacturing capacity outside of Israel in a manner that exceeds the manufacturing capacity that was declared in the Recipient Company's original IIA grant application is subject to prior written approval from the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate, which event requires only a notice to the IIA, which shall be provided in writing prior to the transfer of such manufacturing rights abroad, while the IIA has a right to deny such transfer within 30 days following the receipt of such notice). In general, the transfer of manufacturing capacity outside of Israel may be subject an increase in the royalties' cap (*inter alia*, depending on the manufacturing volume that is performed outside of Israel) and such transfer will be subject to payment of royalties in accelerated rate; and

- **IIA Funded Know-How transfer limitation**. Under the IIA's rules and guidelines, a Recipient Company is prohibited from transferring the IIA Funded Know-How outside of Israel except with the approval of the Research Committee and in certain circumstances, 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, generally up to 6 time the grants received plus Annual Interest as such term is defined under the rules, or A Redemption Fee). For calculating the Redemption Fee which shall be paid to the IIA in the event of a transfer of IIA Funded Know-How outside of Israel, inter alia, the following factors will be taken into account: the scope of the IIA support received, the royalties that have already paid to the IIA, the amount of time that has lapsed since the Recipient Company has finalized the IIA Approved Program, the sale price and the form of transaction. A transfer for the purpose of the Innovation Law and the IIA's rules means an actual sale of the IIA-Funded Know-How, or any other transaction which in essence constitutes a transfer of such know-how (such as providing an exclusive license to a foreign entity for R&D purposes, which precludes the Recipient Company from further using such IIA Funded Know-How). A mere license solely to market products resulting from the IIA Funded Know-How would not be deemed a transfer for the purpose of the Innovation Law and the IIA's rules. Upon payment of the Redemption Fee, the IIA Funded Know-How and the manufacturing rights of the products developed using such IIA funding cease to be subject to the Innovation Law and the IIA's rules.

- Subject to the IIA's prior approval, a Recipient Company may transfer IIA Funded Know-How to another Israeli company, provided that the acquiring company assumes all of the Recipient Company's responsibilities towards the IIA. Such transfer will not be subject to the payment of the Redemption Fee; however, the income from such transaction will generally be subject to the obligation to pay royalties to the IIA (other than in specific circumstances that will be examined by the IIA, mainly when the transfer is between related entities).

- **IIA Funded Know-How license limitation**. The grant to a foreign entity of a right to use the IIA Funded Know-How for R&D purposes (which does not entirely prevent the Recipient 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 the IIA's rules (which distinguish between the manner of the payment for such license grant, i.e., one-time payment or payment in installments) and such payment shall be no less than the amount of the IIA grants received (plus Annual Interest), and no more than the cap stated in the IIA's rules and will generally be due only upon the receipt of the license fee from the licensee).

  The IIA's rules also include a mechanism with respect to the grant of a license by a Recipient Company (which is part of a multinational corporation) to its group entities to use its IIA 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, with the cap of the royalties increasing to 150% of the grant amount. Such mechanism includes certain requirements which must be met in order to be able to enjoy such lower royalty payment.

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. The obligation to comply with the Innovation Law and the IIA's rules (including with respect to the restriction of the transfer of IIA Funded Know-How and manufacturing rights outside of Israel) remains in effect even after full repayment of all amounts payable to the IIA. Once a Redemption Fee is paid on a transfer of IIA Funded Know-How outside Israel, all obligations towards the IIA (including the royalty obligation) cease.

The government of Israel does not own intellectual property rights in technology developed with IIA funding and the IIA's approval is not required for the export of any products resulting from the IIA research or development grants.

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, 2025.

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 an innovative dermatology company with a successful track record of two NDA approvals and advanced orphan drugs pipeline. We successfully developed pioneer topical drugs Twyneo and Epsolay, respectively approved for the treatments of acne and inflammatory lesions of rosacea. Since 2022, both products have been marketed in the United States by our U.S. commercial partner, Galderma. In terms of our proprietary assets in development, we are developing topical patidegib (SGT-610) for the prevention of new BCC in Gorlin syndrome patients, and topical erlotinib (SGT-210) for the treatment of rare hyperkeratinization disorders.

Gorlin syndrome is a rare disease with no therapies currently approved by the FDA or the EC for this disease. Gorlin syndrome affects approximately 1 in 31,000 people and is an autosomal dominant genetic disorder, mostly caused by inheritance of one defective copy of the tumor suppressor gene PTCH1. The PTCH1 gene blocks the SMO gene, turning off the hedgehog signaling pathway when it is not needed. However, mutations in PTCH1 may cause loss of PTCH1 function, release of SMO, and may allow BCC tumor cells to divide uncontrollably. Gorlin syndrome is also called nevoid BCC syndrome because approximately 90% of individuals with this syndrome develop multiple BCCs, ranging from a few to many thousands of lesions during a patient's lifetime. Gorlin syndrome patients are also susceptible to many abnormalities, including, most frequently, palmar and plantar pits and jaw cysts, and, most devastatingly, medulloblastomas.

We are developing the new chemical entity SGT-610 (Patidegib Topical Gel), a hedgehog signaling pathway blocker, for the chronic use and prevention of new BCC in Gorlin syndrome patients. Gorlin syndrome is a rare disease with no therapies approved by the FDA or the EC for this disease. SGT-610 is aimed to prevent new BCCs in adults with Gorlin syndrome without systemic adverse events. We believe it has the potential to be the first drug approved for the treatment of Gorlin syndrome patients. SGT-610 has been granted Orphan Drug Designation by the FDA and the EC as well as Breakthrough Designation by the FDA. If approved by the FDA, SGT-610 has the potential to generate, at peak, annual net sales in excess of $300 million (based on good faith estimates derived from our knowledge and based in part on independent sources). Although we believe such data and estimate to be reliable, it involves a number of assumptions and limitations, including without limitations the number of patients, the penetration level of the treatment, and the expected treatment annual price.

On November 30, 2023 we announced that we have begun screening patients for our Phase 3 study. In the patidegib's seller, PellePharm Inc. ("PellePharm") study the SGT-610 arm was found to be as tolerable as the vehicle and the significant adverse events commonly seen with oral hedgehog inhibitors were not observed. Our clinical study includes essential modifications to the former Phase 3 study conducted by PellePharm. We have refined screening criteria in order to enroll subjects with more severe disease at baseline reflected in a higher baseline number of facial BCC lesions. This refinement may help to better demonstrate the preventive effect of our medication candidate. We are also pre-screening patients for a specific genetic mutation associated with Gorlin syndrome that is considered relevant for HH inhibitors. In an effort to increase patient study compliance we reduced the number of study visits over the 12 months of treatment. We plan to conduct the Phase 3 study to investigate SGT-610 in approximately 140 subjects at approximately 40 experienced clinical centers in North America, United Kingdom and Europe. We currently expect results of our Phase 3 study by the end of 2025.

The rights to SGT-610 were purchased on January 30, 2023, pursuant to an asset purchase agreement with PellePharm, dated January 23, 2023.

Twyneo, is a once-daily, non-antibiotic topical cream, containing a fixed-dose combination of encapsulated benzoyl peroxide, or E-BPO, and encapsulated tretinoin for the treatment of acne. 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. 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. Twyneo was approved for marketing by the FDA in July 2021in the United States and was licensed to Galderma exclusively in the United States in June 2021.

Epsolay, is a once-daily topical cream containing 5% encapsulated benzoyl peroxide, that we have developed for the treatment of inflammatory lesions of rosacea in adults. 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 in 2017, 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. 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. Epsolay, is the first product containing BPO that is marketed for the treatment of subtype II rosacea. Epsolay was approved for marketing by the FDA in April 2022 and was licensed to Galderma exclusively in the United States in June 2021.

Our other investigational product candidate is SGT-210 that we are developing for the treatment of rare hyperkeratinization disorders, such as Darier PC, PPK, and Olmsted, a group of skin conditions characterized by thickening of the skin, among others. SGT-210 is designed to be used alone or in combination for the treatment of hyperproliferation and hyperkeratinization disorders.

In June 2021, we entered into two five-year exclusive license agreements with Galderma pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo and Epsolay. Pursuant to the agreement, we received $11 million in upfront payments to and regulatory approval milestone payments. We are also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments. We also expect to collaborate with third parties that have sales and marketing experience in order to commercialize Epsolay and Twyneo outside of the United States and our investigational product candidates, if approved by the FDA for commercial sale, in lieu of our own sales force and distribution systems. 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 June 2023, we entered into exclusive license agreements with Searchlight pursuant to which the agreements, Searchlight has the exclusive right, and is responsible for, all commercial activities for Twyneo and Epsolay in Canada, over a fifteen-year term that is renewable for subsequent five-year periods. Searchlight will be responsible for obtaining and maintaining ay regulatory approvals required to market and sell the drugs in Canada with support from us. In consideration for the grant of such rights, we will receive up to $11 million in potential upfront payments and regulatory and sales milestones for both drugs, combined. In addition, we will be entitled to royalty percentages of all Canadian net sales ranging from low-double-digits to high teens.

In November 2021, we announced that we had signed an agreement with Padagis, pursuant to which we sold our rights related to 10 generic collaborative programs and retained the collaboration rights to two generic programs. Under the terms of the agreement with Padagis, effective as of November 2021, we received $21.5 million over 24 months, in lieu of our share in ten generic programs, two of which were approved by the FDA, and eight of which are unapproved. Pursuant to the agreement, effective as of November 1, 2021, we ceased paying any outstanding and future operational costs related to those collaborative programs, the rights of which were sold to Padagis.

In January 2023, we entered into an asset purchase agreement with PellePharm, pursuant to which we purchased the topically-applied patidegib, a hedgehog signaling pathway blocker, for the treatment of Gorlin syndrome. Under the terms of the agreement upon closing of the transaction, the Company paid an upfront payment of $4 million to PellePharm, the remaining principal amount outstanding of $0.7 million has not been transferred as of the issuance date of this report. We are also required to pay:

- up to $6 million in total development and NDA acceptance milestone payments;
- up to $64 million in commercial milestone payments, which amount increases to $89 million when sales exceed $500 million; and
- single digit royalties, which increase to double digit royalties when sales exceed $500 million.

Since our inception, we have incurred significant operating losses. We generated a net profit of $3.2 million for the year ended December 31, 2021, and we incurred a net losses of $14.9 million and $ 27.2 million for the years ended December 31, 2022 and December 31, 2023, respectively. As of December 31, 2023, we had an accumulated deficit of $220.3 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, we completed an underwritten public offering, in which we 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. we completed an underwritten public offering in which we 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 expired 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 our shareholders, Arkin Dermatology Ltd., our controlling shareholder, 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, 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.

On January 27, 2023, we entered into a securities purchase agreement with Armistice Capital pursuant to which the Company issued to Armistice Capital (i) 2,560,000 ordinary shares in a registered direct offering at a price of $5.00 per ordinary share and (ii) in a concurrent private placement unregistered warrants to purchase up to 2,560,000 Ordinary Shares. The gross proceeds from the offering were approximately $12.8 million. Concurrently with the signing of the purchase agreement, we also entered into a subscription agreement with Arkin Dermatology Ltd., pursuant to which Arkin Dermatology Ltd. purchased 2,000,000 unregistered ordinary shares and unregistered warrants to purchase up to 2,000,000 ordinary shares in a concurrent private placement exempt from the registration of the Securities Act, at a price equal to the offering price of the ordinary shares in the offering. This private placement closed in April 2023 following shareholder approval. The aggregate gross proceeds to us from the transaction with Armistice Capital and Arkin Dermatology Ltd. were approximately $22.8 million.

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. We were previously a party to collaboration agreements with Perrigo pursuant to which we shared development costs with Perrigo and shared equally the gross profits generated from sales of the product. During the years ended December 31, 2019 and December 2020, the Company recognized revenues from royalties related to sales of one of the products from this collaboration in the amount of $22.9 million and $8.7 million, respectively. During the year ended December 31, 2021, we generated a total of $31.3 million in revenue, out of which $20.4 million was generated from the sale to Padagis of 10 generic collaborative programs, $3.3 million was generated from our collaboration agreements with Perrigo, with respect to products the rights for which were later sold to Padagis, and $7.5 million was generated from our license agreements with Galderma. During the years ended December 31, 2022 and 2023, we recognized revenues from royalties and milestone payment related to our collaboration agreements with Galderma and Searchlight in the amount of $3.9 million and $1.6 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 Twyneo, Epsolay and 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 product candidates' commercial potential. As we obtain results from clinical trials, we or our partners 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.

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,		
	2021	2022	2023
	(in thousands)		
Collaboration Revenues	$ 23,772	$	$
License Revenues	7,500	3,883	1,554
Total Revenues	$ 31,272	$ 3,883	1,554
Research and development	20,381	12,682	23,541
General and administrative	8,451	7,445	7,373
OTHER INCOME, net	524	-	55
Total operating income (loss)	2,964	(16,244)	(29,305)
Financial income, net	257	1,321	2,067
Income (Loss) before income taxes	3,221	(14,923)	(27,238)
Income (loss) for the year	$ 3,221	$ (14,923)	$ (27,238)

Year ended December 31, 2022 compared to year ended December 31, 2023

Revenues

We generated a total of $1.6 million in revenues in 2023, mainly related to the license agreements with Galderma and Searchlight, comprised of milestone and royalty payments, compared with $3.9 million total revenues in 2022. The decrease in revenues in 2023 resulted mainly from the milestone payment from Galderma in the amount of $3.5 million in relation to FDA approval of Epsolay in 2022.

Research and development expenses

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

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Payroll and related expenses	$ 6,530	$ 5,650
Clinical and preclinical trials expenses	602	5,745
Professional consulting and subcontracted work	2,173	10,134
Other	3,376	2,012
Total research and development expenses	$ 12,682	$ 23,541

Our research and development expenses were $12.7 million for the year ended December 31, 2022 compared to $23.5 million for the year ended December 31, 2023. The increase of $10.9 million was primarily attributed to the $4.7 million upfront payment associated with the acquisition of topically applied patidegib, or SGT-610, $4.2 million related to the pivotal Phase 3 clinical trial for SGT-610 and $2.8 million related to clinical expenses for a generic product.

General and administrative expenses

Our general and administrative expenses were $7.4 million for the year ended December 31, 2022, compared to $7.4 million for the year ended December 31, 2023.

Financial income, net

Our financial income, net, was $1.3 million for the year ended December 31, 2022 compared to $2.1 million for the year ended December 31, 2023.

Year ended December 31, 2021 compared to year ended December 31, 2022

This analysis can be found in Item 5 of the Company's Annual Report on Form 20-F for the year ended December 31, 2022.

JOBS Act

On April 5, 2012, the JOBS Act was signed into law. Subject to certain conditions set forth in the JOBS Act, an "emerging growth company," 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). Although we have ceased to be an "emerging growth company" and accordingly we are no longer exempt from the requirement to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding supplement to the auditor's report providing additional information about the audit and the financial statements. Due to our 'public float' we are currently exempt from the requirement to provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404.

B. Liquidity and Capital Resources

Overview

Since our inception, we have devoted substantially all of our resources to developing Twyneo, Epsolay, SGT-610, and 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. Other than Twyneo and Epsolay, we do not currently have any approved products.

From inception through December 31, 2023, 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. As of December 31, 2023, our cash and cash equivalents, bank deposits and marketable securities were $38.0million.

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

From the effective date of the agreement through April 2022, 41,154 shares were sold under the program for total gross proceeds of approximately $0.5 million. In April 2022, we terminated this agreement.

On January 27, 2023, we entered into a securities purchase agreement with Armistice Capital pursuant to which we issued to Armistice Capital (i) 2,560,000 ordinary shares in a registered direct offering at a price of $5.00 per ordinary share and (ii) in a concurrent private placement unregistered warrants to purchase up to 2,560,000 Ordinary Shares. Concurrently with the signing of the purchase agreement, we also entered into a subscription agreement with Arkin Dermatology Ltd., pursuant to which Arkin Dermatology Ltd. purchased 2,000,000 unregistered ordinary shares and unregistered warrants to purchase up to 2,000,000 ordinary shares in a concurrent private placement exempt from the registration of the Securities Act, at a price equal to the offering price of the ordinary shares in the offering. The aggregate gross proceeds to the Company from these transactions were approximately $22.8 million.

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

	Year Ended December 31,		
	2021	2022	2023
	(in thousands)		
Net cash used in operating activities	$ (7,691)	(9,484)	$ (17,730)
Net cash provided by (used in) investing activities	19,872	1,699	(9,742)
Net cash provided by financing activities	837	15	21,810
Effect of exchange rates on cash and cash equivalents	$ (55)	133	(73)
Increase (decrease) in cash and cash equivalents	$ 12,908	$ (7,637)	$ (5,735)

Operating Activities

Net cash used in operating activities was $9.5 million during the year ended December 31, 2022 compared to $17.7million during the year ended December 31, 2023.

Net cash used in operating activities in the year ended December 31, 2023 primarily resulted from our loss of $27.2 million during the period, net of $7.7 million of net changes in working capital and non-cash expenses of $1.9 million share-based compensation expenses and $0.3 million of depreciation of property and equipment.

Net cash used in operating activities in the year ended December 31, 2022, primarily resulted from our net loss of $14.9 million during the period, net of $3.5 million of net changes in working capital and non-cash expenses of $1.5 million share-based compensation expenses and $0.6 million of depreciation of property and equipment.

Investing Activities

Net cash provided by investing activities was $1.7 million during the year ended December 31, 2022, compared to net cash used in investing activities of $9.7 million during the year ended December 31, 2023. The 2022 net cash provided by investing activities resulted mainly from $10 million investments in marketable securities, net of $3 million proceeds from sale and maturity of marketable securities, offset by proceeds from bank deposits of $8.9 million. The 2023 net cash used in investing activities resulted mainly from $23.2 million investments in marketable securities net of $11.8 million proceeds from sale and maturity of marketable securities, offset by proceeds from bank deposits of $1.7 million.

Financing Activities

Net cash from financing activities was effectively none during the year ended December 31, 2022, , compared to $21.8 million during the year ended December 31, 2023, mainly from issuance of shares and warrants through public offering and private placement from the controlling shareholder, net of issuance cost.

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 the net proceeds from the 2023 registered direct offering and the concurrent private placement, together with its existing cash resources, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the filing date of this annual report. 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. Recently, based on lower than expected future revenue streams from Twyneo and Epsolay and a delay in the development of SGT-210, we adopted cost-saving measures, including a headcount reduction of about 25 employees, to maintain the cash runway for at least 12 months from the filing date of this annual report, and delayed the planned clinical study for SGT-210.

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; and
- the expenses of, and timing for, expanding our manufacturing agreements for production of sufficient clinical and commercial quantities of our product candidates.

Other than revenue that we expect to generate from the commercialization of Twyneo and Epsolay, 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 our products. 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, 2022 compared to Year ended December 31, 2023 - 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, 2023 to December 31, 2023 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. Critical Accounting Policies

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, 2023, 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. The Company calculates the fair value of stock-based option awards on the date of grant using the Black-Scholes option pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected share price volatility and the expected option term. The computation of expected volatility is based on historical volatility of the Company's shares and of similar companies in the healthcare sector. The expected option term is calculated using the simplified method, as the Company concludes that its historical share option exercise experience does not provide a reasonable basis to estimate its expected option term. The interest rate for periods within the expected term of the award is based on the U.S. Treasury yield curve in effect at the time of grant. The Company's expected dividend rate is zero since the Company does not currently pay cash dividends on its shares and does not anticipate doing so in the foreseeable future. Each of the above factors requires the Company to use judgment and make estimates in determining the percentages and time periods used for the calculation. If the Company were to use different percentages or time periods, the fair value of stock-based option awards could be different. The fair values of the Company's RSUs are measured based on the fair value of the Company's ordinary shares on the date of grant.

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	71	Executive Chairman of the Board of Directors
Alon Seri-Levy	62	Chief Executive Officer and Director
Gilad Mamlok	55	Chief Financial Officer
Ofer Toledano	59	Vice President Research and Development
Ofra Levy-Hacham	57	Vice President Clinical, Regulatory Affairs and Quality
Michael Glezin	42	Vice President Business Development
Karine Neimann	52	Vice President Projects and Planning, Chief Chemist
Itzik Yosef	47	Chief Operating Officer
Tamar Fishman Jutkowitz	48	Vice President and General Counsel
Itai Arkin	35	Director
Hani Lerman	51	Director
Sharon Kochan	55	Director
Jonathan B. Siegel	50	Independent Director
Ran Gottfried	79	Lead Independent Director
Jerrold S. Gattegno	71	Independent Director
Yuval Yanai	71	Independent Director

Mr. Moshe Arkin has served as chairman of our board of directors since 2014. in May 2022 Mr. Moshe Arkin's role has been expanded to Executive Chairman to reflect Mr. Arkin's expanded role at the Company. Mr. Moshe Arkin currently sits on the board of directors of several private pharmaceutical and medical device companies including 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. Mr. Mamlok has over two decades of track record in public and private companies and the public sector. Mr. Mamlok served as a member of the senior management team of leading technology companies and worked closely with CEO's and Board of Directors. In 2015 to 2016, Mr. Mamlok served as the CFO of Medigus (NASDAQ: MDGS). From September 2005 to July 2015, Mr. Mamlok served as Senior Vice President of Global Finance and Accounting at Given Imaging (NASDAQ: GIVN, sold to Medtronic in 2014 (NYSE: MDT). Before that, from 2002 to 2005, Mr. Mamlok served in a few CFO positions at Medical device companies (Simbionix, Impulse Dynamics, and MetaCure), and from 1997-2001, Mr. Mamlok served as a Director of Finance at Nice Systems. (Nasdaq: NICE). 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 quality, clinical and regulatory affairs since January 2024, 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.

Mr. Michael Glezin has served as our vice president of business development since September 2022. Prior to joining Sol-Gel Mr. Glezin served from 2011 to 2022 as the Head of Generic Business Development and in various other business development positions at Dexcel Pharma, an international specialty pharmaceutical company. Mr. Glezin has over a decade of experience leading both in-licensing and out-licensing deals in multiple territories such as Europe,the U.S. and Israel. Throughout his career, he has identified technology transfer opportunities for both prescription and over-the-counter drug segments, as well as led numerous merger and acquisition deals in Europe and surrounding areas. Mr. Glezin has an Executive MBA from Haifa University in Israel in partnership with Tongi University in China. He has a BA from Haifa University in Economics and Management and he studied Accounting at Bar Ilan University.

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 Chief Operating Officer since 2020, and as our vice president of operations since from 2016 until 2020. 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.

Adv. Tamar Fishman Jutkowitz joined us as our vice president and general counsel in March 2023. From August 2015 to March 2023, Ms. Fishman Jutkowitz worked at Gross & Co. Law Firm, where she was a partner from January 2018. From December 2011 to March 2015, Ms. Fishman Jutkowitz served as general counsel of Compugen Ltd., a biotechnology company dual listed on Nasdaq and TASE. From February 2006 to December 2011, Ms. Fishman Juktowitz served as General Counsel of Rosetta Genomics Ltd., a biotechnology company listed on Nasdaq. Ms. Fishman Jutkowitz holds a Master's degree in business economics from Bar Ilan University and a L.L.B degree (cum laude) from Bar-Ilan University, Israel.

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. 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.

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 served as a board member of Exalenz Bioscience and of Sphera Global Healthcare. 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.

Mr. Sharon Kochan became a member of our board of directors in June 2023. Mr. Kochan serves as Operating Director with SK Capital Partners of NYC, board member of Apotex Inc. of Toronto, and Woodstock Sterile Solutions Inc. of Chicago since January 15th, 2024, as well as Director with Top Gum Industries Ltd. (TASE). Prior to that, Mr. Kochan has served as President and CEO of Padagis LLC from its incorporation in July 2021, when it was carved out of Perrigo Company Plc. ("Perrigo"), a global, over-the-counter, consumer goods and specialty pharmaceutical company listed on the New York Stock Exchange, until February 2023. Prior to that, Mr. Kochan served as Executive Vice President & President Pharmaceuticals from 2018 for Perrigo, President International, from 2012 until 2018, and President Prescription Pharmaceuticals from 2007. From 2005 to 2007, Mr. Kochan served as Senior Vice President of Business Development and Strategy for Perrigo. Mr. Kochan was Vice President, Business Development of Agis Industries (1983) Ltd. ("Agis") from 2001 until Perrigo acquired Agis in 2005. Mr. Kochan has served as a board member of MediWound Ltd. from July 2017 to June 2023 and served as a board member of Exalenz BioScience Ltd. from July 2016 to March 2020 when it was acquired by Meridian. Mr. Kochan completed the Senior Management Program at the Technion Institute of Management in Haifa, Israel, received a Master of Science in Operations Research & Management Science from Columbia University in New York City and received a Bachelor of Science in Industrial Engineering from Tel-Aviv University, Israel.

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 its formation in 2017. In June 2021, he also assumed the role as CEO and Chairman of the board of OPY Acquisition Corp. I, that was a public Nasdaq-listed company between October 2021 and December 2023. 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 since 2018, and has served on the board of advisors of Vitalis LLC, a private pharmaceutical company, since March 2019 and as a director of Napo Therapeutics S.p.A, the majority owned Italian subsidiary of Napo Pharmaceuticals and Jaguar Health, Inc. since November 2021. 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 and as the lead independent director. 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 served as a director at Shufersal Ltd from 2018 until 2022.

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 a managing partner in Deloitte's Washington National Tax Office, as the partner-in-charge and founding partner of Deloitte's multistate tax practice 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.

Mr. Yuval Yanai became a member of our board of directors in February 2024. Mr. Yanai currently serves as a director in multiple companies, both public and private. He is currently a director and the Chairman of the Audit Committee, Chairman of the Finance Committee and Chairman of the Compensation Committee of Check-Cap Ltd., a medical company traded on Nasdaq Stock Market; an external director and Chairman of the Finance (Balance Sheet), Compensation and Audit Committee of Clal Biotechnology Industries, an Israeli life sciences investment company traded on the Tel Aviv Stock Exchange; a director in S&P Global Ratings Maalot Ltd., a finance rating company; and a director in PulseNmore Ltd., a medical device company traded on the Tel Aviv Stock Exchange. Mr. Yanai also serves as a director at a number of private medical companies. From 2005 until 2014, Mr. Yanai served as CFO of Given Imaging Ltd., a medical company traded on Nasdaq Stock Marketand on the Tel Aviv Stock Exchange, and from 2000 until 2005. Mr. Yanai served as Senior Vice President and CFO of Koor Industries Ltd., an industrial holding company traded on the New York Stock Exchange and on the Tel Aviv Stock Exchange. From 1998 until 2000, Mr. Yanai served as CFO of Nice Systems Ltd., a technology company traded on the Nasdaq Stock Market, and from 1985 until 1998, Mr. Yanai served as CFO of Elscint Ltd., a technology company traded on the New York Stock Exchange. Mr. Yanai holds a B.A. in accounting and finance from Tel-Aviv University, Israel.

B. Compensation

The aggregate compensation paid by us to our executive officers and directors for the year ended December 31, 2023 was approximately $2.7 million. This amount includes approximately $0.4million 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, 2023. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2023.

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 2023 monthly average representative U.S. dollar – NIS rate of exchange)					
Alon Seri-Levy / Chief Executive Officer	325	63	787	23	1,198
Gilad Mamlok / Chief Financial Officer	263	54	276	50	643
Ofer Toledano / VP R&D	205	57	196	24	482
Ofra Levy-Hacham / VP Clinical, RA & QAA	172	49	157	24	403
Itzik Yosef / Chief Operating Officer	163	47	52	26	288

(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 2023.

(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 2023 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 2021, 2022 and 2023 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 "Item 6. Directors, Senior Management and Employees - C. Board Practices – Exculpation, Insurance and Indemnification of Directors and Officers".

Director Compensation

We currently pay our external directors and our other independent directors is as follows: (i) $40,000 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).

In addition, in 2018 and 2019 each of our external directors and our other independent directors received an aggregate of 11,500 Restricted Share Units ("RSUs") for the first three years of their service as a director, with a three-year vesting and in accordance with the Company's 2014 Share Incentive Plan, in 2021 each of our external directors and our other independent directors received 45,000 options ("Options"), at an exercise price of $10.02 with a three-year vesting and in accordance with the Company's 2014 Share Incentive Plan. On February 28, 2024 our shareholders approved the grant of options to purchase 75,000 ordinary shares of the Company at an exercise price equal to $1.20 per ordinary share to each of our external and independent directors (other than Mr. Jerrold S Gattegno whose term of office ends on March 22, 2024) with a three-year vesting and in accordance with the Company's 2014 Share Incentive Plan.

There is no limit regarding the number and/or hours of meetings, and the director compensation includes all meetings of the Board and any Board's committees. 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, and was amended on our annual general meetings held on June 23, 2022 and on July 26, 2023, 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. Our compensation policy for the following maximum base salaries: (i) for a Company CEO resident in Israel, a maximum monthly base salary not exceeding NIS 120,000 and total fixed and variable compensation (including equity based compensation) not to exceed NIS 5 million per year; (ii) for Company executive officers (other than Board of Directors member or CEO) resident in Israel, a monthly base salary not exceeding NIS 90,000; (iii) for a Company CEO resident in the U.S. or another location outside of Israel, such base salary as shall be determined by the shareholders pursuant to applicable law; and (iv) for Company executive officers (other than Board of Directors member or CEO) resident in the U.S. or another location outside of Israel, an annual base salary not exceeding USD 400,000, in each case subject to increases in the consumer price index in the relevant jurisdiction in which the executive resides. For purposes of calculating the maximum fixed and variable compensation each year, the value of any equity award will be allocated equally over the number of years during which such equity award vests 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 provides for the following maximum compensation of our external directors and our other independent directors: (i) $67,275 annually in cash; (ii) $7,475 annually in cash for service on each of the Audit Committee and/or Compensation Committee (as the case may be), (iii) $37,375 annually in cash for service as chairman of the Board, (iv) $14,950 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), and (v) $14,950 annually in cash for service as a lead independent director (all cash amounts to be paid quarterly). Equity based-compensation granted to the Company's directors shall not exceed 55% of the total compensation paid to the Company's directors. 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.

Policy for Recovery of Erroneously Awarded Compensation

In accordance with the Nasdaq listing rules, our Company has adopted a Policy for Recovery of Erroneously Awarded Compensation, or a Clawback Policy, which became effective as of October 2, 2023.

C. Board Practices

Appointment of Directors and Terms of Officers

Our board of directors currently consists of nine directors, including three external directors, and appointment fulfills the requirements of the Companies Law for the company to have two external directors (see "Item 6. Directors, Senior Management and Employees - C. Board Practices – External Directors"). These three directors, as well as two 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 (10), 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, the Israeli Companies Law and our articles of association provide that directors are elected annually at the general meeting of our shareholders by a vote of the holders of a majority of the voting power represented present and voting, in person or by proxy, at that meeting. We have only one class of directors. Mr. Ran Gottfried , Mr. Jerrold S Gattegno and Mr. Yuval Yanai currently serve as our external directors. On February 28, 2024, Mr. Ran Gottfried was re-appointed, and Mr. Yuval Yanai was appointed, as external directors for a term of three years. Mr. Gattegno's term as external director ends on March 22, 2024.

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 "Item 6. Directors, Senior Management and Employees - C. Board Practices – 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 "Item 6. Item 6. Directors, Senior Management and Employees - C. Board Practices – 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, Sharon Kochan, and Yuval Yanai, Yuval Yanai 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 each of Jerrold S. Gattegno, Mr. Ran Gottfried and Mr. Yuval Yanai 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 "Item 6. Directors, Senior Management and Employees - C. Board Practices – 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, Mr. Yuval Yanai 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 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 appointed Mr. Oren Grupi, CPA, who serves as partner at KPMG Somekh Chaikin, as 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 "Item 6. Directors, Senior Management and Employees - C. Board Practices – 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:

- 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 to disclose the compensation of our chief executive officer and certain other 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 "Item 6. Directors, Senior Management and Employees - C. Board Practices – 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, 2023, we had 36 employees, all of whom are located in Israel.

	As of December 31,					
	2021		2022		2023	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management	9		9		8	
Research and development and other	44		46		28	

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. Major Shareholders and Related Party Transactions – 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 March 1, 2024, we had an aggregate of 641,914 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, 2022, options to purchase 2,053,296 ordinary shares, at a weighted average exercise price of $6.78 per share, were outstanding under our Plan.

F. Disclosure of a registrant's action to recover erroneously awarded compensation

None.

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 March 1, 2024 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 March 1, 2023, 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 27,857,620 ordinary shares outstanding as of March 1, 2024.

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)	18,068,564	60.52%
Migdal Insurance & Financial Holdings Ltd. (2)	1,227,548	4.40%
Phoenix Holdings Ltd. (3)	2,574,922	9.24%
Directors and executive officers		
Moshe Arkin (1)	18,154,564	61.35%
Alon Seri-Levy (4)	322,722	1.15%
Gilad Mamlok	*	*
Ofer Toledano	*	*
Ofra Levy-Hacham	*	*
Karine Neimann	*	*
Itzik Yosef	*	*
Itai Arkin	*	*
Ran Gottfried	*	*
Jerrold S. Gattegno	*	*
Hani Lerman	*	*
Jonathan Siegel		
Sharon Kochan	*	*
Yuval Yanai	*	*
All directors and executive officers as a group (14 persons)	18,186,836	62.50%

* Less than 1%.

(1) Arkin Dermatology directly owns 16,068,564 ordinary shares and 2,000,000 warrants to purchase up to 2,000,000 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 January 31, 2024, the ordinary shares are beneficially owned by, among others, (i) provident funds, mutual funds, pension funds and insurance policies, which are managed by direct and indirect subsidiaries of Migdal Insurance & Financial Holdings Ltd, each of which operates under independent management and makes independent voting and investment decisions, (ii) companies for the management of funds for joint investments in trusteeship, each of which operates under independent management and makes independent voting and investment decisions, and (iii) their own account (Nostro account).

(3) Based on the Schedule 13G/A filed with the SEC on February 12, 2024, 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.

(4) Consists of options to purchase 322,722 ordinary shares exercisable within 60 days of March 1, 2024. The exercise price of these options ranges between $1.59 and $11.21 per share and the options expire between March 2025 and July 2033.

Record Holders

As of March 1, 2024, 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, 13,667,923 ordinary shares, representing approximately 49.0% of the outstanding ordinary shares as of March 1, 2024. 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 January 27, 2023, we entered into subscription agreement with Arkin Dermatology Ltd., pursuant to which Arkin Dermatology Ltd. agreed to purchase 2,000,000 unregistered ordinary shares and unregistered warrants to purchase up to 2,000,000 ordinary shares in a concurrent private placement exempt from the registration of the Securities Act, at a price equal to the offering price of the ordinary shares in the January 2023 registered direct offering. Each of the warrants issued to Arkin Dermatology is exercisable for one ordinary share, has an initial exercise price of $5.85 per share, is exercisable beginning six months from the date of issuance and will expire on January 27, 2028 and is subject to certain adjustments. This private placement closed in April 2023 following shareholder approval.

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 were party to 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. This registration rights agreement expired on February 5, 2023. Our audit committee and board of directors have approved the renewal of the registration rights agreement on substantially the same terms as the agreement that expired, and our shareholders approved this renewal at a special shareholder meeting held on March 30, 2023.

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, 2022.

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 March 13, 2024, the last reported closing price of our Ordinary Shares on The Nasdaq Global Market was $1.055 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 (10) 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, we have only one class of directors. 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 a year, and may be elected for additional terms of a year except in the case of external directors whose terms of office are governed by the Israeli Companies Law, 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, subject to certain exceptions with respect to the buyback by the Company of its ordinary shares, 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) 10% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 10% or more of our outstanding voting power.

Under Israeli law, one or more shareholders holding at least 5% of the voting rights at a general meeting of shareholders may request that our board of directors include a proposal that relates to the election or removal of a director in the agenda of a general meeting of shareholders to be convened in the future. 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 any other 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 60 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 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.

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."

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 Equinity 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 2023. 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 certain income (such as from defense loans, capital gains, interest and dividends) is derived from an "Industrial Enterprise" owned by it and which is located in Israel or in the "Area" (as defined under Section 3A of the Israeli Tax Ordinance). 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 were purchased in good faith and are used for the development or advancement of the Industrial Enterprise, commencing on the year in which they were first used;
- 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 commencing on the year of the offering.

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 research and 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 2024 (iii) non-Israeli residents — 20%, which may be reduced down to 4% in 2024, 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. 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.

New Tax benefits under the 2017 Amendment that became effective on January 1, 2017.

The 2017 Amendment was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and was effective as of January 1, 2017. The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a Preferred company satisfying certain conditions will qualify as having a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income," as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in development zone A. In addition, a Preferred Company qualified as having a "Preferred Technological Enterprise" will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the National Authority for Technological Innovation (previously known as the Israeli Office of the Chief Scientist), to which we refer as IIA.

The 2017 Amendment further provides that a Preferred company satisfying certain conditions (including group consolidated revenues of at least NIS 10 billion) may qualify as having a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by the Special Preferred Technology Enterprise or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from IIA. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, 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 (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld. If such dividends are distributed to a foreign company and other conditions are met, the withholding tax rate will be 4%.

We currently are not entitled to tax benefits under the 2017 Amendment.

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 2024.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income —23% for corporations in 2024, 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 2024) 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, provided that (among other conditions) (i) such income was not generated from business conducted in Israel by the taxpayer, (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed and an advance payment does not need to be made, and (iii) the taxpayer is not obligated to pay Excess Tax (as further explained below). 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 (among other conditions) (i) such income was not generated from a business conducted in Israel by the taxpayer, (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed, and (iii) the taxpayer is not obligated to pay Excess Tax (as further explained below).

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 721,560 for 2024 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

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

We believe that we were a passive foreign investment company, or PFIC, for our 2023 taxable year. A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will generally be a 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 cash or other 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.

Because the value of our assets for purposes of the PFIC asset test will generally be determined by reference to the market price of our ordinary shares, based on the value and composition of our assets for our 2023 taxable year (including, in particular, the size of our cash and other passive assets) and the changes in the market price of our ordinary shares during our 2023 taxable year, we expect that we will be treated as a PFIC for U.S. federal income tax purposes for our 2023 taxable year.

A separate determination must be made after the close of each taxable year as to whether we were a PFIC for that year. Depending on the market price of our ordinary shares and the composition of our assets, our status as a PFIC may change in subsequent years. However, if we are or were a PFIC for any taxable year during your holding period for our ordinary shares (or under proposed U.S. Treasury 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. You are advised to consult your own tax advisor regarding the potential availability of a "deemed sale" election that would allow you to eliminate this continuing PFIC status under certain circumstances.

For each taxable year that we are treated as a PFIC with respect to you, you will be subject to adverse consequences under 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 or "qualified electing fund" election, each as discussed below, and each of 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 or were 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, or QEF election, to include in income its share of the entity's income on a current basis. A U.S. Holder of our ordinary shares can make a QEF election, if we provide the certain necessary information with respect to our annual ordinary earnings and net capital gain, in the first taxable year that we are treated as a PFIC with respect to the U.S. Holder. A U.S. Holder must make the QEF election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to its timely filed U.S. federal income tax return. We plan to provide upon request or otherwise make available the information necessary for a U.S. Holder to make a QEF election with respect to us and will use commercially reasonable efforts to cause each lower-tier PFIC which we control, if any, to provide such information with respect to such lower-tier PFIC. However, no assurance can be given that such information will be available for any lower-tier PFIC.

If you make a QEF election with respect to a PFIC, you will be currently taxable on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC. If you make a QEF election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in your income as a result of the QEF election will not be taxable to you. You will increase your tax basis in our ordinary shares by an amount equal to any income you have included as a result of the QEF election and will decrease your tax basis in our ordinary shares by any amount distributed on the ordinary shares that you have not included in your income. In addition, you will recognize capital gain or loss on the disposition of our ordinary shares in an amount equal to the difference between the amount realized and your adjusted tax basis in our ordinary shares. You should note that if you make QEF elections with respect to us and any lower-tier PFICs, you may be required to pay U.S. federal income tax with respect to our ordinary shares for any taxable year significantly in excess of any cash distributions received on your ordinary shares for such taxable year.

A QEF election may not be available for our warrants regardless of whether we provide the information described above. You are strongly advised to consult your own tax advisors regarding making QEF elections in your particular circumstances.

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 OR QUALIFIED ELECTING FUND 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. There are additional significant and complex limits on a U.S. Holder's ability to claim foreign tax credits, and recently issued U.S. Treasury regulations that apply to foreign income taxes further restrict the availability of any such credit based on the nature of the tax imposed by the foreign jurisdiction. 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.

Although there is no direct legal authority as to the U.S. federal income tax treatment of an exercise of our warrants on a cashless basis, if required to do so, we intend to take the position that such exercise will not be taxable, either because the exercise is not a gain realization event or because it qualifies as a tax-free recapitalization. In the former case, the holding period of our ordinary shares received upon exercise of the warrants should commence on the day after the ordinary warrants are exercised. In the latter case, the holding period of our ordinary shares received upon exercise of the ordinary warrants would include the holding period of the exercised ordinary warrants. However, such position is not binding on the IRS, and the IRS may treat a cashless exercise of the ordinary warrants as, in part, a taxable exchange. U.S. Holders are urged to consult their tax advisors as to the consequences of an exercise of the ordinary warrants on a cashless basis, including with respect to potential treatment as a taxable disposition of warrants for PFIC purposes, and the holding period and tax basis in our ordinary shares received.

