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, 2021

OR

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

OR

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

Date of event requiring this shell company report _____

Commission file number 001-38367

Sol-Gel Technologies Ltd.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

Israel

(Jurisdiction of incorporation or organization)

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

(Address of principal executive offices)

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

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

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

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

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

None

(Title of Class)

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

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 23,126,804 Ordinary Shares, par value NIS 0.1 per share

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Yes ☒ No ☐

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

Yes ☒ No ☐

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

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

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

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

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

U.S. GAAP ☒

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

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

Item 17 ☐ Item 18 ☐

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

Yes ☐ No ☒

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INTRODUCTION

All references to "Sol-Gel," "Sol-Gel Technologies," "we," "us," "our," "the Company" and similar designations refer to Sol-Gel Technologies Ltd. The terms "shekels," "Israeli shekels" and "NIS" refer to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar," "US$" or "$" refer to U.S. dollars, the lawful currency of the United States. Unless derived from our financial statements or otherwise indicated, U.S. dollar translations of NIS amounts presented in this annual report are translated using the rate of NIS 3.11, NIS 3.215 and NIS 3.456 to $1.00, based on the exchange rates reported by the Bank of Israel on December 31, 2021, December 31, 2020 and December 31, 2019, respectively.

All references to the term "Twyneo® " refers to 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. All references to the term "Epsolay®" refers to a novel, once-daily investigational topical cream containing encapsulated benzoyl peroxide that we are developing for the treatment of papulopustular (subtype II) rosacea; "SGT-210" refers to SGT-210 (erlotinib), under investigation for the treatment of keratoderma; "erlotinib" refers to an epidermal growth factor receptor inhibitor; "SGT-310" refers to SGT-310 (tapinarof), an investigational aryl hydrocarbon receptor agonist; "SGT-510" refers to SGT-510 (roflumilast and agent A); and "roflumilast" refers to an investigational phosphodiesterase 4 inhibitor. SGT-210, SGT-310 and SGT-510 are each a potential treatment of various pharmaceutical indications. All references to the term "investigational product candidates" include Epsolay® SGT-210, SGT-310 and SGT-510. All references to the terms "generic product candidates" include two generic programs related to four generic drug candidates developed in collaboration with Padagis Israel Pharmaceuticals Ltd ("Padagis"). All references to the term "product candidates" include both investigational product candidates and generic product candidates.

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

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

We make forward-looking statements in this annual report that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when 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 complete the development of our investigational product candidates;
- our dependance on the success of Galderma Holding SA ("Galderma") in commercializing Twyneo® and Epsolay®;
- the right of Galderma to terminate the collaboration agreement with respect to Epsolay®, if Epsolay® is not approved for marketing by the FDA, by March 31, 2022;
- our ability to find suitable co-development, contract manufacturing and marketing partners;
- our ability to obtain and maintain regulatory approvals for our investigational product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our investigational product candidates even if regulatory approval is obtained;
- our ability to commercialize and launch our pharmaceutical investigational product candidates;
- our ability to obtain and maintain adequate protection of our intellectual property;
- our ability to manufacture our investigational product candidates in commercial quantities, at an adequate quality or at an acceptable cost;
- acceptance of Twyneo®, Epsolay® and our other investigational product candidates by healthcare professionals and patients;
- the possibility that we may face third-party claims of intellectual property infringement;
- the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- potential product liability claims;
- potential adverse federal, state and local government regulation in the United States, Europe or Israel;
- the impact of ongoing pandemics such as Novel Coronavirus Disease 2019, or COVID-19, on our business and financial condition; and
- loss or retirement of key executives and research scientists.

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

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

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, 2021 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 have a limited operating history in the dermatological prescription drug space which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We may need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy. If we are successful in raising additional capital, this may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or investigational product candidates.
- We are largely dependent on the success of Twyneo®, Epsolay® and our other investigational product candidates for the treatment of topical dermatological conditions.

- We are dependent on the success of Galderma in commercializing Twyneo® and Epsolay® in the U.S.. If Galderma is not successful in its commercialization efforts in the U.S. or does not perform as expected, our business may be substantially harmed.

- Galderma has the right to terminate our collaboration agreement with respect to Epsolay®, if we do not receive marketing approval from the FDA, by March 31, 2022.

- We currently have limited marketing capabilities, and are dependent on the success of Galderma in commercializing Twyneo® and Epsolay® in the U.S.. If we are unable to establish adequate sales and marketing capabilities through third parties for Twyneo® and Epsolay® outside of the U.S. or for our other investigational product candidates, we may be required to establish sales and marketing capabilities on our own, or we may be unable to successfully commercialize such products if approved by the FDA or generate product revenues.

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

- Our continued growth is dependent on our ability to successfully develop and commercialize new product candidates in a timely manner. We expend a significant amount of resources on research and development efforts that may not lead to successful product candidate introductions or the recovery of our research and development expenditures.

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

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

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

- Twyneo® Epsolay® and our other 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.

- Twyneo® Epsolay® and, our other product candidates, will face significant competition and our failure to compete effectively may prevent us and our commercial partners from achieving significant market penetration and expansion.

- The ongoing COVID-19 pandemic may adversely affect our development timeline, the availability of our contract manufacturers, of utensils, raw materials and human resources and patients for clinical trials and as a result may adversely affect our business, revenues, results of operations and financial condition.

- Any collaborative arrangements that we have (including our agreement with Galderma) 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 product candidates to patients, once approved, and the development or commercialization of our product candidates could be delayed or stopped.

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

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

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

Risks Related to Our Business and Industry

We are a 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 net losses of $24.6 million in 2019, $29.3 million in 2020 and a profit of $3.2 million in 2021. As of December 31, 2021, we had an accumulated deficit of $178.1 million. Our losses have resulted principally from expenses incurred in research and development of Twyneo® 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 investigational product candidates. The extent of our future operating losses and the timing of generating revenues and becoming profitable are highly uncertain, and we may never achieve or sustain profitability. We anticipate that our expenses will increase substantially as we:

- conduct Phase I clinical studies of SGT-210 and SGT-310, and continue the research and development of SGT-210, SGT-310, and SGT-510 and 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 products;

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

- seek to enhance our technology platform;
- maintain, expand and protect our intellectual property portfolio;
- seek new drug candidates and expand our disease portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

We have financed our operations primarily through public offerings in the U.S., private placements of equity securities and investments and loans from our controlling shareholder. To date, we have devoted a significant portion of our financial resources and efforts to developing Twyneo®, Epsolay® and generic product candidates which include a generic product, the rights to which we have since sold, and developing our other investigational product candidates. Although we have received approval of from FDA with respect to our marketing applications for Twyneo® and are anticipating a decision from the FDA with respect to our marketing application for Epsolay® in 2022, to become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical studies and clinical trials for our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any product candidates for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

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

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

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

Conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales of our product candidates. We expect to continue to incur significant expenses and operating losses over the next several years as we seek marketing approval for Epsolay®, conduct Phase I clinical studies of SGT-210 and SGT-310, and advance SGT-210, SGT-310, SGT-510, and our other investigational product candidates. In addition, Twyneo® and, if approved by the FDA, Epsolay®, and our other product candidates, may not achieve commercial success. Substantial revenue, if any, will be derived from sales of Twyneo® and if approved, Epsolay®, and our other product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the timing and success for obtaining marketing approval for Epsolay®;
- the progress and results of our development activities for SGT-210, SGT-310 and SGT-510;
- the scope, progress, results and costs of development, laboratory testing and clinical trials for our generic product candidates;
- the cost of manufacturing clinical supplies and exhibition batches of our investigational product candidates;
- the costs, timing and outcome of regulatory reviews of any of our 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 costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims by third parties that we are infringing upon their intellectual property rights;
- the amount of revenue, if any, received from commercial sales of Twyneo®, Epsolay ® and our other product candidates for which we receive marketing approval; and
- the extent to which we acquire or invest in businesses, product candidates and technologies, including entering into licensing or collaboration arrangements for any of our 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.

We are largely dependent on the success of Twyneo®, Epsolay ® and our other product candidates for the treatment of topical dermatological conditions.

We have invested a majority of our efforts and financial resources in the research and development of Twyneo® for the treatment of acne and Epsolay® for the treatment of papulopustular (subtype II) rosacea. 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, if approved by the FDA, Epsolay®. The success of our business depends largely on Galderma'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 investigational product candidates in the United States in a timely manner.

If we do not receive FDA approval for the marketing of Epsolay® by March 31, 2022, Galderma has the right to terminate our license agreement with respect to the Epsolay® product.

In June 2021, we entered into a 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 Epsolay®, subject to the approval of Epsolay® by the FDA. Pursuant to the terms of the license agreement, if Epsolay® does not receive marketing approval by the FDA by March 31, 2022, Galderma may, in its sole discretion, terminate such agreement immediately upon delivery of written notice to us no later than thirty (30) days after such date. If Eposlay® does not receive regulatory approval by such date, and Galderma elects to terminate the licesne agreement, we will be required to either locate an alternative commercial partner, or to commercialize Epsolay® on our own through the establishment of commercialization resources which we do not currently have. Either alternative will be costly and time consuming, and may have a material adverse impact on our business.

Other than for Twyneo®, we have not obtained regulatory approval for most of our product candidates in the United States or any other country.

Other than for Twyneo® and one generic product the rights to which we have since sold and for which our collaborator received final FDA approval in February 2019, we do not currently have any product candidates, that have obtained regulatory approval for sale in the United States or any other country, and we cannot guarantee that our 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 our product candidates. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication and, when subject to the requirements of section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, 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.

To date, we have submitted two NDAs that were accepted for filing by the FDA, one for Twyneo®, which was subsequently approved by the FDA, and one for Epsolay® with a Prescription Drug User Fee Act, or PDUFA, goal date originally assigned by the FDA of April 26, 2021, which has since been delayed due to COVID-19 related travel restrictions. The FDA conducted a pre-approval inspection of the production site for Epsolay® during the week of February 14, 2022.

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.

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

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

Market perception of our business is very important, especially market perception of the safety and quality of our product candidates. If Twyneo®, Epsolay® any of our other investigational 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 product candidates could have a material adverse impact on our business.

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

Although we have entered into exclusive license agreements with Galderma for all U.S. commercial activities for Twyneo®, and, if approved by the FDA, 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 investigational and generic 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, if approved by the FDA, Epsolay®. 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, in lieu of our own sales force and distribution systems. We cannot provide you with any assurances as to when, if ever, we will obtain approvals or generate sufficient revenues to achieve sustained profitability. Our ability to successfully commercialize our product candidates and become profitable is subject to a number of challenges, including, among others, that:

- we may not have adequate financial or other resources;
- we or our partners may not be able to manufacture our product candidates 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 product candidates;

- 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 product candidates;
- 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 product candidates, which may adversely affect patients' willingness to purchase our product candidates;
- uncertainty as to market demand may result in inefficient pricing of our product candidates;
- we may face third-party claims of intellectual property infringement;
- we 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
- delays due to shortages in supply and human resources resulting from the COVID-19 pandemic.