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 more than half of our expenses in the year ended December 31, 2023, 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 2.33% during the fiscal year ended on December 31, 2023. 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, 2023 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, 2023.

(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, 2023 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that each of Mr. Jerrold S. Gattegno, Mr. Ran Gottfried and Mr. Yuval Yanai is an audit committee financial expert. Mr. Gattegno Mr. Ran Gottfried and Mr. Yuval Yanai, are independent directors 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	**2023**	**2022**
	(U.S. dollars in thousands)	
Audit Fees (1)	220	189
Tax (2)	7	19
Other (3)	2	1
Total	229	204

(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.

(3) Other fees relate to license fees for use of accounting research tools.

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 do not expect to, 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 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. See "Item 6. Directors, Senior Management and Employees — C. Board Practices."

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

Pursuant to applicable SEC transition guidance, the disclosure required by Item 16J will only be applicable to the Company from the fiscal year ending on December 31, 2024.

ITEM 16K. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the best common practice for our industry, ISO 27001 standards and SOX requirements. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the ISO 27001 and SOX requirements as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.]

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment;
- a team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors who have access to our critical systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled "Risk Factor— General Risk Factors— Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cyber-security."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function. The Board oversees implementation of our cybersecurity risk management program by management and our external information technology service provider.

The Board receives periodic reports from management on our cybersecurity risks. In addition, management updates the Board, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

Board members receive presentations on cybersecurity topics from our Chief Operating Officer (COO), internal security staff or external experts as part of the Board's continuing education on topics that impact public companies.

Our management team, including our COO and external Information Technologies services provider, are responsible for assessing and managing our material risks from cybersecurity threats. We have outsourced implementation and day-to-day function of our overall cybersecurity risk management program to our third-party information technology services provider. Our management team supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

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 131.

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.
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.
2.3*	Registration Rights Agreement by and between the Registrant and M. Arkin Dermatology Ltd., dated as of March 30, 2023.

4.1	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).
4.2	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).
4.3*	Compensation Policy.
4.4 ∞	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).
4.5∞	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).
4.6∞	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).
4.7∞	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).
4.8∞	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).
4.9∞	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).
4.10∞	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).
4.11∞	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).
4.12∞	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).
4.13*	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of June 25, 2023.
4.14†	License Agreement between Sol-Gel Technologies Ltd. and Galderma Holding SA, dated June 21, 2021 (incorporated by reference to Exhibit 4.19 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 4, 2022).
4.15†	Supply Agreement between Sol-Gel Technologies Ltd., Galderma Holding SA, and Douglas Manufacturing Limited, dated June 21, 2021 (incorporated by reference to Exhibit 4.21 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 4, 2022).
4.16†	Termination Agreement between Padagis Israel Pharmaceuticals Ltd, and Sol-Gel Technologies Ltd., dated November 3, 2021 (incorporated by reference to Exhibit 4.22 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 4, 2022).

4.17†	Termination Agreement between Padagis Israel Pharmaceuticals Ltd, and Sol-Gel Technologies Ltd., dated November 3, 2021 (incorporated by reference to Exhibit 4.23 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 4, 2022).
4.18†^	Asset Purchase Agreement between Sol-Gel Technologies Ltd. and Pellepharm, Inc., dated January 23, 2023 (incorporated by reference to Exhibit 4.23 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 10, 2023).
4.19	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Report of Foreign Private Issuer on Form 6-K submitted to the Securities and Exchange Commission on January 31, 2023).
4.20	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Report of Foreign Private Issuer on Form 6-K submitted to the Securities and Exchange Commission on January 31, 2023).
4.21	Form of Subscription Agreement (incorporated by reference to Exhibit 10.2 of the Report of Foreign Private Issuer on Form 6-K submitted to with the Securities and Exchange Commission on January 31, 2023).
4.22*†	License Agreement between Sol-Gel Technologies Ltd. and Searchlight Pharma Inc. dated June 5, 2023.
4.23*†	License Agreement between Sol-Gel Technologies Ltd. and Searchlight Pharma Inc., dated June 5, 2023.
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.
13.1 *	Certification by Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2 *	Certification by Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1 *	Consent of Independent Registered Public Accounting Firm
97.1 *	Sol-Gel Technologies Ltd. Policy for Recovery of Erroneously Awarded Compensation (*)
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2022, 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.
*	Filed herewith.
†	Certain confidential portions of this exhibit have been redacted from the publicly filed document because such portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.
^	Certain schedules and/or exhibits to this Exhibit have been omitted in accordance with the instructions to Item 19 of Form 20-F. A copy of any omitted schedule and/or exhibit will be furnished supplementally to the Securities and Exchange Commission or its staff upon request.
∞	Informal translation of the original Hebrew document.

The exhibits filed with or incorporated into this Registration Statement are listed in the index of exhibits below.

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 13, 2024

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2023

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2023

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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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 in conformity with accounting principles generally accepted in the United States of America.

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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

Tel-Aviv, Israel
March 13, 2024

/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	
	2022	2023
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 12,448	$ 7,513
Bank deposits	12,500	10,012
Marketable securities	8,678	20,471
Accounts receivables	62	377
Receivables from collaborative arrangements	7,858	-
Prepaid expenses and other current assets	1,509	2,794
TOTAL CURRENT ASSETS	43,055	41,167
NON-CURRENT ASSETS:		
Restricted long-term deposits and cash equivalents	1,288	1,284
Property and equipment, net	660	434
Operating lease right-of-use assets	876	1,721
Other long-term assets	-	55
Funds in respect of employee rights upon retirement	749	626
TOTAL NON-CURRENT ASSETS	3,573	4,120
TOTAL ASSETS	$ 46,628	$ 45,287
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 251	$ 154
Other accounts payable	2,360	3,921
Current maturities of operating leases	718	447
TOTAL CURRENT LIABILITIES	3,329	4,522
LONG-TERM LIABILITIES:		
Operating leases liabilities	54	1,206
Liability for employee rights upon retirement	1,032	915
TOTAL LONG-TERM LIABILITIES	1,086	2,121
TOTAL LIABILITIES	4,415	6,643
COMMITMENTS (Note 7)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2022 and 2023, respectively; issued and outstanding: 23,129,469 and 27,857,620 as of December 31, 2022 and December 31, 2023, respectively	638	774
Additional paid-in capital	234,640	258,173
Accumulated deficit	(193,065)	(220,303)
TOTAL SHAREHOLDERS' EQUITY	42,213	38,644
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 46,628	$ 45,287

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,		
	2021	**2022**	**2023**
COLLABORATION REVENUES	23,772	-	-
LICENSE REVENUES	7,500	3,883	1,554
TOTAL REVENUES	31,272	3,883	1,554
RESEARCH AND DEVELOPMENT EXPENSES	20,381	12,682	23,541
GENERAL AND ADMINISTRATIVE EXPENSES	8,451	7,445	7,373
OTHER INCOME, net	524	-	55
TOTAL OPERATING INCOME (LOSS)	2,964	(16,244)	(29,305)
FINANCIAL INCOME, net	257	1,321	2,067
NET INCOME (LOSS) FOR THE YEAR	3,221	(14,923)	(27,238)
BASIC EARNINGS (LOSS) PER ORDINARY SHARE	0.14	(0.65)	(1.01)
DILUTED EARNINGS (LOSS) PER ORDINARY SHARE	0.14	(0.65)	(1.01)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED EARNINGS (LOSS) PER SHARE:			
BASIC	23,063,493	23,128,722	27,087,081
DILUTED	23,566,182	23,128,722	27,087,081

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

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, 2021	23,000,782	635	231,577	(181,363)	50,849
CHANGES DURING 2021:					
Net income for the year	-	-		3,221	3,221
Issuance of shares through ATM, net of issuance costs	41,154	1	504	-	505
Vesting of restricted share units	19,170	*	*	-	*
Exercise of options	65,698	2	330	-	332
Share-based compensation	-	-	687	-	687
BALANCE AS OF DECEMBER 31, 2021	23,126,804	638	233,098	(178,142)	55,594
CHANGES DURING 2022:					
Net loss for the year	-	-	-	(14,923)	(14,923)
Exercise of options	2,665	*	15	-	15
Share-based compensation	-	-	1,527	-	1,527
BALANCE AS OF DECEMBER 31, 2022	23,129,469	638	234,640	(193,065)	42,213
CHANGES DURING 2023:					
Net loss for the year				(27,238)	(27,238)
Issuance of shares and warrants through public offering, net of issuance costs	2,560,000	74	11,468		11,542
Issuance of shares and warrants through private placement from the controlling shareholder	2,000,000	56	9,944		10,000
Exercise of options	168,151	6	262		268
Share-based compensation			1,859		1,859
BALANCE AS OF DECEMBER 31, 2023	27,857,620	774	258,173	(220,303)	38,644

* less than $1 thousand

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,		
	2021	**2022**	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss) for the year	3,221	(14,923)	(27,238)
Adjustments required to reconcile net income (loss) to net cash used in operating activities:			
Depreciation	880	562	342
Loss (income) from disposal of property and equipment	29	-	(55)
Changes in accrued liability for employee rights upon retirement	(32)	20	6
Share-based compensation expenses	687	1,527	1,859
Net changes in operating leases	14	(194)	35
Changes in fair value of marketable securities	(125)	119	(436)
Financial expenses (income), net	55	(133)	89
Changes in operating asset and liabilities:			
Receivables from collaborative arrangements	(18,314)	12,609	7,858
Accounts receivables	-	(62)	(315)
Prepaid expenses and other current assets	274	(709)	(1,340)
Accounts payable, accrued expenses and other	5,620	(8,300)	1,465
Net cash used in operating activities	(7,691)	(9,484)	(17,730)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(143)	(171)	(134)
Proceeds from sale of property and equipment	-	-	74
Short-term deposits	(48)	8,948	2,488
Long-term deposits	(5)	10	(813)
Investments in marketable securities	(6,716)	(10,006)	(23,164)
Proceeds from sale and maturity of marketable securities	26,784	2,918	11,807
Net cash provided by (used in) investing activities	19,872	1,699	(9,742)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of shares through ATM, net of issuance costs	505	-	-
Proceeds from exercise of options	332	15	268
Proceeds from issuance of shares and warrants through placement from the controlling shareholder	-	-	10,000
Proceeds from issuance of shares and warrants through public offering, net of issuance costs	-	-	11,542
Net cash provided by financing activities	837	15	21,810
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS AND RESTRICTED CASH EQUIVALENTS	(55)	133	(73)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH EQUIVALENTS	12,963	(7,637)	(5,735)
CASH AND CASH EQUIVALENTS AND RESRICTED CASH EQUIVALENTS AT BEGINNING OF THE YEAR	8,272	21,235	13,598
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH EQUIVALENTS AT END OF THE YEAR	21,235	13,598	7,863
Cash and Cash equivalents	20,085	12,448	7,513
Restricted cash equivalents	1,150	1,150	350
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH EQUIVALENTS SHOWN IN STATEMENT OF CASH FLOWS	21,235	13,598	7,863
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Recognition of new operating lease ROU and liabilities	253	88	1,590
SUPPLEMENTARY INFORMATION:			
Income taxes paid	34	-	-
Interest received	774	392	1,261

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

NOTE 1 - NATURE OF OPERATIONS

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

The Company is an innovative dermatology company with a successful track record of two NDA approvals and advanced orphan drugs pipeline. The Company has two approved drugs: (i) Twyneo®, which was developed for the treatment of acne vulgaris and received marketing authorization by the U.S. Food and Durg Administration (the "FDA") on July 27, 2021 and (ii) Epsolay®, a treatment for subtype II rosacea that received marketing authorization by the FDA on April 25, 2022. In June 2021, the Company entered into two exclusive license agreements with Galderma for the commercialization of Twyneo® and Epsolay®, in the United States, see Note 9a. On April 14, 2022, the Company announced that Twyneo® is available for purchase by consumers who obtain a prescription from their physician. On June 2, 2022, the Company announced that Epsolay® is available for purchase by consumers who obtain a prescription from their physician. In addition to the novel products, the Company's products included the approved generic products Acyclovir, Ivermectin and other generic product candidates. In November 2021, the Company entered into an agreement with Padagis, to sell its rights in relation to ten generic collaborative agreements between the parties, including the agreements for the two aforementioned approved generic drug products. Under the new agreement, the Company has retained collaboration rights to two generic programs related to four generic drug candidates, see Note 8c.

On January 27, 2023 the Company entered into an asset purchase agreement ("APA") with PellePharm, Inc. (hereafter-"PellePharm"), pursuant to which the Company agreed to purchase all of the assets related to the topically-applied patidegib, a hedgehog signaling pathway blocker, for the treatment of Gorlin syndrome (such compound designated as investigational compound SGT-610). On January 30, 2023, upon closing of the transaction, the Company paid an upfront payment (hereafter- "upfront payment") of $4 million to PellePharm. The Company is required to pay an additional amount of $0.7 million, subject to the terms as defined in the APA, 15 months from the closing date. In addition, the Company will be required to pay total development and NDA acceptance milestones of up to $6 million, and up to $64 million in commercial milestones which amount increases to $89 million when sales exceed $500 million as well as single digit royalties which increase to double digit royalties when sales exceed $500 million.

The upfront payment and the additional development milestone payments under the APA represent payments for research and development in-process ("IPR&D") acquired as part of an asset purchase, which has not reached technological feasibility and has no alternative future use. Accordingly, such payments are expensed as incurred and are recognized as research and development expenses.

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.

In October 2023, Hamas terrorists infiltrated Israel's southern border and launched a series of attacks against Israel. Following these attacks, Israel's security cabinet declared war against Hamas and initiated a military campaign. As of the issuance date of this report, there was no material impact on the Company's ongoing operations in Israel. The Company continues to monitor its ongoing activities and will make any needed adjustments to ensure continuity of its business, while supporting the safety and well-being of its employees.

Risk and Uncertainties

Since incorporation through December 31, 2023, the Company has an accumulated deficit of approximately $220,303 and its activities have been funded mainly by its shareholders, collaboration revenues and license agreements, see also Notes 8 and 9. The Company expects to continue to incur significant research and development and other costs related to its ongoing operations.

NOTE 1 - NATURE OF OPERATIONS (continued):

In addition, management is continuing to analyze cash resources and considering raising additional funding from different sources, such as corporate collaborations, public or private equity offerings and/or debt financings. On August 9, 2023, following a recent assessment of partner licensing revenues and the delay in the development of SGT-210, the Company announced a restructuring plan to reduce operating expenses as part of cost-saving measures. The restructuring plan's cost-saving measures included workforce reductions of about 25 employees, as well as other cost-mitigation measures and was completed during the third quarter.

Management expects that the Company's cash and cash equivalents, deposits and marketable securities as of December 31, 2023 will allow the Company to fund its operating plan through at least the next 12 months from the financial statement issuance date.

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.

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: (1) for transactions — exchange rates at transaction dates or average rates; and (2) 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.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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 1.8%-5.9% in 2023. 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.

As of December 31, 2023, the Company has a restricted deposit in the amount of $1,167 in order to secure certain transactions with its banks. This amount is presented under restricted long-term deposits and cash.

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. Marketable securities are classified under current assets in the consolidated balance sheet as they represent the investment of funds available for the Company's current operations.

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 derivatives do not qualify for hedge accounting, 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.

g. Accounts receivables

Accounts receivable are initially recognized at the transaction price and subsequently measured at amortized cost less any allowance for expected credit losses.

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 based on 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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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 these assets' carrying amount, an impairment loss would be recognized. The assets would then be written down to their estimated fair values.

During the three years ended December 31, 2023, the Company did not recognize an impairment loss on its long-lived assets.

j. Share-based compensation

The Company accounts for employees' and non-employees' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment compensation is recognized as an expense over the requisite service period.

The Company elected to recognize compensation costs for awards to employee conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach.

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 candidates, which are not part of a business combination and that have no alternative use, 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 7a(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.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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, as applicable. At contract inception, the entity assesses the goods or services promised within each contract, determines whether they are performance obligations and assesses whether each promised good or service is distinct. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. 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.

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 revenues 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.

For arrangements that include a significant financing component, the company separates the significant financing component from the revenue and interest income is recorded when payments are received. See Note 8.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Revenue recognition (continued):

Licensing agreements

The Company has license agreements with two parties, Galderma and Searchlight.

In its license agreements with Galderma, the Company has identified one performance obligation (see Note 9a): grant of the license and use of its IP. The grant of the license and use of its IP performance obligation is considered to be a right to use IP in accordance with ASC 606. Therefore, revenue is recognized at a point in time, upon transfer of control over the license to the licensee.

In its license agreements with Searchlight (see Note 9b), the Company has identified two performance obligations: grant of the license and use of its IP, as well as continuing support during the regulatory approval process. The grant of the license is recognized at a point in time, upon transfer of control over the license to the licensee, while the services are recognized over time as the services are performed.

ASC 606 defines the 'Transaction Price' as the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to a customer. License agreements may contain variable consideration contingent upon the licensee achieving certain milestones, as well as sales-based royalties, in accordance with the relevant agreement. Variable payments, contingent on achieving additional milestones, are included in the transaction price based on most likely amount method. Amounts included in the transaction price are recognized only when it is probable that a significant reversal of cumulative revenues will not occur, usually upon achievement of the specific milestone, in accordance with the relevant agreement. Sales-based royalties are not included in the transaction price. Rather, they are recognized as the related sale occurs, due to the specific exception of ASC 606 for sales-based royalties in licensing of intellectual properties.

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.

2) 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

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 the commencement date based on the present value of lease payments over the lease term. The Company's lease terms may include periods covered by options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option to extend the lease or not exercise the option to terminate the lease.

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 operating lease 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.

o. 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, marketable securities and certain receivables. The Company deposits cash and cash equivalents with highly rated financial institutions. In addition, all marketable securities either 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.

p. Earnings (loss) per share

Basic earnings (loss) per share is computed based on net earnings (loss) for the period divided by the weighted average number of ordinary shares outstanding during the period. Diluted earnings (loss) per share is based upon the weighted average number of ordinary shares and of potential ordinary shares outstanding when dilutive. Potential ordinary shares include outstanding stock options and warrants, which are included under the treasury stock method when dilutive.

The calculation of diluted earnings (loss) per share does not include 3,397,834 , 3,900,837 and 7,070,688 options and warrants for the years ended December 31, 2021, 2022 and 2023, respectively, because their effect would be anti-dilutive.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

q. 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.

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 fair value of bank deposits approximates their carrying value, since they bear interest at rates close to the prevailing market rates. In addition, due to the short-term nature and/or low-risk nature of the Company's cash and cash equivalents, restricted cash equivalents, accounts receivable, accounts payable and other payables , their carrying amounts approximates their fair value.

r. Recently issued accounting pronouncement

In November 2023, the FASB issued ASU 2023-07 “Segment Reporting: Improvements to Reportable Segment Disclosures”. This guidance expands public entities’ segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment’s profit or loss and assets. Public entities with a single reportable segment are required to provide the new disclosures and all the disclosures required under ASC 280. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments are required to be applied retrospectively to all prior periods presented in an entity’s financial statements. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements and related disclosures.

NOTE 3 - MARKETABLE SECURITIES:

The following table sets forth the Company’s marketable securities for the indicated period:

	December 31,	
	2022	**2023**
Level 2 securities:		
U.S government and agency bonds	1,494	2,583
Other foreign government bonds	-	1,946
Corporate bonds*	7,184	15,942
Total	8,678	20,471

* Investments in Corporate bonds rated A or higher.

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.

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 cost of marketable securities as of December 31, 2023 is $20,180.

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, 2022 and 2023:

	December 31,	
	2022	**2023**
Balance at beginning of the year	$ 1,709	$ 8,678
Additions	10,006	23,164
Sale or maturity	(2,918)	(11,807)
Changes in fair value during the year	(119)	436
Balance at end of the year	$ 8,678	$ 20,471

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

NOTE 3 - MARKETABLE SECURITIES (continued):

As of December 31, 2023, all the Company's debt securities had the following maturity dates:

	Market value December 31, 2023
Due within one year	16,127
Between 1-2 years	4,344

NOTE 4 - PROPERTY AND EQUIPMENT

	December 31	
	2022	2023
Cost:		
Laboratory equipment	$ 3,688	$ 3,514
Office equipment and furniture	265	288
Computers and software	428	451
Leasehold improvements	1,993	1,985
	6,374	6,238
Less:		
Accumulated depreciation and amortization	(5,714)	(5,804)
Property and equipment, net	$ 660	$ 434

Depreciation and amortization expense totaled $880, $562 and $342 for the years ended December 31, 2021, 2022 and 2023, respectively.

NOTE 5 - LEASES:

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 were to expire in December 2023. In June 2023, the Company signed on extension to the office lease agreement, for the period starting January 1, 2024 for an additional period of two years, with an option to extend the agreement for another two years, meaning a maximum extension period of four years. These agreements are classified as operating leases and are presented under operating lease right-of-use assets and operating leases liabilities. A restricted deposit of $116 has been deposited 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 classified 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 5 - LEASES (continued):

Lease Position

The table below presents the lease-related assets and liabilities recorded on the consolidated balance sheet:

	As of December 31,	
	2022	**2023**
Assets		
Operating Leases		
Operating lease right-of-use assets	876	1,721
Liabilities		
Current liabilities		
Current maturities of operating leases	718	447
Long-term liabilities		
Non-current operating leases	54	1,206
Weighted Average Remaining Lease Term		
Operating leases	0.45	3.73
Weighted Average Discount Rate		
Operating leases	6.11%	13.3%

Lease Costs

The table below presents certain information related to lease costs of operating leases:

	Year Ended December 31,	
	2022	**2023**
Operating lease cost:	797	745

The table below presents supplemental cash flow information related to leases:

	Year Ended December 31,	
	2022	**2023**
Cash paid for amounts included in the measurement of leases liabilities:		
Operating cash flows from operating leases	989	799

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

NOTE 5 - LEASES (continued):

Undiscounted Cash Flows

The table below reconciles the undiscounted cash flows under leases as of December 31, 2023 were as follows:

	Operating Leases
For the year ending December 31,	
2024	592
2025	539
2026 and thereafter	912
Total minimum lease payments	2,043
Less: amount of lease payments representing interest	(390)
Present value of future minimum lease payments	1,653
Less: Current maturities of operating leases	447
Long-term operating leases liabilities	1,206

NOTE 6 - EMPLOYEE SEVERANCE BENEFITS:

The Company is required to make severance payments upon dismissal of an employee or upon termination of employment in certain circumstances.

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").

For employees whose employment term began prior to August 2014, the severance payment liability (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.

This 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 $445, $461 and $445 for the years ended December 31, 2023, 2022 and 2021, respectively, of which $389, $405 and $404 in the years ended December 2023, 2022 and 2021, respectively, were in respect of the Contribution Plan.

The Company expects to contribute approximately $401 in the year ending December 31, 2024 to insurance companies in connection with its expected severance liabilities for that year.

NOTE 7 - 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 the 12-month SOFR rate as published by CME Group on the first day of commerce or any other body certified by the Federal Reserve, or according to an alternative bulletin as published by the Bank of Israel.

Up to December 31, 2023, the Company had recognized and received grants from the IIA in the aggregate amount of $1,430 (no grants were received in the years ended December 31, 2021, 2022 and 2023). Through December 31, 2023, the Company recorded an accumulated royalty expense of $2,170 as royalties to the IIA with respect to revenue recognized through December 31, 2023 ($23, $24 and $37 were recorded in 2021, 2022 and 2023 accordingly, as an expense in the consolidated statements of operations).

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.

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. 1.5% – 8% of proceeds received by the Company for the sublicense or license of certain patents.

Royalty expenses in immaterial amounts were recorded in 2021, 2022 and 2023 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. As to collaboration agreements, see detailed information in Note 8.

NOTE 8 - COLLABORATION AGREEMENTS:

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

b. In 2016 through 2020, the Company entered into several collaboration agreements mainly with one third party (the "Partner") for the development, manufacturing and commercialization of several 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).

c. Under the agreements, the Partner is obligated to conduct regulatory, scientific, clinical and technical activities necessary to develop the product and prepare and file an abbreviated new drug application ("ANDA"), with the FDA and gain regulatory approval. The Company participates in the development of the product candidates, including participation in joint steering committees and is obligated for sourcing the active pharmaceutical ingredient (API) during the development phase.

Upon FDA approval, the Partner has exclusive rights and is required to use diligent efforts to commercialize these products in territories defined under the agreements, including all required sales, marketing and distributing activities associated with the agreements. The Company is entitled to a share of the Partner's gross profits related to the sale of the products, as such term is defined in each of the agreements.

These Agreements are considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company recognizes collaboration revenues when the related sales occur.

In November 2021, the Company entered into a new agreement ("New Agreement") with the Partner, to sell its rights to the Partner in relation to ten generic collaborative agreements between the parties in consideration of $21,500 which was paid over 24 months. Under the New Agreement, the Company has retained collaboration rights to two generic programs related to four generic drug candidates, and is no longer entitled to receive its share in profit as detailed above.

In addition, the Company ceased paying any outstanding and future operational costs related to these collaborative agreements.

NOTE 9 – LICENSE AGREEMENTS:

a. In June 2021, the Company entered into two exclusive license agreements with Galderma for the commercialization of two of the Company's most advanced investigational drug products (Twyneo® and Epsolay®) in the United States. The Company is entitled to amounts of up to $7.5 million per product in upfront payments and regulatory approval milestone payments assuming 2021 approval of each respective product. The Company is also eligible to receive tiered double-digit royalties ranging from mid-teen to high-teen percentage of net sales as well as up to $9 million in sales milestone payments.

According to the agreement, the Company has an option to regain commercialization rights five years following first commercialization.

On July 27, 2021, the Company announced that the FDA approved the Company’s first proprietary drug product, Twyneo®. On April 14, 2022, the Company announced that Twyneo® is available for purchase by consumers who obtain a prescription from their physician, see further details in Note 1. In March 2022, the Company had refunded the $4 million upfront payment to Galderma, since FDA approval for Epsolay® had not been received as of December 31, 2021. On April 25, 2022, the Company announced that the FDA approved the drug product, Epsolay®, which entitled the Company to a $3.5 million milestone payment, as per the license agreement. In May 2022, the Company has received the $3.5 million payment from Galderma. On June 2, 2022, the Company announced that Epsolay® is available for purchase by consumers who obtain a prescription from their physician, see further details in Note 1. During 2023 and 2022, the Company recognized $1,027 and $306, respectively, as revenue from royalties in respect of the license agreement for both products.

NOTE 9 – LICENSE AGREEMENTS (continued):

b. On June 6, 2023, the Company and Searchlight Pharma Inc. ("Searchlight"), a private Canadian specialty pharmaceutical company, signed on an exclusive license agreements for Twyneo® and Epsolay® for the Canadian market, over a fifteen-year term that is renewable for subsequent five-year periods. Searchlight will be responsible for obtaining and maintaining any regulatory approvals required to market and sell the drugs in Canada, with support from the Company.

Under the agreement, the Company will receive up to $11 million in upfront payments and regulatory and sales milestones for both drugs, combined. In addition, the Company will be entitled to royalty percentages of all Canadian net sales ranging from low-double-digits to high teens.

In June 2023, the Company received $500 as an upfront payment in connection with the license agreement and related support provided to Searchlight for obtaining the regulatory approval in the Canadian market. The Company is also required to support Searchlight during such period if needed based on agreed upon rates. The Company has identified two performance obligations in the license agreement as follows: (i) the license to market the products in Canada; and (ii) continuing support during the regulatory approval process. Accordingly, the Company recognized $380 as license revenue in the period and recorded $120 as contract liability in respect of the support services.

NOTE 10 - SHARE CAPITAL:

a. Ordinary shares

Rights of the Company's ordinary shares

Each ordinary share is entitled to one vote. The holder of an ordinary share 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.

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

Under the 2021 ATM Agreement, 41,154 shares were sold under the program for total gross proceeds of approximately $0.5 million. On April 2022, the Company terminated the 2021 ATM Agreement, effective on the same date.

2) On January 27, 2023, the Company entered into a securities purchase agreement (hereafter - "Purchase Agreement") with Armistice Capital, pursuant to which the Company issued to Armistice Capital (i) 2,560,000 ordinary shares of the Company (the "Ordinary Shares"), par value NIS 0.1 per share in a registered direct offering (the " Registered Direct Offering") at a price of $5.00 per ordinary share and (ii) in a concurrent private placement unregistered warrants to purchase up to 2,560,000 Ordinary Shares (the "Investor Warrants"). Each of the Investor Warrants are exercisable for one ordinary share, have an exercise price of $5.85 and will become exercisable beginning six months from the date of issuance and will expire on January 27, 2028. The sale of the Ordinary Shares in the Registered Direct Offering was made by means of a shelf registration statement. The Offering closed on January 31, 2023. The gross proceeds from the Registered Direct Offering were approximately $12.8 million.

Concurrently with the signing of the Purchase Agreement, the Company also entered into a subscription agreement (hereafter - "Subscription Agreement") between the Company and M. Arkin Dermatology Ltd., the Controlling Shareholder of the Company, pursuant to which M. Arkin Dermatology Ltd. agreed to purchase 2,000,000 unregistered Ordinary Shares and unregistered warrants to purchase up to 2,000,000 ordinary shares (the "PIPE Warrants" and, together with the Investor Warrants, the "Warrants") in a concurrent private placement (hereafter- "Affiliate Private Placement"), at a price equal to the offering price of the Ordinary Shares in the Offering. The Affiliate Private Placement agreement was contingent on certain conditions and was approved by the Company's shareholders in March 2023. The total proceeds of $10,000 were received in April 2023.

NOTE 10 - SHARE CAPITAL (continued):

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, grant options or restricted share units and other share-based awards (hereafter — the Awards) to the Company's employees, consultants, directors and other service providers.

In March 2023, 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 1,250,000 ordinary shares.

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, pursuant and subject to Section 3(i) of the Israeli Tax Ordinance and under Internal Revenue Code Section 422.

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 the Plan is estimated using the Black-Scholes option pricing method. Expected volatility is based on the historical volatility of the company and 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, 2023, 641,404 ordinary shares remain available for future grants under the Plan.

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

NOTE 10 - SHARE CAPITAL (continued):

2) **Options grants**

a. Option granted to employees and directors

During the twelve months ended December 31, 2023, the Company granted 749,750 options to employees and executive officers:

i. In March 2023, the Company granted a total of 53,092 options to several employees to purchase ordinary shares at exercise prices of either $4.63 or $5.6 per share.

The options vest over a period of 4 years; one quarter of the options vest on the first anniversary of the vesting commencement date (as described in each agreement) and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of their grant date.

ii. In March 2023, the Company granted a total of 439,314 options to several executive officers to purchase ordinary shares at an exercise price of $4.63 or $5.6 per share.

The options vest over a period of 4 years; one quarter of the options vest on the first anniversary of the vesting commencement date (as described in each agreement) and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of their grant date.

iii. In March 2023, the board of directors approved and recommended the Company's shareholders to approve a grant of 257,344 options to the Company's CEO to purchase ordinary shares at an exercise price of $5.6 per share. The Company's shareholders approved the grant on July 26, 2023.

The options vest over a period of 4 years; one quarter of the options vest on the first anniversary of the vesting commencement date (as described in each agreement) and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of their grant date.

The weighted average fair value of options granted in 2022 and 2023 was $4.49 and 2.01, respectively. The underlying data used for computing the fair value of the options are as follows:

	2022	2023
Value of one ordinary share	$4.98-$10.0	$3.59-$3.8
Dividend yield	0%	0%
Expected volatility	57.8%-62.6%	55%-56%
Risk-free interest rate	2.5%-4.2%	3.97%-4.1%
Expected term	7 years	7 years

The total unrecognized compensation cost of employee options at December 31, 2023 is $1,497, which is expected to be recognized over a period of 3.19 years.

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

NOTE 10 - SHARE CAPITAL (continued):

The following table summarizes the number of options granted to employees under the Plan for the year ended December 31, 2023, and related information:

	Year ended December 31					
	2022			2023		
	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	1,131,029	$ 5.64	5.73	1,864,377	$ 7.09	7.11
Granted	747,488	$ 9.31	9.21	749,750	$ 5.52	9.15
Exercised	(2,665)	$ 5.69	-	(168,151)	$ 2.8	-
Expired	(450)	$ 9.93	-	(57,740)	$ 8.63	-
Forfeited	(11,025)	$ 7.58	-	(67,114)	$ 7.8	-
Options outstanding at the end of the year	1,864,377	$ 7.09	7.11	2,321,122	$ 6.57	6.54
Options exercisable at the end of the year	1,179,132	$ 5.14	3.99	1,547,237	$ 6.17	3.72

b. Option granted to non-employees

All compensation cost of non-employees' options were fully recognized as of December 31, 2023.

The following table summarizes the number of options granted to non-employees under the Plan as of December 31, 2023, and related information (no options were granted to non-employees in 2023):

	December 31		
	2023		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at the end of the year	198,575	$ 7.70	3.84
Options exercisable at the end of the year	198,575	$ 7.70	3.84

c. 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, 2023, the RSUs had vested.

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

NOTE 10 - SHARE CAPITAL (continued):

The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31		
	2021	**2022**	**2023**
Research and development expenses	$ 33	$ 665	$ 701
General and administrative expenses	$ 654	$ 862	$ 1,158
	$ 687	$ 1,527	$ 1,859

NOTE 11 - TAXES ON INCOME:

a. Tax rates in Israel

The Company is taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2021, 2022 and 2023 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, 2023, 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 11 - 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, 2023, 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 2018 are considered to be final.

e. Losses for tax purposes carried forward to future years

As of December 31, 2023, the Company had approximately $187.4 million of net carry forward tax losses which are available to reduce future taxable income with no limited period of use.

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

NOTE 11 - TAXES ON INCOME (continued):

f. Deferred income taxes:

	December, 31	
	2022	**2023**
In respect of:		
Net operating loss carry forward	40,779	43,113
Research and development expenses	3,254	4,337
Other	661	462
Less – valuation allowance	(44,694)	(47,912)
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 as of January 1, 2021	$ 43,053
Additions	2,255
Balance as of December 31, 2021	$ 45,308
Deductions	(614)
Balance as of December 31, 2022	$ 44,694
Additions	3,218
Balance as of December 31, 2023	$ 47,912

i. Provision for uncertain tax positions

As of December 31, 2022, and 2023, the Company does not have a provision for uncertain tax positions.

NOTE 12 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Other accounts payables and accruals

	December, 31	
	2022	**2023**
Accrued expenses	$ 1,257	$ 2,054
Employees payables	883	603
APA payable (see note 1)	-	700
Other	220	564
	$ 2,360	$ 3,921

NOTE 13 - 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 10b(2)a and Note 10d.

c. As to the Subscription Agreement with the controlling shareholder, see Note 9a(2).

Exhibit 1.2

SOL-GEL TECHNOLOGIES LTD.

AMENDED AND RESTATED ARTICLES OF ASSOCIATION

LAST AMENDED ON: JUNE 22, 2022

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AMENDED AND RESTATED ARTICLES OF ASSOCIATION

of

SOL-GEL TECHNOLOGIES LTD.

INTERPRETATION

1. In these Articles the following terms shall bear the meanings set opposite to them, unless the context otherwise requires:

T E R M S		**M E A N I N G S**
Articles		These Amended and Restated Articles of Association as may be amended from time to time.
Auditor (*Roeh Cheshbon Mevaker)*		As defined under the Law.
Board		The Board of Directors of the Company.
CEO		Chief Executive Officer, also referred to under the Law as the general manager.
Class Meeting		A meeting of the holders of a class of shares.
Chairman		Chairman of the Board.
Company		Sol-Gel Technologies Ltd.
Companies Regulations		All regulations promulgated from time to time under the Companies Law.
Distribution		As defined under the Law.
External Director		As defined under the Law.
Internal Auditor		An internal auditor appointed to the Company in accordance with Section 146(a) of the Companies Law.
The Law or the Companies Law		The Israeli Companies Law, 5759 – 1999 and the Companies Regulations, or any other law and regulations which may come in their stead, in each case, as amended from time to time.
NIS		New Israeli Shekel, the lawfully denominated currency of the State of Israel.
The Office		The registered office of the Company from time to time.
Office Holder		As defined under the Law.
Ordinary Share(s)		The Company's Ordinary Shares, NIS 0.1 par value each.
Register		The Company's shareholders register, maintained in accordance with the Companies Law.
Simple Majority		A majority of more than fifty percent (50%) of the votes cast by those shareholders voting in person or by proxy (including by voting deed), not taking into consideration abstaining votes.
Special Majority		A majority of sixty six and two thirds percent (66-2⁄3%) or more of the votes cast by those shareholders voting in person or by proxy (including by voting deed), not taking into consideration abstaining votes.
The Statutes		The Law and to the extent applicable to the Company, the Israeli Companies Ordinance (New Version) 1983, the Securities Law, 5728 – 1968 (the "Securities Law") and all applicable laws and regulations applicable in any relevant jurisdiction (including without limitation U.S. federal laws and regulations), and rules of any stock market in which the Company's shares are registered for trading as shall be in force from time to time.

Subject to the provisions of this Article 1 and unless the context necessitates another meaning, terms and expressions in these Articles which have been defined in the Companies Law shall have the meanings ascribed to them therein.

2. Words importing the singular shall include the plural, and *vice versa*. Any pronoun shall include the corresponding masculine, feminine and neuter forms; and words importing persons shall include corporate bodies.
Any provision or part thereof of these Articles, prohibited by applicable law, shall be ineffective, without invalidating any other part of these Articles.

NAME OF THE COMPANY

3. The name of the Company is Sol-Gel Technologies Ltd. (and in Hebrew: סול-ג'ל טכנולוגיות בע"מ).

OBJECTIVES

4. The objectives of the Company shall be to engage in any lawful activity.

PUBLIC COMPANY

5. The Company is a public company as such term is defined under the Companies Law.

LIMITED LIABILITY

6. The liability of each shareholder for the Company's obligations is limited to the unpaid sum, if any, owing to the Company in consideration for the issuance of the shares by the Company to such shareholder, subject to the provisions of the Companies Law.

CAPITAL, SHARES AND RIGHTS

7. The registered share capital of the Company consists of 50,000,000 Ordinary Shares, par value NIS 0.10 per share.

8. All issued and outstanding shares of the Company of the same class are of equal rights between them for all intents and purposes concerning the rights set forth below.

9. Each issued Ordinary Share entitles its holder to the rights as described below:

   9.1. The equal right to participate in and vote at the Company's general meetings, whether ordinary meetings or special meetings, and each of the shares in the Company shall entitle the holder thereof, who is present at the meeting and participating in the vote, whether in person, or by proxy, to one vote.

   9.2. The equal right to participate in any Distribution or distribution of bonus shares.

   9.3. The equal right to participate in the distribution of assets available for distribution in the event of liquidation of the Company.

10.

   10.1. If two or more persons are registered as joint holders of any shares, any one of such persons may give effectual receipts for any dividend or other monies in respect of such share and his or her confirmation will bind all holders of such share.

   10.2. Any payment for a share shall be initially credited against the par value of said share and any excess amount shall be credited as a premium for said share, unless determined otherwise in the conditions of the allocation.

SHARE CERTIFICATES

11. A shareholder who is registered in the Register is entitled to receive from the Company, without payment and at such shareholder’s request, within a period of three months after the allocation or registration of the transfer, one share certificate with respect to all the shares registered in his name, which shall specify the aggregate number of the shares held by such shareholder. In the event of a jointly held share, the Company shall issue one share certificate for all the joint holders of the share, and the delivery of such certificate to one of the joint holders shall be deemed to be delivery to all of them. Every certificate shall bear the Company’s stamp or seal or a facsimile copy thereof and be signed by an Office Holder of the Company, a director of the Company, the Company's secretary or by any other person appointed by the Board for such purpose.

12. The Company may issue a new certificate *in lieu of* a certificate that was issued and was lost, defaced, or destroyed, on the basis of such proof and guarantees as the Company may require, and after payment of an amount that shall be prescribed by the Company, and the Company may also replace existing certificates with new certificates, free of charge, subject to such conditions as the Company shall stipulate.

REGISTERED HOLDER

13. Except as otherwise provided in these Articles, the Company shall be entitled to treat the registered holder of any share as the absolute owner thereof, and, accordingly, shall not, except as ordered by a court of competent jurisdiction, or as required by statute, be bound to recognize any equitable or other claim to, or interest in such share on the part of any other person.

14. To the extent required by the Law a trustee must inform the Company of the fact that such trustee is holding shares of the Company in trust for another person at such time as may be required by the Law. The Company shall register that fact in the Register in respect of such shares. The trustee shall be deemed to be the sole holder of said shares.

TRANSFER OF SHARES

15. Subject to the Statutes, and subject to any applicable agreements or undertakings of any specific shareholder, the shares shall be freely transferable.

16. A transfer of registered shares shall be made in writing or any other manner, in a form specified by the Board or the transfer agent appointed by the Company, and such transfer form should be signed by both the transferee and the transferor and delivered to the Office or to such transfer agent, together with the certificates of the shares due to be transferred, if such certificates have been issued. The Board may approve other methods of recognizing the transfer of shares in order to facilitate the trading of the Company's shares on the Nasdaq Global Market or on any other stock exchange. The transferee shall be deemed to be the shareholder with respect to the transferred shares only from the date of registration of his name in the Register.