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

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

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

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

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

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

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

Risks Related to Development and Clinical Testing of Our Product Candidates

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

Clinical testing, of both innovative and generic products, and the submission of new drug applications under the Sections 505(b)(1) and 505(b)(2) regulatory pathway is expensive, time consuming and has an inherently uncertain outcome. Failure can occur at any time during the clinical trial process, even with active ingredients that have been previously approved by the FDA as safe and effective. Favorable results in pre-clinical studies and early clinical trials for one or more of our product candidates may not be predictive of similar results in future clinical trials for such product candidate. Also, interim results during a clinical trial do not necessarily predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in 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 products.

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

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.

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® for marketing, it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

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

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

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

We have limited experience using the 505(b)(1) and 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. 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 such approval is obtained in the case of our investigational product candidates. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved by the FDA.

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 Twyneo®, Epsolay® or, our other product candidates, could limit the commercial profile of an approved label, or result in significant negative consequences following commercialization, if any.

Undesirable side effects caused by our product candidates could result in the delay, suspension or termination of clinical trials by us, our collaborators, the FDA or other regulatory authorities for a number of reasons. For example, to date, patients treated with Twyneo® and Epsolay® have experienced drug-related side effects including moderate local site irritation such as dryness, erythema, scaling, pruritus, itching, stinging and burning. Results of our clinical trials for other 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 that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, with respect to Twyneo®, Epsolay® and, with respect to one or more of our other product candidates, 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 Twyneo® Epsolay® or our other products candidates, and could significantly harm our business, results of operations and prospects. Our future clinical trial results may not be successful.

We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in our or our partners 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 for which the patient population in 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, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

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

- severity of the disease under investigation;
- size and nature of the patient population;
- eligibility criteria for the trial;
- design of the trial protocol;

- perceived risks and benefits of the product candidate under study;
- physicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any drugs that may be approved for the same indications we are investigating;
- proximity to and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- ability to monitor patients adequately during and after treatment; and
- COVID-19 restrictions and guidelines.

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. For example, 104 patients, or 12.12% of patients enrolled in our Twyneo® Phase 3 clinical trial, did not complete the study protocol. The most common reasons for subjects not completing the study were the withdrawal of informed consent (41 subjects), loss to follow-up (36 subjects) and adverse events (16 subjects). The discontinuation of patients in any one of our trials may cause us to delay or abandon our clinical trial or cause the results from that trial not to be positive or sufficient to support a filing for regulatory approval of the applicable product candidate.

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

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

If the FDA does not conclude that our product candidates for which we are seeking or intend to seek approval under Section 505(b)(1) or 505(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfy the requirements of the applicable regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(1) or 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in all cases may not be successful.

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, which Epsolay remains pending, and we may develop and seek approval for our other product candidates through this regulatory pathway in the future. In addition, we are developing SGT-310 for potential submission through the Section 505(b)(1) regulatory pathway, and may utilize this pathway for other future product candidates.

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.

Further, we are currently developing SGT-310 (tapinarof) for potential submission through the Section 505(b)(1) regulatory pathway. Although this pathway is not subject to the same patent certification requirements as Section 505(b)(2) applications or ANDAs, we may still face patent litigation in connection with this product development program. In addition, if the FDA disagrees that our clinical data is sufficient for submission in a Section 505(b)(1) NDA, we may not be able to seek or obtain approval for this product on the time line we expect, if at all.

Twyneo®, Epsolay® and our other product candidates, 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 or REMS, and/or surveillance requirements to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our product candidates, if any.

The FDA also may approve 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®, and any such approved product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. These requirements include registration with the FDA, listing of our product candidates, payment of annual fees, as well as continued compliance with GCP requirements for any clinical trials that we or our partners conduct post-approval. Application holders must notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product manufacturing changes. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements.

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

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

In addition, our or our partners product labeling, advertising and promotional materials for our product candidates, 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 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. Physicians may nevertheless prescribe Twyneo®, Epsolay® and, any of our other product candidates, to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities and clinical trial sites. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities and trial sites subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. Recently, 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 as it adapts to the evolving 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 other 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 other product candidates, will depend significantly on their broad adoption by dermatologists, pediatricians and other physicians for approved indications and other therapeutic or aesthetic indications that we may seek to pursue if approved by the FDA.

The degree and rate of physician and patient adoption of Twyneo® Epsolay® and our other product candidates, will depend on a number of factors, including:

- the clinical indications for which the product is approved;
- the safety and efficacy of our product as compared to existing therapies for those indications;
- the prevalence and severity of adverse side effects;
- patient satisfaction with the results and administration of our product and overall treatment experience, including relative convenience, ease of use and avoidance of, or reduction in, adverse side effects;
- patient demand for the treatment of acne and rosacea or other indications;
- the cost of treatment in relation to alternative treatments, the extent to which these costs are reimbursed by third-party payors, and patients' willingness to pay for our product candidates; and
- the effectiveness of our sales and marketing efforts, including any head-to-head studies, if conducted, especially the success of any targeted marketing efforts directed toward dermatologists, pediatricians, other physicians, clinics and any direct-to-consumer marketing efforts we may initiate.

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

We conduct research and development primarily to enable us to manufacture and market topical dermatological creams containing drugs in accordance with FDA regulations as well as other regulatory authorities. We spent approximately $40.6 million, $27.9 million and $20.4 million on research and development activities during the years ended December 31, 2019, 2020 and 2021, respectively. We are required to obtain FDA approval before marketing our product candidates in the United States. The FDA approval process is costly, time consuming and inherently risky.

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

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

Our clinical trials for Twyneo®, Epsolay® and our other investigational 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 other investigational product candidates.

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

Certain of our product candidates may be manufactured, warehoused and/or tested at third-party facilities located in 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 (including Covid-19), international terrorism, civil disturbances, political instability, governmental activities, deprivation of contract and property rights and currency valuation changes. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations.

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

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

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

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

- delays or difficulties in supervising the efforts of our contract manufacturers because of travel restrictions, sickness of our or the contract manufacturer employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;

- delays or difficulties in enrolling patients in our and our partners clinical trials;

- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;

- increased rates of patients withdrawing from our or our partners clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;

- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy and safety data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations, or CROs, and vendors;

- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;

- interruption of, or delays in receiving, supplies of our product candidates or of animals for clinical trials from our service providers and our and our partners contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- delays in receiving authorization from local regulatory authorities to initiate our or our partners planned clinical trials;

- limitations on employee or other resources that would otherwise be focused on the conduct of our or our partners clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;

- changes in regulations as part of a response to the COVID-19 pandemic which may require us or our partners to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;

- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and

- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

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

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

In the future, we may acquire or in-license additional 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.

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

Risks Related to Regulatory Matters

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

Healthcare costs in the United States have risen significantly over the past decade. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the 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 product candidates:

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

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

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

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

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

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. Prior to the U.S. Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. 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 of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, 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. For example, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation. 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, or additional pricing pressure.

Risks Related to Commercialization of Our Product Candidates

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

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

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

Twyneo® and if approved by the FDA, Epsolay and our other product candidates, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration and expansion.

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

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

In addition, we may not be able to price Twyneo®, and if approved Epsolay®, and our other investigational product candidates, 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 successfully.

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

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 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 505(b)(2) and generic product candidates. Branded pharmaceutical companies may sell their branded products as "authorized generics," where an approved brand name drug is marketed, either by the brand name drug company or by another company with the brand company's permission, as a generic product without the brand name on its label, and potentially sold at a lower price than the brand name drug. Further, branded pharmaceutical companies may seek to delay FDA approval of our 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 and other indications we are pursuing and enter the market ahead of us.

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

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

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

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

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

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

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

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers 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 product candidates 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; 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.

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 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, or the CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Economic Area, or 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 company, 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; in July 2020, the Court of Justice of the European Union, or CJEU, limited how organizations could lawfully transfer personal data from the European Union / EEA to the U.S. by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the United Kingdom SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. 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 will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million / £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

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

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

Public loss of confidence in the integrity of Twyneo®, Epsolay® or our other product candidates 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, if approved, Epsolay® in the U.S. and on Padagis to develop and commercialize our generic product candidates and may depend on others parties for commercialization of Twyneo® and Epsolay® outside of the U.S, and the development and commercialization of our other investigational product candidates. 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, if approved by the FDA, Epsolay®. In consideration for the grant of such rights, we are entitled to of up to $11 million in upfront payments to us 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 milestone or royalty 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® products 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.

We are currently a party to collaborative arrangements with respect to the development, manufacture, study and commercialization of certain of our 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 develop and commercialize Twyneo® Epsolay® and our other 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 other product candidates;
- We may not be able to locate third party partners for the commercialization of Twyneo® and Epsolay® for territories other than U.S.;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our current or future collaborators may fail to comply with local or any foreign health authorities' laws and regulations, and as a result, the receipt of a site manufacturing, export or import license may be delayed or withheld for an undefined period;

- our current or future collaborators may experience financial difficulties or changes in business focus;
- our current or future collaborators' partners may fail to secure adequate commercial supplies of our product candidates upon marketing approval, if at all;
- our current or future collaborators' partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing product developed either independently or in collaboration with others, including our competitors;
- our current or future collaborators may utilize our proprietary information in a way that could expose us to competitive harm; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our product candidates.

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

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

We also may have other investigational product candidates where it is desirable or essential to enter into agreements with a collaborator who has greater financial resources or different expertise than us, but for which we are unable to find an appropriate collaborator or are unable to do so on favorable terms. If we fail to enter into such collaborative agreements on favorable terms, it could materially delay or impair our ability to develop and commercialize our 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 the commercial scale production of Twyneo®, Epsolay®, and our other investigational product candidates for clinical trials. This increases the risk that we may not have access to sufficient quantities or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

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

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

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 other 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, 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. 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.

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 product candidates to patients, once approved, and the development or commercialization of our product candidates could be delayed or stopped.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

We have granted, and may in the future grant, to third parties licenses to use our intellectual property. Generally, other than the licenses granted to Galderma, these licenses have granted rights to commercialize products outside the pharmaceutical field or to technology we no longer use or to otherwise use our intellectual property for a limited purpose outside the scope of our business interests. For example, in August 2013 we entered into an assignment agreement with Medicis Pharmaceutical Corporation ("Medicis"), according to which Medicis assigned to us its entire interest in one of the patents upon which we rely for our product candidate Twyneo® for the treatment of acne. As part of this assignment agreement, we granted to Medicis a non-exclusive, transferable, sub-licensable, royalty-free, perpetual, license to practice the inventions claimed under the patent. In June 2021, we entered into two five-year exclusive license agreements with Galderma, under our intellectual property rights covering the Twyneo® and Epsolay® products, pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo®, and, if approved by the FDA, Epsolay®

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

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

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

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

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

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

In the event of patent infringement claims, or to avoid potential claims, we 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 product candidates infringe on the patent rights of others are more likely to be asserted after commencement of commercial sales incorporating our technology.

We may be subject to claims that our 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 product candidates. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

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

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

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

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

In the United States, we 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®. Both of these NDA's were accepted for filing by the FDA. The FDA granted marketing approval for Twyneo® in July 2021, and the FDA conducted a pre-approval inspection of the production site for Epsolay® during the week of February 14, 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 addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could result in damage to our facilities and likewise have a material adverse effect on our business, operating results and financial condition.