17. Notwithstanding anything to the contrary herein, shares registered in the name of The Depository Trust Company or its nominee shall be transferrable in accordance with the policies and procedures of The Depository Trust Company.

18. The Board may close the Register and suspend the registration of transfers for such period of time as the Board shall deem fit, provided that the period of closure of any such book shall not exceed 30 days each year. The Company shall notify the shareholders of such decision.

TRANSMISSION OF SHARES

19. In the case of the death, liquidation, bankruptcy, dissolution, winding-up or a similar occurrence of a shareholder, the legal successors, receivers or liquidators (as the case may be) of such shareholder shall be the only persons recognized by the Company as having any title to such shares, but nothing herein contained shall release the estate of the predecessor from any liability in respect of such shares.

20. The legal successors may, upon producing such evidence of title as the Board shall require, be registered themselves as holders of the shares, or subject to the provisions as to transfers herein contained, transfer the same to some other person.

CALLS ON SHARES

21. The Board may, from time to time, make such calls as it may deem appropriate upon shareholders with respect to any sum unpaid in respect of shares held by such shareholders which is not, by the terms of allotment thereof or otherwise, payable at a fixed time, and each shareholder shall pay the amount of every call so made upon him (and of each installment thereof if the same is payable in installments), to the person(s) and at the time(s) and place(s) designated by the Board, as any such time(s) may be thereafter extended and/or such person(s) or place(s) changed. Unless otherwise stipulated by the Board (and in the notice hereafter referred to), each payment in response to a call shall be deemed to constitute a pro rata payment on account of all shares in respect of which such call was made.

22. Notice of any call shall be given in writing to the applicable shareholder(s) not less than fourteen (14) days prior to the time of payment, specifying the time and place of payment, and designating the person to whom and the place where such payment shall be made; provided, however, that before the time for any such payment, the Board may, by notice in writing to such shareholder(s), revoke such call in whole or in part, extend such time, or alter such designated person and/or place. In the event of a call payable in installments, only one notice thereof need be given.

23. If, by the terms of allotment of any share or otherwise, any amount is made payable at any fixed time, every such amount shall be payable at such time as if it were a call duly made by the Board and of which due notice had been given, and all the provisions herein contained with respect to calls shall apply to each such amount.

24. The joint holders of a share shall be jointly and severally liable to pay all calls in respect thereof and all interest payable thereon.

25. Any amount unpaid in respect of a call shall bear interest from the date on which it is payable until actual payment thereof, at such rate (not exceeding the then prevailing debtor rate charged by leading commercial banks in Israel), and at such time(s) as the Board may prescribe.

26. 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 these Articles are deemed to have been delivered to him, together with interest, linkage and expenses, if any, unless otherwise determined by the Board. Upon the allotment of shares, the Board may provide for differences among the allottees of such shares as to the amount of calls and/or the times of payment thereof.

ALTERATIONS OF THE REGISTERED SHARE CAPITAL

27. (a) Subject to the Statutes, a general meeting of shareholders may from time to time resolve to:

(1) alter or add classes of shares that shall constitute the Company's registered capital, including shares with preference rights, deferred rights, conversion rights or any other special rights or limitations;

(2) increase the Company's registered share capital by creating new shares either of an existing class or of a new class;

(3) consolidate and/or split all or any of its share capital into shares of larger or smaller par value than the existing shares;

(4) cancel any registered shares not yet allocated, provided that the Company has made no commitment to allocate such shares; and

(5) reduce the Company's share capital and any reserved fund for redemption of capital.

(b) In executing any resolution adopted according to Article 27(a) above, the Board may, at its discretion, resolve any related issues.

(c) If as a result of a consolidation or split of shares authorized under these Articles, fractions of a share will stand to the credit of any shareholder, the Board is authorized at its discretion, to act as follows:

(1) Determine that fractions of shares that do not entitle their owners to a whole share, will be sold by the Company and that the consideration for the sale be paid to the beneficiaries, on terms the Board may determine;

(2) Allot to every shareholder, who holds a fraction of a share resulting from a consolidation and/or split, shares of the class that existed prior to the consolidation and/or split, in a quantity that, when consolidated with the fraction, will constitute a whole share, and such allotment will be considered valid immediately prior to the consolidation or split;

(3) Determine the manner for paying the amounts to be paid for shares allotted in accordance with Article 27(c)(2) above, including on account of bonus shares; and/or

(4) Determine that the owners of fractions of shares will not be entitled to receive a whole Share in respect of a share fraction or that they may receive a whole share with a different par value than that of the fraction of a share.

28. Except as otherwise provided by or pursuant to these Articles or by the conditions of issue, any new share capital shall be considered as part of the original share capital, and shall be subject to the same provisions of these Articles with reference to payment of calls, lien, transfer, transmission, forfeiture and otherwise, which applies to the original share capital.

MODIFICATION OF CLASS RIGHTS

29. If at any time the share capital is divided into different classes of shares, any change to the rights and privileges of the holders of any such class of shares shall require the approval of a Class Meeting of such class of shares by a Simple Majority (unless otherwise provided by the Statutes or by the terms of issue of the shares of that class), in addition to the Simple Majority of all classes of shares voting together as a single class at a shareholder meeting.

30. The rights and privileges of the holders of any class of shares shall not be deemed to have been altered by creating or issuing shares of any class, including a new class (unless otherwise provided by the terms of issue of the shares of that class).

BORROWING POWERS

31. The Company may, by resolution of the Board, from time to time, raise or borrow or secure the payment of any sum or sums of money for the purposes of the Company. The Company, by resolution of the Board, may also raise or secure the payment or repayment of such sum or sums in such manner and upon such terms and conditions in all respects as it deems fit, and in particular by the issue of debentures or debenture stock of the Company charged upon all or any part of the property of the Company (both present and future) including its unissued and/or its uncalled capital for the time being. Issuance of any series of debentures shall require Board approval.

GENERAL MEETINGS

32. Annual general meetings shall be held at least once a calendar year, at such place and time as determined by the Board, but not later than fifteen (15) months after the last annual general meeting. Such general meetings shall be called "Annual Meetings" and all other general meetings of the Company shall be called "Special Meetings". The Annual Meeting shall review the Company's financial statements and shall transact any other business required pursuant to these Articles or the Law, and any other matter as shall be determined by the Board.

33. The Board may convene a Special Meeting by its resolution, and is required to convene a Special Meeting should it receive a request, in writing, from a person or persons entitled, under the Companies Law, to request such meeting.

    Any request for convening a meeting must specify the purposes for which the meeting is to be called, shall be signed by the persons requesting the meeting, and shall be delivered to the Company's registered offices.

34. In addition, subject to the Law, the Board may accept a request of a shareholder holding not less than 1% of the voting rights at the general meeting to include a subject in the agenda of a general meeting, provided that such subject is a proper subject for action by shareholders under the Law and these Articles and only if the request also sets forth: (a) the name and address of the shareholder making the request; (b) a representation that the shareholder is a holder of record of shares of the Company, holding not less than 1% of the voting rights at the general meeting and intends to appear in person or by proxy at the meeting; (c) a description of all arrangements or understandings between the shareholder and any other person or persons (naming such person or persons) in connection with the subject which is requested to be included in the agenda; and (d) a declaration that all the information that is required under the Law and any other applicable law to be provided to the Company in connection with such subject, if any, has been provided. In addition, if such subject includes a nomination to the Board in accordance with the Articles, the request shall also set forth the consent of each nominee to serve as a director of the Company if so elected and a declaration signed by each nominee declaring that there is no limitation under the Law for the appointment of such nominee. Furthermore, the Board, may, in its discretion to the extent it deems necessary, request that the shareholders making the request provide additional information necessary so as to include a subject in the agenda of a general meeting, as the Board may reasonably require.

35. Subject to applicable law, the Board shall determine the agenda of any general meeting.

Notice of General Meetings

36. Unless otherwise required by the Law and these Articles, the Company is not required to give notice under Section 69 of the Companies Law. A notice of general meeting shall be published by the Company on the website of (i) the United States Securities and Exchange Commission, and (ii) the Company, as a Current Report on Form 6-K (or such other form prescribed by the Statutes), at least 21 days prior to the general meeting (or earlier if so required under the Statutes).

PROCEEDINGS AT GENERAL MEETINGS

Quorum

37. No business shall be transacted at any general meeting of the Company unless a quorum of shareholders is present at the opening of the general meeting.

Except as provided in the following Article with regard to an adjourned general meeting, the quorum for any general meeting shall be the presence of at least two shareholders in person or by proxy (including by voting deed) holding 33 1/3% or more of the voting rights in the Company. For this purpose, abstaining shareholders shall be deemed present at the general meeting.

38. If within half an hour from the time appointed for the holding of a general meeting a quorum is not present, the general meeting shall stand adjourned to the same day in the following week at the same time and place or to such other day, time and place as the Board may indicate in a notice to the shareholders. At such adjourned general meeting any number of shareholders shall constitute a quorum for the business for which the original general meeting was called.

Chairman of the General Meeting

39. The Chairman shall preside as the chairman at every general meeting, but if there shall be no such Chairman or if at any meeting the Chairman shall not be present within fifteen (15) minutes after the time appointed for holding the same, or shall be unwilling to act as chairman, then the Board members present at the meeting shall choose one of the Board members as chairman of the meeting and if they shall not do so then the shareholders present shall choose a Board member, or if no Board member be present or if all the Board members present decline to take the chair, they shall choose any other person present to be chairman of the meeting.

40. The chairman of the general meeting may, with the consent of a general meeting at which a quorum is present, and shall if so directed by the general meeting, adjourn any meeting, discussion or the resolution with respect to a matter that is on the agenda, from time to time and from place to place as the meeting shall determine. Except as may be required by the Law, no shareholder shall be entitled to any notice of an adjournment or of the business to be transacted at an adjourned meeting. No business shall be transacted at any adjourned meeting other than the business which might have been transacted at the meeting from which the adjournment took place.

41. A vote in respect of the election of the chairman of the meeting or regarding a resolution to adjourn the meeting shall be carried out immediately. All other matters shall be voted upon during the meeting at such time and order as decided by the chairman of the general meeting.

VOTE OF SHAREHOLDERS

42. All resolutions proposed at any general meeting will require a Simple Majority, unless otherwise required by the Statutes or these Articles. Except as otherwise required by the Statutes or these Articles, alteration or amendment of these Articles shall require a Simple Majority.

43. A declaration by the chairman of the meeting that a resolution has been carried, or has been carried unanimously or by a particular majority, or rejected, or not carried by a particular majority and an entry to that effect in the minutes of the meeting shall be *prima facie* evidence thereof.

44. The chairman of the meeting will not have a second and/or a casting vote. If the vote is tied with regard to a certain proposed resolution such proposal shall be deemed rejected.

45. If two or more persons are jointly entitled to a share, the vote of the senior one who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other registered holders of the share, and for this purpose seniority shall be determined by the order in which the names stand in the Register.

46. A proxyholder need not be a shareholder of the Company.

47. The instrument appointing a proxy shall be in writing signed by the appointer or of his attorney-in-fact duly authorized in writing. A corporate entity shall vote by a representative duly appointed in writing by such entity. Any instrument appointing a proxy or a representative of a corporate entity (whether for a specified meeting or otherwise) shall be in a form satisfactory to the Company.

    Such instrument shall be duly signed by the appointer or his duly authorized attorney or, if such appointer is a company or other corporate body, under its common seal, stamp or printed name or the hand of its duly authorized agent(s) or attorney(s).

48. Unless otherwise determined by the Board, the instrument of appointment must be submitted to the Office no later than 48 hours prior to the general meeting to be attended by such proxy or representative. Notwithstanding the above, the chairman of the meeting shall have the right to waive the time requirement provided above with respect to all instruments of appointment and to accept any and all instruments of appointment until the beginning of a general meeting.

49. A proxy may be appointed in respect of only some of the shares held by a shareholder, and a shareholder may appoint more than one proxy, each empowered to vote by virtue of a portion of the shares.

50. A shareholder being of unsound mind or pronounced to be unfit to vote by a competent court of law may vote through a legally appointed guardian or any other representative appointed by a court of law to vote on behalf of such shareholder.

51. A shareholder entitled to vote may signify in writing his approval of, or dissent from, or may abstain from any resolution included in a proxy instrument furnished by the Company. A proxy instrument may include resolutions pertaining to such issues which are permitted to be included in a proxy instrument according to the Statutes, and such other issues which the Board may decide, in a certain instance or in general, to allow voting through a proxy. A shareholder voting or abstaining through a proxy instrument shall be taken into account in determining the presence of a quorum as if such shareholder is present at the meeting.

52. The chairman of the general meeting shall be responsible for recording the minutes of the general meeting and any resolution adopted.

53. The provisions of these Articles relating to general meetings shall, mutatis mutandis, apply to Class Meetings.

DIRECTORS

Powers, Number of Directors, Composition & Election

54. The Board shall have and execute all powers and/or responsibilities allocated to the Board by the Statutes and these Articles, including setting the Company's policies and supervision over the execution of the powers and responsibilities of the CEO. The Board may execute any power of the Company that is not specifically allocated by the Statutes or by these Articles to another organ of the Company.

55. The number of directors on the Board shall be no less than five (5) but no more than ten (10), including any External Directors required to be appointed by the Companies Law (if required). A reduction of the maximum number of directors on the Board under this Article 55, shall not affect the term in office of serving directors determined prior to such reduction."

56. The directors, excluding the External Directors, shall be elected at each Annual Meeting by a Simple Majority and shall hold office until the end of the next succeeding Annual Meeting, unless their office is vacated prior thereto in accordance with the provisions of these Articles and the Law. This Article shall not apply to the election and tenure of External Directors, in respect of whom the provisions of the Law shall apply.

57. [Reserved]

58. The Board may at any time and from time to time appoint any person as a director to fill a vacancy (whether such vacancy is due to a director no longer serving or due to the number of directors serving being less than the maximum number stated in Article 55 above). In the event of one or more such vacancies in the Board, the continuing directors may continue to act in every matter; provided, however, that if their number is less than the minimum number provided for pursuant to Article 55 above, they may only act in an emergency or to fill the office of a director which has become vacant up to a number equal to the minimum number provided for pursuant to Article 55 above. The office of a director that was appointed by the Board to fill any vacancy shall be in effect until the next Annual Meeting or until he or she shall cease serving in office pursuant to the provisions of these Articles.. Other than as provided in this Article 58, directors may be elected only at Annual Meetings.

59. The term of office of a director shall commence on the date of such director's election by the Annual Meeting or by the Board or on a later date, should such date be determined in the resolution of appointment of the Annual Meeting or of the Board. An Annual Meeting may dismiss a director during the term only by a Special Majority vote (except for External Directors, who may be dismissed only as set forth under the Law).

60. An amendment to Articles 54-60 shall require a Special Majority.

Remuneration

61. The Company shall determine the remuneration of the directors, if any, in accordance with the Law.

Chairman of the Board

62. The Board shall appoint one of its members to serve as the Chairman and may replace the Chairman from time to time. The Chairman shall preside at meetings of the Board, but if at any meeting the Chairman is not present within fifteen (15) minutes after the time appointed for holding the meeting, the present directors shall choose a present director to be chairman of such meeting.

PROCEEDINGS OF THE DIRECTORS

63. The directors shall meet together for the dispatch of business, adjourn and otherwise regulate their meetings as they deem fit, subject to these Articles.

Unless otherwise determined by the Board, written notice of any meeting of the Board and the agenda setting out the matters to be discussed at such meeting, shall be given to all directors at least seventy two (72) hours (or such shorter notice as all the directors may agree) before the meeting. In urgent cases, a majority of the members of the Board may decide to hold a meeting without such notice.

Quorum

64. No business shall be transacted at any meeting of the Board unless a quorum of directors is present when a meeting is called to order. A quorum shall be deemed to exist when there are present personally or represented by an alternate director at least half of the directors then in office.

If a quorum is not present at the meeting of the Board within half an hour after the time scheduled for the meeting, the meeting may be adjourned to another time as shall be decided by the Chairman, or in his absence, the directors present at the meeting, provided that notice of no less than twenty four (24) hours in advance shall be given to all the directors of the time of the adjourned meeting. The directors may waive the necessity of such notice either beforehand or retrospectively. The quorum for the commencement of the adjourned meeting shall be at least one member of the Board.

Methods of Attending Meetings

65. Some or all of the directors may attend meetings of the Board through computer network, telephone or any other media of communication, enabling the directors to communicate with each other, in the deemed presence of all of them, provided that due prior notice detailing the time and manner of holding a given meeting is served upon all the directors. The directors may waive the necessity of such notice either beforehand or retrospectively.

Any resolution adopted by the Board in such a meeting, pursuant to the provisions of these Articles, will be recorded in writing and signed by the Chairman (or in his absence by the chairman of the meeting), and shall be valid as if adopted at a meeting of the Board duly convened and held.

66. A resolution in writing signed by all of the directors eligible to participate in the discussion and vote on such resolution, or in respect of which all such directors have agreed (in writing by mail, fax or electronic mail) not to convene, shall be as valid and effective for all purposes as if passed at a meeting of the Board duly convened and held.

Any such resolution may consist of several counterparts, each signed by one or more directors. Such resolution in writing shall be effective as of the last date appearing on the resolution, or if the resolution is signed in two or more counterparts, as of the last date appearing on the counterparts.

67. While exercising his/her voting right, each director shall have one vote. Resolutions of the Board will be decided by a simple majority of the directors present and voting, not taking into consideration abstaining votes, except as otherwise provided in these Articles or by the Statutes. In the event the vote is tied, the Chairman of the Board shall not have a casting vote, and such resolution shall be deemed rejected.

Alternate Director

68. Subject to the Law, a director shall be entitled at any time and from time to time to appoint in writing any person who is qualified to serve as a director, to act as his/her alternate and to terminate the appointment of such person. The appointment of an alternate director does not negate the responsibility of the appointing director and such responsibility shall continue to apply to such appointing director - taking into account the circumstances of the appointment.

Alternate directors shall be entitled, while holding office, to receive notices of meetings of the Board and to attend and vote as a director at any meetings at which the appointing director is not present and generally to exercise all the powers, rights, duties and authorities and to perform all functions of the appointing director.

The document appointing an alternate director must be submitted to the Chairman of the Board at least 48 hours before the opening of the first Board meeting to be attended by such alternate director.

Committees

69. The Board may set up committees and appoint members to these committees subject to the Statutes. A resolution passed or an act done by such a committee pursuant to an authority granted to such committee by the Board shall be treated as a resolution passed or act done by the Board, unless expressly otherwise prescribed by the Board or the Statutes for a particular matter or in respect of a particular committee.

70. Meetings of committees and proceedings thereat (including the convening of the meetings, the election of the chairman and the votes) shall be governed by the provisions herein contained for regulating the meetings and proceedings of the Board so far as the same are applicable thereto and unless otherwise determined by the Board, including by an adoption of a charter governing the committee proceedings.

Approval of Certain Transactions with Related Parties

71. Subject to the Law and pursuant to Section 271 of the Law, a transaction between the Company and an Office Holder (other than with respect to the compensation terms of such Office Holder), and a transaction between the Company and another entity in which an Office Holder of the Company has a personal interest, which is not an Extraordinary Transaction (as defined by Law), shall be approved by the Board or a committee of the Board or any other body or person (who has no personal interest in the transaction) authorized by the Board. Such authorization, as well as the actual approval by the authorized body or person, may be for a particular transaction or more generally for specific type of transactions.

Records and Validity of Acts

72. The resolutions of the Board shall be recorded in the Company's Minutes Book, as required under the Statutes, signed by the Chairman or the chairman of a certain meeting. Such signed minutes shall be deemed *prima facie* evidence of the meeting and the resolutions resolved therein.

73. All acts done bona fide by any meeting of the Board or of a committee of the Board or by any person acting as a director, shall, notwithstanding it be afterwards discovered that there was some defect in the appointment of any such director or person acting as aforesaid, or that they or any of them were disqualified, be as valid as if every such person had been duly appointed and was qualified to be a director.

Chief Executive Officer

74. The Board shall appoint at least one CEO, for such period and upon such terms as the Board deems fit.

75. The CEO shall have all managing and execution powers within the policies and guidelines set forth by the Board, and shall be under the supervision of the Board. The CEO may delegate any of his powers to his subordinates, subject to the approval of the Board.

INSURANCE, EXCULPATION, AND INDEMNITY

Insurance of Office Holders

76. The Company may insure the liability of an Office Holder, to the fullest extent permitted under the Statutes.

77. Without derogating from the aforesaid, the Company may enter into a contract to insure the liability of an officer therein for an obligation imposed on him in consequence of an act done in his capacity as an Office Holder, in any of the following cases:

77.1. A breach of the duty of care vis-a-vis the Company or vis-a-vis another person;

77.2. A breach of the fiduciary duty vis-a-vis 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;

77.3. A monetary obligation imposed on him in favor of another person;

77.4. A monetary liability imposed on such Office Holder in favor of a payment to a breach offended at an Administrative Procedure as set forth in Section 52(54)(a)(1)(a) to the Securities Law and expenses regarding Administrative Procedures conducted in connection with such Office Holder and/or in connection with a monetary sanction, including reasonable litigation expenses and reasonable attorney's fees;

77.5. Any other matter in respect of which it is permitted or will be permitted under applicable law to insure the liability of an Office Holder in the Company.

Indemnity of Office Holders

78. The Company may indemnify an Office Holder, to the fullest extent permitted under the Statutes. Without derogating from the aforesaid, the Company may indemnify an Office Holder for a liability or expense imposed on him in consequence of an act done in his capacity as an Office Holder in the Company, as follows:

78.1. 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;

78.2. 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;

78.3. 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 the Office Holder by the Company, on its behalf, or by a third party, or (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;

78.4. a monetary liability imposed on the Office Holder in favor of all the injured parties by the breach in an Administrative Procedure as set forth in Section 52(54)(a)(1)(a) to the Securities Law;

78.5. expenses expended by the Office Holder with respect to an Administrative Procedure under the Securities Law, including reasonable litigation expenses and reasonable attorneys' fees; and

78.6. any other obligation or expense in respect of which it is permitted or will be permitted under applicable law to indemnify an Office Holder.

Advance Indemnity

79. The Company may give an advance undertaking to indemnify an Office Holder therein in respect of the following matters:

79.1. matters as detailed in Article 78.1, provided however, that the undertaking is restricted to events, which in the opinion of the Board, are anticipated in light of the Company's activities at the time of granting the obligation to indemnify and is limited to a sum or measurement determined by the Board as reasonable under the circumstances. The indemnification undertaking shall specify such events and sum or measurement; and

79.2. matters as detailed in Articles 78.2 through 78.6.

Retroactive Indemnity

80. The Company may indemnify an Office Holder retroactively with respect of the matters as detailed in Article 78, subject to any applicable law.

Exculpation

81. The Company may exempt an Office Holder in advance for all or any of his liability for damage in consequence of a breach of the duty of care vis-a-vis the Company, to the fullest extent permitted under the Statutes. However, the Company may not exempt a director in advance from his liability toward the Company due to the breach of his/her duty of care in a Distribution.

Insurance, Exculpation and Indemnity – General

82. The above provisions with regard to insurance, exemption and indemnity are not and shall not limit the Company in any way with regard to its entering into an insurance contract and/or with regard to the grant of indemnity and/or exemption in connection with a person who is not an Office Holder of the Company, including employees, contractors or consultants of the Company, all subject to any applicable law.

83. The Company may enter into a contract in relation to exemption, indemnification and insurance of Office Holders in companies under its control, related companies and other companies in which it has any interest, to the maximum extent permitted under the Statutes, and in this context the foregoing provisions in relation to exemption, indemnification and insurance of Office Holders in the Company shall apply, *mutatis mutandis*.

84. An undertaking in relation to exemption, indemnification and insurance of an Office Holder as aforesaid may also be valid after the office of such Office Holder in the Company has terminated.

APPOINTMENT OF AN AUDITOR

85. Subject to the Statutes, the Annual Meeting shall appoint an Auditor for a period ending at the next Annual Meeting, or for a longer period, but no longer than until the third Annual Meeting after the meeting at which the Auditor has been appointed. The same Auditor may be re-appointed.

Subject to the Statutes, the terms of service of the Auditor for the audit services shall be determined by the Board, at its discretion, or a committee of the Board if such determination was delegated to a committee, including undertakings or payments to the Auditor. The Board shall report the fees of the Auditor to the Annual Meeting.

INTERNAL AUDITOR

86. So long as the Company is a Public Company, the Board shall appoint an Internal Auditor pursuant to the recommendation of the Audit Committee.
87. The organizational superior of the Internal Auditor shall be the Chairman. The Internal Auditor shall submit a proposed annual or periodic work plan to the Audit Committee or the Board of Directors, which will approve such plan with changes as it deems fit, at its discretion.

MERGER AND REORGANIZATION

88. Notwithstanding the provisions of Section 327(a) of the Companies Law, the majority required for the approval of a merger by the general meeting or by a class meeting shall be a Simple Majority.

SIGNATORIES

89. Signatory rights on behalf of the Company shall be determined from time to time by the Board.

DISTRIBUTIONS

90. The Board may decide on a Distribution, subject to the provisions set forth under the Law and these Articles.

91. The Board will determine the method of payment of any Distribution. The receipt of the person whose name appears on the record date on the Register as the owner of any share, or in the case of joint holders, of any one of such joint holders, shall serve as confirmation with respect to all the payments made in connection with that share and in respect of which the receipt was received. All dividends unclaimed after having been declared may be invested or otherwise used by the Directors for the benefit of the Company until claimed, provided however that the Company shall not be required to accept any claim made following the 7th anniversary of the declaration date, or an earlier date as may be determined by the Board. No unpaid dividend shall bear interest or accrue linkage differentials.

92. For the purpose of implementing any resolution concerning any Distribution, the Board may settle, as it deems fit, any difficulty that may arise with respect to the Distribution, including determining the value for the purpose of the said Distribution of certain assets, and deciding that payments in cash shall be made to the shareholders based on the value so determined, and determining provisions with respect to fractions of shares or with respect to the non-payment of small sums.

REDEEMABLE SECURITIES

93. The Company shall be entitled to issue redeemable securities which are, or at the option of the Company may be, redeemed on such terms and in such manner as shall be determined by the Board. Redeemable securities shall not constitute part of the Company's capital, except as provided in the Law.

DONATIONS

94. The Company may make donations of reasonable amounts of money for purposes which the Board deems to be worthy causes, even if the donations are not made in relation to business considerations for increasing the Company's profits.

NOTICES

95. Subject to the Statutes, notice or any other document which the Company shall deliver and which it is entitled or required to give pursuant to the provisions of these Articles and/or the Statutes shall be delivered by the Company to any person, in any one of the following manners as the Company may choose: in person, by mail, transmission by fax or by electronic form.

Any notice or other document which shall be sent shall be deemed to have reached its destination on the third day after the day of mailing if sent by registered mail or regular mail, or on the first day after transmission if delivered in person, transmitted by fax or electronic form.
Should it be required to prove delivery, it shall be sufficient to prove that the notice or document sent contains the correct mailing, e-mail, or fax details as registered in the Register or any other address which the shareholder submitted in writing to the Company as the address and fax or e-mail details for the submission of notices or other documents.

Subject to the provisions of the Statutes, a notice to a shareholder may be served, as a general notice to all shareholders, published by the Company on the website of (i) the United States Securities and Exchange Commission, and (ii) the Company, in accordance with applicable rules and regulations of any stock market upon which the Company's shares are listed.

In cases where it is necessary to give advance notice of a particular number of days or notice which shall remain in effect for a particular period, the day the notice was sent shall be excluded and the scheduled day of the meeting or the last date of the period shall be included in the count.

The Company shall not be required to give notice to its registered shareholders pursuant to the Companies Law, unless otherwise required by Statutes. Subject to the Statutes, the Company shall not be required to send notices to any shareholder who is not registered in the Register or has not provided the Company with accurate and sufficient mailing details.

96. Any notice to be given to the shareholders shall be given, with respect to joint shareholders, to the person whose name appears first in the Register as the holder of the said share, and any notice so given shall be sufficient notice for all holders of the said share.

97. Any notice or other document served upon or sent to any shareholder in accordance with these Articles shall, notwithstanding that he be then deceased or bankrupt, and whether the Company received notice of his death or bankruptcy or not, be deemed to be duly served or sent in respect of any shares held by him (either alone or jointly with others) until some other person is registered in his stead as the holder or joint holder of such shares, and such service or sending shall be a sufficient service or sending on or to his heirs, executors, administrators or assigns and all other persons (if any) interested in such share.

98. The accidental omission to give notice to any shareholder or the non-receipt of any such notice shall not cancel or annul any action made in reliance on the notice.

Exhibit 2.2

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

This section summarizes certain information regarding the ordinary shares, par value NIS 0.1 per share (the "Ordinary Shares") of Sol-Gel Technologies Ltd. (the "Company"). The Ordinary Shares constitute the only class of the Company's securities that is registered under Section 12 of the Securities Exchange Act of 1934, as amended. The following descriptions of our Ordinary Shares and provisions of our amended and restated articles of association (the "Articles") is a summary and does not purport to be complete and is qualified by refence to the Articles, which are filed with the Securities and Exchange Commission as an exhibit to our annual report on Form 20-F.

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 Israeli Companies Law.

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.

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, subject to certain exceptions with respect to the buyback by the Company of its ordinary shares, 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) 10% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 10% or more of our outstanding voting power.

Under Israeli law, one or more shareholders holding at least 5% of the voting rights at a general meeting of shareholders may request that our board of directors include a proposal that relates to the election or removal of a director in the agenda of a general meeting of shareholders to be convened in the future. 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 any other 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 60 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 33⅓% 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 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.

Certain transactions with respect to remuneration of our office holders and directors require further approvals. 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

In connection with the closing of our initial public offering, we entered into a registration rights agreement, pursuant to which we granted demand registration rights, short-form registration rights and piggyback registration rights to M. Arkin Dermatology Ltd., our controlling shareholder. All fees, costs and expenses of underwritten registrations are expected to be borne by us..”

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.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements of 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.

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.

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.

Trading of Ordinary Shares

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

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company, LLC.

Exhibit 2.3

REGISTRATION RIGHTS AGREEMENT

AGREEMENT dated as of March 30, 2023 (this "**Agreement**") among Sol-Gel Technologies Ltd., a company incorporated under the laws of the Israel (the "**Company**"), and M. Arkin Dermatology Ltd.

In consideration of the mutual promises made herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

Section 1.01. *Definitions.* (a) The following terms, as used herein, have the following meanings:

"**Affiliate**" means, with respect to any Person, any other Person directly or indirectly controlling, controlled by or under common control with such Person, *provided* that no security holder of the Company shall be deemed an Affiliate of any other security holder solely by reason of any investment in the Company. For the purpose of this definition, the term "**control**" (including, with correlative meanings, the terms "**controlling**", "**controlled by**" and "**under common control with**"), as used with respect to any Person, shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

"**Business Day**" means any day except a Friday or a Saturday or other day on which most Israeli banking institutions are not open for business.

"**Company Securities**" means the Ordinary Shares held on the date hereof or acquired after the date hereof, including, without limitation, the Ordinary Shares and the Ordinary Shares issuable upon exercise of Warrants acquired or to be acquired by M. Arkin Dermatology Ltd. pursuant to that certain Subscription Agreement, dated as of January 27, 2023, between the Company and M. Arkin Dermatology Ltd.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

"**FINRA**" means the Financial Industry Regulatory Authority (formerly, the National Association of Securities Dealers, Inc.) and any successor thereto.

"**Ordinary Shares**" means ordinary shares, par value NIS 0.1 per share, of the Company and any shares into which such Ordinary Shares may thereafter be converted or changed.

"**Permitted Transferee**" means in the case of any Shareholder, a Person to whom Registrable Securities or any other securities of the Company convertible or exercisable into or exchangeable for Company Securities are Transferred by such Shareholder; *provided that* (i) such Transfer does not violate any agreements between such Shareholder and the Company or any of the Company's subsidiaries, (ii) such Transfer is not made in a registered offering or pursuant to Rule 144, and (iii) such transferee is (A) an Affiliate of the Shareholder or (B) acquires at least 20% of the Shareholder's Registrable Securities (including for these purposes Company Securities that are issuable upon the conversion, exercise or exchange of any other securities of the Company).

"**Person**" means an individual, corporation, limited liability company, partnership, association, trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

"**Public Offering**" means an underwritten public offering of Company Securities (or any securities representing Company Securities) pursuant to an effective registration statement under the Securities Act, other than pursuant to a registration statement on Form S-4, Form F-4 or Form S-8 or any similar or successor form.

"**Registrable Securities**" means, at any time, any Company Securities and any other securities issued or issuable by the Company or any of its successors or assigns in respect of any such Company Securities by way of conversion, exchange, exercise, dividend, split, reverse split, combination, recapitalization, reclassification, merger, amalgamation, consolidation, sale of assets, other reorganization or otherwise, in each case held on the date hereof or acquired after the date hereof, until (i) a registration statement covering such Company Securities or such other securities has been declared effective by the SEC and such Company Securities or such other securities have been disposed of pursuant to such effective registration statement, (ii) such Company Securities or such other securities are sold under circumstances in which all of the applicable conditions of Rule 144 are met or (iii) all of such Company Securities and such other securities held by the holder thereof are eligible for sale by such holder under Rule 144 without any limitation thereunder (including with respect to volume or manner of sale) or need for current public information.

"**Registration Expenses**" means any and all expenses incident to the performance of, or compliance with, any registration or marketing of securities (other than transfer taxes, if any), including without limitation all (i) registration and filing fees, and all other fees and expenses payable in connection with the listing of securities on any securities exchange or automated interdealer quotation system, (ii) fees and expenses of compliance with any securities or "blue sky" laws (including reasonable fees and disbursements of counsel in connection with "blue sky" qualifications of the securities registered), (iii) expenses in connection with the preparation, printing, mailing and delivery of any registration statements, prospectuses and other documents in connection therewith and any amendments or supplements thereto, (iv) security engraving and printing expenses, (v) internal expenses of the Company (including all salaries and expenses of its officers and employees performing legal or accounting duties), (vi) reasonable fees and disbursements of counsel for the Company and customary fees and expenses for independent certified public accountants retained by the Company (including the expenses relating to any comfort letters or costs associated with the delivery by independent certified public accountants of any comfort letters requested pursuant to Section 2.04(h)), (vii) reasonable fees and expenses of any special experts retained by the Company in connection with such registration, (viii) reasonable fees and disbursements of one counsel for all of the Shareholders participating in the offering selected by the Shareholders holding the majority of the Registrable Securities to be sold for the account of all Shareholders in the offering, in an amount not to exceed $50,000, (ix) fees and expenses in connection with any review by FINRA of the underwriting arrangements or other terms of the offering, and all fees and expenses of any "qualified independent underwriter," including the fees and expenses of any counsel thereto, (x) fees and disbursements of underwriters customarily paid by issuers, but excluding any underwriting fees, discounts and commissions attributable to the sale of Registrable Securities, (xi) costs of printing and producing any agreements among underwriters, underwriting agreements, any "blue sky" or legal investment memoranda and any selling agreements and other documents in connection with the offering, sale or delivery of the Registrable Securities, (xii) transfer agents' and registrars' fees and expenses and the fees and expenses of any other agent or trustee appointed in connection with such offering, (xiii) expenses relating to any analyst or investor presentations or any "road shows" undertaken in connection with the registration, marketing or selling of the Registrable Securities, and (xiv) all out-of-pocket costs and expenses incurred by the Company or its appropriate officers in connection with their compliance with Section 2.04(m). Except as set forth in clause (viii) above, Registration Expenses shall not include any out-of-pocket expenses of the Shareholders (or the agents who manage their accounts).

"**Rule 144**" means Rule 144 (or any successor or similar provisions) under the Securities Act.

"**SEC**" means the Securities and Exchange Commission.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Shareholder**" means at any time, any Person (other than the Company) who shall then be a party to or bound by this Agreement (including without limitation any Permitted Transferees who become a party to this Agreement pursuant to Section 5.01(b)), so long as such Person shall "beneficially own" (as such term is defined in Rule 13d-3 of the Exchange Act) any Company Securities.

"**Transfer**" means, with respect to any Company Securities or any other securities of the Company that are convertible or exercisable into or exchangeable for Company Securities, (i) when used as a verb, to sell, assign, dispose of, exchange, pledge, encumber, hypothecate or otherwise transfer such Company Securities or any participation or interest therein, whether directly or indirectly, or agree or commit to do any of the foregoing and (ii) when used as a noun, a direct or indirect sale, assignment, disposition, exchange, pledge, encumbrance, hypothecation, or other transfer of such Company Securities or any participation or interest therein or any agreement or commitment to do any of the foregoing.

Section 1.02. *Other Definitional and Interpretative Provisions.* The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import.

ARTICLE 2
REGISTRATION RIGHTS

Section 2.01. *Demand Registration*. (a) If at any time, subject to the terms of any "lock-up" agreement entered into with one or more underwriters (unless waived by such underwriter(s)), the Company shall receive a request (each such request shall be referred to herein as a "**Demand Registration**") from a Shareholder or group of Shareholders (the requesting Shareholder(s) shall be referred to herein as the "**Requesting Shareholder**"), holding at least thirty percent (30%) of the Registrable Securities then outstanding, that the Company effect the registration under the Securities Act all or any portion of the Requesting Shareholder's Registrable Securities and, in each case, specifying the intended method of disposition thereof, then the Company shall as promptly as practicable following the date of receipt by the Company of such request give notice of such Demand Registration at least fifteen (10) days after receipt of such Demand Registration to the other Shareholders, if any, and thereupon shall (i) as soon as practicable, and in any event within forty five (45) days after the date the Demand Registration is given by the Requesting Shareholder, file a registration statement under the Securities Act, and (ii) use its commercially reasonable efforts to effect, as expeditiously as possible, and in any event within one hundred twenty (120) days after the date the Demand Registration is given by the Requesting Shareholder, the effectiveness of the registration statement, in each case covering:

(i) subject to the restrictions set forth in Sections 2.01(e), all Registrable Securities for which the Requesting Shareholder has requested registration under this Section 2.01, and

(ii) subject to the restrictions set forth in Sections 2.01(e), all other Registrable Securities of the same class as those requested to be registered by the Requesting Shareholder that any other Shareholders (all such Shareholders, together with the Requesting Shareholder, the "**Registering Shareholders**"), if any, have requested the Company to register pursuant to this Section 2.01, by request received by the Company within seven Business Days after such Shareholders receive the Company's notice of the Demand Registration,

all to the extent necessary to permit the disposition (in accordance with the intended methods thereof as aforesaid) of the Registrable Securities so to be registered, *provided* that, the Company shall not be obligated to effect a Demand Registration unless the aggregate proceeds expected to be received from the sale of the Registrable Securities requested to be included in such Demand Registration equals or exceeds $10,000,000. In no event shall the Company be required to effect more than two (2) Demand Registrations pursuant to this Section 2.01.

(b) Promptly after the expiration of the seven-Business Day period referred to in Section 2.01(a)(ii), the Company will notify all Registering Shareholders of the identities of the other Registering Shareholders and the number of shares of Registrable Securities requested to be included therein. At any time prior to the effective date of the registration statement relating to such registration, the Requesting Shareholder may revoke such request, without liability, by providing a notice to the Company revoking such request. Notwithstanding clause (d) below, a request, so revoked, shall be considered to be a Demand Registration unless (i) such revocation arose out of the fault of the Company (in which case the Company shall be obligated to pay all Registration Expenses in connection with such revoked request) or (ii) the Requesting Shareholder reimburses the Company for all Registration Expenses (other than the expenses set forth under clause (v) of the definition of the term Registration Expenses) of such revoked request.

(c) The Company shall be liable for and shall pay all Registration Expenses in connection with any Demand Registration, regardless of whether such Registration is effected, unless the Requesting Shareholder elects to pay such Registration Expenses as described in the last sentence of Section 2.01(b).

(d) A Demand Registration shall not be deemed to have occurred unless the registration statement relating thereto (i) has become effective under the Securities Act and (ii) has remained effective for a period of at least 180 days (or such shorter period in which all Registrable Securities of the Registering Shareholders included in such registration have actually been sold thereunder), *provided* that a Demand Registration shall not be deemed to have occurred if, after such registration statement becomes effective, such registration statement is interfered with by any stop order, injunction or other order or requirement of the SEC or other governmental agency or court.

(e) If the Requesting Shareholder intends to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as part of their request pursuant to section 2.01, and the Company shall include such information in their notice to the other Shareholders. If a Demand Registration involves an underwritten Public Offering and the managing underwriter advises the Company and the Requesting Shareholder that, in its view, the number of shares of Registrable Securities requested to be included in such registration (including any securities that the Company proposes to be included that are not Registrable Securities) exceeds the largest number of shares that can be sold without having an adverse effect on such offering, including the price at which such shares can be sold (the "**Maximum Offering Size**"), the Company shall include in such registration, in the priority listed below, up to the Maximum Offering Size:

(i) first, all Registrable Securities requested to be included in such registration by all Registering Shareholders (allocated, if necessary for the offering not to exceed the Maximum Offering Size, pro rata among such Shareholders on the basis of the relative number of Registrable Securities held by each such Shareholder, or in such other proportion as shall mutually be agreed to by all such Registering Shareholders); and

(ii) second, any securities proposed to be registered by the Company (including for the benefit of any other Persons not party to this Agreement).

(f) The Company may postpone effecting a registration pursuant to this Section 2.01 on two occasions during any period of twelve consecutive months for a reasonable time specified in the notice but not exceeding 90 days in the aggregate in any period of twelve consecutive months (which period may not be extended or renewed), if the Company furnishes to the Requesting Shareholder a certificate signed by the Company's chief executive officer stating that (i) effecting the registration would materially and adversely interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company or (ii) effecting the registration would require the premature disclosure of material information that the Company has a bona fide business purpose to preserve as confidential. In addition, the Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.01 during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration (other than a registration on Form S-8 or any successor or similar forms), provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective.

Section 2.02. *Piggyback Registration*. (a) If at any time the Company proposes to register any Company Securities under the Securities Act (other than (i) a Shelf Registration (defined below), which will be subject to the provisions of Section 2.03; *provided* that any Underwritten Takedown (defined below) will be subject to this Section 2.02, or (ii) a registration on Form S-8, F-4 or S-4, or any successor or similar forms, relating to Ordinary Shares issuable upon exercise of employee stock options or in connection with any employee benefit or similar plan of the Company or in connection with a direct or indirect acquisition by the Company of another Person), whether or not for sale for its own account, the Company shall each such time give prompt notice at least ten (10) Business Days prior to the anticipated filing date of the registration statement relating to such registration to each Shareholder, which notice shall set forth such Shareholder's rights under this Section 2.02 and shall offer such Shareholder the opportunity to include in such registration statement the number of Registrable Securities of the same class or series as those proposed to be registered as each Shareholder may request (a "**Piggyback Registration**"), subject to the provisions of Section 2.02(b). Upon the request of any such Shareholder made within five (5) Business Days after the receipt of notice from the Company (which request shall specify the number of Registrable Securities intended to be registered by such Shareholder), the Company shall use all commercially reasonable efforts to effect the registration under the Securities Act of all Registrable Securities that the Company has been so requested to register by all such Shareholders, to the extent required to permit the disposition of the Registrable Securities so to be registered, *provided* that (A) if such registration involves an underwritten Public Offering, all such Shareholders requesting to be included in the Company's registration must sell their Registrable Securities to the underwriters selected as provided in Section 2.04(f) on the same terms and conditions as apply to the Company, and (B) if, at any time after giving notice of its intention to register any Company Securities pursuant to this Section 2.02(a) and prior to the effective date of the registration statement filed in connection with such registration, the Company shall determine for any reason not to register such securities, the Company shall give notice to all such Shareholders and, thereupon, shall be relieved of its obligation to register any Registrable Securities in connection with such registration. No registration effected under this Section 2.02 shall relieve the Company of its obligations to effect a Demand Registration to the extent required by Section 2.01 or a Shelf Registration to the extent required by Section 2.03. The Company shall pay all Registration Expenses in connection with each Piggyback Registration.

(b) If a Piggyback Registration involves an underwritten Public Offering and the managing underwriter advises the Company that, in its view, the number of Shares that the Company and the Shareholders intend to include in such registration exceeds the Maximum Offering Size, the Company shall include in such registration, in the following priority, up to the Maximum Offering Size:

(i) first, so much of the Company Securities proposed to be registered for the account of the Company (or, if such registration is pursuant to a demand by a Person that is not a Shareholder, for the account of such other Person) as would not cause the offering to exceed the Maximum Offering Size,

(ii) second, all Registrable Securities requested to be included in such registration by any Shareholders pursuant to this Section 2.02 (allocated, if necessary for the offering not to exceed the Maximum Offering Size, pro rata among such Shareholders on the basis of the relative number of Registrable Securities held by each such Shareholder, or in such other proportion as shall mutually be agreed to by all such Registering Shareholders), and

(iii) third, any securities proposed to be registered for the account of any other Persons with such priorities among them as the Company shall determine;

provided that, notwithstanding the foregoing, in no event shall the number of Registrable Securities included in the underwritten Public Offering be reduced below 25% of the total number of securities included in such Public Offering.

Section 2.03. *Shelf Registration*. (a) At any time, if the Company is eligible to use Form F-3 or Form S-3, a Shareholder or group of Shareholders (referred to herein as the "**Shelf Requesting Shareholder**") may request the Company to effect a registration of some or all of the Registrable Securities held by such Shelf Requesting Shareholder under a Registration Statement pursuant to Rule 415 under the Securities Act (or any successor or similar rule) (a "**Shelf Registration**"); *provided* that, the Company shall not be obligated to effect a Shelf Registration unless the aggregate proceeds expected to be received from the sale of the Registrable Securities requested to be included in such Shelf Registration equals or exceeds $5,000,000 (net of discounts and commissions). A Shareholder or group of Shareholders whose Registrable Securities are included in such Shelf Registration or may be included therein without the need for an amendment to such Shelf Registration (other than an automatically effective amendment) may demand that the Company to effectuate a Public Offering from such Shelf Registration (an "**Underwritten Takedown**"), provided that the Company shall only be required to effectuate two Underwritten Takedowns within any twelve-month period. The provisions of Section 2.01 shall apply *mutatis mutandis* to each Underwritten Takedown, with references to "filing of the registration statement" or "effective date" being deemed references to filing of a prospectus or supplement for such offering and references to "registration" being deemed references to the offering; *provided* that Registering Shareholders shall only include Shareholders whose Registrable Securities are included in such Shelf Registration or may be included therein without the need for an amendment to such Shelf Registration (other than an automatically effective amendment). So long as the Shelf Registration is effective, no Shareholder may request any Demand Registration pursuant to Section 2.01 with respect to Registrable Shares that are registered on such Shelf Registration but instead shall have the right to request an Underwritten Takedown as set forth above.

(b) If the Company shall receive a request from a Shelf Requesting Shareholder that the Company effect a Shelf Registration, then the Company shall as promptly as practicable following the date of receipt by the Company of such request give notice of such requested registration and at least ten (10) Business Days prior to the anticipated filing date of the registration statement relating to such Shelf Registration to the other Shareholders and thereupon shall (i) as soon as practicable, and in any event within forty five (45) days after the date the request for a Shelf Registration is given by the Shelf Requesting Shareholder, file a registration statement on Form F-3 or S-3, as applicable, under the Securities Act, and (ii) use its reasonable best efforts to effect, as expeditiously as possible, and in any event within one hundred (120) days after the date the request for a Shelf Registration is given by the Shelf Requesting Shareholder, the effectiveness of a registration statement under the Securities Act, in each case covering:

(i) all Registrable Securities for which the Shelf Requesting Shareholder has requested registration under this Section 2.03, and

(ii) all other Registrable Securities of the same class as those requested to be registered by the Shelf Requesting Shareholder that any other Shareholders (all such Shareholders, together with the Shelf Requesting Shareholder, the "**Shelf Registering Shareholders**") have requested the Company to register by request received by the Company within five (5) Business Days after such Shareholders receive the Company's notice of the Shelf Registration, all to the extent necessary to permit the registration of the Registrable Securities so to be registered on such Shelf Registration.

(c) At any time prior to the effective date of the registration statement relating to such Shelf Registration, the Shelf Requesting Shareholder may revoke such request, without liability, by providing a notice to the Company revoking such request.

(d) The Company shall be liable for and pay all Registration Expenses in connection with any Shelf Registration.

(e) The Company may postpone effecting a registration or an Underwritten Takedown pursuant to this Section 2.03 on two occasions during any period of twelve consecutive months for a reasonable time specified in the notice but not exceeding 90 days in the aggregate in any period of twelve consecutive months (which period may not be extended or renewed), if the Company furnishes to Requesting Shareholder a certificate signed by the Company's chief executive officer stating that (i) effecting the registration would materially and adversely interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company or (ii) effecting the registration would require the premature disclosure of material information that the Company has a bona fide business purpose to preserve as confidential. In addition, the Company shall not be obligated to effect, or to take any action to effect, any registration or any Underwritten Takedown pursuant to Section 2.03 during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration (other than a registration on Form S-8 or any successor or similar forms), provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective.

Section 2.04. *Registration Procedures*. In connection with Section 2.01, 2.02 and 2.03, subject to the provisions of such Sections, the Company shall use all commercially reasonable efforts to effect the registration and the sale of such Registrable Securities in accordance with the intended method of disposition thereof as quickly as practicable, and, in connection with any such request:

(a) The Company shall as expeditiously as possible prepare and file with the SEC a registration statement on any form for which the Company then qualifies or that counsel for the Company shall deem appropriate and which form shall be available for the sale of the Registrable Securities to be registered thereunder in accordance with the intended method of distribution thereof, and use all commercially reasonable efforts to cause such filed registration statement to become and remain effective for a period of not less than 180 days or in the case of a Shelf Registration, three years (or such shorter period in which all of the Registrable Securities of the Shareholders included in such registration statement shall have actually been sold thereunder or cease to be Registrable Securities). Any such registration statement shall be an automatically effective registration statement to the extent permitted by the SEC's rules and regulations.

(b) Prior to filing a registration statement or prospectus or any amendment or supplement thereto (other than any report filed pursuant to the Exchange Act that is incorporated by reference therein), the Company shall, if requested, furnish to each participating Shareholder and each underwriter, if any, of the Registrable Securities covered by such registration statement copies of such registration statement as proposed to be filed, and thereafter the Company shall furnish to such Shareholder and underwriter, if any, such number of copies of such registration statement, each amendment and supplement thereto (in each case including all exhibits thereto and documents incorporated by reference therein), the prospectus included in such registration statement (including each preliminary prospectus and any summary prospectus) and any other prospectus filed under Rule 424, Rule 430A, Rule 430B or Rule 430C under the Securities Act and such other documents as such Shareholder or underwriter may reasonably request in order to facilitate the disposition of the Registrable Securities owned by such Shareholder.

(c) After the filing of the registration statement, the Company shall (i) cause the related prospectus to be supplemented by any required prospectus supplement and, as so supplemented, to be filed pursuant to Rule 424 under the Securities Act, (ii) comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement during the applicable period in accordance with the intended methods of disposition by the Shareholders thereof set forth in such registration statement or supplement to such prospectus and (iii) promptly notify each Shareholder holding Registrable Securities covered by such registration statement of any stop order issued or threatened by the SEC or any state securities commission and take all reasonable actions required to prevent the entry of such stop order or to remove it if entered.

(d) The Company shall use all commercially reasonable efforts to (i) register or qualify the Registrable Securities covered by such registration statement under such other securities or "blue sky" laws of such jurisdictions in the United States as any Registering Shareholder or Shelf Registering Shareholder holding such Registrable Securities reasonably (in light of such Shareholder's intended plan of distribution) requests and (ii) cause such Registrable Securities to be registered with or approved by such other governmental agencies or authorities as may be necessary by virtue of the business and operations of the Company and do any and all other acts and things that may be reasonably necessary or advisable to enable such Shareholder to consummate the disposition of the Registrable Securities owned by such Shareholder, *provided* that the Company shall not be required to (A) qualify generally to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 2.04(d), (B) subject itself to taxation in any such jurisdiction or (C) consent to general service of process in any such jurisdiction.

(e) The Company shall promptly notify each Shareholder holding such Registrable Securities covered by such registration statement, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the occurrence of an event requiring the preparation of a supplement or amendment to such prospectus so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus will not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein in the light of the circumstances under which they were made at such time not misleading and promptly prepare and make available to each such Shareholder and file with the SEC any such supplement or amendment.

(f) The Company shall have the right to select an underwriter or underwriters in connection with any Public Offering resulting from any exercise of a Demand Registration (including any Underwritten Takedown), which underwriter or underwriters shall be reasonably acceptable to the Requesting Shareholder. In connection with any Public Offering, the Company shall enter into customary agreements (including an underwriting agreement in customary form) and take such all other actions as are reasonably required in order to expedite or facilitate the disposition of such Registrable Securities in any such Public Offering, including the engagement of a "qualified independent underwriter" in connection with the qualification of the underwriting arrangements with FINRA.

(g) Upon execution of confidentiality agreements in form and substance reasonably satisfactory to the Company, the Company shall, in connection with a Public Offering make available for inspection by any Shareholder and any underwriter participating in any disposition pursuant to a registration statement being filed by the Company pursuant to this Agreement and any attorney, accountant or other professional retained by any such Shareholder or underwriter (collectively, the "**Inspectors**"), all financial and other records, pertinent corporate documents and properties of the Company (collectively, the "**Records**") as shall be reasonably necessary or desirable to enable any of the Inspectors to exercise its due diligence responsibility, and cause the Company's officers, directors and employees to supply all information reasonably requested by any Inspectors in connection with such registration statement. Records that the Company determines, in good faith, to be confidential and that it notifies the Inspectors are confidential shall not be disclosed by the Inspectors unless (i) the disclosure of such Records is necessary to avoid or correct a material misstatement or omission in such registration statement or (ii) the release of such Records is ordered pursuant to a subpoena or other order from a court of competent jurisdiction. Each Shareholder agrees that information obtained by it as a result of such inspections shall be deemed confidential and shall not be used by it or its Affiliates as the basis for any market transactions in the Company Securities unless and until such information is made generally available to the public. Each Shareholder further agrees that, upon learning that disclosure of such Records is sought in a court of competent jurisdiction, it shall give notice to the Company and allow the Company, at its expense, to undertake appropriate action to prevent disclosure of the Records deemed confidential.

(h) In connection with any Public Offering, the Company shall use its reasonable best efforts to furnish to each underwriter, if any, a signed counterpart, addressed to such underwriter, of (i) an opinion or opinions of counsel to the Company and (ii) a comfort letter or comfort letters from the Company's independent public accountants, each in customary form and covering such matters of the kind customarily covered by opinions or comfort letters, as the case may be, as the managing underwriter therefor reasonably requests.

(i) The Company shall otherwise use its reasonable best efforts to comply with all applicable rules and regulations of the SEC, and make available to its security holders, as soon as reasonably practicable, an earnings statement or such other document covering a period of twelve months, beginning within three months after the effective date of the registration statement, which earnings statement satisfies the requirements of Rule 158 under the Securities Act.

(j) The Company may require each Shareholder promptly to furnish in writing to the Company such information regarding the distribution of the Registrable Securities as the Company may from time to time reasonably request and such other information as may be legally required in connection with such registration. In connection with a Shelf Registration, any Shareholder that does not provide such information within five (5) Business Days of a request by the Company (which request is made before filing of the Shelf Registration) may have its Registrable Securities excluded from such Shelf Registration; *provided* that such securities shall be added within fifteen Business Days after the Shareholder provides such information if the Company may add such securities to such Shelf Registration without the need for a post-effective amendment (other than an automatically effective amendment) to the Shelf Registration.

(k) Each Shareholder agrees that, upon receipt of any notice from the Company of the happening of any event of the kind described in Section 2.04(e), such Shareholder shall forthwith discontinue disposition of Registrable Securities pursuant to the registration statement covering such Registrable Securities until such Shareholder's receipt of the copies of the supplemented or amended prospectus contemplated by Section 2.04(e), and, if so directed by the Company, such Shareholder shall deliver to the Company all copies, other than any permanent file copies then in such Shareholder's possession, of the most recent prospectus covering such Registrable Securities at the time of receipt of such notice. If the Company shall give such notice, the Company shall extend the period during which such registration statement shall be maintained effective (including the period referred to in Section 2.04(a)) by the number of days during the period from and including the date of the giving of notice pursuant to Section 2.04(e) to the date when the Company shall make available to such Shareholder a prospectus supplemented or amended to conform with the requirements of Section 2.04(e).

(l) The Company shall use its reasonable best efforts to list all Registrable Securities covered by such registration statement on any securities exchange or quotation system on which the Ordinary Shares are then listed or traded.

(m) In any Public Offering pursuant to a Demand Registration, the Company shall have appropriate officers of the Company (i) prepare and make presentations at any "road shows" and before analysts and (ii) otherwise use their reasonable best efforts to cooperate as reasonably requested by the underwriters in the offering, marketing or selling of the Registrable Securities.

(n) Each Shareholder agrees that, in connection with any offering pursuant to this Agreement, it will not prepare or use or refer to, any "free writing prospectus" (as defined in Rule 405 of the Securities Act) without the prior written authorization of the Company (which authorization shall not be unreasonably withheld), and will not distribute any written materials in connection with the offer or sale of the Registrable Securities pursuant to any registration statement hereunder other than the prospectus and any such free writing prospectus so authorized.

Section 2.05. *Participation In Public Offering.* No Shareholder may participate in any Public Offering hereunder unless such Shareholder (a) agrees to sell such Shareholder's Registrable Securities on the basis provided in any underwriting arrangements approved by the Persons entitled hereunder to approve such arrangements and (b) completes and executes all questionnaires, powers of attorney, indemnities, underwriting agreements, "lock-up" agreements and other documents reasonably required under the terms of such underwriting arrangements that are in customary form and consistent with the provisions of this Agreement in respect of registration rights.

Section 2.06. *Rule 144 Sales; Cooperation By The Company.* If any Shareholder shall transfer any Registrable Securities pursuant to Rule 144, the Company shall cooperate, to the extent commercially reasonable, with such Shareholder and shall provide to such Shareholder such information as such Shareholder shall reasonably request. Without limiting the foregoing, the Company shall at any time after any of the Company's Ordinary Shares are registered under the Securities Act or the Exchange Act, use commercially reasonable efforts to: (i) make and keep available public information, as those terms are contemplated by Rule 144; (ii) timely file with the SEC all reports and other documents required to be filed under the Securities Act and the Exchange Act; and (iii) furnish to each Shareholder forthwith upon request a written statement by the Company as to its compliance with the reporting requirements of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other information as such Shareholder may reasonably request in order to avail itself of any rule or regulation of the SEC allowing such Shareholder to sell any Registrable Securities without registration.

ARTICLE 3
INDEMNIFICATION AND CONTRIBUTION

Section 3.01. *Indemnification by the Company*. To the extent permitted by law, the Company will indemnify and hold harmless each Shareholder beneficially owning any Registrable Securities covered by a registration statement, its officers, directors, employees, partners, members. agents, legal counsel and accountants, and any underwriter (as defined under the Securities Act) for such Shareholder and its officers and directors, and each Person, if any, who controls such Shareholder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act from and against any and all losses, claims, damages, liabilities and expenses (including reasonable expenses of investigation and reasonable attorneys' fees and expenses) (collectively, "**Damages**") and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred, caused by or relating to any untrue statement or alleged untrue statement of a material fact contained in any registration statement or prospectus relating to the Registrable Securities (as amended or supplemented if the Company shall have furnished any amendments or supplements thereto) or any preliminary prospectus or free-writing prospectus (as defined in Rule 405 under the Securities Act), or caused by or relating to any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law, except insofar as such Damages are caused by or related to any such untrue statement or omission or alleged untrue statement or omission so made in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of such Shareholder, underwriter, controlling Person or other aforementioned Person expressly for use therein.

Section 3.02. *Indemnification by Participating Shareholders*. To the extent permitted by law, each Shareholder holding Registrable Securities included in any registration statement agrees, severally but not jointly, will indemnify and hold harmless the Company, its officers, directors, agents, legal counsel and accountants, any underwriter (as defined in the Securities Act) and its officers and directors, any other Shareholder selling securities in such registration statement, and each Person, if any, who controls the Company, such underwriter or other Shareholder within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the indemnity from the Company to such Shareholder provided in Section 3.01, but only to the extent such Damages arise out of or are based upon actions and omissions made in reliance upon and in conformity with information about such Shareholder furnished in writing by or on behalf of such Shareholder expressly for use in any registration statement or prospectus relating to the Registrable Securities, or any amendment or supplement thereto, or any preliminary prospectus or free-writing prospectus. No Shareholder shall be liable under this Section 3.02 for any Damages in excess of the net proceeds realized by such Shareholder in the sale of Registrable Securities of such Shareholder to which such Damages relate, except in the case of fraud or willful misconduct by such Shareholder.

Section 3.03. *Conduct of Indemnification Proceedings*. If any proceeding (including any governmental investigation) shall be brought or asserted against any Person in respect of which indemnity may be sought pursuant to this Article 3, such Person (an "**Indemnified Party**") shall promptly notify the Person against whom such indemnity may be sought (the "**Indemnifying Party**") in writing and the Indemnifying Party shall assume the defense thereof, including the employment of counsel satisfactory to such Indemnified Party, and shall assume the payment of all fees and expenses, *provided* that the failure of any Indemnified Party so to notify the Indemnifying Party shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that the Indemnifying Party is materially prejudiced by such failure to notify. In any such proceeding, any Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party unless (a) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel, (b) in the reasonable judgment of such Indemnified Party representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them, including one or more defenses or counterclaims that are different from or in addition to those available to the Indemnifying Party, or (c) the Indemnifying Party shall have failed to assume the defense within 30 days of notice pursuant to this Section 3.03. It is understood that, in connection with any proceeding or related proceedings in the same jurisdiction, the Indemnifying Party shall not be liable for the reasonable fees and expenses of more than one separate firm of attorneys (in addition to one local counsel per jurisdiction) at any time for all such Indemnified Parties, and that all such fees and expenses shall be reimbursed as they are incurred. In the case of any such separate firm for the Indemnified Parties, such firm shall be designated in writing by the Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent, or if there be a final judgment for the plaintiff, the Indemnifying Party shall indemnify and hold harmless such Indemnified Parties from and against any loss or liability (to the extent stated above) by reason of such settlement or judgment. Without the prior written consent of the Indemnified Party, no Indemnifying Party shall effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Party is or could have been a party and indemnity could have been sought hereunder by such Indemnified Party, unless such settlement (A) includes an unconditional release of such Indemnified Party from all liability arising out of such proceeding, and (B) does not include any injunctive or other equitable or non-monetary relief applicable to or affecting such Indemnified Person.

Section 3.04. *Contribution*. If the indemnification provided for in this Article 3 is unavailable to or unenforceable by the Indemnified Parties in respect of any Damages, then each Indemnifying Party, in lieu of indemnifying the Indemnified Parties, shall contribute to the amount paid or payable by such Indemnified Party, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Damages as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Damages shall be deemed to include, subject to the limitations set forth in this Agreement, any reasonable attorneys' or other reasonable fees or expenses incurred by such party in connection with any proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Article 3 was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 3.04 were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. Notwithstanding the provisions of this Section 3.04, no Shareholder shall be required to contribute, in the aggregate, any amount in excess of the amount by which the proceeds actually received by such Shareholder from the sale of the Registrable Securities subject to the proceeding exceeds the amount of any damages that such Shareholder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission, except in the case of fraud by such Shareholder. Each Shareholder's obligation to contribute pursuant to this Section 3.03 is several in the proportion that the proceeds of the offering received by such Shareholder bears to the total proceeds of the offering received by all such Shareholders and not joint.

No Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. The indemnity and contribution agreements contained in this Article 3 are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties.

Section 3.05. *Other Indemnification*. Indemnification similar to that provided in this Article 3 (with appropriate modifications) shall be given by the Company and each Shareholder participating therein with respect to any required registration or other qualification of securities under any foreign, federal or state law or regulation or governmental authority other than the Securities Act.

ARTICLE 4
TERMINATION OF REGISTRATION RIGHTS

Section 4.01. *Termination of Registration Rights*. The rights of any Shareholder to request registration or inclusion of Registrable Securities in any registration pursuant to this Agreement shall terminate upon the earlier to occur of: (a) the fifth anniversary of this Agreement, and (b) such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all such Shareholder's Company Securities without limitation during a three-month period without registration.

ARTICLE 5
MISCELLANEOUS

Section 5.01. *Binding Effect; Assignability; Benefit.* (a) This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, successors, legal representatives and permitted assigns. Any Shareholder that ceases to own beneficially any Registrable Securities shall cease to be bound by the terms hereof (other than (i) the provisions of Article 3 applicable to such Shareholder with respect to any offering of Registrable Securities completed before the date such Shareholder ceased to own any Registrable Securities and (ii) this Article 5).

(b) Neither this Agreement nor any right, remedy, obligation or liability arising hereunder or by reason hereof shall be assignable by any party hereto pursuant to any Transfer of Registrable Securities or otherwise, except that each Shareholder may assign rights hereunder to any Permitted Transferee of such Shareholder. Any such Permitted Transferee shall (unless already bound hereby) execute and deliver to the Company an agreement to be bound by this Agreement in the form of Exhibit A hereto (a "**Joinder Agreement**") and shall thenceforth be a "**Shareholder**".

(c) Nothing in this Agreement, expressed or implied, is intended to confer on any Person other than the parties hereto, and their respective heirs, successors, legal representatives and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

Section 5.02. *Notices*. All notices, requests and other communications (each, a "**Notice**") to any party shall be in writing and shall be delivered in person, mailed by certified or registered mail, return receipt requested, or sent by facsimile transmission or email transmission so long as receipt of such email is requested and received,
if to the Company to:

Sol-Gel Technologies Ltd.
7 Golda Meir St., Weizmann Science Park
Ness Ziona, 7403650 Israel
Fax: +972 8 931 3434
Attention: Gilad Mamlok
Email: gilad.mamlok@sol-gel.com

with a copy to:

Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co.
One Azrieli Center
Tel Aviv 67021, Israel
Facsimile: +972 3 607 4411
Attention: Gene Kleinhendler, Adv.
Email: gene@gkhlaw.com

if to any Shareholder, at the address for such Shareholder listed on the signature pages below or otherwise provided to the Company as set forth below.

Any Notice shall be deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. in the place of receipt and such day is a Business Day in the place of receipt. Otherwise, such Notice shall be deemed not to have been received until the next succeeding Business Day in the place of receipt. Any Notice sent by facsimile transmission also shall be confirmed by certified or registered mail, return receipt requested, posted within one Business Day after the date of the sending of such facsimile transmission, or by personal delivery, whether courier or otherwise, made within two Business Days after the date of such facsimile transmission.

Any Person that becomes a Shareholder after the date hereof shall provide its address, fax number and email address to the Company.

Section 5.03. *Waiver; Amendment*. (a) The provisions of this Agreement, including the provisions of this sentence, may not be amended, modified or supplemented, and waivers or consents to departures from the provisions hereof may not be given without the written consent of holders of a majority of the Registrable Securities then outstanding; *provided*, however, that in no event shall the obligations of any holder of Registrable Securities be materially increased or the rights of any Shareholder be adversely affected (without similarly adversely affecting the rights of all Shareholders), except upon the written consent of such holder. Notwithstanding the foregoing, a waiver or consent to depart from the provisions hereof with respect to a matter that relates exclusively to the rights of holders of Registrable Securities whose securities are being sold pursuant to a Registration Statement and that does not directly or indirectly affect the rights of other holders of Registrable Securities may be given by holders of at least a majority of the Registrable Securities being sold by such holders pursuant to such Registration Statement.

Section 5.04. *Governing Law*. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Israel, without regard to the conflicts of laws rules.

Section 5.05. *Jurisdiction*. The parties hereby agree that any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the transactions contemplated hereby shall be brought in the competent courts located in Tel Aviv-Jaffa, and that any cause of action arising out of this Agreement shall be deemed to have arisen from a transaction of business in the State of Israel, and each of the parties hereby irrevocably consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding which is brought in any such court has been brought in an inconvenient form. Process in any such suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each party agrees that service of process on such party as provided in Section 5.02 shall be deemed effective service of process on such party.

Section 5.06. *Specific Enforcement*. Each party hereto acknowledges that the remedies at law of the other parties for a breach or threatened breach of this Agreement would be inadequate and, in recognition of this fact, any party to this Agreement, without posting any bond or furnishing other security, and in addition to all other remedies that may be available, shall be entitled to obtain equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy that may then be available.

Section 5.07. *Counterparts; Effectiveness*. This Agreement may be executed (including by facsimile or other electronic image scan transmission) with counterpart signature pages or in any number of counterparts, each of which shall be deemed to be an original, and all of which shall, taken together, be considered one and the same agreement, it being understood that each party need not sign the same counterpart. This Agreement shall become effective when each party hereto shall have executed and delivered this Agreement. Until and unless each party has executed and delivered this Agreement, this Agreement shall have no effect and no party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication).

Section 5.08. *Entire Agreement*. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes all prior and contemporaneous agreements and understandings, both oral and written, among the parties hereto with respect to the subject matter hereof.

Section 5.09. *Severability*. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such a determination, the parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner so that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

Section 5.10. *Other Registration Rights.* From and after the date of this Agreement, the Company shall not, without the prior written consent of holders of a majority of the Registrable Securities, enter into any agreement with any holder or prospective holder of any securities of the Company giving such holder or prospective holder any registration rights the terms of which would reduce the amount of Registrable Securities the Shareholders can include in any registration statement, unless such rights are subordinate to those of the Shareholders hereunder.

Section 5.11. *Confidentiality.* Each Shareholder agrees that any notice received pursuant to this Agreement, including any notice of a proposed underwritten public offering or postponement of an offering or effecting of a registration, is confidential information and that any trading in securities of the Company following receipt of such information may only be done in compliance with all applicable securities laws.

Section 5.12. *Independent Nature of Shareholders' Obligations and Rights.* The obligations of each Shareholder hereunder are several and not joint with the obligations of any other Shareholder hereunder, and no Shareholder shall be responsible in any way for the performance of the obligations of any other Shareholder hereunder. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Shareholder pursuant hereto or thereto, shall be deemed to constitute the Shareholders as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Shareholders are in any way acting in concert with respect to such obligations or the transactions contemplated by this Agreement. Each Shareholder shall be entitled to protect and enforce its rights, including the rights arising out of this Agreement, and it shall not be necessary for any other Shareholder to be joined as an additional party in any proceeding for such purpose.

[Signature pages follow.]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement or have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

SOL-GEL TECHNOLOGY LTD.

By:/s/ Alon Seri – Levy
Name: Alon Seri – Levy
Title: CEO

By:/s/ Gilad Mamlok
Name: Gilad Mamlok
Title: CFO

M. ARKIN DERMATOLOGY LTD.

By:/s/ Moshe Arkin
Name: Moshe Arkin
Title: Chairman

Address for Notices:
7 Golda Meir St., Ness Ziona 7403650
Israel
Attn: Gilad Mamlok
Email: gilad.mamlok@sol-gel.com

[*Signature page to the Registration Rights Agreement*]

EXHIBIT A

JOINDER TO REGISTRATION RIGHTS AGREEMENT

This Joinder Agreement (this "**Joinder Agreement**") is made as of the date written below by the undersigned (the "**Joining Party**") in accordance with the Registration Rights Agreement dated as of February 5, 2018 (as the same may be amended from time to time, the "**Registration Rights Agreement**"), among Sol-Gel Technologies Ltd. and the Shareholders party thereto. Capitalized terms used, but not defined, herein shall have the meaning ascribed to such terms in the Registration Rights Agreement.

The Joining Party hereby acknowledges, agrees and confirms that, by its execution of this Joinder Agreement, the Joining Party shall be deemed to be a party to the Registration Rights Agreement as of the date hereof as a "**Permitted Transferee**" of a Shareholder thereto, and shall have all of the rights and obligations of a "**Shareholder**" thereunder as if it had executed the Registration Rights Agreement. The Joining Party hereby ratifies, as of the date hereof, and agrees to be bound by, all of the terms, provisions and conditions contained in the Registration Rights Agreement (including, without limitation, Section 5.01 thereof).

IN WITNESS WHEREOF, the undersigned has executed this Joinder Agreement as of the date written below.

Date:_____ ____, _____

[NAME OF JOINING PARTY]

By: _____

Name:

Title:

Address for Notices:

[Address]

[Fax number]

[Email address]

Exhibit 4.3

COMPENSATION POLICY

SOL-GEL TECHNOLOGIES LTD.

Compensation Policy for Executive Officers and Directors

ADOPTED: July 26 2023

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**

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**

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. **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.

[1] Based on the fair value on the date of grant, calculated annually, on a linear basis.

6.2. Position: Company CEO in Israel.

6.3. The monthly Base Salary for the Company CEO resident is Israel shall not exceed NIS 120,000 for a full time position. The total fixed and variable compensation (including equity based compensation) payable to the Company CEO shall not exceed NIS 5 million per year. Such maximum amounts may be increased from time to time based on increases in the Israeli Consumer Price Index from the date of approval of this Policy. For purposes of calculating the total fixed and variable compensation payable to the Company CEO each year, the value of any equity award granted to the Company CEO determined on the date of Board approval will be allocated equally over the number of years during which such equity award vests.

6.4. Position: Executive Officers in Israel (other than Board member or CEO)

The monthly Base Salary for Executive Officers (other than Board member or CEO) resident in Israel shall not exceed NIS 90,000 for a full time position. Such maximum amount may be increased from time to time based on increases in the Israeli Consumer Price Index from the date of approval of this Policy.

6.5. Position: Company CEO in the U.S. or other location outside of Israel

The annual Base Salary for the Company CEO resident in the U.S. or another location outside of Israel shall be determined by the shareholders pursuant to applicable law.

6.6. Position: Officers in the U.S. or other location outside of Israel (other than Board member or CEO).

The annual Base Salary for the Executive Officers (other than Board member or CEO) resident in the U.S. or other location outside of Israel shall not exceed USD 400,000 for a full time position. Such amount may be linked to increases in the Consumer Price Index in the U.S. (or in such other location, as the case may be) from the date of approval of this Policy.

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; provided, however, that in no event shall the special bonus and any discretionary bonus paid pursuant to section 9 exceed twelve (12) months in the aggregate.

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")**

11.2.1. In the event of an accounting restatement, Sol-Gel shall recover from its Executive Officers the bonus compensation or performance-based equity compensation received by each such Executive Officer during the three completed fiscal years immediately preceding the date that the company is required to prepare an accounting restatement in the amount in which such bonus exceeded what would have been paid under the financial statements, as restated ("**Compensation Recovery**"), For purposes of this Policy, when compensation is deemed to be “received”, the date on which a restatement shall be deemed to be required, and the type of restatement for which this provision shall apply, shall be as provided in the SEC Clawback Rule (as defined below).

11.2.2. 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 GAAP financial reporting standards as determined by the Company's outside auditor; or

- The Company (subject to any required approval by the applicable law) has determined that the direct expense paid to a third party to assist in enforcing the policy would exceed the amount to be recovered; or

- Otherwise as provided in the SEC Clawback Rule.

11.2.3. The Company intends to adopt a clawback policy ("Nasdaq Clawback Policy") that complies with the listing standards ("Nasdaq Standards") to be adopted by The Nasdaq Stock Market LLC ("Nasdaq") in accordance with the provisions of Rule 10D-1 under the Securities and Exchange Act of 1934, as amended (as amended from time to time, the "SEC Clawback Rule"), which directs national securities exchanges, including Nasdaq, to establish listing standards for purposes of complying with such rule. Any provision of the Nasdaq Clawback Policy as required by the Nasdaq Standards shall be deemed to comply with this Compensation Policy. In the event of any inconsistency between this Policy and the Nasdaq Clawback Policy, the Nasdaq Clawback Policy shall prevail to the extent the Nasdaq Clawback Policy expands the obligation of the Company to conduct a Compensation Recovery. For the avoidance of any doubt, no amendments to, or further corporate approvals in connection with, this Compensation Policy will be required in connection with the adoption of the Nasdaq Clawback Policy.

11.2.4. Nothing in this Section 11 derogates from any other "Clawback" or similar provisions regarding disgorging of profits imposed on Executive Officers by virtue of other applicable securities or other laws, regulations or listing standard

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]

2 The equity based compensation is based on the fair value on the date of approval of the Board, calculated annually, on a linear basis.

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.

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 three years, while the first tranche of the grant may not vest and become exercisable prior to the first anniversary of the date of the grant 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).

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3 Calculated annually, on a linear basis.

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; provided, however, that the adjustment period/retirement bonus and Advance Notice Period shall not exceed twelve (12) months in the aggregate.

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 $58,500 per year (the "**Base Payment**");

    27.2. Chairman of the Board- an additional amount of $32,500 per year to the Base Payment;

    27.3. Committee Chairman- an additional amount of $13,000 per year to the Base Payment;

    27.4. Committee member- an additional amount of $6,500 per year to the Base Payment;

28. Following June 23, 2023, the maximum compensation of the Company's directors (including external directors and independent directors) will increase by 15% and shall not exceed the following:

    28.1. Base payment of $67,275 per year (the "Base Payment");

    28.2. Chairman of the Board- an additional amount of $37,375 per year to the Base Payment;

    28.3. Committee Chairman- an additional amount of $14,950 per year to the Base Payment;

    28.4. Lead Independent Director – an additional amount of $14,950 per year to the Base Payment; and

    28.5. Committee member- an additional amount of $7,475 per year to the Base Payment.

29. 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.

30. 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]

31. Equity based-compensation granted to the Company's directors shall not exceed 55% of the total compensation paid to the Company's directors.

32. 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

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

****

4 The equity based compensation is based on the fair value on the date of approval of the Board, calculated annually, on a linear basis.
5 Based on the fair value on the date of grant, calculated annually, on a linear basis.

Exhibit 4.13

Dr. Moshe Eliash
Barrister-at-law, Advocate and Notary
2 Hasoreg St., POB 433
Telephone 651681, 6054281
Faximilia 6254282
Jerusalem 91003
Eliash7@bezeqint.net

Sunday, 25 June 2023

To: Sol-Gel
Golda Meir 7
Ness Ziona

Re: Extension of the lease periods

The owners of the property agree to extend all the lease periods in accordance with all the lease agreements, so that the aforementioned lease periods end on December 31, 2025 (the "Additional Extension Period").

The terms of the lease agreements will apply to the Additional Extension Period with necessary modifications. In addition to the above, the landlords are prepared to offer you the option to extend the lease periods in accordance with all the lease agreements by an additional two years beyond the Additional Extension Period (the "Additional Option Period"), on the condition that you provide written notice to the landlords six months prior to the end of the Additional Extension Period, expressing your intention to exercise this option. In case you choose to exercise this option, the terms of the existing lease agreements, with necessary amendments, shall apply to the extended periods.

If you agree to extend the lease period as stated above, please confirm your approval on a copy of this letter and return to me.

Respectfully,

/s/ Moshe Eliash
Dr. Moshe Eliash, Adv.

We agree and confirm.

/s/ Gilad Mamlok
Gilad Mamlok, CFO
Sol-Gel Technologies Ltd.

Exhibit 4.22

CERTAIN IDENTIFIED INFORMATION MARKED [***] HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

Execution Version

LICENSE AGREEMENT

BY AND BETWEEN

SEARCHLIGHT PHARMA INC.

AND

SOL-GEL TECHNOLOGIES LTD.

TABLE OF CONTENTS

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of June 5, 2023 ("**Effective Date**") between Sol-Gel Technologies Ltd., with a principal place of business at 7 Golda Meir St. Ness Ziona Israel ("**Sol-Gel**"), and Searchlight Pharma Inc., with a principal place of business at 1600 Notre-Dame Street West, Suite 312, Montreal, Quebec, H3J 1M1, Canada ("**SLP**"). Sol-Gel and SLP may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Sol-Gel is the owner of, or otherwise controls, the Licensed Technology in the Territory (each as defined below);

WHEREAS, SLP is interested in obtaining an exclusive license to Develop and Commercialize the Licensed Product in the Territory (each as defined below); and

WHEREAS, the Parties desire for Sol-Gel to grant such license to SLP to Develop and Commercialize the Licensed Product in the Territory, all under the terms and conditions as set forth in this Agreement.

NOW THEREFORE, the Parties agree as follows:

ARTICLE I.

DEFINITIONS

Section 1.01 "**Accounting Standards**" means the then-current International Financial Reporting Standards, as consistently applied.

Section 1.02 "**Additional MOQ Period**" means the consecutive [***] ([***]) Year periods, following the Initial MOQ Period during the Term of this Agreement.

Section 1.03 "**Affiliate**" means, with respect to an entity, any corporation or other business entity controlled by, controlling, or under common control with such entity, with "control" meaning (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of, the applicable entity (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction and is sufficient to grant the holder of such voting stock or interest the power to direct the management and policies of such entity) or (b) possession, directly or indirectly, of the power to direct the management and policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise.

Section 1.04 "**Business Day**" means a day other than (a) a Saturday or a Sunday or (b) a day on which banking institutions in Toronto, Ontario, Canada and Montreal, Quebec, Canada, are authorized or required by Law to remain closed.

Section 1.05 "**Canada**" shall mean Canada, its provinces and territories.

Section 1.06 "**CMO**" means a contract manufacturing organization identified and introduced to SLP by Sol-Gel or independently identified by SLP.

Section 1.07 "**Commercialization**" **or** "**Commercialize**" means, with respect to a pharmaceutical product, any and all activities directed to the marketing, promotion, importation, distribution, pricing, reimbursement approval, offering for sale and/or sale of such pharmaceutical product. Commercialization shall exclude Development and Manufacturing.

Section 1.08 "**Commercialization Plan**" means the plan setting out activities to be undertaken by SLP in Commercializing the Licensed Product in the Field in the Territory following initial Regulatory Approval, attached hereto as Exhibit B.

Section 1.09 "**Commercially Reasonable Efforts**" means, with respect to a Party's performance of obligations under this Agreement, the carrying out of such obligations in a sustained and diligent manner, using efforts and resources that are consistent with the efforts and resources typically used by [***] with respect to the Development or Commercialization of products of similar market potential, profit potential and strategic value and of a stage in Development or product life, including the use of reasonably necessary personnel, based on conditions then prevailing and taking into account issues of safety and efficacy, product profile, difficulty in Developing such product, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of such product, the regulatory structure involved and the potential profitability of such product, as applicable, but without regard for any payment obligations under this Agreement, [***].