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

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

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

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

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

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

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

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

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

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

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

We have received royalty-bearing grants from the government of Israel through the National Authority for Technological Innovation, or the Israel Innovation Authority, also known as the IIA (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS, for the financing of a portion of our research and development expenditures in Israel. These IIA grants relate to a peripheral line of product candidates which forms a negligible part of our activities. We are required to pay the IIA royalties from the revenues generated from the sale of products (and related services) or services developed (in all or in part) 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 Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, or the Innovation Law, and related rules and regulations), up to the aggregate amount of the total grants received by the IIA, plus annual interest at an annual rate based on LIBOR. As we received grants from the IIA, we are subject to certain restrictions under the Innovation Law and related rules and regulations. These restrictions may impair our ability to perform or outsource manufacturing 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 of the full amount of royalties payable pursuant to the grants. In addition, the government of the State of Israel may from time to time audit sales of products which it claims incorporate 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 enter into agreements for IIA Funded Know-How product candidates or technologies without the approval of the IIA. We cannot be certain that any approval of the IIA will be obtained on terms that are acceptable to us, or at all. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of 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 amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the IIA's rules and guidelines and the Innovation Law may subject us to financial sanctions, to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings.

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.

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

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

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

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

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

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

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

Some of our operations in Israel may entitle us to certain tax benefits under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, once we begin to produce revenues. If we do not meet the requirements for maintaining these benefits, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which is set at 23% in 2022. In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we have already received, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current "Benefited Enterprise" is entitled to may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefits programs. See "Item 10. Additional Information — Israeli Tax Considerations and Government Programs — Tax Benefits Under the 2011 Amendment" for additional information concerning these tax benefits.

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

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

Risks Related to Employee Matters

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

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

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

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

Risks Related to Our Ordinary Shares

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

Arkin Dermatology is currently our controlling shareholder. As of March 1, 2022, Arkin Dermatology beneficially owned approximately 62.4% of the voting power of our outstanding ordinary shares. Therefore, Arkin Dermatology has the ability to substantially influence us and exert significant control through this ownership position. For example, Arkin Dermatology is able to control elections of directors, amendments of our organizational documents, and approval of any merger, amalgamation, sale of assets or other major corporate transaction. Arkin Dermatology's interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. So long as it continues to own a significant amount of our equity, Arkin Dermatology will continue to be able to strongly influence and significantly control our decisions.

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

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

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

As of February 26, 2022, there were 23,000,782 ordinary shares outstanding. Future sales by us or our shareholders of a substantial number of our ordinary shares in the public market, or the perception that these sales might occur, could cause the market price of our ordinary shares to decline or could impair our ability to raise capital through a future sale of, or pay for acquisitions using, our equity securities. Of our issued and outstanding shares, all of the ordinary shares listed for trading are freely transferable, except for any shares held by our "affiliates," as that term is defined in Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

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

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

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

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

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

We intend to use the remaining net proceeds from our public offering February 2020 (and concurrent private placement with our controlling shareholder, Arkin Dermatology) to fund development activities for our product candidates. 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 our initial public offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from our public offerings in a manner that does not produce income.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will be a passive foreign investment company, or PFIC, for any taxable year if either (i) at least 75% of its gross income for such year is passive income or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets) during such year is attributable to assets that produce passive income or are held for the production of passive income. For our 2019, through 2021 taxable years we generated revenue under our then collaboration agreement with Perrigo UK Finco Limited Partnership, or Perrigo, for the development of a generic product candidate. In 2021, we sold our rights to this and other generic products and will unconditionally receive further revenue over 24 months in lieu of our share in the collaboration agreements with respect to these products. Starting in 2021, we began generating revenue under our license agreements with Galderma for Twyneo®, and Epsolay®. See "Item 4. Information on the Company – B. Business Overview". .. Though the application of the relevant rules governing the characterization of the foregoing revenue for purposes of the PFIC income test is uncertain, we intend to take the position that, based on our involvement and management contributions throughout the development process, such revenue is non-passive for PFIC purposes. As a result, based on the current and anticipated value and composition of our income and assets, we do not expect that we will be treated as a PFIC for U.S. federal income tax purposes for our current taxable year or for foreseeable future years. However, there are substantial factual and legal ambiguities regarding the nature of the revenue and the application of the relevant PFIC rules, and thus, the determination that such revenue is non-passive is not without doubt, and alternative characterizations are possible.

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

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

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

General Risk Factors

Our business and operations 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 and personal 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 internal information technology systems, and those of third parties on which we rely, are vulnerable to attack and damage or interruption from computer viruses, malware (e.g. ransomware), 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, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. . 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.

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 disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed.

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

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

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

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

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

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

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

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

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

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, starting with the Annual Report for the year ended on December 31, 2019, our management is required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an "emerging growth company" under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above and depending on our status as per Rule 12b-2 of the Exchange Act, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting under Section 404. The process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls requires the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, while our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2021, 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, 2021, our internal control over financial reporting was effective, we cannot predict the outcome of our testing or any subsequent testing by our auditor in future periods. Any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information and affect our reputation, which could have a negative effect on the trading price of our ordinary shares.

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

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

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

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

Our capital expenditures for the years ended December 31, 2019, 2020 and 2021 were approximately $597, $449 and $143, respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are a dermatology company focused on identifying, developing and commercializing investigational and generic topical drug products for the treatment of skin diseases. In addition to Twyneo®, which has been approved by the FDA, our current product candidate pipeline consists of clinical stage and early-stage investigational product candidates, some of which leverage our development platform, and several generic product candidates across multiple indications.