Section 1.10 [***]

Section 1.11 "**Confidential Information**" means, subject to **Section 11.02**, Know-How, the terms of this Agreement, and any technical, scientific, trade, research, manufacturing, business, financial, compliance, marketing, product, supplier, intellectual property or other information that may be disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form.

Section 1.12 "**Controls**", "**Controlled**" means, with respect to a Party, and any Know- How, Patent Right, Regulatory Documents or other intellectual property right, that such Party or any of its Affiliates has the ability (other than pursuant to a license granted to such Party under this Agreement) to grant to the other Party a license or sublicense to, and other applicable rights (including without limitation sharing such Know-How, Patent Right, Regulatory Documents with licensees and Third Parties) with respect to, such Know-How, Patent Right, Regulatory Documents or other intellectual property right without violating the terms of any pre-existing agreement with any Third Party or any applicable Law and without the need for any consent (or further consent) from such Third Party.

Section 1.13 "**Cover**", "**Covering**" or "**Covered**" means, with respect to a product, composition, technology, process or method and a Patent Right, that, in the absence of ownership of, or a license granted under, a claim in such Patent Right, the manufacture, use, offer for sale, sale or importation of such product or composition or the practice of such technology, process or method would infringe such claim (directly, indirectly by contributory infringement or by inducement to infringe) or, in the case of a claim of a pending patent application, would infringe such claim if it were to issue as a claim of an issued patent.

Section 1.14 "**Develop**" or "**Development**" means pre-clinical research and clinical development activities reasonably related to the development and submission of information to a Regulatory Authority, including without limitation (i) clinical trials of a pharmaceutical compound or product, investigator sponsored trials and registry studies; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials or obtain Regulatory Approval of a pharmaceutical product; (iii) activities relating to the development of chemistry, manufacturing, and controls data. Development shall include clinical trials initiated prior to or following receipt of Regulatory Approval, but shall exclude Manufacturing and Commercialization.

Section 1.15 "**Dollars**" **or** "**$**" means the legal tender of the U.S.

Section 1.16 "**Drug Approval Application**" means a submission or application to be filed with the Regulatory Authority in accordance with applicable Law for the purpose of obtaining marketing approval for a pharmaceutical product in the Territory, including a New Drug Submission or an application for a Drug Identification Number ("DIN").

Section 1.17 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

Section 1.18 "**Field**" means the treatment, prevention, cure, or amelioration of Rosacea (or within the Rosacea indication, as approved by the Regulatory Authority) in humans.

Section 1.19 "**First Commercial Sale**" means, with respect to the Licensed Product, the first [***] sale of the Licensed Product in the Territory to a Third Party after [***]. For clarity, [***] shall not be deemed "First Commercial Sale".

Section 1.20 "**Generic Product**" means, with respect to a Licensed Product, any pharmaceutical product that (a) has the same active ingredients as the Licensed Product; (b) is approved by [***] on the basis of [***]; and, (c) is approved by the Regulatory Authority in the Territory in the Field.

Section 1.21 "**Governmental Authority**" means any federal, national, multinational, state, provincial, territorial, county, city or local government or any court, arbitrational tribunal, administrative agency or commission or government authority acting under the authority of any national, multinational, provincial, territorial, county, city or local government.

Section 1.22 "**Initial MOQ Period**" means the initial period of [***] ([***]) Years commencing as of the First Commercial Sale.

Section 1.23 "**Know-How**" means trade secrets, data, chemical and biological materials, formulations, information, documents, studies, results, data, regulatory approvals, regulatory filings and related correspondence (including DMFs), including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, formulations, samples, whether or not patented or patentable.

Section 1.24 "**Law**" means any law, statute, rule, regulation, policy, guidance, order, judgment, standard or ordinance of any Governmental Authority.

Section 1.25 "**Licensed Know-How**" means all Know-How that is Controlled by Sol- Gel or any of its Affiliates during the Term of the Agreement and is in Sol-Gel's reasonable judgment, necessary or useful for the use or Commercialization of the Licensed Product in the Field in the Territory. Licensed Know-How does not include [***].

Section 1.26 "**Licensed Patent Rights**" means any Patent Rights owned or Controlled by Sol-Gel or any of Sol-Gel's Affiliates during the Term of the Agreement that Cover the [***], including those set forth in Exhibit A. Licensed Patent Rights does not include [***].

Section 1.27 "**Licensed Product**" means Sol-Gel's proprietary topical product containing an antibiotic-free, fixed dose 5% encapsulated benzoyl peroxide as the main active ingredient, known and intended to be marketed under the name "Epsolay".

Section 1.28 "**Licensed Technology**" means Licensed Know-How and Licensed Patent Rights.

Section 1.29 "**Licensed Trademark**" means "Epsolay®" as set forth in Exhibit A.

Section 1.30 "M&A Know-How" [***].

Section 1.31 "M&A Patents" [***]

Section 1.32 "**Manufacture**" or "**Manufacturing**" means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, filling, finishing, packaging, labeling, shipping, exporting, importing or storage of pharmaceutical compounds or materials, including process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

Section 1.33 "Net Sales" means the gross amount [***]from the sale, lease or other transfer or provision of Licensed Products to [***]for consideration (the "**Gross Sales**"), reduced by [***]:

(a) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

If non-monetary consideration is received by a SLP Entity for the Licensed Product, the average price charged for such Licensed Product will be calculated [***], as applicable, [***], or in the absence of such [***].

Section 1.34 "**Patent Right(s)**" means all rights under any patent or patent application, certificate of inventions, application for certificate of invention or priority patent filing in the Territory or under any international convention or treaty, including any patents issuing on such patent applications, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, division, continuation or continuation-in-part of any of the foregoing.

Section 1.35 "**PMPRB"** means the Patented Medicine Prices Review Board of Canada.

Section 1.36 "**PMPRB Reference Countries"** means the countries listed in the schedule to the Patented Medicines Regulations SOR/94-688, as may be amended. The current countries are Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Section 1.37 "**Regulatory Approval**" means, with respect to a particular regulatory jurisdiction, an approval, notice of compliance, license, registration or authorization of any Governmental Authority that provides marketing approval for the commercial sale, or reimbursement approval, of a pharmaceutical product in one or more specified indications in such regulatory jurisdiction.

Section 1.38 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including Health Canada and any other applicable Governmental Authority in the Territory having jurisdiction over pharmaceutical products.

Section 1.39 "**Regulatory Documents**" means, (i) (a) all submissions to Regulatory Authorities in the Territory, including, without limitation, all applications (including Drug Approval Applications), submissions, registrations, licenses, authorizations, approvals (including Regulatory Approvals) and marketing or regulatory exclusivities, including, without limitation, all INDs, NDAs, sNDAs, CTAs, all and any aggregate safety reports, NDSs, SNDSs, CMC Data, drug master files, filings with PMPRB, filings for listing with Canadian provincial drug plans; (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files; and (c) preclinical, clinical and other data, results, analyses, publications, and reports contained or referred to in any of the foregoing; as well as (ii) all submissions to the Pharmaceutical Advertising Advisory Board and Ad Standards or any other regulator responsible for advertising, as well as all filings for listings with private payers. For the avoidance of doubt, Regulatory Documents include Regulatory Approvals and Regulatory Filings.

Section 1.40 "**Regulatory Filings**" means all applications, filings, dossiers, Regulatory Documents, Regulatory Approvals, and the like submitted to a Regulatory Authority for the purpose of Developing, Manufacturing or Commercializing the Licensed Product, including obtaining Regulatory Approval from that Regulatory Authority. Regulatory Filings include all INDs, CTAs, Drug Approval Applications and other Regulatory Approval (including reimbursement approval) submissions.

Section 1.41 "**SLP Entity**" means, as applicable, (a) SLP, (b) any of SLP's Affiliates. SLP shall be responsible for the breach of this Agreement by any SLP Entity.

Section 1.42 "**SLP Regulatory Documents**" means Regulatory Documents Controlled by SLP at any time during the Term that relate to a Licensed Product in the Territory.

Section 1.43 "**Sol-Gel Entity**" means, as applicable, (a) Sol-Gel or (b) any of Sol-Gel's Affiliates. Sol-Gel shall be responsible for the breach of this Agreement by any Sol-Gel Entity.

Section 1.44 "**Sol-Gel Regulatory Documents**" means Regulatory Documents Controlled by Sol-Gel [***] that relate to a Licensed Product.

Section 1.45 "**Supply Agreement**" means [***].

Section 1.46 "**Target Price"** means the target net-selling price of the Licensed Product set forth in Exhibit C.

Section 1.47 "**Territory**" means Canada.

Section 1.48 "**Third Party**" means any person or entity other than the Parties and their Affiliates.

Section 1.49 "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

Section 1.50 "**U.S.**" or "**United States**" means the United States of America, including its districts, territories and possessions.

Section 1.51 "**Year**" means a consecutive twelve-month period beginning as of the date of First Commercial Sale of the Licensed Product in the Territory.

Additional Defined Terms	Section
Abandoned Patent Rights	Section 8.02
Additional Term	Section 13.01
Alliance Manager	Section 3.11
Arbitration Request	Section 14.01(a)
Bankrupt Party	Section 13.03
Breaching Party	Section 13.02
Commercialization Plan	Section 5.01
Event of Bankruptcy	Section 13.04(a)
Executive Officer	Section 3.06
Government Official	Section 10.04(a)
Indemnified Party	Section 12.03
Indemnifying Party	Section 12.03
Infringement Activity	Section 8.03(a)
Infringement Action	Section 8.03(b)
Initial Term	Section 13.01
Inventions	Section 8.01(c)
JSC	Section 3.01
Key Regulatory Submissions	Section 4.01(a)
Losses	Section 12.01
Minimum Orders	Section 5.01
Non-breaching Party	Section 13.02
Other Covered Party	Section 10.04
Other Party	Section 13.04(a)
Payment	Section 7.10(a)
Public Statement	Section 11.04
Publication	Section 11.05
Recipient	Section 11.02
Representatives	Section 11.01
Revised Financial Terms	Section 4.03(b)
Rules	Section 14.01
Safety Data Exchange Agreement	Section 9.02
Severed Clause	Section 16.03
[***]	Section 5.01
[***]	Section 5.01
SLP Indemnitee	Section 12.01
SLP Trademark	Section 8.01(c)
Sol-Gel Indemnitee	Section 12.02
Sol-Gel Product Data	Section 4.02
Sol-Gel Recommended CMO[***]	Section 6.01
Term	Section 13.01
Withholding Tax Action	Section 7.10(c)

Section 1.52 Interpretation. (a) Whenever any provision of this Agreement uses the word "including," "include," "includes," or "*e.g.*," such word shall be deemed to mean "including without limitation" and "including but not limited to"; (b) "herein," "hereby," "hereunder," "hereof" and other equivalent words shall refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) a capitalized term not defined herein but reflecting a different part of speech from that of a capitalized term which is defined herein shall be interpreted in a correlative manner; (d) wherever used herein, any pronoun or pronouns shall be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the Schedules and the Exhibits to this Agreement, and the terms and conditions incorporated in such recitals and Schedules and Exhibits, shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such recitals and Schedules and Exhibits and the terms and conditions incorporated in such recitals and Schedules and Exhibits; *provided* that, in the event of any conflict between the terms and conditions of the body of this Agreement and any terms and conditions set forth in the recitals, Schedules or Exhibits, the terms of the body of this Agreement shall control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement or otherwise, the terms and conditions of this Agreement shall govern; (g) this Agreement shall be construed as if both Parties drafted it jointly, and shall not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections,

Articles and Schedules in this Agreement are to Sections, Articles, Exhibits and Schedules of and to this Agreement; (i) any reference to any Law shall mean such Law as in effect as of the relevant time, including all rules and regulations thereunder and any successor Law in effect as of the relevant time, and including the then-current amendments thereto; (j) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) references to a Party's knowledge shall be taken to refer to the actual knowledge of such Party's CEO and his/her direct reports as of the Effective Date; (l) the captions and table of contents used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits or limitations; and (m) the word "year" means any consecutive twelve (12) month period, unless otherwise specified.

ARTICLE II.

LICENSES

Section 2.01 Grants of Licenses; Limitation.

(a) Subject to the terms and conditions of this Agreement, Sol-Gel hereby grants to SLP and SLP's Affiliates (i) an exclusive (including as to Sol-Gel and its Affiliates), royalty- bearing, transferable (subject to **Section 15.01 (Assignment)**) license solely during the Term under the Licensed Technology solely to Develop, have Developed, register, have registered, use, have used, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold, and otherwise exploit or have exploited the Licensed Product in the Field in the Territory; (ii) an exclusive, transferable (subject to **Section 15.01 (Assignment)**) license to use the Licensed Trademark in connection with the Licensed Product in the Territory; and (iii) a non-exclusive transferable (subject to **Section 15.01 (Assignment)**) license to use [***]that are non-exclusively licensed to a Third Party. The license granted in this **Section 2.01** may be sublicensed by SLP pursuant to a separate written agreement to a Third Party [***]. Any sublicense granted shall be made subject to the terms and conditions of this Agreement and require a sublicensee to be bound by the terms of this Agreement. Any breach by a sublicensee of such terms and conditions of this Agreement as applicable to a sublicensee in such sublicense agreement shall be deemed to be a breach by SLP under this Agreement. Promptly after the execution of any sublicense agreement, SLP shall notify Sol-Gel and provide Sol-Gel with a copy of such agreement, [***]. No such sublicense shall relieve SLP of any of its obligations or responsibilities under this Agreement.

(b) As between the Parties, all rights not expressly licensed to SLP under the Licensed Technology in **Section 2.02(a)** shall be retained by Sol-Gel, including the right to Develop, Manufacture and Commercialize the Licensed Product outside the Territory, and the right to Develop and Manufacture the Licensed Product anywhere in the world (including within the Territory) for use outside the Territory and for use within the Territory after the termination or expiration of this Agreement.

(c) SLP agrees that neither it, nor any of its Affiliates, shall offer to sell or otherwise provide the Licensed Products to any Third Party if SLP or its relevant Affiliates, knows, or has reason to believe, that the Licensed Products offered for sale, sold or provided to such Third Party would be sold or transferred outside the Territory.

Section 2.02 Competing Product. During the Term[***].

ARTICLE III.

GOVERNANCE

Section 3.01 General. Within [***]days following the Effective Date, the Parties shall establish a Joint Steering Committee ("**JSC**") to facilitate the exchange of information and cooperation between the Parties with respect to the Development and Commercialization of the Licensed Product in the Field in the Territory. The JSC shall have decision-making authority with respect to the matters within its purview to the extent expressly provided herein.

Section 3.02 Plans, Forecasts and Activities. At least [***]weeks in advance of each meeting of the JSC, SLP shall provide the JSC with [***].

Section 3.03 Joint Steering Committee.

(a) The JSC shall:

(i) monitor and discuss the Commercialization Plan;

(ii) monitor and discuss the progress of the Development and Commercialization of the Licensed Product in the Field in the Territory;

(iii) monitor and discuss the written sales forecasts and descriptions of anticipated resources provided to the JSC pursuant to **Section 3.02 (Plans, Forecasts and Activities)**;

(iv) monitor and discuss the pricing of the Licensed Product in all PMPRB Reference Countries (both current and proposed countries);

(v) serve as a forum for exchanging information regarding the conduct of the Development and Commercialization of the Licensed Product in the Field in the Territory;

(vi) serve as a form for exchanging information regarding Manufacturing of the Licensed Product;

(vii) serve as a forum for exchanging information regarding the prosecution, maintenance and issuance of the Licensed Patent Rights, as well as the patent listing activities specified in Section 8.06;

(viii) discuss whether to create any additional subcommittee(s) or working group(s);

(ix) serve as a forum to facilitate dispute resolution; and

(x) perform such other duties as are specifically assigned to the JSC under this Agreement.

Section 3.04 Membership. The JSC shall be composed [***]representatives from [***], each of which representatives shall be of the seniority and experience appropriate for service on the JSC in light of the functions, responsibilities and authority of such committee and the status of activities within the scope of the authority and responsibility of such committee. Each Party may replace any of its representatives on the JSC at any time with written notice to the other Party; *provided* that such replacement meets the standard described in the preceding sentence. Each Party's representatives and any replacement of a representative shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in **Article XI (Confidentiality)**. Each Party may invite [***]of its or its Affiliates' employees as required or useful to discuss the applicable agenda items. The JSC shall appoint a chairperson from among its members, with the first chairperson of the JSC being a representative of [***]. Each chairperson (whether initially appointed or any successor therefor) shall serve a term of [***], at which time, the JSC shall select a successor chairperson who is a representative of the Party other than the Party represented by the outgoing chairperson (*e.g.*, the second chairperson of the JSC shall be a representative of [***], the third chairperson of the JSC shall be a representative of [***], etc.). Within [***]days following each JSC meeting, the chairperson shall circulate to all committee members a draft of the minutes of such meeting. The JSC shall then approve, by mutual agreement, such minutes within [***]days following circulation. No chairperson of the JSC shall have any greater authority than any other representative of such committee.

Section 3.05 Meetings.

(a) The JSC shall hold an initial meeting within [***]days after its formation or as otherwise agreed by the Parties. Thereafter, unless the Parties otherwise agree, the JSC shall meet at least [***]. Each such meeting may be in person, by video, by teleconference, or by any other agreed upon means. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JSC meetings.

Section 3.06 JSC Decision Making. All decisions of the JSC shall be made by [***], and shall be set forth in minutes approved by both Parties. If the JSC is unable to reach agreement on any matter within [***]after a matter is referred to it or first considered by it, such matter shall be referred to the Executive Officers for resolution in accordance with **Section 3.07 (Executive Officers; Disputes)**.

Section 3.07 Executive Officers; Disputes. Each Party shall ensure that an executive officer is designated for such Party at all times during the Term for dispute resolution purposes (each such individual, such Party's "**Executive Officer**"), and shall promptly notify the other Party of its initial, or any change in its, Executive Officer. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the Executive Officers, who shall attempt in good faith to resolve such dispute.

Section 3.08 Final Decision-Making Authority. If the Parties are unable to resolve a given dispute within the purview of the JSC within [***]after referring such dispute to the Executive Officers pursuant to **Section 3.07 (Executive Officers; Disputes)**, then, subject to **Section 3.09 (Limitations on Decision-Making)**:

(a) [***].

(b) [***].

(c) Any decision made by [***]shall be deemed to be a decision of the JSC.

Section 3.09 Limitations on Decision-Making.

(a) Neither Party shall have the deciding vote on, and the JSC shall have no decision- making authority regarding, any of the following matters:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***]; or

(vii) [***].

(b) The decision-making Party shall make its decision in good faith, subject to the terms and conditions of this Agreement.

(c) In no event may the decision-making Party [***].

(d) In no event may [***].

(e) In no event may [***].

(f) [***]

Section 3.10 Scope of Governance. Notwithstanding the creation of the JSC or anything to the contrary in this **Article III (Governance)**, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and the JSC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by the JSC are only those specific issues that are expressly provided in this Agreement to be decided by such committee.

Section 3.11 Alliance Managers. Each of the Parties shall appoint a single individual to manage Development, Manufacturing and Commercialization obligations between the Parties under this Agreement (each, an "**Alliance Manager**"). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers may attend any JSC meetings. Each Alliance Manager shall be a non-voting participant in such Committee and Subcommittee meetings, unless s/he is also appointed a member of the JSC; *provided, however*, that an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Party's Alliance Manager and any substitute for an Alliance Manager shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in **Article XI** (**Confidentiality**). Each Alliance Manager will also: (a) plan and coordinate cooperative efforts and internal and external communications; and

(b) facilitate the governance activities hereunder and the fulfillment of action items resulting from JSC meetings.

ARTICLE IV.

REGULATORY; TECHNOLOGY SHARING

Section 4.01 Regulatory Responsibility.

(a) SLP shall be responsible for preparing, obtaining, and maintaining all Regulatory Filings and Regulatory Approvals and conducting communications with the Regulatory Authorities in the Territory. Without limiting the foregoing, SLP shall have sole responsibility for seeking Regulatory Approval in Canada, and shall use Commercially Reasonable Efforts to obtain such Regulatory Approval. For clarity, SLP shall have no obligation to conduct any pre-clinical testing or clinical studies. All Regulatory Approvals in the Territory shall be held in the name of SLP, who shall be the Marketing Authorization Holder ("MAH") and the importer of record, and SLP shall maintain the right to transfer the Regulatory Approvals to an Affiliate. SLP shall provide Sol-Gel with copies of all [***] (collectively, the "**Key Regulatory Submissions**") prior to submission to a Regulatory Authority and Sol-Gel shall have [***], or a shorter time period if required by Law, from receipt of such Key Regulatory Submissions to provide comments. SLP shall reasonably consider and, if reasonable, in SLP's sole judgment, incorporate such comments, prior to submission to the Regulatory Authority.

(b) Sol-Gel shall provide timely support and consult SLP in its efforts to perform its obligations set forth in section 4.01(a) above. In support of SLP's preparation of any Regulatory Filing with respect to the Licensed Product in the Field in the Territory, to the extent required and upon SLP's written request, Sol-Gel shall provide SLP access to a complete electronic copy of and a right of reference to all current and as updated (i) Regulatory Documents Controlled by any Sol- Gel Entity (including those generated by any of Sol-Gel's licensees that are Controlled by Sol-Gel) that are related to the Licensed Product in the Field, and (ii) any other information requested by Regulatory Authorities in the Territory in connection with SLP's Regulatory Filings solely to the extent (A) Controlled by the Sol-Gel Entities, and (B) subject to Sol-Gel's Commercially Reasonable Efforts to obtain, and Sol-Gel's actual obtaining of the prior written consent of any Sol-Gel Entities' Third Party licensees, in each case ((i) through (ii)) to the extent permitted by applicable Law, and if applicable by the agreements entered between Sol-Gel Entities and its licensees. Without limiting the foregoing, Sol-Gel shall (i) provide SLP with the Key Regulatory Submissions filed for the product in the United States that corresponds to the Licensed Product in both word and pdf format which are within its Control, and with respect to which it has the contractual rights to share with SLP; (ii) perform Commercially Reasonable Efforts to assist SLP with causing the manufacturers of the API for the Licensed Product to file electronic drug master files with the Regulatory Authority in the Territory in order to permit SLP to reference such information in the Licensed Product submission; and (iii) perform Commercially Reasonable Efforts to assist with SLP with causing the manufacturers of the API for the Licensed Product to provide SLP with any required documentation as requested by the Regulatory Authority in order to comply with Laws.

(c) [***] in conducting its regulatory responsibilities under this **Section 4.01**, and will [***] [***]. All Third Party vendors and their activities require advance approval [***].

Section 4.02 Technology Sharing.

(a) Sol-Gel shall provide to SLP all data and documents Controlled by the Sol-Gel Entities and related to the Licensed Product that are reasonably necessary for SLP to Commercialize Licensed Product in the Territory, including Licensed Know-How, regulatory data, and clinical data. Throughout the Term, Sol-Gel shall provide SLP with an update of any material regulatory developments (e.g., NDA or NDS filed, meetings with Regulatory Authority, or Regulatory Approval) relating to a Licensed Product made by Sol-Gel, or Sol-Gel's Affiliates or licensees, and upon SLP's request, Sol-Gel shall make available to SLP copies of Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case that are related to Licensed Product in the Field and Controlled by the Sol-Gel Entities or any of their licensees (collectively, the "**Sol-Gel Product Data**"), to the extent (i) such Sol-Gel Product Data are reasonably necessary for any SLP Entity to Commercialize the Licensed Product in the Field in the Territory in accordance with this Agreement and are Controlled by the Sol-Gel Entities, (ii) such Sol-Gel Product Data are required by Regulatory Authority in the Territory in connection with the Commercialization of Licensed Product in the Field in the Territory and are Controlled by the Sol-Gel Entities, or (iii) subject to Sol-Gel's exercise of Commercially Reasonable Efforts to obtain, and Sol-Gel's actual obtaining of, the prior written consent of any Sol-Gel Entities' licensee, such Sol-Gel Product Data are required by Regulatory Authority in the Territory in connection with the Commercialization of Licensed Product in the Field in the Territory and are Controlled by any such Third Party licensee.

(b) SLP shall make available to Sol-Gel copies of SLP Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case that pertain to Licensed Product and are Controlled by a SLP Entity or its sub-contractor (collectively, the "**SLP Product Data**"), to the extent such SLP Product Data are reasonably necessary for Sol-Gel, its Affiliates or (sub)licensees to exercise its retained rights. SLP hereby grants to Sol-Gel and Sol- Gel's Affiliates or licensees a right to access, use and reference the SLP Product Data in any Regulatory Filing made by Sol-Gel (or its Affiliates or (sub)licensees as the case may be) pertaining to Licensed Product in connection with the exercise of its retained rights. Without limiting the foregoing, SLP shall provide to the appropriate regulatory contacts as set out in the Safety Data Exchange Agreement, copies of any annual or other periodic reports required to be submitted to any Regulatory Authority regarding the progress of any post-marketing requirements with respect to Regulatory Approval for the Licensed Product.

Section 4.03 Licensed Product Pricing.

(a) SLP, in consultation with Sol-Gel, will be responsible for obtaining and maintaining any pricing approvals required or offered by PMPRB to market and sell the Licensed Products in the Territory, including but not limited to compliance with Patent Act, R.S.C., 1985, c. P-4, and Patented Medicines Regulations, and, if applicable, for negotiations with governmental and private insurance payors.

(b) The JSC will review and discuss the list price of the Licensed Product in all (current proposed, and then-current) PMPRB Reference Countries. Sol-Gel will share with the JSC the information regarding the pricing of the Licensed Product in the (current, proposed and any then- current) PMPRB Reference Countries Controlled by Sol-Gel Entities, provided that it is legally and contractually permitted to share such information. [***].

(c) In the event that PMPRB requires a payment in respect of excess revenues generated through the sales of the Licensed Product in the Territory or the Parties agree to a payment of excess revenues by way of a voluntary compliance undertaking to resolve any investigation by the PMPRB, then (i) if such payment is required [***]; and (ii) if such payment is required in any other case, [***].

Section 4.04 Generic Products. SLP will in no event during the Term or at any time after expiration or termination of this Agreement seek Regulatory Approval for or otherwise engage in the Development, Manufacture, and/or Commercialization of (i) any pharmaceutical product which uses the Licensed Product as a reference listed drug as defined in the *Food and Drug Regulations* (C.R.C., c. 870 as amended); or (ii) any Generic Product, [***].

ARTICLE V.

COMMERCIALIZATION

Section 5.01 General; Diligence. SLP shall use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Territory for use in the Field, which efforts shall include, without limitation, (i) taking all actions set forth in Exhibit B (the "**Commercialization Plan**"), and (ii) purchasing annual minimum amounts of Licensed Product ("**Minimum Orders**"). **Exhibit D** sets forth the Minimum Orders to be purchased by SLP during the Initial MOQ Period. Thereafter [***]. Notwithstanding the foregoing, the Parties shall consult with each other through the JSC prior to taking any action in connection with the Commercialization of the Licensed Product in the Territory which would reasonably be expected to prevent or adversely affect in any material respect the ability of the other Party to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize or otherwise exploit the Licensed Product outside of the Territory at any time or inside the Territory after termination or expiration of this Agreement in the case of Sol-Gel, or within the Territory during the Term in the case of SLP. If SLP orders less than the Minimum Order Quantities of Licensed Product for a particular Year during the Term (such period, [***]), then no later than [***] days following the conclusion of such Shortfall Period, SLP shall either [***].

Section 5.02 **Exceptions to Minimum Order Requirement**. Notwithstanding any provision to the contrary set forth in this Agreement, any failure of SLP to comply with its obligations under **Section 5.01** with respect to the Licensed Product will be excused, including but not limited to any [***], to the extent that such failure results solely from [***] subject to SLP's use of Commercially Reasonable Efforts to [***].

Section 5.03 **Compliance with Law**. SLP shall bear all responsibility for complying with all applicable Law in connection with its Commercialization of the Licensed Product in the Territory. Without limiting the foregoing, SLP shall bear all responsibility for (i) ensuring compliance of all marketing and promotional materials which SLP distributes in connection with Commercialization of the Licensed Product in the Territory, and (ii) complying with all reporting requirements under applicable Law.

ARTICLE VI.

MANUFACTURE AND SUPPLY

Section 6.01 SLP, through [***] CMO [***], shall have sole control over the Manufacturing of the Licensed Product inside or outside the Territory for purposes of Commercialization in the Field in the Territory during the Term. As of the Effective Date, Sol-Gel has qualified one CMO for supply of the Licensed Product in the United States [***] ("**Sol-Gel Recommended CMO**[***]"). Sol-Gel shall assist and cooperate with SLP's efforts to [***]. Sol-Gel shall assist and cooperate with SLP's efforts to enter into a Supply Agreement during the Term with the Sol-Gel Recommended CMO[***] and Sol-Gel shall grant the Sol-Gel Recommended CMO[***] all the rights necessary to Manufacture and supply the Licensed Product to the Territory and shall share with SLP all chemistry, manufacturing and controls documentation and other validation documentation and any other product development documentation related to the non-Territory versions of the Licensed Product Controlled by Sol-Gel including but not limited to provision of [***]. Sol-Gel shall have a right of approval to qualify any additional non-Sol- Gel Recommended CMO to supply the Licensed Product in the Territory. In the event [***], Sol-Gel at SLP's expense will use Commercially Reasonable Efforts to assist SLP in either [***].

ARTICLE VII.

PAYMENTS

Section 7.01 Upfront Payment. Within [***] following the Effective Date, and receipt of an invoice therefor, SLP shall pay Sol-Gel a one-time, non-creditable, non- refundable upfront payment of Two Hundred Fifty Thousand Dollars ($250,000), by wire transfer.

Section 7.02 Regulatory Milestone Payments.

(a) Within [***] days following [***] SLP shall pay Sol-Gel a further one-time, non-refundable, non-creditable payment of [***].

(b) Within [***] days following the later of [***], and [***], SLP shall pay Sol-Gel, upon receipt of an invoice therefor, a further one-time, non- refundable, non-creditable payment of [***].

Section 7.03 Sales Milestone Payments. SLP shall pay to Sol-Gel the following one- time payments after the first achievement of Net Sales of Licensed Product in a calendar year period in the Territory that meet or exceed the minimum annual Net Sales thresholds set forth below, which payment shall be made no later than [***] after receipt of an invoice therefor pursuant to **Section 7.06**:

Annual Net Sales Threshold	Payment Amount
Equal to or greater than $ [***]	$ [***]
Equal to or greater than $ [***]	$ [***]
Equal to or greater than $ [***]	$ [***]
Equal to or greater than $ [***]	$ [***]

For clarity, each milestone payment in this **Section 7.03 (Sales Milestone Payments)** shall be payable only once, upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone in subsequent calendar years. The Net Sales of Licensed Product in a calendar year shall be aggregated within such calendar year for purposes of determining whether any milestone in the table above has been met. If more than one of the milestones set forth in the table above are first achieved in a single calendar year, then SLP shall pay to Sol-Gel in such calendar year all of the payments corresponding to all of the milestones achieved in such calendar year under this **Section 7.03 (Sales Milestone Payments)**.

Section 7.04 Royalties.

(a) SLP agrees to pay to Sol-Gel, on a calendar quarterly basis, a royalty payment based on annual Net Sales of the Licensed Product for each calendar year as set forth below:

(i) An amount equal to [***] percent ([***]%)of the first [***] aggregate Net Sales in such calendar year;

(ii) An amount equal to [***] percent ([***] %) on the portion of Net Sales exceeding [***] dollars ($[***]) in aggregate Net Sales in such calendar year up to and including aggregate Net Sales of [***] Dollars ($[***]) in such calendar year; and

(iii) An amount equal to [***] percent ([***] %) on the portion of Net Sales exceeding [***] ($[***]) in such calendar year.

(b) Notwithstanding the provisions of **Section 7.04(a)** (Royalties), after [***], the following changes to the royalties shall apply:

(i) [***], the royalty rates payable by SLP under **Section 7.04(a)** (Royalties) for the Territory for the remainder of the Term shall be equal to [***]; and

(ii) [***].

(c) To the extent [***] to enter into a license agreement under Patent Rights from any Third Party(ies) that would be infringed by [***] Development use or Commercialization of the Licensed Product in the Field in the Territory and [***] obtains such a license, [***] may offset [***] % such payments from the royalty payments otherwise due to Sol-Gel by SLP under this **Section 7.04** (Royalties).

Section 7.05 Payments due to Patents Abandonment. In the event that Sol-Gel elects not to continue to maintain all Licensed Patent Rights covering the Licensed Product in the Territory, and following such election, [***], Sol-Gel shall pay to SLP the following one-time payments after [***], in a calendar year period as set forth below, which payment shall be made no later than [***] after receipt of an invoice therefor pursuant to **Section 7.06**:

Year of [***]	**Compensation Amount**
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]
[***]	$ [***]

Section 7.06 Royalty and Sales Milestone Payments and Reports.

(a) During the Term, SLP agrees to provide [***] written reports to Sol-Gel within [***] days after the end of each calendar [***], covering all [***], each such written report stating for the period in question [***]. Such report shall include written notice of any occurrence of the milestones set forth in **Section**

7.03. Upon receipt of such report, Sol-Gel shall remit an invoice to SLP for payment of the applicable Sales Milestone Payment (**Section 7.03**) or applicable Royalty Payment (**Section 7.04**).

(b) SLP shall make the Sales Milestone Payments and Royalty Payments due hereunder within [***] days after receipt of an invoice from Sol-Gel pursuant to **Section 7.06(a)**.

(c) SLP, at its sole option, may elect to set off any Royalty or Sales Milestone Payment amounts owing to Sol-Gel throughout the Term by the value of any payments that may become payable to SLP pursuant to **Section 7.05**.

Section 7.07 Recordkeeping. Each SLP Entity shall keep accurate records of Licensed Product that is made, used or sold under this Agreement, in accordance with the Accounting Standards consistently applied, for a period of at least [***] after the end of the calendar year to which the records relate, setting forth the sales of Licensed Product in sufficient detail to enable royalties and other amounts payable to Sol-Gel hereunder to be determined. Each SLP Entity further agrees to permit its books and records to be examined (i) by an independent accounting firm selected by Sol-Gel and reasonably acceptable to SLP no more than [***], to verify any reports and payments delivered under this Agreement during the [***] most recently-ended calendar years, during regular business hours and to commence on a date that is mutually agreeable to both Sol-Gel and SLP but is to commence within [***] days of the examination request by Sol-Gel and subject to a reasonable confidentiality agreement. The Parties shall reconcile any underpayment or overpayment within [***] days after the accounting firm delivers the results of any audit. Such examination is to be made at the expense of [***] or more during the periods being audited, in which case reasonable audit fees for such examination shall be paid by [***].

Section 7.08 Currency Conversion. Wherever it is necessary to convert currencies for Net Sales invoiced in a currency other than the Dollar, such conversion shall be made into Dollars at the conversion rate published by the Bank of Canada using the simple average of the published rate during the applicable calendar quarter or, if such rate is unavailable, a substitute therefor reasonably selected by Sol-Gel. All payments due to Sol-Gel under this Agreement shall be made without deduction of exchange, collection or other charges. Once the amount of Net Sales paid to Sol-Gel in respect of a particular calendar quarter has been converted into Dollars, such amount of Dollars shall be used for the purpose of calculating the total amount of Net Sales during the calendar year that includes such calendar quarter.

Section 7.09 Methods of Payment. All payments due under this Agreement shall be made in U.S. Dollars by wire transfer to a bank account of Sol-Gel or SLP as applicable.

Section 7.10 Taxes.

(a) **General**. The milestones, royalties and other amounts payable by SLP to Sol-Gel pursuant to this Agreement (each, a "**Payment**") will be paid free and clear of any and all taxes, except for any withholding taxes required by applicable Law. Except as provided in this **Section 7.10 (Taxes)**, [***] will be solely responsible for paying any and all taxes (other than withholding taxes required by applicable Law to be deducted from Payments and remitted by SLP) levied on account of, or measured in whole or in part by reference to, any Payments it receives.

(b) **Withholding Tax.** The Parties agree to cooperate with one another and use Commercially Reasonable Efforts in accordance with applicable Law to eliminate or reduce to the extent possible, withholding taxes and similar obligations on payments made under this Agreement. [***]. Notwithstanding the foregoing, if Sol-Gel is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to SLP or the appropriate Governmental Authority (with the assistance of SLP to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve SLP of its obligation to withhold such tax and SLP will apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that SLP has received evidence, in a form reasonably satisfactory to SLP, of Sol-Gel's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] days prior to the time that the Payments are due. If, in accordance with the foregoing, SLP withholds any amount, it will pay to Sol-Gel the balance when due, make timely payment to the proper taxing authority of the withheld [***].

(c) **No Withholding Tax Adjustment**. In the event that any Payment is subject to a deduction or withholding of tax (each, a "**Withholding Tax Action**"), then notwithstanding **Section 7.10(a)**, the payment by SLP (in respect of which such deduction or withholding of tax is required to be made) shall be treated for all purposes of this Agreement has having been paid to Sol-Gel in respect of which such deduction and withholding was made by SLP.

Section 7.11 Invoices. Any invoice which Sol-Gel delivers to SLP under this Agreement may be delivered by email to apdept@searchlightpharma.ca (which email address may be changed by SLP from time to time upon written notice to Sol-Gel), with a hard copy confirmed by mailing to:

Attention: Accounts Payable Searchlight Pharma Inc.
1600 Notre-Dame Street West, Suite 312 Montreal, Quebec, H3J 1M1
Canada

(which addresses may be changed by SLP from time to time upon written notice to Sol-Gel).

Section 7.12 Late Payments. If Sol-Gel does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Sol- Gel from the due date until the date of payment at the [***] as reported by The Wall Street Journal from time to time, plus [***] per annum or the maximum applicable legal rate, if less. The interest payment shall be due from the day the original payment was due until the day that the payment was received by Sol-Gel; provided, that, with respect to any bona fide disputed payments, [***] , calculated from [***].

ARTICLE VIII.

INTELLECTUAL PROPERTY

Section 8.01 Ownership of Intellectual Property

(a) Sol-Gel shall retain sole and exclusive ownership of all rights, title and interests in and to the Licensed Technology.

(b) Subject to **Section 8.01(c)**, ownership of Trademarks, developments or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by or on behalf of either Party during the Term in the course of performing activities under this Agreement, and any and all intellectual property rights therein ("**Inventions**") will be determined based on the principles of inventorship in accordance with United States patent laws.

(c) Notwithstanding **Section 8.01(b)**, and regardless of inventorship, any and all Inventions, Patents Rights and Know-How that (i) relate to the Licensed Product and/or the composition, use, administration, formulation or other aspect thereof, (ii) are developed or generated by or on behalf of Sol-Gel or any of its Affiliates or jointly developed or generated by or on behalf of both Parties, (iii) relate to or are developed with the use of or reference to, incorporate and/or rely upon Sol-Gel's Confidential Information or the Licensed Technology, and all intellectual property rights therein; and/or (iv) improve upon and/or are derived from Sol-Gel's Confidential Information or the Licensed Technology or any SLP Product Data, ("**Sol-Gel Inventions**") shall be owned exclusively and solely by Sol-Gel. SLP hereby assigns and shall assign to Sol-Gel all of its rights, title and interests it may have in and to all Sol-Gel Inventions, without any remuneration or compensation. SLP shall, and shall cause each of its employees, contractors, and agents to, cooperate with Sol-Gel and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect Sol-Gel's right, title and interest in and to the Sol-Gel Inventions. In the event that SLP is required to register a new Trademark related to the Licensed Product because the Regulatory Authority in the Territory rejects the use of the Licensed Trademark, Sol-Gel shall have the first option to pay for and assume all expenses related to the registration and maintenance of such Trademark and such new Trademark shall be included in this Agreement as a Licensed Trademark. If Sol-Gel declines to pay and assume expenses related to such Trademark, then such Trademark shall be owned by SLP. In the event that SLP elects to register a new Trademark related to the Licensed Product, SLP shall be responsible for, and shall pay for all expenses related to the registration and maintenance of such Trademark and SLP shall own such Trademark(the "**SLP Trademark**").

(d) Sol-Gel hereby grants SLP, during the Term only, a non-exclusive, royalty-bearing, transferable (subject to **Section 15.01**) license under all Sol-Gel Inventions solely to Develop and Commercialize the Licensed Product in the Field in the Territory, subject to and in accordance with the terms of this Agreement, and any Patent Rights which are part of the Sol-Gel Inventions shall be treated a part of the Licensed Patent Rights and any Know-How which are part of the Sol- Gel Inventions shall be treated a part of the Licensed Know How.