Our FDA-approved product, 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 vulgaris, or acne.

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

Our investigational product candidate, Epsolay®, is a novel, once-daily investigational topical cream containing encapsulated benzoyl peroxide, that we are developing for the treatment of papulopustular (subtype II) rosacea. On July 8, 2019, we announced positive top-line results from our Phase 3 program evaluating Epsolay®. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Epsolay® demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving "clear" or "almost clear" in the Investigator Global Assessment (IGA) relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay® demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. In addition, Epsolay® was found to be well- tolerated. Our NDA for Epsolay® was accepted for filing by the FDA, which originally assigned a PDUFA goal date of April 26, 2021, which has since been delayed due to COVID-19 related travel restrictions. The FDA conducted a pre-approval inspection of the production site for Epsolay® during the week of February 14, 2022.

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, if approved by the FDA, Epsolay®.

Other investigational product candidates are SGT-210 that we are developing for the treatment of various keratodermas; SGT-310, an investigational aryl hydrocarbon receptor agonist; and SGT-510.

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

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 related to four generic drug candidates for skin diseases. Under the terms of the agreement with Padagis, effective as of November 1, 2021, we are to unconditionally receive $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 were unapproved.

Twyneo®, a novel, once-daily, non-antibiotic topical cream, developed for the treatment of acne, containing a fixed-dose combination of encapsulated benzoyl peroxide, or E-BPO, and encapsulated tretinoin. Acne is one of the three most prevalent skin diseases in the world and is the most commonly treated skin disease in the United States. According to the American Academy of Dermatology, acne affects approximately 40 to 50 million people in the United States, of which approximately 10% are treated with prescription medications. 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. 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.

Our leading investigational product candidate, Epsolay®, is a topical cream containing 5% encapsulated benzoyl peroxide, which we are developing for the treatment of papulopustular (subtype II) rosacea. Rosacea is a chronic skin disease characterized by facial redness, inflammatory lesions, burning and stinging. According to the U.S. National Rosacea Society, approximately 16 million people in the United States are affected by rosacea. According to a study we commissioned 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. If approved by the FDA, we expect Epsolay® to be the first product containing BPO that is marketed for the treatment of subtype II rosacea. On July 8, 2019, we announced positive top-line results from our Phase 3 program evaluating Epsolay®. The program enrolled 733 patients aged 18 and older in two identical, double-blind, vehicle-controlled Phase 3 clinical trials at 54 sites across the United States. Epsolay® demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving "clear" or "almost clear" in the Investigator Global Assessment (IGA) relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12. In an additional analysis, Epsolay® demonstrated rapid efficacy, achieving statistically significant improvements on both co-primary endpoints compared with vehicle as early as Week 2. In addition, Epsolay® was found to be well-tolerated. On February 12, 2020, we announced positive topline results from our open-label, long-term safety study, evaluating Epsolay® for a treatment duration up to 52 weeks. Our NDA for Epsolay® has been accepted for filing by the FDA, which originally assigned a PDUFA goal date of April 26, 2021, which has since been delayed due to COVID-19 related travel restrictions. The FDA conducted a pre-approval inspection of the production site for Epsolay® during the week of February 14, 2022.

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

- SGT-210 that we are developing for the treatment of various keratoderma, such as PC, PPK, 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, including PPK. 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 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 profile.

- We are conducting pre-clinical testing to explore the possible activity of SGT-210, SGT-310 and SGT-510 in various new pharmaceutical indications. A total of 25 provisional patent applications for these investigational drug candidates have been submitted to date, including patent applications covering the use of tapinarof in ophthalmic disorders such as dry eye, uveitis, and blepharitis with or without demodex involvement.

We are also currently developing a portfolio of two generic programs related to four generic drug candidates in collaboration with Padagis, by assignment from Perrigo.

In June 2021, we entered into two exclusive license agreements with Galderma, each for a period of five years following Galderma's first commercial sale of the applicable product in the U.S., pursuant to which Galderma has the exclusive right to, and is responsible for, all U.S. commercial activities for Twyneo®, and, if approved by the FDA, Epsolay®, including promotion and distribution, and we are responsible for obtaining all regulatory approvals of the products until approval in the U.S. Following approval, Galderma will assume responsibility 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 is responsible for entering into a supply agreement with a third party for the supply of the Epsolay® product, once approved. In consideration for the grant of such rights, we are entitled to of up to $11 million in upfront payments to us 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.

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

Our Approved Product and Investigational Product Candidates

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. We expect that Twyneo® will compete directly with Winlevi, Aklief, Epiduo and Epiduo Forte. We have utilized the FDA's 505(b)(2) regulatory pathway in seeking approval of Twyneo® in the United States.

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. 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/erythromycin and clindamycin/tretinoin. These target multiple components that contribute to the development of acne, though topical side effects are common.

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

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

Twyneo® Phase 3 Trial Design

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

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

- the proportion of subjects who achieve at least a two-grade reduction in the IGA score and either “clear” or “almost clear” at week 12;

- the mean absolute change from baseline in the number of inflammatory acne lesions at week 12; and

- the mean absolute change from baseline in the number of non-inflammatory acne lesions at week 12.