Section 8.02 Prosecution of Patent Rights. Sol-Gel shall be responsible for and have sole control over, at its cost, the preparation, filing, prosecution and maintenance of all Licensed Patent Rights in Sol-Gel's name in the Territory. Sol-Gel will: (i) instruct such patent counsel to provide SLP with copies of all filings and formal correspondences relating to such Licensed Patent Rights in the Territory and (ii) keep SLP advised of the status of actual and prospective patent filings related to the Licensed Product in the Territory. Sol-Gel will give SLP the opportunity to provide and will reasonably consider comments on the preparation, filing, prosecution and maintenance of the Licensed Patent Rights in the Territory. Sol-Gel, reserves the sole right to make all final decisions regarding the preparation, filing, prosecution and maintenance of the Licensed Patent Rights. Each Party will treat any consultation regarding the preparation, filing, prosecution and maintenance of such Licensed Patent Rights, along with any information disclosed by each Party in connection therewith (including any information concerning patent expenses), as part of Sol-Gel's Confidential Information. Sol-Gel may elect at its sole discretion not to continue to seek or maintain any Licensed Patent Rights covering the Licensed Product in the Territory [***] jurisdiction. In such case, Sol-Gel will provide SLP with [***] days advance written notice of its intention to abandon such Licensed Patent Rights. If Sol-Gel elects not to continue to seek or maintain any Licensed Patent Rights covering the Licensed Product in the Territory for any other reason (the "**Abandoned Patent Rights**"), then Sol-Gel shall provide SLP with timely notice with respect to its decision, and will provide SLP with a reasonable opportunity to assume responsibility for the continued prosecution and maintenance of such Licensed Patent Rights at its own cost, in the name of SLP, and Sol-Gel will free of charge assign and transfer to SLP the ownership and interest in such Licensed Patent Rights.

Section 8.03 Enforcement.

(a) If either Party becomes aware of any Third Party activity, including any Development activity (whether or not an exemption from infringement liability for such Development activity is available under applicable Law), that infringes (or that is directed to the Development of a product that would infringe) a Licensed Patent Right, then the Party becoming aware of such activity shall give prompt written notice to the other Party regarding such alleged infringement or misappropriation (collectively, "**Infringement Activity**").

(b) During the Term, and provided that SLP is not then in material breach of the Agreement, SLP shall have the first right, but not the obligation, to attempt to resolve any Infringement Activity related to the Licensed Patent Rights in the Territory by commercially appropriate steps at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. SLP shall (i) keep Sol-Gel reasonably informed regarding such infringement or misappropriation suit (including by providing Sol-Gel with drafts of each filing within a reasonable period before the deadline for such filing and promptly providing Sol- Gel with copies of all final filings and correspondence), and (ii) consult with SLP on such infringement or misappropriation suit. If SLP notifies Sol-Gel that SLP will not take steps to enforce the Licensed Patent Rights in the Territory against Infringement Action, or fails to resolve such Infringement Activity in the Territory, or to initiate a suit with respect thereto by the date that is [***]days before any deadline for taking action to avoid any loss of material enforcement rights or remedies, then, Sol-Gel will have the right, but not the obligation, to attempt to resolve such Infringement Activity by commercially appropriate steps at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice.

(c) Any amounts recovered by a Party as a result of an action pursuant to **Section 8.03(b)**, whether by settlement or judgment, shall be allocated first to the reimbursement of any expenses incurred by the Party bringing such action, and then to the reimbursement of any expenses incurred by the other Party in such action, and any remaining amounts shall be retained by the enforcing Party; however, any amounts recovered by SLP, after reimbursement or deduction of costs and expenses incurred by each Party in connection with such infringement or misappropriation suit [***].

(d) In any event, at the request and expense of the Party bringing an infringement or misappropriation action under **Section 8.03(b)**, the other Party shall provide reasonable assistance in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and be joined as a party to the suit if necessary for the initiating or defending Party to bring or continue such suit. Neither Party may settle any action or proceeding brought under **Section 8.03(b),** or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in any Licensed Patent Rights without the written consent of such other Party. Each Party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit or other action instituted by the other Party pursuant to **Section 8.03(b)**.

Section 8.04 Defense of Third Party Infringement and Misappropriation Claims.

(a) If a Third Party asserts that a Patent Right or other right Controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement or a Party becomes aware of a Patent Right or other right that might form the basis for such a claim, the Party first obtaining knowledge of such a claim or such potential claim shall immediately provide the other Party with notice thereof and the related facts in reasonable detail. The Parties shall discuss what commercially appropriate steps, if any, to take to avoid infringement or misappropriation of said Third Party Patent Right or other right controlled by such Third Party in the Territory.

(b) If a Third Party asserts that a Patent Right or other right Controlled by it in the Territory is infringed or misappropriated by the Manufacture, use, or Commercialization of Licensed Product, SLP shall have the first right, but not the obligation, to resolve any such claim, whether by obtaining a license from such Third Party or by defending itself against such Third Party assertion. SLP shall be solely responsible for its defense of such action. SLP shall keep Sol- Gel reasonably informed regarding such assertion and such defense. Subject to Sol-Gel's indemnification obligations under **Section 12.01**, SLP shall bear all costs incurred in connection with its defense of any such Third Party assertion.

Section 8.05 Notice of Actions; Settlement. SLP shall promptly inform Sol-Gel of any action or suit relating to Licensed Patent Rights and shall not enter into any settlement, consent judgment or other voluntary final disposition of any action relating to Licensed Patent Rights, including but not limited to appeals, without the prior written consent of Sol-Gel, such consent not to be unreasonably withheld or delayed.

Section 8.06 Patent Listings. Throughout the Term, Sol-Gel shall use Commercially Reasonable Efforts to assist SLP to timely list any Licensed Patent Rights with the Regulatory Authority on the patent register in the Territory. SLP shall bear all expenses related to such activities. Sol-Gel shall immediately notify SLP when any of the Licensed Patent Rights receive a notice of allowance from the Canadian Patent office as well as when such patent application issues, in order for SLP to timely list said patent on the patent register.

ARTICLE IX.

ADVERSE DRUG EVENTS AND REPORTS

Section 9.01 Complaints. Each Party shall maintain a record of all non-medical and medical product-related complaints it receives with respect to the Licensed Product. Each Party shall notify the appropriate contact pursuant to the Safety Data Exchange Agreement of any material complaint received by it in sufficient detail, and shall provide such contact with copies of any safety reports or other submissions to any Regulatory Authority in connection with the reporting of adverse events, in each case in accordance with the timeframes and procedures for reporting established by the Parties within the Safety Data Exchange Agreement, and in any event in sufficient time to allow each Sol-Gel Entity and their respective sublicensees (with regards to Sol-Gel Entity's sublicensees, solely to the extent such sublicensees are subject to similar obligations under this **Section 9.01 (Complaints)**) and each SLP Entity to comply with any and all regulatory requirements imposed upon it. The Party that holds the applicable Regulatory Filing(s) in a particular country or jurisdiction shall investigate and respond to all such complaints in such country or jurisdiction with respect to the Licensed Product as soon as reasonably practicable. All such responses shall be made in accordance with the procedures established pursuant to applicable Law and all applicable guidelines. The Party responsible for responding to such complaint shall promptly provide the other Party with a copy of any such response.

Section 9.02 Adverse Drug Events. At least [***] days prior to the anticipated approval date of the Licensed Product in the Territory by the Regulatory Authority, the Parties shall enter into a separate pharmacovigilance agreement that delineates the safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as safety data sharing and exchange, and adverse events reporting (the "**Safety Data Exchange Agreement**"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other important safety information, and Licensed Product quality and Licensed Product complaints involving adverse events, sufficient to permit each Party, its Affiliates, or sublicensees to comply with its legal obligations. The Parties shall promptly update the Safety Data Exchange Agreement if required by changes in applicable Law. Each Party shall comply with its respective obligations under the Safety Data Exchange Agreement and shall cause its Affiliates and sublicensees to comply with such obligations. For clarity, Sol-Gel shall be responsible for the global safety database for the Licensed Product.

ARTICLE X.

REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section 10.01 Mutual Representations and Warranties. Each of SLP and Sol-Gel hereby represents and warrants to the other Party as of the Effective Date that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) it is not a party to any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement;

(d) to its knowledge, no consent, approval or agreement of any person or Governmental Authority is required to be obtained in connection with the execution and delivery of this Agreement; and

(e) it has not been debarred by the FDA, is not the subject of a conviction described in Section 306 of the FD&C Act, and is not subject to any similar sanction of any other Governmental Authority outside of the U.S., and neither it nor any of its Affiliates has used, in any capacity, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction inside or outside of the U.S.

Section 10.02 Mutual Covenants. Each of SLP and Sol-Gel hereby covenants to the other Party that:

(a) it will not engage, in any capacity in connection with this Agreement or any ancillary agreement, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any similar sanction inside or outside of the U.S., and such Party shall inform the other Party in writing promptly if such Party or any person or entity engaged by such Party who is performing services under this Agreement, or any ancillary agreement, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act or any similar sanction inside or outside of the U.S., or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to any such debarment or conviction of a Party, any of its Affiliates or any such person or entity performing services hereunder or thereunder;

(b) during the Term, it will not make any commitment to any Third Party in conflict with the rights granted by it hereunder; and

(c) it will comply with all applicable Laws in performing its activities hereunder and shall ensure such compliance by its Affiliates.

Section 10.03 Additional Sol-Gel Warranties. Sol-Gel hereby represents and warrants to SLP as of the Effective Date that:

(a) Sol-Gel solely owns or Controls the entire right, title, and interest in and to the Licensed Technology, and that such Licensed Technology is free and clear of all liens and encumbrances;

(b) Sol-Gel and its Affiliates have not, prior to the Effective Date, entered into any written agreement with a Third Party under which Sol-Gel and its Affiliates has granted any rights in or to its ownership interest in the Licensed Technology, which, to its knowledge, are inconsistent with the rights granted to SLP under this Agreement;

(c) to Sol-Gel's knowledge, Exhibit A contains a list of all Patent Rights and Trademark(s) that are Controlled by Sol-Gel as of the Effective Date and Cover Commercialization of the Licensed Product as they exist on the Effective Date in the Field in the Territory;

(d) all of the issued Patent Rights and Trademark(s) listed in Exhibit A are in full force and effect, and, to the best of Sol-Gel's knowledge, are not invalid or unenforceable, in whole or in part;

(e) Sol-Gel is unaware of any pending claim, action, or proceeding in the Territory challenging the validity or enforceability of any of the Licensed Patent Rights or Trademark(s) listed in Exhibit A or alleging that the Commercialization of the Licensed Product or its ingredients infringes or misappropriates any patent rights or other intellectual property rights of any Third Party;

(f) Neither Sol-Gel nor any of its Affiliates has received any written notification from a Third Party that the Development, Manufacture, use, or Commercialization of Licensed Products in the Territory would infringe or misappropriate any Patent Rights or Know-How owned or Controlled by such Third Party;

(g) to Sol-Gel's knowledge, none of the Manufacture, use, Development or Commercialization of the Licensed Products in the Field in the Territory infringes any valid enforceable claim of any existing Patent not Controlled by Sol-Gel;

(h) to Sol-Gel's knowledge, there are no ongoing activities by a Third Party that would constitute infringement or misappropriation of the Licensed Technology within the Territory.

(i) to Sol-Gel's knowledge, Sol-Gel has not received written notice of any investigations, inquiries, actions or other proceedings pending before or threatened by any Regulatory Authority or other Governmental Authority in the Territory with respect to the Licensed Product in the Territory arising from any action or default by Sol-Gel or any of its Affiliates or a Third Party acting on behalf Sol-Gel in the discovery or Development of the Licensed Product;

(j) to Sol-Gel's knowledge, there is no existing scientific fact or circumstance that would materially adversely affect the efficacy, safety or market performance of the Licensed Product which Sol-Gel has not communicated to SLP;

(k) Sol-Gel has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of the Licensed Know-How; and

(l) To Sol-Gel's knowledge, there are no Key Regulatory Submissions required for the Territory that they will not be able to provide to SLP.

Section 10.04 Anti-Corruption.

(a) Anti-Corruption Provisions. Each Party represents and warrants to the other Party that such Party has not, directly or indirectly, offered, promised, paid, authorized or given, and each Party agrees that such Party will not, in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official (as defined below) or Other Covered Party (as defined below) for the purpose, pertaining to this Agreement, of: (i) influencing any act or decision of such Government Official or Other Covered Party; (ii) inducing such Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing such Government Official or Other Covered Party to influence the act or decision of a Governmental Authority, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

For purposes of this Agreement: (A) "**Government Official**" means any official, officer, employee or representative of: (1) any Governmental Authority; (2) any public international organization or any department or agency thereof; or (3) any company or other entity owned or controlled by any Governmental Authority; and (B) "**Other Covered Party**" means any political party or party official, or any candidate for political office.

(b) Anti-Corruption Compliance.

(i) In performing under this Agreement, each Party, on behalf of itself, its respective Affiliates and (in the case of Sol-Gel) other Sol-Gel Entities and (in the case of SLP) other SLP Entities, agrees to comply with all applicable anti-corruption Laws of the Territory.

(ii) Each Party represents and warrants to the other Party that such Party is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.

(iii) No Party, nor any Affiliate of any Party (and (in the case of Sol-Gel) no other Sol-Gel Entity and (in the case of SLP) no other SLP Entity), shall give, offer, promise or pay any political contribution or charitable donation at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity.

(iv) SLP Entities shall in all cases, refrain from engaging in any activities or conduct which would cause any Sol-Gel Entity to be in violation of any applicable anti-bribery Laws. To the extent allowed by Law, if any SLP Entity proposes to provide any information, data or documentation to any governmental or regulatory authority in respect of the Licensed Product that relates to or may result in a violation of any applicable anti-bribery Law, it shall first obtain the prior written approval of Sol-Gel, which will not be unreasonably withheld, or shall provide such information, data or documentation in accordance with Sol-Gel's written instructions.

(v) SLP agrees that should it learn or have reason to know of: (i) any payment, offer, or agreement to make a payment to a foreign official or political party for the purpose of obtaining or retaining business or securing any improper advantage for Sol-Gel under this Agreement or otherwise, or (ii) any other development during the Term that in any way makes inaccurate or incomplete the representations, warranties and certifications of SLP hereunder given or made as of the date hereof or at any time during the Term, relating to anti-bribery Law, SLP will immediately advise Sol-Gel in writing of such knowledge or suspicion and the entire basis known to SLP therefor.

(vi) In the event that a Party violates any anti-corruption Law of the Territory or any other applicable anti-corruption Law, or breaches any provision in this **Section 10.04** **(Anti- Corruption)**, the other Party shall have the right to terminate this Agreement pursuant to **Section 13.02** (**Termination for Breach**).

Section 10.05 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY SOL-GEL TO SLP HEREIN ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

Section 10.06 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, EXEMPLARY, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER. THE FOREGOING SHALL NOT LIMIT (a) [***]OR (b) [***]**,** OR (c) [***].

ARTICLE XI.

CONFIDENTIALITY

Section 11.01 Generally. During the Term and for a period of [***] years thereafter, each Party (a) shall maintain in confidence all Confidential Information of the other Party or any of such Party's Affiliates; (b) shall not use such Confidential Information for any purpose except to fulfill its obligations or exercise its rights (for the avoidance of doubt, including, with respect to Sol-Gel, the right to Commercialize the Licensed Product outside of the Field or Territory (and inside of the Field and Territory after any termination or expiration of this Agreement) and to Develop and Manufacture the Licensed Product in accordance with this Agreement) under this Agreement; and (c) shall not disclose such Confidential Information to anyone other than those of its Affiliates, directors, investors, [***] employees, consultants, financial or legal advisors, or other agents or contractors (collectively, "**Representatives**") who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this **Article XI** **(Confidentiality)** and to whom such disclosure, under this Agreement, is necessary in connection with the fulfillment of such Party's obligations or exercise of such Party's rights under this Agreement or in connection with *bona fide* financing or acquisition activities. Each Party shall (i) ensure that such Party's Representatives who receive any of the other Party's (or any of such Party's Affiliates') Confidential Information comply with the obligations set forth in this **Article XI** **(Confidentiality)** and (ii) be responsible for any breach of these obligations by any of its Representatives who receive any of the other Party's (or any of such Party's Affiliates') Confidential Information. Each Party shall notify the other Party promptly on discovery of any unauthorized use or disclosure of the other's (or any of its Affiliates') Confidential Information.

Section 11.02 Exceptions. The obligations of confidentiality, non-disclosure, and non- use set forth in **Section 11.01 (Generally)** shall not apply to, and "Confidential Information" shall exclude, any information to the extent the receiving Party (the "**Recipient**") can demonstrate that such information: (a) was in the public domain or publicly available at the time of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement, or thereafter entered the public domain or became publicly available, in each case other than as a result of any action of the Recipient, or any of its Representatives, in breach of this Agreement; (b) was rightfully known by the Recipient or any of its Affiliates (as shown by competent proof) prior to the date of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement; (c) was received by the Recipient or any of its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the disclosing Party or any of its Affiliates; or (d) was independently developed by or for the Recipient or any of its Affiliates without reference to or reliance on the Confidential Information of the other Party or any of its Affiliates (as demonstrated by competent proof).

Section 11.03 Permitted Disclosures. Notwithstanding any other provision of this Agreement, Recipient's (or its Affiliates') disclosure of the other Party's (or any of such Party's Affiliates') Confidential Information shall not be prohibited if such disclosure: (a) is in response to a valid order of a court or other Governmental Authority, including the rules and regulations promulgated by the U.S. Securities Exchange Commission and the Ontario Securities Commission (or similar foreign authority) or any other Governmental Authority; (b) is otherwise required by applicable Law or rules of a nationally or internationally recognized securities exchange, including but not limited to the Toronto Stock Exchange or Nasdaq; (c) is: (i) [***]; (d) is to patent offices in order to seek or obtain Patent Rights or to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials or to gain Regulatory Approval with respect to the Licensed Product as contemplated by this Agreement; *provided* that such disclosure may be made only to the extent reasonably necessary to seek or obtain such Patent Rights or Regulatory Approvals, and the Recipient (or its applicable Affiliate(s)) shall use Commercially Reasonable Efforts to obtain confidential treatment of such information; or (e) is in response to a direction to SLP by a Regulatory Authority in the Territory to disclose such Confidential Information pursuant to the Access to Information regime or a Freedom of Information regime and/or the Public Release of Clinical Information regime; provided that such disclosure may be made only if SLP has used Commercially Reasonable Efforts to keep such information confidential. If a Recipient is required to disclose Confidential Information pursuant to **Section 11.03(a)**, **Section 11.03(b)** or **Section 11.03(e)**, prior to any disclosure the Recipient shall, to the extent legally permitted and practicable, provide the disclosing Party with prior written notice of such disclosure in order to permit the disclosing Party to seek a protective order or other confidential treatment of such disclosing Party's Confidential Information.

Section 11.04 Publicity. The Parties will issue a joint press release in connection with this Agreement. The Parties recognize that each Party may from time-to-time desire to issue press releases and make other public statements or public disclosures in respect of this Agreement, including the Development or Commercialization of Licensed Product in the Territory (each, a "**Public Statement**"). If SLP desires to make a Public Statement, it shall provide Sol-Gel a copy of such Public Statement at least [***]prior to the date it desires to make such public disclosure. SLP shall not issue a Public Statement without Sol-Gel's prior written approval, which advance approval shall not be unreasonably withheld, conditioned or delayed. Sol-Gel shall provide to SLP a preliminary draft of any Public Statement that it intends to make on a global basis with respect to Development of Licensed Product at least [***]in advance of such public disclosure and shall provide a final draft of such Public Statement at least [***]in advance of such public disclosure; *provided* that, if such Public Statement includes data owned by SLP with respect to a clinical study or pre-clinical research conducted by SLP in the Territory, Sol-Gel shall obtain SLP's prior written approval to include such data, which approval shall not be unreasonably withheld, conditioned or delayed. Once any public statement or public disclosure has been approved in accordance with this **Section 11.04** (**Publicity**), then the applicable Party may appropriately communicate information contained in such permitted statement or disclosure. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this **Section 11.04**. Notwithstanding anything to the contrary in this **Section 11.04 (Publicity)**, nothing in this **Section 11.04 (Publicity)** shall be deemed to limit either Party's rights under **Section 11.04 (Permitted Disclosures)** or either Party's ability to issue press releases or make other public statements or public disclosures required by applicable Law or rules of a nationally or internationally recognized securities exchange, including but not limited to the Toronto Stock Exchange or Nasdaq.

Section 11.05 Publications. Sol-Gel acknowledges SLP's interest in publishing certain key results of SLP's Development and Commercialization of Licensed Product in the Field in the Territory. SLP recognizes the mutual interest in obtaining valid patent protection and Sol-Gel's interest in protecting its proprietary information. Consequently, except for disclosures permitted pursuant to **Section 11.02 (Exceptions)**, **Section 11.03 (Permitted Disclosures)** or **Section 11.04 (Publicity)**, if SLP wishes to make a publication or public presentation with respect to its Development or Commercialization of Licensed Product in the Field in the Territory, or with respect to key marketing material (collectively a "**Publication**"), SLP shall deliver to Sol-Gel a copy of the proposed written Publication at least [***]days prior to submission for Publication. Sol-Gel shall have the right (a) to require modifications to the Publication for patent or any other business reasons, and SLP will remove all of Sol-Gel's Confidential Information if requested by Sol-Gel, and (b) to require a reasonable delay in Publication in order to protect patentable information. If Sol-Gel requests a delay, then SLP shall delay submission of the Publication for a period of [***] (or such shorter period as may be mutually agreed by the Parties) to enable Sol-Gel to file patent applications protecting Sol-Gel's rights in such information. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this **Section 11.05**.

Section 11.06 Injunctive Relief. Each Party acknowledges and agrees that there may be no adequate remedy at law for any breach of its obligations under this **Article XI (Confidentiality)**, that any such breach may result in irreparable harm to the other Party and, therefore, that upon any such breach or any threat thereof, such other Party may seek appropriate equitable relief in addition to whatever remedies it might have at law, without the necessity of showing actual damages.

ARTICLE XII.

INDEMNIFICATION

Section 12.01 Indemnification by Sol-Gel. Sol-Gel shall indemnify, hold harmless and defend any SLP Entity, and their respective directors, officers, and employees (the "**SLP Indemnitees**") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, costs, damages, deficiencies, obligations or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) ("**Losses**") to the extent that such Losses arise out of (a) any breach of this Agreement by Sol-Gel, (b) the Development, Manufacture or Commercialization of the Licensed Product by or on behalf of any Sol-Gel Entity or their sublicensees or (c) the negligence or willful misconduct of any Sol-Gel Indemnitee. Notwithstanding the foregoing, Sol-Gel shall not have any obligation to indemnify the SLP Indemnitees to the extent that the applicable Losses arise out of any activities set forth in **Section 12.02** for which SLP is obligated to indemnify Sol-Gel.

Section 12.02 Indemnification by SLP. SLP shall indemnify, hold harmless and defend any Sol-Gel Entity, and their respective directors, officers, and employees (the "**Sol-Gel Indemnitees**") from and against any and all Losses, to the extent that such Losses arise out of (a) any breach of this Agreement by SLP, (b) the Manufacture or Commercialization of the Licensed Product by or on behalf of any SLP Entity or (c) the negligence or willful misconduct of any SLP Indemnitee. Notwithstanding the foregoing, SLP shall not have any obligation to indemnify the Sol-Gel Indemnitees to the extent that the applicable Losses arise out of any activities set forth in **Section 12.01** for which Sol-Gel is obligated to indemnify SLP.

Section 12.03 Procedure. In the event of a claim by a Third Party against a SLP Indemnitee or Sol-Gel Indemnitee entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified Party shall promptly notify the Party obligated to provide such indemnification ("**Indemnifying Party**") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto and does not impose any obligations on the Indemnified Party, unless the Indemnified Party otherwise agrees in writing. No Indemnified Party may settle any claim for which it is being indemnified under this Agreement without the Indemnifying Party's prior written consent.

Section 12.04 Insurance. Each Party, at its own expense, shall maintain commercial general liability insurance and product liability and other appropriate insurance, in amounts consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall maintain such insurance for the period commencing promptly after the Effective Date until [***]after the Term. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon request. It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations under this Agreement.

ARTICLE XIII.

TERM AND TERMINATION

Section 13.01 Term. The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this **Article XIII** (**Term and Termination**), will continue for an initial term of fifteen (15) Years as of the First Commercial Sale of Licensed Product in the Territory (the "**Initial Term**"). Following the Initial Term, the Agreement shall be automatically renewed (unless earlier terminated in accordance with the terms of this **Article XIII** (**Term and Termination**)), for additional consecutive terms of five (5) Years each (each such additional term the "**Additional Term**" collectively with the Initial Term the "**Term**").

Section 13.02 Termination for Breach. Subject to the terms and conditions of this **Section 13.02** (**Termination for Breach**), a Party (the "**Non-Breaching Party**") shall have the right, in addition to any other rights and remedies available to such Party at Law or in equity, to terminate this Agreement in the event the other Party (the "**Breaching Party**") is in material breach of its obligations under this Agreement. The Non-Breaching Party shall first provide written notice to the Breaching Party, which notice shall identify with particularity the alleged breach (the "**Breach Notice**"). With respect to material breaches of any payment provision hereunder, the Breaching Party shall have a period of [***]days after such Breach Notice is provided to cure such breach. With respect to all other breaches, the Breaching Party shall have a period of [***]days after such Breach Notice is provided to cure such breach. If such breach is not cured within the applicable period set forth above, the Non-Breaching Party may, at its election, terminate this Agreement upon written notice to the Breaching Party. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

Section 13.03 Termination due to Decision not to File an Application. Upon Sol-Gel's receipt of written notice from SLP, during the first [***]months as of the Effective Date, indicating a decision not to move forward with filing an application for Regulatory Approval in the Territory, this Agreement shall immediately terminate.

Section 13.04 Termination for Bankruptcy and Rights in Bankruptcy.

(a) To the extent permitted under applicable Law, if, at any time during the Term, an Event of Bankruptcy (as defined below) relating to either Party (the "**Bankrupt Party**") occurs, the other Party (the "**Other Party**") shall have, in addition to all other legal and equitable rights and remedies available to such Party, the option to terminate this Agreement upon [***] days written notice to the Bankrupt Party. It is agreed and understood that, if the Other Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the Other Party shall continue to make all payments required of it under this Agreement as if the Event of Bankruptcy had not occurred, and the Bankrupt Party shall not have the right to terminate any license granted herein. The term "**Event of Bankruptcy**" means: (i) filing in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or taking the benefit of any statue in force for bankrupt or insolvent debtors, including for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Bankrupt Party or of its assets, (ii) making an assignment for the benefit of creditors,

(iii) appointing or suffering appointment of a receiver or trustee over substantially all of a Party's property that is not discharged within [***]days after such appointment, or (iv) being served with an involuntary petition against the Bankrupt Party, filed in any insolvency proceeding, where such petition is not dismissed within [***]days after the filing thereof.

(b) All rights and licenses granted under or pursuant to this Agreement by SLP and Sol-Gel are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as sublicensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

Section 13.05 Termination for Patent Challenge. Except to the extent the following is unenforceable under the applicable Laws, this Agreement shall terminate automatically in its entirety immediately if any SLP Entity, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any of the Licensed Patent Rights.

Section 13.06 Termination for not Meeting the Minimum Orders. In the event that for any particular Year during the Term, SLP has [***] Sol-Gel shall have the right to terminate the Agreement by providing SLP with a [***] days' prior written notice. In the event that during the [***] Years of the Term, SLP has not ordered the Minimum Orders, but [***], SLP shall have the right to terminate the Agreement by providing Sol-Gel with a [***] days' prior written notice, and, in the event that after [***] of the Term, SLP has not ordered [***], then SLP shall have the right to terminate the Agreement by providing Sol-Gel with [***]days' prior written notice.

Section 13.07 Termination for [***]. In the event the Parties have not agreed on [***] SLP shall have the right at its sole discretion to terminate this Agreement, by providing Sol-Gel with a [***]days' notice.

Section 13.08 Effect of Termination.

(a) In the event of expiration of this Agreement or termination of this Agreement pursuant to Sections **13.02** (solely for a material breach by SLP), **13.03**, **13.04**, **13.05** or **13.06**:

(i) all license grants in this agreement from Sol-Gel to SLP shall terminate;

(ii) SLP shall in advance of and effective as of the effective date of expiration or termination, assign and transfer to Sol-Gel all SLP Product Data, Regulatory Approvals, Regulatory Documents, Licensed Trademarks, including preparing and providing to Sol-Gel or filing directly with Health Canada all necessary authorizations, free of additional charge. Sol-Gel may request that SLP shall assign and transfer to Sol-Gel the SLP Trademark and the Abandoned Patent Rights, and in the event that the Agreement expires or is terminated for any reason [***];

(iii) Sol-Gel shall, at its option, purchase from SLP all of [***]after the effective date of termination or expiration of this Agreement;

(iv) effective upon the effective date of expiration or termination, SLP shall grant, and hereby grants to Sol-Gel a perpetual, irrevocable, non-exclusive, worldwide, sublicensable, royalty-free and fully paid-up license for (a) all Know-How incorporated by SLP into the Licensed Product or otherwise necessary or reasonably useful for the Development, Manufacture, and/or Commercialization of the Licensed Product as it exists as of the effective date of expiration or termination and (b) all Patent Rights necessary or reasonably useful for the Development, Manufacture, and Commercialization of the Licensed Product, in each case (a) and (b), Controlled by SLP or its Affiliates as of the effective date of such termination, to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize or otherwise exploit the Licensed Product inside and outside of the Territory in the Field (it being understood that such Know How and Patents Rights, shall not include Sol-Gel Inventions which remain the sole and exclusive property of Sol-Gel);

(v) At Sol-Gel's request, any existing agreements between SLP or its Affiliates and any Third Party that are solely related to the Commercialization of the Licensed Product, and all of SLP's and its Affiliates' right, title and interest therein and thereto, shall at Sol-Gel's option be terminated or assigned and transferred to Sol-Gel or its designee, to the extent permissible pursuant to the terms thereof (and for any such agreement that by its terms cannot be so assigned, SLP shall reasonably cooperate with Sol-Gel to provide to Sol-Gel the benefits of such agreement);

(vi) Upon Sol-Gel's written request, SLP shall, [***], assign all contract manufacturing, research service, or other vendor agreements related to the Licensed Product to Sol-Gel, or, [***];

(vii) SLP shall remain responsible for all its non-cancellable Third Party obligations incurred with respect to the Licensed Product; and

(viii) SLP shall, and shall cause its employees, contractors, and agents to, cooperate with Sol-Gel and take all other actions as reasonably required by Sol-Gel to assist in enabling Sol-Gel to promptly assume Commercialization of the Licensed Product in the Field in the Territory.

(b) In the event of termination of this Agreement by SLP pursuant to **Section 13.02** (solely for a material breach by Sol-Gel):

(i) All rights and licenses granted by Sol-Gel to SLP hereunder shall become irrevocable and perpetual rights and licenses;

(ii) All milestone and royalty payments pursuant to Article VII that have not accrued prior to the date of termination shall cease; and

(iii) All other obligations of SLP relating to activities contemplated by this Agreement shall terminate.

Section 13.09 Survival; Accrued Rights. The following articles and sections of this Agreement shall survive expiration or early termination for any reason: **Article I (Definitions)**, **Article VII (Payments)** (solely to the extent any payments became payable prior to the effective date of such expiration or termination), **Article IX (Adverse Drug Events and Reporting)**, **Section 4.03 (Licensed Product Pricing), Section 4.03 (Generic Products), Section 8.01 (Ownership of Intellectual Property)**, **Section 8.02 (Prosecution of Patent Rights), 8.03 (Enforcement), 8.04 (Defense of Third Party Claims), Section 10.06 (Limitation of Liability)**, **Article XI (Confidentiality)**, **Section 12.01 (Indemnification by Sol-Gel), Section 12.02 (Indemnification by SLP), Section 12.03 (Procedure)**, **Section 13.08 (Effect of Termination)**, **Section 13.09 (Survival; Accrued Rights)**, **Article XIV (Dispute Resolution; Governing Law)**, **Section 15.01 (Assignment)** (solely with respect to the last sentence in clause (a) and the entirety of clause (b)) and **Article XVI (Miscellaneous)**. In any event, expiration or termination of this Agreement shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

ARTICLE XIV.

DISPUTE RESOLUTION; GOVERNING LAW

Section 14.01 Arbitration. Subject to **Section 14.01(d)**, any disputes, claims or controversies in connection with this Agreement, including any questions regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination, that are not resolved in accordance with **Article III (Governance)** and are not subject to a Party's final decision-making authority in accordance with **Article III (Governance)** shall be referred to and finally resolved by binding arbitration administered by the American Arbitration Association, in accordance with the then current Commercial Rules of the American Arbitration Association (the "**Rules**"), which rules are deemed to be incorporated by reference into this **Section 14.01** (**Arbitration**), in the manner described below; provided that, prior to commencing of arbitration or other legal proceedings with respect to any disputes, claims or controversies in connection with this Agreement, the CEOs of both Parties shall discuss in good faith such disputes, claims or controversies for at least [***]days.

(a) **Arbitration Request**. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution.

(b) **Additional Issues**. Within [***]days after the receipt of an Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

(c) **General Arbitration Procedure for Disputes**. The seat of arbitration will be in New York, New York and it will be conducted in the English language. The arbitration will be conducted by a single arbitrator, who will be appointed according to the Rules or by mutual agreement of the Parties; notwithstanding anything in the foregoing, the Arbitrator must be an attorney admitted to practice Law in the state of New York. The arbitral award shall be final, definitive and binding on the Parties and their successors. The Parties reserve the right to apply to a competent judicial court to obtain urgent remedies to protect rights before establishment of the arbitration panel, without such recourse being considered as a waiver of arbitration. Except as otherwise determined by the arbitrator, the Parties shall each bear half of the fees and expenses of the arbitrators and the arbitration, and each Party shall bear the costs and fees of its own attorneys. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, Confidential Information, Know-How, intellectual property rights or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, any arbitrators chosen hereunder shall have educational training or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology and pharmaceuticals. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The Parties intend that each award rendered by an arbitrator hereunder shall be entitled to recognition and enforcement under the United Nations Convention on the Recognition and Enforcement of Arbitral Awards (New York, 1958).

(d) **Intellectual Property Disputes**. Notwithstanding **Section 14.01(d)**, unless otherwise agreed by the Parties, a dispute between the Parties relating to the validity or enforceability of any Patent Right shall not be subject to arbitration and shall be submitted to a court or patent office of competent jurisdiction in the relevant country or jurisdiction in which such patent was issued or, if not issued, in which the underlying patent application was filed.

Section 14.02 Choice of Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, shall be construed under and governed by the State of New York, exclusive of its conflicts of laws principles. This Agreement shall not be governed by the provisions of the United Nations Convention on Contracts for the International Sale of Goods.

Section 14.03 Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. All consents, notices, reports and other written documents to be delivered or provided by a Party under this Agreement shall be in the English language, and, in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation shall control.

ARTICLE XV.

ASSIGNMENT AND ACQUISITIONS

Section 15.01 Assignment.

(a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party in the field to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations.

(b) The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this **Section 15.01 (Assignment)** will be null and void *ab initio*.

ARTICLE XVI.

MISCELLANEOUS

Section 16.01 Force Majeure. If either Party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure, which may include any act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, pandemic, act of terrorism, government action, strike or labor differences, in each case outside of such Party's reasonable control, such Party shall not be liable to the other therefor, and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. The Party invoking the force majeure rights of this **Section 16.01** (**Force Majeure**) must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) within a period of [***] days of both the first and last day of the force majeure unless the force majeure renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds [***] months, the other Party may terminate this Agreement immediately upon written notice to the Party invoking the force majeure rights of this **Section 16.01** (**Force Majeure)**.

Section 16.02 Entire Agreement. This Agreement, together with the Exhibits and Schedules attached hereto, constitutes the entire agreement between Sol-Gel or any of its Affiliates, on the one hand, and SLP or any of its Affiliates, on the other hand, with respect to the subject matter hereof, supersedes all prior understandings and writings between Sol-Gel or any of its Affiliates, on the one hand, and SLP or any of its Affiliates, on the other hand relating to such subject matter, and shall not be modified, amended or (subject to **Article XIII (Term and Termination)**) terminated, except by another agreement in writing executed by the Parties.

Section 16.03 Severability. If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision of this Agreement (such invalid or unenforceable provision, a "**Severed Clause**"), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use their reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

Section 16.04 Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be mailed by internationally recognized express delivery service, or sent by facsimile or email and confirmed by mailing, as follows (or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith):

If to Sol-Gel:

Sol-Gel Technologies Ltd. 7 Golda Meir St.
Ness Ziona Israel, 7403650

Attn: Gilad Mamlok, Chief Financial Officer
Email: Gilad.Mamlok@Sol-Gel.com

With a copy to: Adv. Tami Fishman, VP & General Counsel
Email: Tami.Fishman@Sol-Gel.com

If to SLP:

Searchlight Pharma Inc.
1600 Notre-Dame Street West, Suite 312 Montreal, QC
Canada

H3J 1M1

Attention: Mark Nawacki, President & CEO
Email: [***]

With a copy to:

Attention: Legal Department
Email: [***]

Any such notice shall be deemed to have been given (a) when delivered if personally delivered, (b) on receipt if sent by overnight courier or (c) on receipt if sent by mail.

Section 16.05 Agency. Neither Party is, nor will be deemed to be a partner, employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

Section 16.06 No Waiver. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other Party, shall not constitute a waiver of such Party's rights to the enforcement of any of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.

Section 16.07 Cumulative Remedies. Except as may be expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law or in equity.

Section 16.08 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than (a) to the extent provided in **Section 12.01 (Indemnification by Sol-Gel)**, the SLP Indemnitees and (b) to the extent provided in **Section12.02 (Indemnification by SLP)**, the Sol-Gel Indemnitees.

Section 16.09 Performance by Affiliates. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder; *provided* that such Party so notifies the other Party in writing and *provided*, *further*, that such Party shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

Section 16.10 Counterparts. This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

SOL-GEL TECHNOLOGIES, LTD.

By: /s/ Gilad Mamlok
Name: Gilad Mamlok
Title: CFO

SEARCHLIGHT PHARMA INC.

By:/s/ Mark Nawacki
Name: Mark Nawacki
Title: President & CEO

Exhibit A

Licensed Patents & Trademark

[***]

Exhibit B

Commercialization Plan

SLP to provide at least [***] months prior to commercial launch in the Territory

Exhibit C

Target Price

SLP's target net-selling price for Licensed Product is [***] [***]

Exhibit D

Minimum Orders

[***]

Exhibit E

[***]Rates [***]

[***]

Exhibit 4.23

CERTAIN IDENTIFIED INFORMATION MARKED [***] HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

Execution Version

LICENSE AGREEMENT

BY AND BETWEEN

SEARCHLIGHT PHARMA INC.

AND

SOL-GEL TECHNOLOGIES LTD.

TABLE OF CONTENTS

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of June 5, 2023 ("**Effective Date**") between Sol-Gel Technologies Ltd., with a principal place of business at 7 Golda Meir St. Ness Ziona Israel ("**Sol-Gel**"), and Searchlight Pharma Inc., with a principal place of business at 1600 Notre-Dame Street West, Suite 312, Montreal, Quebec, H3J 1M1, Canada ("**SLP**"). Sol-Gel and SLP may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Sol-Gel is the owner of, or otherwise controls, the Licensed Technology in the Territory (each as defined below);

WHEREAS, SLP is interested in obtaining an exclusive license to Develop and Commercialize the Licensed Product in the Territory (each as defined below); and

WHEREAS, the Parties desire for Sol-Gel to grant such license to SLP to Develop and Commercialize the Licensed Product in the Territory, all under the terms and conditions as set forth in this Agreement.

NOW THEREFORE, the Parties agree as follows:

ARTICLE I.

DEFINITIONS

Section 1.01 "**Accounting Standards**" means the then-current International Financial Reporting Standards, as consistently applied.

Section 1.02 "**Additional MOQ Period**" means the consecutive [***] ([***]) Year periods, following the Initial MOQ Period during the Term of this Agreement.

Section 1.03 "**Affiliate**" means, with respect to an entity, any corporation or other business entity controlled by, controlling, or under common control with such entity, with "control" meaning (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of, the applicable entity (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction and is sufficient to grant the holder of such voting stock or interest the power to direct the management and policies of such entity) or (b) possession, directly or indirectly, of the power to direct the management and policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise.

Section 1.04 "**Business Day**" means a day other than (a) a Saturday or a Sunday or (b) a day on which banking institutions in Toronto, Ontario, Canada and Montreal, Quebec, Canada, are authorized or required by Law to remain closed.

Section 1.05 "**Canada**" shall mean Canada, its provinces and territories.

Section 1.06 "**CMO**" means a contract manufacturing organization identified and introduced to SLP by Sol-Gel or independently identified by SLP.

Section 1.07 "**Commercialization**" **or** "**Commercialize**" means, with respect to a pharmaceutical product, any and all activities directed to the marketing, promotion, importation, distribution, pricing, reimbursement approval, offering for sale and/or sale of such pharmaceutical product. Commercialization shall exclude Development and Manufacturing.

Section 1.08 "**Commercialization Plan**" means the plan setting out activities to be undertaken by SLP in Commercializing the Licensed Product in the Field in the Territory following initial Regulatory Approval, attached hereto as Exhibit B.

Section 1.09 "**Commercially Reasonable Efforts**" means, with respect to a Party's performance of obligations under this Agreement, the carrying out of such obligations in a sustained and diligent manner, using efforts and resources that are consistent with the efforts and resources typically used by [***] with respect to the Development or Commercialization of products of similar market potential, profit potential and strategic value and of a stage in Development or product life, including the use of reasonably necessary personnel, based on conditions then prevailing and taking into account issues of safety and efficacy, product profile, difficulty in Developing such product, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of such product, the regulatory structure involved and the potential profitability of such product, as applicable, but without regard for any payment obligations under this Agreement, [***].

Section 1.10 [***].

Section 1.11 "**Confidential Information**" means, subject to **Section 11.02**, Know-How, the terms of this Agreement, and any technical, scientific, trade, research, manufacturing, business, financial, compliance, marketing, product, supplier, intellectual property or other information that may be disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form.

Section 1.12 "**Controls**", "**Controlled**" means, with respect to a Party, and any Know- How, Patent Right, Regulatory Documents or other intellectual property right, that such Party or any of its Affiliates has the ability (other than pursuant to a license granted to such Party under this Agreement) to grant to the other Party a license or sublicense to, and other applicable rights (including without limitation sharing such Know-How, Patent Right, Regulatory Documents with licensees and Third Parties) with respect to, such Know-How, Patent Right, Regulatory Documents or other intellectual property right without violating the terms of any pre-existing agreement with

any Third Party or any applicable Law and without the need for any consent (or further consent) from such Third Party.

Section 1.13 "**Cover**", "**Covering**" or "**Covered**" means, with respect to a product, composition, technology, process or method and a Patent Right, that, in the absence of ownership of, or a license granted under, a claim in such Patent Right, the manufacture, use, offer for sale, sale or importation of such product or composition or the practice of such technology, process or method would infringe such claim (directly, indirectly by contributory infringement or by inducement to infringe) or, in the case of a claim of a pending patent application, would infringe such claim if it were to issue as a claim of an issued patent.

Section 1.14 "**Develop**" or "**Development**" means pre-clinical research and clinical development activities reasonably related to the development and submission of information to a Regulatory Authority, including without limitation (i) clinical trials of a pharmaceutical compound or product, investigator sponsored trials and registry studies; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials or obtain Regulatory Approval of a pharmaceutical product; (iii) activities relating to the development of chemistry, manufacturing, and controls data. Development shall include clinical trials initiated prior to or following receipt of Regulatory Approval, but shall exclude Manufacturing and Commercialization.

Section 1.15 "**Dollars**" **or** "**$**" means the legal tender of the U.S.

Section 1.16 "**Drug Approval Application**" means a submission or application to be filed with the Regulatory Authority in accordance with applicable Law for the purpose of obtaining marketing approval for a pharmaceutical product in the Territory, including a New Drug Submission or an application for a Drug Identification Number ("DIN").

Section 1.17 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

Section 1.18 "**Field**" means the treatment, prevention, cure, or amelioration of Acne vulgaris (or within the acne indication, as approved by the Regulatory Authority) in humans.

Section 1.19 "**First Commercial Sale**" means, with respect to the Licensed Product, the first [***] sale of the Licensed Product in the Territory to a Third Party after [***]. For clarity, [***] shall not be deemed "First Commercial Sale".

Section 1.20 "**Generic Product**" means, with respect to a Licensed Product, any pharmaceutical product that (a) has the same active ingredients as the Licensed Product; (b) is approved by [***] on the basis of [***]; and, (c) is approved by the Regulatory Authority in the Territory in the Field.

Section 1.21 "**Governmental Authority**" means any federal, national, multinational, state, provincial, territorial, county, city or local government or any court, arbitrational tribunal, administrative agency or commission or government authority acting under the authority of any national, multinational, provincial, territorial, county, city or local government.

Section 1.22 "**Initial MOQ Period**" means the initial period of [***] ([***]) Years commencing as of the First Commercial Sale.

Section 1.23 "**Know-How**" means trade secrets, data, chemical and biological materials, formulations, information, documents, studies, results, data, regulatory approvals, regulatory filings and related correspondence (including DMFs), including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, formulations, samples, whether or not patented or patentable.

Section 1.24 "**Law**" means any law, statute, rule, regulation, policy, guidance, order, judgment, standard or ordinance of any Governmental Authority.

Section 1.25 "**Licensed Know-How**" means all Know-How that is Controlled by Sol- Gel or any of its Affiliates during the Term of the Agreement and is in Sol-Gel's reasonable judgment, necessary or useful for the use or Commercialization of the Licensed Product in the Field in the Territory. Licensed Know-How does not include [***].

Section 1.26 "**Licensed Patent Rights**" means any Patent Rights owned or Controlled by Sol-Gel or any of Sol-Gel's Affiliates during the Term of the Agreement that Cover the [***], including those set forth in Exhibit A. Licensed Patent Rights does not include [***].

Section 1.27 "**Licensed Product**" means Sol-Gel's proprietary topical product containing an antibiotic-free, fixed dose combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% as the main active ingredients, known and intended to be marketed under the name "Twyneo".

Section 1.28 "**Licensed Technology**" means Licensed Know-How and Licensed Patent Rights.

Section 1.29 "**Licensed Trademark**" means "Twyneo®" as set forth in Exhibit A.

Section 1.30 **"M&A Know-How**" [*******].

Section 1.31 **"M&A Patents**" **[*****].

Section 1.32 "**Manufacture**" or "**Manufacturing**" means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, filling, finishing, packaging, labeling, shipping, exporting, importing or storage of pharmaceutical compounds or materials, including process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

Section 1.33 "**Net Sales**" means the gross amount [***] from the sale, lease or other transfer or provision of Licensed Products to [***] for consideration (the "**Gross Sales**"), reduced by [***]:

(a) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

If non-monetary consideration is received by a SLP Entity for the Licensed Product, the average price charged for such Licensed Product will be calculated [***], as applicable, [***], or in the absence of such [***].

Section 1.34 "**Patent Right(s)**" means all rights under any patent or patent application, certificate of inventions, application for certificate of invention or priority patent filing in the Territory or under any international convention or treaty, including any patents issuing on such patent applications, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, division, continuation or continuation-in-part of any of the foregoing.

Section 1.35 "**PMPRB"** means the Patented Medicine Prices Review Board of Canada.

Section 1.36 "**PMPRB Reference Countries"** means the countries listed in the schedule to the Patented Medicines Regulations SOR/94-688, as may be amended. The current countries are Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom.

Section 1.37 "**Regulatory Approval**" means, with respect to a particular regulatory jurisdiction, an approval, notice of compliance, license, registration or authorization of any Governmental Authority that provides marketing approval for the commercial sale, or reimbursement approval, of a pharmaceutical product in one or more specified indications in such regulatory jurisdiction.

Section 1.38 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including Health Canada and any other applicable Governmental Authority in the Territory having jurisdiction over pharmaceutical products.

Section 1.39 "**Regulatory Documents**" means, (i) (a) all submissions to Regulatory Authorities in the Territory, including, without limitation, all applications (including Drug Approval Applications), submissions, registrations, licenses, authorizations, approvals (including Regulatory Approvals) and marketing or regulatory exclusivities, including, without limitation, all INDs, NDAs, sNDAs, CTAs, all and any aggregate safety reports, NDSs, SNDSs, CMC Data, drug master files, filings with PMPRB, filings for listing with Canadian provincial drug plans; (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files; and (c) preclinical, clinical and other data, results, analyses, publications, and reports contained or referred to in any of the foregoing; as well as (ii) all submissions to the Pharmaceutical Advertising Advisory Board and Ad Standards or any other regulator responsible for advertising, as well as all filings for listings with private payers. For the avoidance of doubt, Regulatory Documents include Regulatory Approvals and Regulatory Filings.

Section 1.40 "**Regulatory Filings**" means all applications, filings, dossiers, Regulatory Documents, Regulatory Approvals, and the like submitted to a Regulatory Authority for the purpose of Developing, Manufacturing or Commercializing the Licensed Product, including obtaining Regulatory Approval from that Regulatory Authority. Regulatory Filings include all INDs, CTAs, Drug Approval Applications and other Regulatory Approval (including reimbursement approval) submissions.

Section 1.41 "**SLP Entity**" means, as applicable, (a) SLP, (b) any of SLP's Affiliates.
SLP shall be responsible for the breach of this Agreement by any SLP Entity.

Section 1.42 "**SLP Regulatory Documents**" means Regulatory Documents Controlled by SLP at any time during the Term that relate to a Licensed Product in the Territory.

Section 1.43 "**Sol-Gel Entity**" means, as applicable, (a) Sol-Gel or (b) any of Sol-Gel's Affiliates. Sol-Gel shall be responsible for the breach of this Agreement by any Sol-Gel Entity.

Section 1.44 "**Sol-Gel Regulatory Documents**" means Regulatory Documents Controlled by Sol-Gel [***] that relate to a Licensed Product.

Section 1.45 "**Supply Agreement**" means [***].

Section 1.46 "**Target Price"** means the target net-selling price of the Licensed Product set forth in Exhibit C.

Section 1.47 Territory" means Canada.

Section 1.48 "**Third Party**" means any person or entity other than the Parties and their Affiliates.

Section 1.49 "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

Section 1.50 "**U.S.**" or "**United States**" means the United States of America, including its districts, territories and possessions.

Section 1.51 "**Year**" means a consecutive twelve-month period beginning as of the date of First Commercial Sale of the Licensed Product in the Territory.

Additional Defined Terms	Section
Abandoned Patent Rightst	Section 8.02
Additional Term	Section 13.01
Alliance Manager	Section 3.11
Arbitration Request	Section 14.01(a)
Bankrupt Party	Section 13.034
Breaching Party	Section 13.02
Commercialization Plan	Section 5.01
Event of Bankruptcy	Section 13.04(a)
Executive Officer	Section 3.067
Government Official	Section 10.04(a)
Indemnified Party	Section 12.03
Indemnifying Party	Section 12.03
Infringement Activity	Section 8.03(a)
Infringement Action	Section 8.03(b)
Initial Term	Section 13.01
Inventions	Section 8.01(c)
JSC	Section 3.01
Key Regulatory Submissions	Section 4.01(a)
Losses	Section 12.01
Minimum Orders	Section 5.01
Non-breaching Party	Section 13.02
Other Covered Party	Section 10.04
Other Party	Section 13.04(a)
Payment	Section 7.10(a)
Public Statement	Section 11.04
Publication	Section 11.05
Recipient	Section 11.02
Representatives	Section 11.01
Revised Financial Terms	Section 4.03(b)
Rules	Section 14.01
Safety Data Exchange Agreement	Section 9.02
Severed Clause	Section 16.03
[***]	Section 5.01
[***]	Section 5.01
SLP Indemnitee	Section 12.01
SLP Trademark	Section 8.01(c)
Sol-Gel Indemnitee	Section 12.02
Sol-Gel Product Data	Section 4.02
Sol-Gel Recommended CMO[***]	Section 6.01
Term	Section 13.01
Withholding Tax Action	Section 7.10(c)

Section 1.52 Interpretation. (a) Whenever any provision of this Agreement uses the word "including," "include," "includes," or "*e.g.*," such word shall be deemed to mean "including without limitation" and "including but not limited to"; (b) "herein," "hereby," "hereunder," "hereof" and other equivalent words shall refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) a capitalized term not defined herein but reflecting a different part of speech from that of a capitalized term which is defined herein shall be interpreted in a correlative manner; (d) wherever used herein, any pronoun or pronouns shall be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the Schedules and the Exhibits to this Agreement, and the terms and conditions incorporated in such recitals and Schedules and Exhibits, shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such recitals and Schedules and Exhibits and the terms and conditions incorporated in such recitals and Schedules and Exhibits; *provided* that, in the event of any conflict between the terms and conditions of the body of this Agreement and any terms and conditions set forth in the recitals, Schedules or Exhibits, the terms of the body of this Agreement shall control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement or otherwise, the terms and conditions of this Agreement shall govern; (g) this Agreement shall be construed as if both

Parties drafted it jointly, and shall not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections, Articles and Schedules in this Agreement are to Sections, Articles, Exhibits and Schedules of and to this Agreement; (i) any reference to any Law shall mean such Law as in effect as of the relevant time, including all rules and regulations thereunder and any successor Law in effect as of the relevant time, and including the then-current amendments thereto; (j) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) references to a Party's knowledge shall be taken to refer to the actual knowledge of such Party's CEO and his/her direct reports as of the Effective Date; (l) the captions and table of contents used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits or limitations; and (m) the word "year" means any consecutive twelve (12) month period, unless otherwise specified.

ARTICLE II.

LICENSES

Section 2.01 Grants of Licenses; Limitation.

(a) Subject to the terms and conditions of this Agreement, Sol-Gel hereby grants to SLP and SLP's Affiliates (i) an exclusive (including as to Sol-Gel and its Affiliates), royalty- bearing, transferable (subject to **Section 15.01 (Assignment)**) license solely during the Term under the Licensed Technology solely to Develop, have Developed, register, have registered, use, have used, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold, and otherwise exploit or have exploited the Licensed Product in the Field in the Territory; (ii) an exclusive, transferable (subject to **Section 15.01 (Assignment)**) license to use the Licensed Trademark in connection with the Licensed Product in the Territory; and (iii) a non-exclusive transferable (subject to **Section 15.01 (Assignment)**) license to use [***] that are non-exclusively licensed to a Third Party. The license granted in this **Section 2.01** may be sublicensed by SLP pursuant to a separate written agreement to a Third Party [***]. Any sublicense granted shall be made subject to the terms and conditions of this Agreement and require a sublicensee to be bound by the terms of this Agreement. Any breach by a sublicensee of such terms and conditions of this Agreement as applicable to a sublicensee in such sublicense agreement shall be deemed to be a breach by SLP under this Agreement. Promptly after the execution of any sublicense agreement, SLP shall notify Sol-Gel and provide Sol-Gel with a copy of such agreement, [***]. No such sublicense shall relieve SLP of any of its obligations or responsibilities under this Agreement.

(b) As between the Parties, all rights not expressly licensed to SLP under the Licensed Technology in **Section 2.02(a)** shall be retained by Sol-Gel, including the right to Develop, Manufacture and Commercialize the Licensed Product outside the Territory, and the right to Develop and Manufacture the Licensed Product anywhere in the world (including within the Territory) for use outside the Territory and for use within the Territory after the termination or expiration of this Agreement.

(c) SLP agrees that neither it, nor any of its Affiliates, shall offer to sell or otherwise provide the Licensed Products to any Third Party if SLP or its relevant Affiliates, knows, or has reason to believe, that the Licensed Products offered for sale, sold or provided to such Third Party would be sold or transferred outside the Territory.

Section 2.02 Competing Product. During the Term[***].

ARTICLE III.

GOVERNANCE

Section 3.01 General. Within [***] days following the Effective Date, the Parties shall establish a Joint Steering Committee ("**JSC**") to facilitate the exchange of information and cooperation between the Parties with respect to the Development and Commercialization of the Licensed Product in the Field in the Territory. The JSC shall have decision-making authority with respect to the matters within its purview to the extent expressly provided herein.

Section 3.02 Plans, Forecasts and Activities. At least [***] weeks in advance of each meeting of the JSC, SLP shall provide the JSC with [***].

Section 3.03 Joint Steering Committee.

(a) The JSC shall:

(i) monitor and discuss the Commercialization Plan;

(ii) monitor and discuss the progress of the Development and Commercialization of the Licensed Product in the Field in the Territory;

(iii) monitor and discuss the written sales forecasts and descriptions of anticipated resources provided to the JSC pursuant to **Section 3.02 (Plans, Forecasts and Activities)**;

(iv) monitor and discuss the pricing of the Licensed Product in all PMPRB Reference Countries (both current and proposed countries);

(v) serve as a forum for exchanging information regarding the conduct of the Development and Commercialization of the Licensed Product in the Field in the Territory;

(vi) serve as a form for exchanging information regarding Manufacturing of the Licensed Product;

(vii) serve as a forum for exchanging information regarding the prosecution, maintenance and issuance of the Licensed Patent Rights, as well as the patent listing activities specified in Section 8.06;

(viii) discuss whether to create any additional subcommittee(s) or working group(s);

(ix) serve as a forum to facilitate dispute resolution; and

(x) perform such other duties as are specifically assigned to the JSC under this Agreement.

Section 3.04 Membership. The JSC shall be composed [***] representatives from [***], each of which representatives shall be of the seniority and experience appropriate for service on the JSC in light of the functions, responsibilities and authority of such committee and the status of activities within the scope of the authority and responsibility of such committee. Each Party may replace any of its representatives on the JSC at any time with written notice to the other Party; *provided* that such replacement meets the standard described in the preceding sentence. Each Party's representatives and any replacement of a representative shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in **Article XI (Confidentiality)**. Each Party may invite [***] of its or its Affiliates' employees as required or useful to discuss the applicable agenda items. The JSC shall appoint a chairperson from among its members, with the first chairperson of the JSC being a representative of [***]. Each chairperson (whether initially appointed or any successor therefor) shall serve a term of [***], at which time, the JSC shall select a successor chairperson who is a representative of the Party other than the Party represented by the outgoing chairperson (*e.g.*, the second chairperson of the JSC shall be a representative of [***], the third chairperson of the JSC shall be a representative of [***], etc.). Within [***] days following each JSC meeting, the chairperson shall circulate to all committee members a draft of the minutes of such meeting. The JSC shall then approve, by mutual agreement, such minutes within [***] days following circulation. No chairperson of the JSC shall have any greater authority than any other representative of such committee.

Section 3.05 Meetings.

(a) The JSC shall hold an initial meeting within [***] days after its formation or as otherwise agreed by the Parties. Thereafter, unless the Parties otherwise agree, the JSC shall meet at least [***]. Each such meeting may be in person, by video, by teleconference, or by any other agreed upon means. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JSC meetings.

Section 3.06 JSC Decision Making. All decisions of the JSC shall be made by [***], and shall be set forth in minutes approved by both Parties. If the JSC is unable to reach agreement on any matter within [***] after a matter is referred to it or first considered by it, such matter shall be referred to the Executive Officers for resolution in accordance with **Section 3.07 (Executive Officers; Disputes)**.

Section 3.07 Executive Officers; Disputes. Each Party shall ensure that an executive officer is designated for such Party at all times during the Term for dispute resolution purposes (each such individual, such Party's "**Executive Officer**"), and shall promptly notify the other Party of its initial, or any change in its, Executive Officer. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the Executive Officers, who shall attempt in good faith to resolve such dispute.

Section 3.08 Final Decision-Making Authority. If the Parties are unable to resolve a given dispute within the purview of the JSC within [***] after referring such dispute to the Executive Officers pursuant to **Section 3.07 (Executive Officers; Disputes)**, then, subject to

Section 3.09 (Limitations on Decision-Making):

(a) [***].

(b) [***]

(c) Any decision made by [***]shall be deemed to be a decision of the JSC.

Section 3.09 Limitations on Decision-Making.

(a) Neither Party shall have the deciding vote on, and the JSC shall have no decision- making authority regarding, any of the following matters:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***];

or

(vii) [***]

.

(b) The decision-making Party shall make its decision in good faith, subject to the terms and conditions of this Agreement.

(c) In no event may the decision-making Party [***].

(d) In no event may [***].

(e) In no event may [***].

(f) [***].

Section 3.10 Scope of Governance. Notwithstanding the creation of the JSC or anything to the contrary in this **Article III (Governance)**, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and the JSC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by the JSC are only those specific issues that are expressly provided in this Agreement to be decided by such committee.

Section 3.11 Alliance Managers. Each of the Parties shall appoint a single individual to manage Development, Manufacturing and Commercialization obligations between the Parties under this Agreement (each, an "**Alliance Manager**"). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers may attend any JSC meetings. Each Alliance Manager shall be a non-voting participant in such Committee and Subcommittee meetings, unless s/he is also appointed a member of the JSC; *provided, however*, that an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Party's Alliance Manager and any substitute for an Alliance Manager shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in **Article XI** (**Confidentiality**). Each Alliance Manager will also:

(a) plan and coordinate cooperative efforts and internal and external communications; and

(b) facilitate the governance activities hereunder and the fulfillment of action items resulting from JSC meetings.

ARTICLE IV.

REGULATORY; TECHNOLOGY SHARING

Section 4.01 Regulatory Responsibility.

(a) SLP shall be responsible for preparing, obtaining, and maintaining all Regulatory Filings and Regulatory Approvals and conducting communications with the Regulatory Authorities in the Territory. Without limiting the foregoing, SLP shall have sole responsibility for seeking Regulatory Approval in Canada, and shall use Commercially Reasonable Efforts to obtain such Regulatory Approval. For clarity, SLP shall have no obligation to conduct any pre-clinical testing or clinical studies. All Regulatory Approvals in the Territory shall be held in the name of SLP, who shall be the Marketing Authorization Holder ("MAH") and the importer of record, and SLP shall maintain the right to transfer the Regulatory Approvals to an Affiliate. SLP shall provide Sol-Gel with copies of all [***] (collectively, the "**Key Regulatory Submissions**") prior to submission to a Regulatory Authority and Sol-Gel shall have [***], or a shorter time period if required by Law, from receipt of such Key Regulatory Submissions to provide comments. SLP shall reasonably consider and, if reasonable, in SLP's sole judgment, incorporate such comments, prior to submission to the Regulatory Authority.

(b) Sol-Gel shall provide timely support and consult SLP in its efforts to perform its obligations set forth in section 4.01(a) above. In support of SLP's preparation of any Regulatory Filing with respect to the Licensed Product in the Field in the Territory, to the extent required and upon SLP's written request, Sol-Gel shall provide SLP access to a complete electronic copy of and a right of reference to all current and as updated (i) Regulatory Documents Controlled by any Sol- Gel Entity (including those generated by any of Sol-Gel's licensees that are Controlled by Sol-Gel) that are related to the Licensed Product in the Field, and (ii) any other information requested by Regulatory Authorities in the Territory in connection with SLP's Regulatory Filings solely to the extent (A) Controlled by the Sol-Gel Entities, and (B) subject to Sol-Gel's Commercially Reasonable Efforts to obtain, and Sol-Gel's actual obtaining of the prior written consent of any Sol-Gel Entities' Third Party licensees, in each case ((i) through (ii)) to the extent permitted by applicable Law, and if applicable by the agreements entered between Sol-Gel Entities and its licensees. Without limiting the foregoing, Sol-Gel shall (i) provide SLP with the Key Regulatory Submissions filed for the product in the United States that corresponds to the Licensed Product in both word and pdf format which are within its Control, and with respect to which it has the contractual rights to share with SLP; (ii) perform Commercially Reasonable Efforts to assist SLP with causing the manufacturers of the API for the Licensed Product to file electronic drug master files with the Regulatory Authority in the Territory in order to permit SLP to reference such information in the Licensed Product submission; and (iii) perform Commercially Reasonable Efforts to assist with SLP with causing the manufacturers of the API for the Licensed Product to provide SLP with any required documentation as requested by the Regulatory Authority in order to comply with Laws.

(c) [***] in conducting its regulatory responsibilities under this **Section 4.01**, and will [***] [***]. All Third Party vendors and their activities require advance approval [***].

Section 4.02 Technology Sharing.

(a) Sol-Gel shall provide to SLP all data and documents Controlled by the Sol-Gel Entities and related to the Licensed Product that are reasonably necessary for SLP to Commercialize Licensed Product in the Territory, including Licensed Know-How, regulatory data, and clinical data. Throughout the Term, Sol-Gel shall provide SLP with an update of any material regulatory developments (e.g., NDA or NDS filed, meetings with Regulatory Authority, or Regulatory Approval) relating to a Licensed Product made by Sol-Gel, or Sol-Gel's Affiliates or licensees, and upon SLP's request, Sol-Gel shall make available to SLP copies of Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case that are related to Licensed Product in the Field and Controlled by the Sol-Gel Entities or any of their licensees (collectively, the "**Sol-Gel Product Data**"), to the extent (i) such Sol-Gel Product Data are reasonably necessary for any SLP Entity to Commercialize the Licensed Product in the Field in the Territory in accordance with this Agreement and are Controlled by the Sol-Gel Entities,

(ii) such Sol-Gel Product Data are required by Regulatory Authority in the Territory in connection with the Commercialization of Licensed Product in the Field in the Territory and are Controlled by the Sol-Gel Entities, or (iii) subject to Sol-Gel's exercise of Commercially Reasonable Efforts to obtain, and Sol-Gel's actual obtaining of, the prior written consent of any Sol-Gel Entities' licensee, such Sol-Gel Product Data are required by Regulatory Authority in the Territory in connection with the Commercialization of Licensed Product in the Field in the Territory and are Controlled by any such Third Party licensee.

(b) SLP shall make available to Sol-Gel copies of SLP Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case that pertain to Licensed Product and are Controlled by a SLP Entity or its sub-contractor (collectively, the "**SLP Product Data**"), to the extent such SLP Product Data are reasonably necessary for Sol-Gel, its Affiliates or (sub)licensees to exercise its retained rights. SLP hereby grants to Sol-Gel and Sol- Gel's Affiliates or licensees a right to access, use and reference the SLP Product Data in any Regulatory Filing made by Sol-Gel (or its Affiliates or (sub)licensees as the case may be) pertaining to Licensed Product in connection with the exercise of its retained rights. Without limiting the foregoing, SLP shall provide to the appropriate regulatory contacts as set out in the Safety Data Exchange Agreement, copies of any annual or other periodic reports required to be submitted to any Regulatory Authority regarding the progress of any post-marketing requirements with respect to Regulatory Approval for the Licensed Product.

Section 4.03 Licensed Product Pricing.

(a) SLP, in consultation with Sol-Gel, will be responsible for obtaining and maintaining any pricing approvals required or offered by PMPRB to market and sell the Licensed Products in the Territory, including but not limited to compliance with Patent Act, R.S.C., 1985, c. P-4, and Patented Medicines Regulations, and, if applicable, for negotiations with governmental and private insurance payors.

(b) The JSC will review and discuss the list price of the Licensed Product in all (current proposed, and then-current) PMPRB Reference Countries. Sol-Gel will share with the JSC the information regarding the pricing of the Licensed Product in the (current, proposed and any then- current) PMPRB Reference Countries Controlled by Sol-Gel Entities, provided that it is legally and contractually permitted to share such information. [***].

(c) In the event that PMPRB requires a payment in respect of excess revenues generated through the sales of the Licensed Product in the Territory or the Parties agree to a payment of excess revenues by way of a voluntary compliance undertaking to resolve any investigation by the PMPRB, then (i) if such payment is required [***]; and (ii) if such payment is required in any other case, [***].

Section 4.04 Generic Products. SLP will in no event during the Term or at any time after expiration or termination of this Agreement seek Regulatory Approval for or otherwise engage in the Development, Manufacture, and/or Commercialization of (i) any pharmaceutical product which uses the Licensed Product as a reference listed drug as defined in the *Food and Drug Regulations* (C.R.C., c. 870 as amended); or (ii) any Generic Product, [***].

ARTICLE V.

COMMERCIALIZATION

Section 5.01 General; Diligence. SLP shall use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Territory for use in the Field, which efforts shall include, without limitation, (i) taking all actions set forth in Exhibit B (the "**Commercialization Plan**"), and (ii) purchasing annual minimum amounts of Licensed Product ("**Minimum Orders**"). **Exhibit D** sets forth the Minimum Orders to be purchased by SLP during the Initial MOQ Period. Thereafter [***]. Notwithstanding the foregoing, the Parties shall consult with each other through the JSC prior to taking any action in connection with the Commercialization of the Licensed Product in the Territory which would reasonably be expected to prevent or adversely affect in any material respect the ability of the other Party to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize or otherwise exploit the Licensed Product outside of the Territory at any time or inside the Territory after termination or expiration of this Agreement in the case of Sol-Gel, or within the Territory during the Term in the case of SLP. If SLP orders less than the Minimum Order Quantities of Licensed Product for a particular Year during the Term (such period, [***]), then no later than [***] days following the conclusion of such Shortfall Period, SLP shall either [***].

Section 5.02 Exceptions to Minimum Order Requirement. Notwithstanding any provision to the contrary set forth in this Agreement, any failure of SLP to comply with its obligations under **Section 5.01** with respect to the Licensed Product will be excused, including but not limited to any [***], to the extent that such failure results solely from [***] subject to SLP's use of Commercially Reasonable Efforts to [***].

Section 5.03 Compliance with Law. SLP shall bear all responsibility for complying with all applicable Law in connection with its Commercialization of the Licensed Product in the Territory. Without limiting the foregoing, SLP shall bear all responsibility for (i) ensuring compliance of all marketing and promotional materials which SLP distributes in connection with Commercialization of the Licensed Product in the Territory, and (ii) complying with all reporting requirements under applicable Law.

ARTICLE VI.

MANUFACTURE AND SUPPLY

Section 6.01 SLP, through [***] CMO[***], shall have sole control over the Manufacturing of the Licensed Product inside or outside the Territory for purposes of Commercialization in the Field in the Territory during the Term. As of the Effective Date, Sol-Gel has qualified one CMO for supply of the Licensed Product in the United States [***] ("**Sol-Gel Recommended CMO**[***]"). Sol-Gel shall assist and cooperate with SLP's efforts to [***]. Sol-Gel shall assist and cooperate with SLP's efforts to enter into a Supply Agreement during the Term with the Sol-Gel Recommended CMO[***]and Sol-Gel shall grant the Sol-Gel Recommended CMO[***] all the rights necessary to Manufacture and supply the Licensed Product to the Territory and to share with SLP all chemistry, manufacturing and controls documentation and other validation documentation and any other product development documentation related to the non-Territory versions of the Licensed Product Controlled by Sol-Gel, including but not limited to provision of [***]. Sol-Gel shall have a right of approval to qualify any additional non-Sol-Gel Recommended CMO to supply the Licensed Product in the Territory. In the event [***], Sol-Gel at SLP's expense will use Commercially Reasonable Efforts to assist SLP in either [***].

ARTICLE VII.

PAYMENTS

Section 7.01 **Upfront Payment**. Within [***] following the Effective Date,
and receipt of an invoice therefor, SLP shall pay Sol-Gel a one-time, non-creditable, non- refundable upfront payment of Two Hundred Fifty Thousand Dollars ($250,000), by wire transfer.

Section 7.02 **Regulatory and PMPRB Milestone Payments**.

(a) Within [***] days following [***], SLP shall pay Sol-Gel a further one-time, non-refundable, non-creditable payment of [***]

(b) Within [***] days following the later of [***] , and [***] , SLP shall pay Sol-Gel, upon receipt of an invoice therefor, a further one-time, non- refundable, non-creditable payment of [***].

(c) Within [***]following either [***] ;or (ii) [***], SLP shall pay Sol-Gel, upon receipt of an invoice therefore, a further one-time, non-refundable, non-creditable payment of [***].

Section 7.03 Sales Milestone Payments. SLP shall pay to Sol-Gel the following one- time payments after the first achievement of Net Sales of Licensed Product in a calendar year period in the Territory that meet or exceed the minimum annual Net Sales thresholds set forth below, which payment shall be made no later than [***]after receipt of an invoice therefor pursuant to **Section 7.06**:

Annual Net Sales Threshold	Payment Amount
Equal to or greater than $[***]	$[***]
Equal to or greater than $[***]	$[***]
Equal to or greater than $[***]	$[***]
Equal to or greater than $[***]	$[***]

For clarity, each milestone payment in this **Section 7.03 (Sales Milestone Payments)** shall be payable only once, upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone in subsequent calendar years. The Net Sales of Licensed Product in a calendar year shall be aggregated within such calendar year for purposes of determining whether any milestone in the table above has been met. If more than one of the milestones set forth in the table above are first achieved in a single calendar year, then SLP shall pay to Sol-Gel in such calendar year all of the payments corresponding to all of the milestones achieved in such calendar year under this **Section 7.03 (Sales Milestone Payments)**.

Section 7.04 Royalties.

(a) SLP agrees to pay to Sol-Gel, on a calendar quarterly basis, a royalty payment based on annual Net Sales of the Licensed Product for each calendar year as set forth below:

(i) An amount equal to [***]percent ([***]%) of the first [***] aggregate Net Sales in such calendar year;

(ii) An amount equal to [***]percent ([***]%) on the portion of Net Sales exceeding [***]dollars ($[***]) in aggregate Net Sales in such calendar year up to and including aggregate Net Sales of [***]Dollars ($[***]) in such calendar year; and

(iii) An amount equal to [***]percent ([***]%) on the portion of Net Sales exceeding [***]($[***]) in such calendar year.

(b) Notwithstanding the provisions of **Section 7.04(a)** (Royalties), after [***], the following changes to the royalties shall apply:

(i) [***], the royalty rates payable by SLP under **Section 7.04(a)** (Royalties) for the Territory for the remainder of the Term shall be equal to [***]; and

(ii) [***].

(c) To the extent [***]to enter into a license agreement under Patent Rights from any Third Party(ies) that would be infringed by [***] Development use or Commercialization of the Licensed Product in the Field in the Territory and [***]obtains such a license, [***]may offset [***]% such payments from the royalty payments otherwise due to Sol-Gel by SLP under this **Section 7.04** (Royalties).

Section 7.05 Payments due to Patents Abandonment. In the event that Sol-Gel elects not to continue to maintain all Licensed Patent Rights covering the Licensed Product in the Territory, and following such election, [***], Sol-Gel shall pay to SLP the following one-time payments after [***], in a calendar year period as set forth below, which payment shall be made no later than [***]after receipt of an invoice therefor pursuant to **Section 7.06**:

Year of [***]	**Compensation Amount**
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]

Section 7.06 Royalty and Sales Milestone Payments and Reports.

(a) During the Term, SLP agrees to provide [***]written reports to Sol-Gel within [***]days after the end of each calendar [***], covering all [***], each such written report stating for the period in question [***]. Such report shall include written notice of any occurrence of the milestones set forth in **Section 7.03**. Upon receipt of such report, Sol-Gel shall remit an invoice to SLP for payment of the applicable Sales Milestone Payment (**Section 7.03**) or applicable Royalty Payment (**Section 7.04**).

(b) SLP shall make the Sales Milestone Payments and Royalty Payments due hereunder within [***]days after receipt of an invoice from Sol-Gel pursuant to **Section 7.06(a)**.

(c) SLP, at its sole option, may elect to set off any Royalty or Sales Milestone Payment amounts owing to Sol-Gel throughout the Term by the value of any payments that may become payable to SLP pursuant to **Section 7.05**.

Section 7.07 Recordkeeping. Each SLP Entity shall keep accurate records of Licensed Product that is made, used or sold under this Agreement, in accordance with the Accounting Standards consistently applied, for a period of at least [***]after the end of the calendar year to which the records relate, setting forth the sales of Licensed Product in sufficient detail to enable royalties and other amounts payable to Sol-Gel hereunder to be determined. Each SLP Entity further agrees to permit its books and records to be examined (i) by an independent accounting firm selected by Sol-Gel and reasonably acceptable to SLP no more than [***], to verify any reports and payments delivered under this Agreement during the [***]most recently-ended calendar years, during regular business hours and to commence on a date that is mutually agreeable to both Sol-Gel and SLP but is to commence within [***]days of the examination request by Sol-Gel and subject to a reasonable confidentiality agreement. The Parties shall reconcile any underpayment or overpayment within [***] days after the accounting firm delivers the results of any audit. Such examination is to be made at the expense of [***] or more during the periods being audited, in which case reasonable audit fees for such examination shall be paid by [***].

Section 7.08 Currency Conversion. Wherever it is necessary to convert currencies for Net Sales invoiced in a currency other than the Dollar, such conversion shall be made into Dollars at the conversion rate published by the Bank of Canada using the simple average of the published rate during the applicable calendar quarter or, if such rate is unavailable, a substitute therefor reasonably selected by Sol-Gel. All payments due to Sol-Gel under this Agreement shall be made without deduction of exchange, collection or other charges. Once the amount of Net Sales paid to Sol-Gel in respect of a particular calendar quarter has been converted into Dollars, such amount of Dollars shall be used for the purpose of calculating the total amount of Net Sales during the calendar year that includes such calendar quarter.

Section 7.09 Methods of Payment. All payments due under this Agreement shall be made in U.S. Dollars by wire transfer to a bank account of Sol-Gel or SLP as applicable.

Section 7.10 Taxes.

(a) **General**. The milestones, royalties and other amounts payable by SLP to Sol-Gel pursuant to this Agreement (each, a "**Payment**") will be paid free and clear of any and all taxes, except for any withholding taxes required by applicable Law. Except as provided in this **Section 7.10 (Taxes)**, [***]will be solely responsible for paying any and all taxes (other than withholding taxes required by applicable Law to be deducted from Payments and remitted by SLP) levied on account of, or measured in whole or in part by reference to, any Payments it receives.

(b) **Withholding Tax.** The Parties agree to cooperate with one another and use Commercially Reasonable Efforts in accordance with applicable Law to eliminate or reduce to the extent possible, withholding taxes and similar obligations on payments made under this Agreement. [***]. Notwithstanding the foregoing, if Sol-Gel is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to SLP or the appropriate Governmental Authority (with the assistance of SLP to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve SLP of its obligation to withhold such tax and SLP will apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that SLP has received evidence, in a form reasonably satisfactory to SLP, of Sol-Gel's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***]days prior to the time that the Payments are due. If, in accordance with the foregoing, SLP withholds any amount, it will pay to Sol-Gel the balance when due, make timely payment to the proper taxing authority of the withheld[***].

(c) **No Withholding Tax Adjustment**. In the event that any Payment is subject to a deduction or withholding of tax (each, a "**Withholding Tax Action**"), then notwithstanding **Section 7.10(a)**, the payment by SLP (in respect of which such deduction or withholding of tax is required to be made) shall be treated for all purposes of this Agreement has having been paid to Sol-Gel in respect of which such deduction and withholding was made by SLP.

Section 7.11 Invoices. Any invoice which Sol-Gel delivers to SLP under this Agreement may be delivered by email to apdept@searchlightpharma.ca (which email address may be changed by SLP from time to time upon written notice to Sol-Gel), with a hard copy confirmed by mailing to:

Attention: Accounts Payable
Searchlight Pharma Inc.
1600 Notre-Dame Street West, Suite 312
Montreal, Quebec, H3J 1M1
Canada

(which addresses may be changed by SLP from time to time upon written notice to Sol-Gel).

Section 7.12 Late Payments. If Sol-Gel does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Sol- Gel from the due date until the date of payment at the [***]as reported by The Wall Street Journal from time to time, plus [***]per annum or the maximum applicable legal rate, if less. The interest payment shall be due from the day the original payment was due until the day that the payment was received by Sol-Gel; provided, that, with respect to any bona fide disputed payments, [***], calculated from [***].

ARTICLE VIII.

INTELLECTUAL PROPERTY

Section 8.01 Ownership of Intellectual Property

(a) Sol-Gel shall retain sole and exclusive ownership of all rights, title and interests in and to the Licensed Technology.

(b) Subject to **Section 8.01(c)**, ownership of Trademarks, developments or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by or on behalf of either Party during the Term in the course of performing activities under this Agreement, and any and all intellectual property rights therein ("**Inventions**") will be determined based on the principles of inventorship in accordance with United States patent laws.

(c) Notwithstanding **Section 8.01(b)**, and regardless of inventorship, any and all Inventions, Patents Rights and Know-How that (i) relate to the Licensed Product and/or the composition, use, administration, formulation or other aspect thereof, (ii) are developed or generated by or on behalf of Sol-Gel or any of its Affiliates or jointly developed or generated by or on behalf of both Parties, (iii) relate to or are developed with the use of or reference to, incorporate and/or rely upon Sol-Gel's Confidential Information or the Licensed Technology, and all intellectual property rights therein; and/or (iv) improve upon and/or are derived from Sol-Gel's Confidential Information or the Licensed Technology or any SLP Product Data, ("**Sol-Gel Inventions**") shall be owned exclusively and solely by Sol-Gel. SLP hereby assigns and shall assign to Sol-Gel all of its rights, title and interests it may have in and to all Sol-Gel Inventions, without any remuneration or compensation. SLP shall, and shall cause each of its employees, contractors, and agents to, cooperate with Sol-Gel and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect Sol-Gel's right, title and interest in and to the Sol-Gel Inventions. In the event that SLP is required to register a new Trademark related to the Licensed Product because the Regulatory Authority in the Territory rejects the use of the Licensed Trademark, Sol-Gel shall have the first option to pay for and assume all expenses related to the registration and maintenance of such Trademark and such new Trademark shall be included in this Agreement as a Licensed Trademark. If Sol-Gel declines to pay and assume expenses related to such Trademark, then such Trademark shall be owned by SLP. In the event that SLP elects to register a new Trademark related to the Licensed Product, SLP shall be responsible for, and shall pay for all expenses related to the registration and maintenance of such Trademark and SLP shall own such Trademark (the "**SLP Trademark**").

(d) Sol-Gel hereby grants SLP, during the Term only, a non-exclusive, royalty-bearing, transferable (subject to **Section 15.01**) license under all Sol-Gel Inventions solely to Develop and Commercialize the Licensed Product in the Field in the Territory, subject to and in accordance with the terms of this Agreement, and any Patent Rights which are part of the Sol-Gel Inventions shall be treated a part of the Licensed Patent Rights and any Know-How which are part of the Sol- Gel Inventions shall be treated a part of the Licensed Know How.

Section 8.02 Prosecution of Patent Rights. Sol-Gel shall be responsible for and have sole control over, at its cost, the preparation, filing, prosecution and maintenance of all Licensed Patent Rights in Sol-Gel's name in the Territory. Sol-Gel will: (i) instruct such patent counsel to provide SLP with copies of all filings and formal correspondences relating to such Licensed Patent Rights in the Territory and (ii) keep SLP advised of the status of actual and prospective patent filings related to the Licensed Product in the Territory. Sol-Gel will give SLP the opportunity to provide and will reasonably consider comments on the preparation, filing, prosecution and maintenance of the Licensed Patent Rights in the Territory. Sol-Gel, reserves the sole right to make all final decisions regarding the preparation, filing, prosecution and maintenance of the Licensed Patent Rights. Each Party will treat any consultation regarding the preparation, filing, prosecution and maintenance of such Licensed Patent Rights, along with any information disclosed by each Party in connection therewith (including any information concerning patent expenses), as part of Sol-Gel's Confidential Information. Sol-Gel may elect at its sole discretion not to continue to seek or maintain any Licensed Patent Rights covering the Licensed Product in the Territory [***] jurisdiction. In such case, Sol-Gel will provide SLP with [***] days advance written notice of its intention to abandon such Licensed Patent Rights. If Sol-Gel elects not to continue to seek or maintain any Licensed Patent Rights covering the Licensed Product in the Territory for any other reason (the "**Abandoned Patent Rights**"), then Sol-Gel shall provide SLP with timely notice with respect to its decision, and will provide SLP with a reasonable opportunity to assume responsibility for the continued prosecution and maintenance of such Licensed Patent Rights at its own cost, in the name of SLP, and Sol-Gel will free of charge assign and transfer to SLP the ownership and interest in such Licensed Patent Rights.

Section 8.03 Enforcement.

(a) If either Party becomes aware of any Third Party activity, including any Development activity (whether or not an exemption from infringement liability for such Development activity is available under applicable Law), that infringes (or that is directed to the Development of a product that would infringe) a Licensed Patent Right, then the Party becoming aware of such activity shall give prompt written notice to the other Party regarding such alleged infringement or misappropriation (collectively, "**Infringement Activity**").

(b) During the Term, and provided that SLP is not then in material breach of the Agreement, SLP shall have the first right, but not the obligation, to attempt to resolve any Infringement Activity related to the Licensed Patent Rights in the Territory by commercially appropriate steps at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. SLP shall (i) keep Sol-Gel reasonably informed regarding such infringement or misappropriation suit (including by providing Sol-Gel with drafts of each filing within a reasonable period before the deadline for such filing and promptly providing Sol- Gel with copies of all final filings and correspondence), and (ii) consult with SLP on such infringement or misappropriation suit. If SLP notifies Sol-Gel that SLP will not take steps to enforce the Licensed Patent Rights in the Territory against Infringement Action, or fails to resolve such Infringement Activity in the Territory, or to initiate a suit with respect thereto by the date that is [***]days before any deadline for taking action to avoid any loss of material enforcement rights or remedies, then, Sol-Gel will have the right, but not the obligation, to attempt to resolve such Infringement Activity by commercially appropriate steps at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice.

(c) Any amounts recovered by a Party as a result of an action pursuant to **Section 8.03(b)**, whether by settlement or judgment, shall be allocated first to the reimbursement of any expenses incurred by the Party bringing such action, and then to the reimbursement of any expenses incurred by the other Party in such action, and any remaining amounts shall be retained by the enforcing Party; however, any amounts recovered by SLP, after reimbursement or deduction of costs and expenses incurred by each Party in connection with such infringement or misappropriation suit[***].

(d) In any event, at the request and expense of the Party bringing an infringement or misappropriation action under **Section 8.03(b)**, the other Party shall provide reasonable assistance in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and be joined as a party to the suit if necessary for the initiating or defending Party to bring or continue such suit. Neither Party may settle any action or proceeding brought under **Section 8.03(b),** or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in any Licensed Patent Rights without the written consent of such other Party. Each Party shall always have the right to be represented by counsel of its own selection and at its own expense in any suit or other action instituted by the other Party pursuant to **Section 8.03(b)**.

Section 8.04 Defense of Third Party Infringement and Misappropriation Claims.

(a) If a Third Party asserts that a Patent Right or other right Controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement or a Party becomes aware of a Patent Right or other right that might form the basis for such a claim, the Party first obtaining knowledge of such a claim or such potential claim shall immediately provide the other Party with notice thereof and the related facts in reasonable detail. The Parties shall discuss what commercially appropriate steps, if any, to take to avoid infringement or misappropriation of said Third Party Patent Right or other right controlled by such Third Party in the Territory.

(b) If a Third Party asserts that a Patent Right or other right Controlled by it in the Territory is infringed or misappropriated by the Manufacture, use, or Commercialization of Licensed Product, SLP shall have the first right, but not the obligation, to resolve any such claim, whether by obtaining a license from such Third Party or by defending itself against such Third Party assertion. SLP shall be solely responsible for its defense of such action. SLP shall keep Sol- Gel reasonably informed regarding such assertion and such defense. Subject to Sol-Gel's indemnification obligations under **Section 12.01**, SLP shall bear all costs incurred in connection with its defense of any such Third Party assertion.

Section 8.05 Notice of Actions; Settlement. SLP shall promptly inform Sol-Gel of any action or suit relating to Licensed Patent Rights and shall not enter into any settlement, consent judgment or other voluntary final disposition of any action relating to Licensed Patent Rights, including but not limited to appeals, without the prior written consent of Sol-Gel, such consent not to be unreasonably withheld or delayed.

Section 8.06 Patent Listings. Throughout the Term, Sol-Gel shall use Commercially Reasonable Efforts to assist SLP to timely list any Licensed Patent Rights with the Regulatory Authority on the patent register in the Territory. SLP shall bear all expenses related to such activities. Sol-Gel shall immediately notify SLP when any of the Licensed Patent Rights receive a notice of allowance from the Canadian Patent office as well as when such patent application issues, in order for SLP to timely list said patent on the patent register.

ARTICLE IX.

ADVERSE DRUG EVENTS AND REPORTS

Section 9.01 Complaints. Each Party shall maintain a record of all non-medical and medical product-related complaints it receives with respect to the Licensed Product. Each Party shall notify the appropriate contact pursuant to the Safety Data Exchange Agreement of any material complaint received by it in sufficient detail, and shall provide such contact with copies of any safety reports or other submissions to any Regulatory Authority in connection with the reporting of adverse events, in each case in accordance with the timeframes and procedures for reporting established by the Parties within the Safety Data Exchange Agreement, and in any event in sufficient time to allow each Sol-Gel Entity and their respective sublicensees (with regards to Sol-Gel Entity's sublicensees, solely to the extent such sublicensees are subject to similar obligations under this **Section 9.01** **(Complaints)**) and each SLP Entity to comply with any and all regulatory requirements imposed upon it. The Party that holds the applicable Regulatory Filing(s) in a particular country or jurisdiction shall investigate and respond to all such complaints in such country or jurisdiction with respect to the Licensed Product as soon as reasonably practicable. All such responses shall be made in accordance with the procedures established pursuant to applicable Law and all applicable guidelines. The Party responsible for responding to such complaint shall promptly provide the other Party with a copy of any such response.

Section 9.02 Adverse Drug Events. At least [***]days prior to the anticipated approval date of the Licensed Product in the Territory by the Regulatory Authority, the Parties shall enter into a separate pharmacovigilance agreement that delineates the safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as safety data sharing and exchange, and adverse events reporting (the "**Safety Data Exchange Agreement**"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other important safety information, and Licensed Product quality and Licensed Product complaints involving adverse events, sufficient to permit each Party, its Affiliates, or sublicensees to comply with its legal obligations. The Parties shall promptly update the Safety Data Exchange Agreement if required by changes in applicable Law. Each Party shall comply with its respective obligations under the Safety Data Exchange Agreement and shall cause its Affiliates and sublicensees to comply with such obligations. For clarity, Sol-Gel shall be responsible for the global safety database for the Licensed Product.

ARTICLE X.

REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section 10.01 Mutual Representations and Warranties. Each of SLP and Sol-Gel hereby represents and warrants to the other Party as of the Effective Date that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) it is not a party to any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement;

(d) to its knowledge, no consent, approval or agreement of any person or Governmental Authority is required to be obtained in connection with the execution and delivery of this Agreement; and

(e) it has not been debarred by the FDA, is not the subject of a conviction described in Section 306 of the FD&C Act, and is not subject to any similar sanction of any other Governmental Authority outside of the U.S., and neither it nor any of its Affiliates has used, in any capacity, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction inside or outside of the U.S.

Section 10.02 Mutual Covenants. Each of SLP and Sol-Gel hereby covenants to the other Party that:

(a) it will not engage, in any capacity in connection with this Agreement or any ancillary agreement, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any similar sanction inside or outside of the U.S., and such Party shall inform the other Party in writing promptly if such Party or any person or entity engaged by such Party who is performing services under this Agreement, or any ancillary agreement, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act or any similar sanction inside or outside of the U.S., or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to any such debarment or conviction of a Party, any of its Affiliates or any such person or entity performing services hereunder or thereunder;

(b) during the Term, it will not make any commitment to any Third Party in conflict with the rights granted by it hereunder; and

(c) it will comply with all applicable Laws in performing its activities hereunder and shall ensure such compliance by its Affiliates.

Section 10.03 Additional Sol-Gel Warranties. Sol-Gel hereby represents and warrants to SLP as of the Effective Date that:

(a) Sol-Gel solely owns or Controls the entire right, title, and interest in and to the Licensed Technology, and that such Licensed Technology is free and clear of all liens and encumbrances;

(b) Sol-Gel and its Affiliates have not, prior to the Effective Date, entered into any written agreement with a Third Party under which Sol-Gel and its Affiliates has granted any rights in or to its ownership interest in the Licensed Technology, which, to its knowledge, are inconsistent with the rights granted to SLP under this Agreement;

(c) to Sol-Gel's knowledge, Exhibit A contains a list of all Patent Rights and Trademark(s) that are Controlled by Sol-Gel as of the Effective Date and Cover Commercialization of the Licensed Product as they exist on the Effective Date in the Field in the Territory;

(d) all of the issued Patent Rights and Trademark(s) listed in Exhibit A are in full force and effect, and, to the best of Sol-Gel's knowledge, are not invalid or unenforceable, in whole or in part;

(e) Sol-Gel is unaware of any pending claim, action, or proceeding in the Territory challenging the validity or enforceability of any of the Licensed Patent Rights or Trademark(s) listed in Exhibit A or alleging that the Commercialization of the Licensed Product or its ingredients infringes or misappropriates any patent rights or other intellectual property rights of any Third Party;

(f) Neither Sol-Gel nor any of its Affiliates has received any written notification from a Third Party that the Development, Manufacture, use, or Commercialization of Licensed Products in the Territory would infringe or misappropriate any Patent Rights or Know-How owned or Controlled by such Third Party;

(g) to Sol-Gel's knowledge, none of the Manufacture, use, Development or Commercialization of the Licensed Products in the Field in the Territory infringes any valid enforceable claim of any existing Patent not Controlled by Sol-Gel;

(h) to Sol-Gel's knowledge, there are no ongoing activities by a Third Party that would constitute infringement or misappropriation of the Licensed Technology within the Territory.

(i) to Sol-Gel's knowledge, Sol-Gel has not received written notice of any investigations, inquiries, actions or other proceedings pending before or threatened by any Regulatory Authority or other Governmental Authority in the Territory with respect to the Licensed Product in the Territory arising from any action or default by Sol-Gel or any of its Affiliates or a Third Party acting on behalf Sol-Gel in the discovery or Development of the Licensed Product;

(j) to Sol-Gel's knowledge, there is no existing scientific fact or circumstance that would materially adversely affect the efficacy, safety or market performance of the Licensed Product which Sol-Gel has not communicated to SLP;

(k) Sol-Gel has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of the Licensed Know-How; and

(l) To Sol-Gel's knowledge, there are no Key Regulatory Submissions required for the Territory that they will not be able to provide to SLP.

Section 10.04 Anti-Corruption.

(a) Anti-Corruption Provisions. Each Party represents and warrants to the other Party that such Party has not, directly or indirectly, offered, promised, paid, authorized or given, and each Party agrees that such Party will not, in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official (as defined below) or Other Covered Party (as defined below) for the purpose, pertaining to this Agreement, of: (i) influencing any act or decision of such Government Official or Other Covered Party; (ii) inducing such Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing such Government Official or Other Covered Party to influence the act or decision of a Governmental Authority, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

For purposes of this Agreement: (A) "**Government Official**" means any official, officer, employee or representative of: (1) any Governmental Authority; (2) any public international organization or any department or agency thereof; or (3) any company or other entity owned or controlled by any Governmental Authority; and (B) "**Other Covered Party**" means any political party or party official, or any candidate for political office.

(b) Anti-Corruption Compliance.

(i) In performing under this Agreement, each Party, on behalf of itself, its respective Affiliates and (in the case of Sol-Gel) other Sol-Gel Entities and (in the case of SLP) other SLP Entities, agrees to comply with all applicable anti-corruption Laws of the Territory.

(ii) Each Party represents and warrants to the other Party that such Party is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.

(iii) No Party, nor any Affiliate of any Party (and (in the case of Sol-Gel) no other Sol-Gel Entity and (in the case of SLP) no other SLP Entity), shall give, offer, promise or pay any political contribution or charitable donation at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity.

(iv) SLP Entities shall in all cases, refrain from engaging in any activities or conduct which would cause any Sol-Gel Entity to be in violation of any applicable anti-bribery Laws. To the extent allowed by Law, if any SLP Entity proposes to provide any information, data or documentation to any governmental or regulatory authority in respect of the Licensed Product that relates to or may result in a violation of any applicable anti-bribery Law, it shall first obtain the prior written approval of Sol-Gel, which will not be unreasonably withheld, or shall provide such information, data or documentation in accordance with Sol-Gel's written instructions.

(v) SLP agrees that should it learn or have reason to know of: (i) any payment, offer, or agreement to make a payment to a foreign official or political party for the purpose of obtaining or retaining business or securing any improper advantage for Sol-Gel under this Agreement or otherwise, or (ii) any other development during the Term that in any way makes inaccurate or incomplete the representations, warranties and certifications of SLP hereunder given or made as of the date hereof or at any time during the Term, relating to anti-bribery Law, SLP will immediately advise Sol-Gel in writing of such knowledge or suspicion and the entire basis known to SLP therefor.

(vi) In the event that a Party violates any anti-corruption Law of the Territory or any other applicable anti-corruption Law, or breaches any provision in this **Section 10.04** **(Anti- Corruption)**, the other Party shall have the right to terminate this Agreement pursuant to **Section 13.02** (**Termination for Breach**).

Section 10.05 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY SOL-GEL TO SLP HEREIN ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

Section 10.06 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, EXEMPLARY, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER. THE FOREGOING SHALL NOT LIMIT (a) [***]OR (b) [***]**,** OR (c) [***].

ARTICLE XI.

CONFIDENTIALITY

Section 11.01 Generally. During the Term and for a period of [***] years thereafter, each Party (a) shall maintain in confidence all Confidential Information of the other Party or any of such Party's Affiliates; (b) shall not use such Confidential Information for any purpose except to fulfill its obligations or exercise its rights (for the avoidance of doubt, including, with respect to Sol-Gel, the right to Commercialize the Licensed Product outside of the Field or Territory (and inside of the Field and Territory after any termination or expiration of this Agreement) and to Develop and Manufacture the Licensed Product in accordance with this Agreement) under this Agreement; and (c) shall not disclose such Confidential Information to anyone other than those of its Affiliates, directors, investors, [***]employees, consultants, financial or legal advisors, or other agents or contractors (collectively, "**Representatives**") who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this **Article XI (Confidentiality)** and to whom such disclosure, under this Agreement, is necessary in connection with the fulfillment of such Party's obligations or exercise of such Party's rights under this Agreement or in connection with *bona fide* financing or acquisition activities. Each Party shall (i) ensure that such Party's Representatives who receive any of the other Party's (or any of such Party's Affiliates') Confidential Information comply with the obligations set forth in this **Article XI (Confidentiality)** and (ii) be responsible for any breach of these obligations by any of its Representatives who receive any of the other Party's (or any of such Party's Affiliates') Confidential Information. Each Party shall notify the other Party promptly on discovery of any unauthorized use or disclosure of the other's (or any of its Affiliates') Confidential Information.

Section 11.02 Exceptions. The obligations of confidentiality, non-disclosure, and non- use set forth in **Section 11.01 (Generally)** shall not apply to, and "Confidential Information" shall exclude, any information to the extent the receiving Party (the "**Recipient**") can demonstrate that such information: (a) was in the public domain or publicly available at the time of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement, or thereafter entered the public domain or became publicly available, in each case other than as a result of any action of the Recipient, or any of its Representatives, in breach of this Agreement; (b) was rightfully known by the Recipient or any of its Affiliates (as shown by competent proof) prior to the date of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement; (c) was received by the Recipient or any of its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the disclosing Party or any of its Affiliates; or (d) was independently developed by or for the Recipient or any of its Affiliates without reference to or reliance on the Confidential Information of the other Party or any of its Affiliates (as demonstrated by competent proof).

Section 11.03 Permitted Disclosures. Notwithstanding any other provision of this Agreement, Recipient's (or its Affiliates') disclosure of the other Party's (or any of such Party's Affiliates') Confidential Information shall not be prohibited if such disclosure: (a) is in response to a valid order of a court or other Governmental Authority, including the rules and regulations promulgated by the U.S. Securities Exchange Commission and the Ontario Securities Commission (or similar foreign authority) or any other Governmental Authority; (b) is otherwise required by applicable Law or rules of a nationally or internationally recognized securities exchange, including but not limited to the Toronto Stock Exchange or Nasdaq; (c) is: (i) [***]; (d) is to patent offices in order to seek or obtain Patent Rights or to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials or to gain Regulatory Approval with respect to the Licensed Product as contemplated by this Agreement; *provided* that such disclosure may be made only to the extent reasonably necessary to seek or obtain such Patent Rights or Regulatory Approvals, and the Recipient (or its applicable Affiliate(s)) shall use Commercially Reasonable Efforts to obtain confidential treatment of such information; or (e) is in response to a direction to SLP by a Regulatory Authority in the Territory to disclose such Confidential Information pursuant to the Access to Information regime or a Freedom of Information regime and/or the Public Release of Clinical Information regime; provided that such disclosure may be made only if SLP has used Commercially Reasonable Efforts to keep such information confidential. If a Recipient is required to disclose Confidential Information pursuant to **Section 11.03(a)**, **Section 11.03(b)** or **Section 11.03(e)**, prior to any disclosure the Recipient shall, to the extent legally permitted and practicable, provide the disclosing Party with prior written notice of such disclosure in order to permit the disclosing Party to seek a protective order or other confidential treatment of such disclosing Party's Confidential Information.

Section 11.04 Publicity. The Parties will issue a joint press release in connection with this Agreement. The Parties recognize that each Party may from time-to-time desire to issue press releases and make other public statements or public disclosures in respect of this Agreement, including the Development or Commercialization of Licensed Product in the Territory (each, a "**Public Statement**"). If SLP desires to make a Public Statement, it shall provide Sol-Gel a copy of such Public Statement at least [***]prior to the date it desires to make such public disclosure. SLP shall not issue a Public Statement without Sol-Gel's prior written approval, which advance approval shall not be unreasonably withheld, conditioned or delayed. Sol-Gel shall provide to SLP a preliminary draft of any Public Statement that it intends to make on a global basis with respect to Development of Licensed Product at least [***]in advance of such public disclosure and shall provide a final draft of such Public Statement at least [***]in advance of such public disclosure; *provided* that, if such Public Statement includes data owned by SLP with respect to a clinical study or pre-clinical research conducted by SLP in the Territory, Sol-Gel shall obtain SLP's prior written approval to include such data, which approval shall not be unreasonably withheld, conditioned or delayed. Once any public statement or public disclosure has been approved in accordance with this **Section 11.04** (**Publicity**), then the applicable Party may appropriately communicate information contained in such permitted statement or disclosure. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this **Section 11.04**. Notwithstanding anything to the contrary in this **Section 11.04 (Publicity)**, nothing in this **Section 11.04 (Publicity)** shall be deemed to limit either Party's rights under **Section 11.04 (Permitted Disclosures)** or either Party's ability to issue press releases or make other public statements or public disclosures required by applicable Law or rules of a nationally or internationally recognized securities exchange, including but not limited to the Toronto Stock Exchange or Nasdaq.

Section 11.05 Publications. Sol-Gel acknowledges SLP's interest in publishing certain key results of SLP's Development and Commercialization of Licensed Product in the Field in the Territory. SLP recognizes the mutual interest in obtaining valid patent protection and Sol-Gel's interest in protecting its proprietary information. Consequently, except for disclosures permitted pursuant to **Section 11.02 (Exceptions)**, **Section 11.03 (Permitted Disclosures)** or **Section 11.04 (Publicity)**, if SLP wishes to make a publication or public presentation with respect to its Development or Commercialization of Licensed Product in the Field in the Territory, or with respect to key marketing material (collectively a "**Publication**"), SLP shall deliver to Sol-Gel a copy of the proposed written Publication at least [***]days prior to submission for Publication. Sol-Gel shall have the right (a) to require modifications to the Publication for patent or any other business reasons, and SLP will remove all of Sol-Gel's Confidential Information if requested by Sol-Gel, and (b) to require a reasonable delay in Publication in order to protect patentable information. If Sol-Gel requests a delay, then SLP shall delay submission of the Publication for a period of [***](or such shorter period as may be mutually agreed by the Parties) to enable Sol-Gel to file patent applications protecting Sol-Gel's rights in such information. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this **Section 11.05**.

Section 11.06 Injunctive Relief. Each Party acknowledges and agrees that there may be no adequate remedy at law for any breach of its obligations under this **Article XI (Confidentiality)**, that any such breach may result in irreparable harm to the other Party and, therefore, that upon any such breach or any threat thereof, such other Party may seek appropriate equitable relief in addition to whatever remedies it might have at law, without the necessity of showing actual damages.

ARTICLE XII.

INDEMNIFICATION

Section 12.01 Indemnification by Sol-Gel. Sol-Gel shall indemnify, hold harmless and defend any SLP Entity, and their respective directors, officers, and employees (the "**SLP Indemnitees**") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, costs, damages, deficiencies, obligations or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) ("**Losses**") to the extent that such Losses arise out of (a) any breach of this Agreement by Sol-Gel, (b) the Development, Manufacture or Commercialization of the Licensed Product by or on behalf of any Sol-Gel Entity or their sublicensees or (c) the negligence or willful misconduct of any Sol-Gel Indemnitee. Notwithstanding the foregoing, Sol-Gel shall not have any obligation to indemnify the SLP Indemnitees to the extent that the applicable Losses arise out of any activities set forth in **Section 12.02** for which SLP is obligated to indemnify Sol-Gel.

Section 12.02 Indemnification by SLP. SLP shall indemnify, hold harmless and defend any Sol-Gel Entity, and their respective directors, officers, and employees (the "**Sol-Gel Indemnitees**") from and against any and all Losses, to the extent that such Losses arise out of (a) any breach of this Agreement by SLP, (b) the Manufacture or Commercialization of the Licensed Product by or on behalf of any SLP Entity or (c) the negligence or willful misconduct of any SLP Indemnitee. Notwithstanding the foregoing, SLP shall not have any obligation to indemnify the Sol-Gel Indemnitees to the extent that the applicable Losses arise out of any activities set forth in **Section 12.01** for which Sol-Gel is obligated to indemnify SLP.

Section 12.03 Procedure. In the event of a claim by a Third Party against a SLP Indemnitee or Sol-Gel Indemnitee entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified Party shall promptly notify the Party obligated to provide such indemnification ("**Indemnifying Party**") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto and does not impose any obligations on the Indemnified Party, unless the Indemnified Party otherwise agrees in writing. No Indemnified Party may settle any claim for which it is being indemnified under this Agreement without the Indemnifying Party's prior written consent.

Section 12.04 Insurance. Each Party, at its own expense, shall maintain commercial general liability insurance and product liability and other appropriate insurance, in amounts consistent with sound business practice and reasonable in light of its obligations under this Agreement. Each Party shall maintain such insurance for the period commencing promptly after the Effective Date until [***]after the Term. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon request. It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations under this Agreement.

ARTICLE XIII.

TERM AND TERMINATION

Section 13.01 Term. The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this **Article XIII** (**Term and Termination**), will continue for an initial term of fifteen (15) Years as of the First Commercial Sale of Licensed Product in the Territory (the "**Initial Term**"). Following the Initial Term, the Agreement shall be automatically renewed (unless earlier terminated in accordance with the terms of this **Article XIII** (**Term and Termination**)), for additional consecutive terms of five (5) Years each (each such additional term the "**Additional Term**" collectively with the Initial Term the "**Term**").

Section 13.02 Termination for Breach. Subject to the terms and conditions of this **Section 13.02** (**Termination for Breach**), a Party (the "**Non-Breaching Party**") shall have the right, in addition to any other rights and remedies available to such Party at Law or in equity, to terminate this Agreement in the event the other Party (the "**Breaching Party**") is in material breach of its obligations under this Agreement. The Non-Breaching Party shall first provide written notice to the Breaching Party, which notice shall identify with particularity the alleged breach (the "**Breach Notice**"). With respect to material breaches of any payment provision hereunder, the Breaching Party shall have a period of [***]days after such Breach Notice is provided to cure such breach. With respect to all other breaches, the Breaching Party shall have a period of [***]days after such Breach Notice is provided to cure such breach. If such breach is not cured within the applicable period set forth above, the Non-Breaching Party may, at its election, terminate this Agreement upon written notice to the Breaching Party. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

Section 13.03 Termination due to Decision not to File an Application. Upon Sol-Gel's receipt of written notice from SLP, during the first [***]months as of the Effective Date, indicating a decision not to move forward with filing an application for Regulatory Approval in the Territory, this Agreement shall immediately terminate.

Section 13.04 Termination for Bankruptcy and Rights in Bankruptcy.

(a) To the extent permitted under applicable Law, if, at any time during the Term, an Event of Bankruptcy (as defined below) relating to either Party (the "**Bankrupt Party**") occurs, the other Party (the "**Other Party**") shall have, in addition to all other legal and equitable rights and remedies available to such Party, the option to terminate this Agreement upon [***] days written notice to the Bankrupt Party. It is agreed and understood that, if the Other Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the Other Party shall continue to make all payments required of it under this Agreement as if the Event of Bankruptcy had not occurred, and the Bankrupt Party shall not have the right to terminate any license granted herein. The term "**Event of Bankruptcy**" means: (i) filing in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or taking the benefit of any statue in force for bankrupt or insolvent debtors, including for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Bankrupt Party or of its assets, (ii) making an assignment for the benefit of creditors, (iii) appointing or suffering appointment of a receiver or trustee over substantially all of a Party's property that is not discharged within [***] days after such appointment, or (iv) being served with an involuntary petition against the Bankrupt Party, filed in any insolvency proceeding, where such petition is not dismissed within [***]days after the filing thereof.

(b) All rights and licenses granted under or pursuant to this Agreement by SLP and Sol-Gel are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as sublicensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

Section 13.05 Termination for Patent Challenge. Except to the extent the following is unenforceable under the applicable Laws, this Agreement shall terminate automatically in its entirety immediately if any SLP Entity, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any of the Licensed Patent Rights.

Section 13.06 Termination for not Meeting the Minimum Orders. In the event that for any particular Year during the Term, SLP has [***], Sol-Gel shall have the right to terminate the Agreement by providing SLP with a [***]days' prior written notice. In the event that during the [***] Years of the Term, SLP has not ordered the Minimum Orders, but [***], SLP shall have the right to terminate the Agreement by providing Sol-Gel with a [***] days' prior written notice, and, in the event that after [***] of the Term, SLP has not ordered [***], then SLP shall have the right to terminate the Agreement by providing Sol-Gel with [***]days' prior written notice.

Section 13.07 Termination for [***]. In the event the Parties have not agreed on [***] SLP shall have the right at its sole discretion to terminate this Agreement, by providing Sol-Gel with a [***]days' notice.

Section 13.08 Effect of Termination.

(a) In the event of expiration of this Agreement or termination of this Agreement pursuant to Sections **13.02** (solely for a material breach by SLP), **13.03**, **13.04**, **13.05** or **13.06**:

(i) all license grants in this agreement from Sol-Gel to SLP shall terminate;

(ii) SLP shall in advance of and effective as of the effective date of expiration or termination, assign and transfer to Sol-Gel all SLP Product Data, Regulatory Approvals, Regulatory Documents, Licensed Trademarks, including preparing and providing to Sol-Gel or filing directly with Health Canada all necessary authorizations, free of additional charge. Sol-Gel may request that SLP shall assign and transfer to Sol-Gel the SLP Trademark and the Abandoned Patent Rights, and in the event that the Agreement expires or is terminated for any reason [***];

(iii) Sol-Gel shall, at its option, purchase from SLP all of [***]after the effective date of termination or expiration of this Agreement;

(iv) effective upon the effective date of expiration or termination, SLP shall grant, and hereby grants to Sol-Gel a perpetual, irrevocable, non-exclusive, worldwide, sublicensable, royalty-free and fully paid-up license for (a) all Know-How incorporated by SLP into the Licensed Product or otherwise necessary or reasonably useful for the Development, Manufacture, and/or Commercialization of the Licensed Product as it exists as of the effective date of expiration or termination and (b) all Patent Rights necessary or reasonably useful for the Development, Manufacture, and Commercialization of the Licensed Product, in each case (a) and (b), Controlled by SLP or its Affiliates as of the effective date of such termination, to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize or otherwise exploit the Licensed Product inside and outside of the Territory in the Field (it being understood that such Know How and Patents Rights, shall not include Sol-Gel Inventions which remain the sole and exclusive property of Sol-Gel);

(v) At Sol-Gel's request, any existing agreements between SLP or its Affiliates and any Third Party that are solely related to the Commercialization of the Licensed Product, and all of SLP's and its Affiliates' right, title and interest therein and thereto, shall at Sol-Gel's option be terminated or assigned and transferred to Sol-Gel or its designee, to the extent permissible pursuant to the terms thereof (and for any such agreement that by its terms cannot be so assigned, SLP shall reasonably cooperate with Sol-Gel to provide to Sol-Gel the benefits of such agreement);

(vi) Upon Sol-Gel's written request, SLP shall, [***], assign all contract manufacturing, research service, or other vendor agreements related to the Licensed Product to Sol-Gel, or, [***];

(vii) SLP shall remain responsible for all its non-cancellable Third Party obligations incurred with respect to the Licensed Product; and

(viii) SLP shall, and shall cause its employees, contractors, and agents to, cooperate with Sol-Gel and take all other actions as reasonably required by Sol-Gel to assist in enabling Sol-Gel to promptly assume Commercialization of the Licensed Product in the Field in the Territory.

(b) In the event of termination of this Agreement by SLP pursuant to **Section 13.02** (solely for a material breach by Sol-Gel):

(i) All rights and licenses granted by Sol-Gel to SLP hereunder shall become irrevocable and perpetual rights and licenses;

(ii) All milestone and royalty payments pursuant to Article VII that have not accrued prior to the date of termination shall cease; and

(iii) All other obligations of SLP relating to activities contemplated by this Agreement shall terminate.

Section 13.09 Survival; Accrued Rights. The following articles and sections of this Agreement shall survive expiration or early termination for any reason: **Article I (Definitions)**, **Article VII (Payments)** (solely to the extent any payments became payable prior to the effective date of such expiration or termination), **Article IX (Adverse Drug Events and Reporting)**, **Section 4.03 (Licensed Product Pricing), Section 4.03 (Generic Products), Section 8.01 (Ownership of Intellectual Property)**, **Section 8.02 (Prosecution of Patent Rights), 8.03 (Enforcement), 8.04 (Defense of Third Party Claims), Section 10.06 (Limitation of Liability)**, **Article XI (Confidentiality)**, **Section 12.01 (Indemnification by Sol-Gel), Section 12.02 (Indemnification by SLP), Section 12.03 (Procedure)**, **Section 13.08 (Effect of Termination)**,

Section 13.09 (Survival; Accrued Rights), **Article XIV (Dispute Resolution; Governing Law)**, **Section 15.01 (Assignment)** (solely with respect to the last sentence in clause (a) and the entirety of clause (b)) and **Article XVI (Miscellaneous)**. In any event, expiration or termination of this Agreement shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

ARTICLE XIV.

DISPUTE RESOLUTION; GOVERNING LAW

Section 14.01 Arbitration. Subject to **Section 14.01(d)**, any disputes, claims or controversies in connection with this Agreement, including any questions regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination, that are not resolved in accordance with **Article III (Governance)** and are not subject to a Party's final decision-making authority in accordance with **Article III (Governance)** shall be referred to and finally resolved by binding arbitration administered by the American Arbitration Association, in accordance with the then current Commercial Rules of the American Arbitration Association (the "**Rules**"), which rules are deemed to be incorporated by reference into this **Section 14.01** (**Arbitration**), in the manner described below; provided that, prior to commencing of arbitration or other legal proceedings with respect to any disputes, claims or controversies in connection with this Agreement, the CEOs of both Parties shall discuss in good faith such disputes, claims or controversies for at least [***] days.

(a) **Arbitration Request**. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution.

(b) **Additional Issues**. Within [***]days after the receipt of an Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

(c) **General Arbitration Procedure for Disputes**. The seat of arbitration will be in New York, New York and it will be conducted in the English language. The arbitration will be conducted by a single arbitrator, who will be appointed according to the Rules or by mutual agreement of the Parties; notwithstanding anything in the foregoing, the Arbitrator must be an attorney admitted to practice Law in the state of New York. The arbitral award shall be final, definitive and binding on the Parties and their successors. The Parties reserve the right to apply to a competent judicial court to obtain urgent remedies to protect rights before establishment of the arbitration panel, without such recourse being considered as a waiver of arbitration. Except as otherwise determined by the arbitrator, the Parties shall each bear half of the fees and expenses of the arbitrators and the arbitration, and each Party shall bear the costs and fees of its own attorneys. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, Confidential Information, Know-How, intellectual property rights or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, any arbitrators chosen hereunder shall have educational training or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology and pharmaceuticals. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The Parties intend that each award rendered by an arbitrator hereunder shall be entitled to recognition and enforcement under the United Nations Convention on the Recognition and Enforcement of Arbitral Awards (New York, 1958).

(d) **Intellectual Property Disputes**. Notwithstanding **Section 14.01(d)**, unless otherwise agreed by the Parties, a dispute between the Parties relating to the validity or enforceability of any Patent Right shall not be subject to arbitration and shall be submitted to a court or patent office of competent jurisdiction in the relevant country or jurisdiction in which such patent was issued or, if not issued, in which the underlying patent application was filed.

Section 14.02 Choice of Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, shall be construed under and governed by the State of New York, exclusive of its conflicts of laws principles. This Agreement shall not be governed by the provisions of the United Nations Convention on Contracts for the International Sale of Goods.

Section 14.03 Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. All consents, notices, reports and other written documents to be delivered or provided by a Party under this Agreement shall be in the English language, and, in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation shall control.

ARTICLE XV.

ASSIGNMENT AND ACQUISITIONS

Section 15.01 Assignment.

(a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party in the field to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations.

(b) The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this **Section 15.01** **(Assignment)** will be null and void *ab initio*.

ARTICLE XVI.

MISCELLANEOUS

Section 16.01 Force Majeure. If either Party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure, which may include any act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, pandemic, act of terrorism, government action, strike or labor differences, in each case outside of such Party's reasonable control, such Party shall not be liable to the other therefor, and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. The Party invoking the force majeure rights of this **Section 16.01** (**Force Majeure**) must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) within a period of [***]days of both the first and last day of the force majeure unless the force majeure renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds [***]months, the other Party may terminate this Agreement immediately upon written notice to the Party invoking the force majeure rights of this **Section 16.01** (**Force Majeure)**.

Section 16.02 Entire Agreement. This Agreement, together with the Exhibits and Schedules attached hereto, constitutes the entire agreement between Sol-Gel or any of its Affiliates, on the one hand, and SLP or any of its Affiliates, on the other hand, with respect to the subject matter hereof, supersedes all prior understandings and writings between Sol-Gel or any of its Affiliates, on the one hand, and SLP or any of its Affiliates, on the other hand relating to such subject matter, and shall not be modified, amended or (subject to **Article XIII (Term and Termination)**) terminated, except by another agreement in writing executed by the Parties.

Section 16.03 Severability. If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision of this Agreement (such invalid or unenforceable provision, a "**Severed Clause**"), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use their reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

Section 16.04 Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be mailed by internationally recognized express delivery service, or sent by facsimile or email and confirmed by mailing, as follows (or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith):

If to Sol-Gel:

Sol-Gel Technologies Ltd. 7 Golda Meir St.
Ness Ziona Israel, 7403650

Attn: Gilad Mamlok, Chief Financial Officer
Email: Gilad.Mamlok@Sol-Gel.com

With a copy to: Adv. Tami Fishman, VP & General Counsel
Email: Tami.Fishman@Sol-Gel.com

If to SLP:

Searchlight Pharma Inc.
1600 Notre-Dame Street West, Suite 312 Montreal, QC
Canada

H3J 1M1

Attention: Mark Nawacki, President & CEO
Email: [***]

With a copy to:

Attention: Legal Department
Email: [***]

Any such notice shall be deemed to have been given (a) when delivered if personally delivered, (b) on receipt if sent by overnight courier or (c) on receipt if sent by mail.

Section 16.05 Agency. Neither Party is, nor will be deemed to be a partner, employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

Section 16.06 No Waiver. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other Party, shall not constitute a waiver of such Party's rights to the enforcement of any of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.

Section 16.07 Cumulative Remedies. Except as may be expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law or in equity.

Section 16.08 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than (a) to the extent provided in **Section 12.01 (Indemnification by Sol-Gel)**, the SLP Indemnitees and (b) to the extent provided in **Section 12.02 (Indemnification by SLP)**, the Sol-Gel Indemnitees.

Section 16.09 Performance by Affiliates. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder; *provided* that such Party so notifies the other Party in writing and *provided*, *further*, that such Party shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

Section 16.10 Counterparts. This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

SOL-GEL TECHNOLOGIES, LTD.

By: /s/ Gilad Mamlok
Name: Gilad Mamlok
Title: CFO

SEARCHLIGHT PHARMA INC.

By:/s/ Mark Nawacki
Name: Mark Nawacki
Title: President & CEO

Exhibit A

Licensed Patents & Trademark

[***]

Exhibit B

Commercialization Plan

SLP to provide at least [***]months prior to commercial launch in the Territory

Exhibit C

Target Price

SLP's target net-selling price for Licensed Product is [***] [***]

Exhibit D

Minimum Orders

[***]

Exhibit E

[***]Rates [***]

[***]

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 13, 2024

/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:

    e) 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;

    f) 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;

    g) 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

    h) 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):

    c) 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

    d) 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 13, 2024

/s/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer

Exhibit 13.1

CERTIFICATION BY CHIEF EXECUTIVE 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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer 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 13, 2024

/s/ Alon Seri-Levy
Alon Seri-Levy
Chief Executive Officer

Exhibit 13.2

CERTIFICATION BY 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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer 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 13, 2024

/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 (Nos. 333-223915 and 333-270477) and Form F-3 (No. 333-264190) of Sol-Gel Technologies Ltd. of our report dated March 13, 2024, relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
March 13, 2024

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Exhibit 97.1

Sol-Gel Technologies Ltd.
POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Sol-Gel Technologies Ltd. (the ***"Company")*** has adopted this Policy for Recovery of Erroneously Awarded Compensation (the ***"Policy"),*** effective as of October 2, 2023 (the ***"Effective Date").*** Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to and be binding and enforceable on current and former Officers. In addition, the Committee and the Board may apply this Policy to persons who are not Officers, and such application shall apply in the manner determined by the Committee and the Board in their sole discretion.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly and in accordance with Section 4 below, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee and the Board have determined that recovery from the relevant current or former Officer would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any Officer's right to voluntarily terminate employment for "good reason" or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee and the Board shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, shareholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy shall be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any Other Recovery Arrangements. Without limiting the foregoing, in the event of a conflict between this Policy and the Compensation Policy, the latter shall prevail, except with respect to the recovery of any portion of Incentive-Based Compensation that is Erroneously Awarded Compensation that would not be recoverable under the Compensation Policy, in which case this Policy shall prevail. Subject to Section 4, the remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company or is otherwise required by applicable law and regulations.

9. Severability

The provisions in this Policy are intended to be applied to the iullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association in the U.S.

11. Definitions

"Applicable Rules" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"Board" means the Board of Directors of the Company.

"Compensation Policy" means the Company's compensation policy for officers and directors, as adopted in accordance with the Israeli Companies Law 5759-1999 and as in effect from time to time.

"Committee" means the Compensation Committee of the Board or, in the absence of such a committee, a majority of the independent directors serving on the Board.

"Erroneously Awarded Compensation" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"Financial Reporting Measure" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non- GAAP/IFRS financial measures, as well as stock price and total shareholder return.

"GAAP" means United States generally accepted accounting principles.

"IFRS" means international financial reporting standards as adopted by the International Accounting Standards Board.

"Impracticable" means (a) the direct expense paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company has (i) made reasonable attempt(s) to recover the Erroneously Awarded Compensation, (ii) documented such reasonable attempt(s) and (iii) provided such documentation to the relevant listing exchange or association, (b) the recovery would violate the Company's home country laws adopted prior to November 28, 2022 pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such a violation and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"Incentive-Based. Compensation" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after such person began
service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the Company has a class of securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"Officer" means each person who the Company determines serves as a Company officer, as defined in Section 16 of the Securities Exchange Act of 1934, as amended.

"Other Recovery Arrangements" means any clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (including, without limitation, the Compensation Policy).

"Restatement' means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"Three-Year Period' means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.