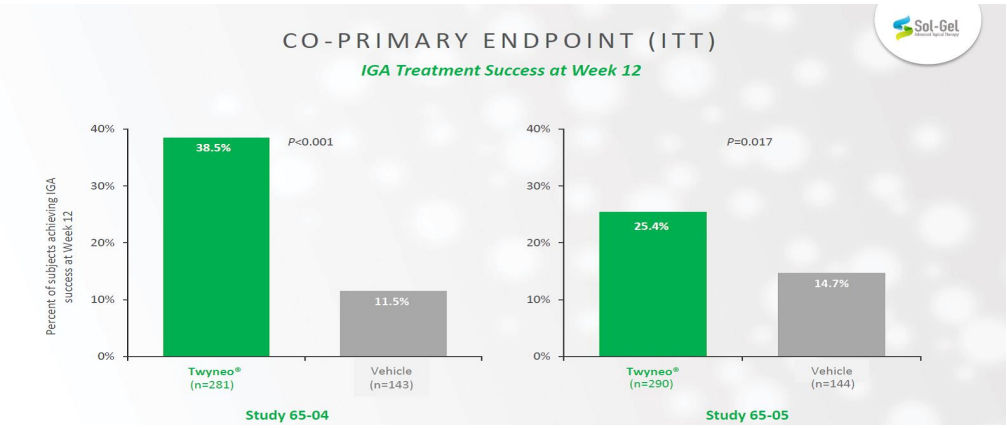
Twyneo® Phase 3 Trial Results

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

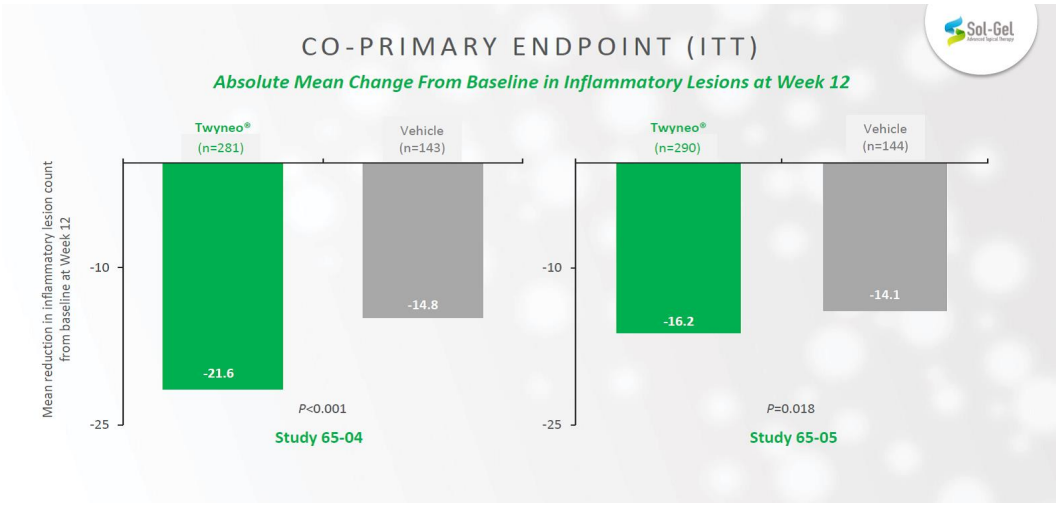
In trial SGT-65-04, 39.9% of patients treated with Twyneo® achieved success in IGA versus 14.3% in the vehicle treated group (P<0.001) at week 12. In trial SGT-65-05, 26.8% of patients treated with Twyneo® achieved success in IGA versus 15.1% in the vehicle group (P=0.017) at week 12. In trial SGT-65-04, the absolute mean change from baseline of inflammatory lesion count for Twyneo® was -21.6 versus -14.8 for the vehicle group (P<0.001) at week 12. In trial SGT-65-05, the absolute change from baseline of inflammatory lesion count for Twyneo® was -16.2 versus -14.1 for the vehicle group (P=0.021) at week 12. In trial SGT-65-04, the absolute mean change from baseline of non-inflammatory lesion count for Twyneo® was -29.7 versus -19.8 for the vehicle group (P<0.001). In trial SGT-65-05, the absolute mean change from baseline of non-inflammatory lesion count for Twyneo was -24.2 versus -17.4 for the vehicle group (P<0.001) at week 12.

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

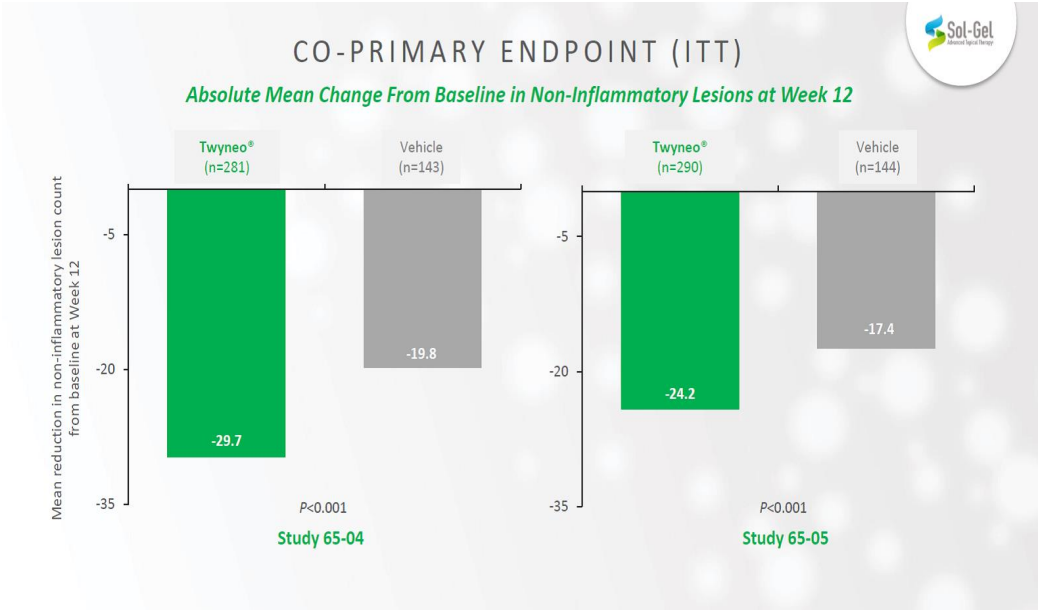
The following chart presents the proportion of subjects in the ITT population in studies SGT 65-04 and SGT 65-05 who achieved a successful improvement in the severity of their disease at week 12, as assessed using the IGA:



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



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



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

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

Epsolay® for Subtype II Rosacea

Epsolay® *Overview*

Epsolay® is a once-daily investigational topical cream containing 5% encapsulated benzoyl peroxide that we have developed for the treatment of papulopustular (subtype II) rosacea. We believe Epsolay® has the potential to become the first product to contain encapsulated benzoyl peroxide for the treatment of subtype II rosacea and, if approved by the FDA, has the potential to redefine the standard of care for the treatment of inflammatory lesions associated with subtype II rosacea. Subtype II rosacea is characterized by small, dome-shaped erythematous papules, tiny surmounting pustules on the central aspects of the face, solid facial erythema and edema, and thickening/overgrowth of skin. Subtype II rosacea resembles acne, except that comedones are absent, and patients may report associated burning and stinging sensations. We expect that Epsolay®, if approved by the FDA, will compete 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. Our NDA for Epsolay® has been accepted for filing by the FDA, which originally assigned a PDUFA goal date of April 26, 2021, which has since been delayed due to COVID-19 related travel restrictions. The FDA conducted a pre-approval inspection of the production site for Epsolay® during the week of February 14, 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. Currently, there is no approved benzoyl peroxide product in the rosacea treatment landscape as a result of potential tolerability issues, despite clinical studies showing that treatment with benzoyl peroxide could be efficacious. According to a published study, benzoyl peroxide was found to be an effective treatment for rosacea but caused irritation. Using our proprietary, silica-based microencapsulation technology platform, we believe our Epsolay® candidate for the treatment of papulopustular (subtype II) rosacea can improve on current subtype II rosacea treatments in the following ways:

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

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

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

Epsolay® Phase 3 Trial Design

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

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

Epsolay® Phase 3 Trial Results

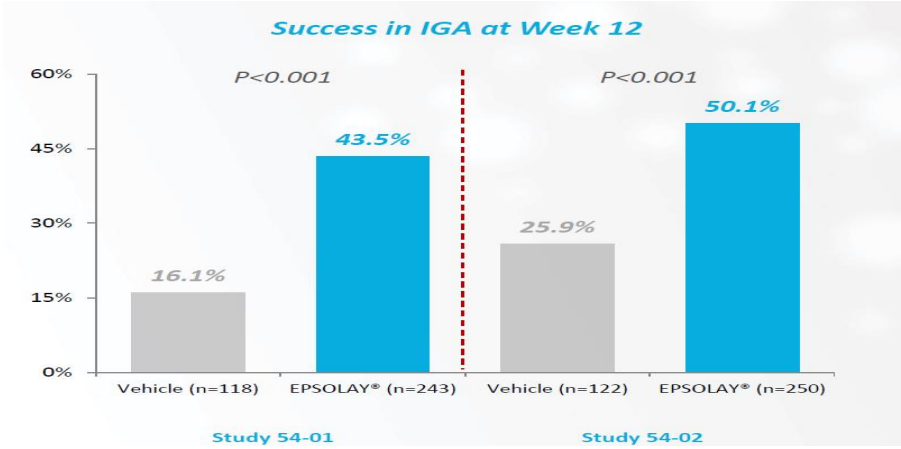
As outlined below, Epsolay demonstrated statistically significant improvement in both co-primary endpoints of (1) the number of patients achieving “clear” or “almost clear” in the IGA relative to baseline at week 12 and (2) absolute mean reduction from baseline in inflammatory lesion count at week 12.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

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

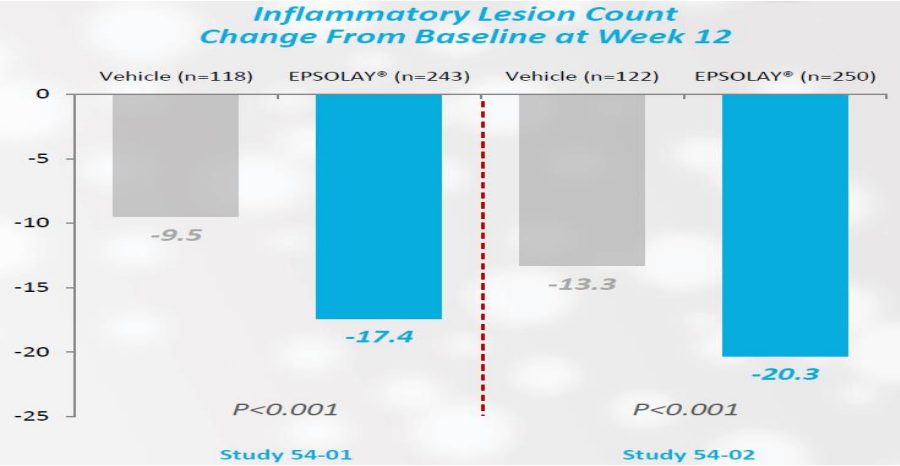
As outlined below, Epsolay® met all co-primary endpoints in both Phase 3 trials. Epsolay® demonstrated statistically significant improvement in each of the co-primary endpoints described above.

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

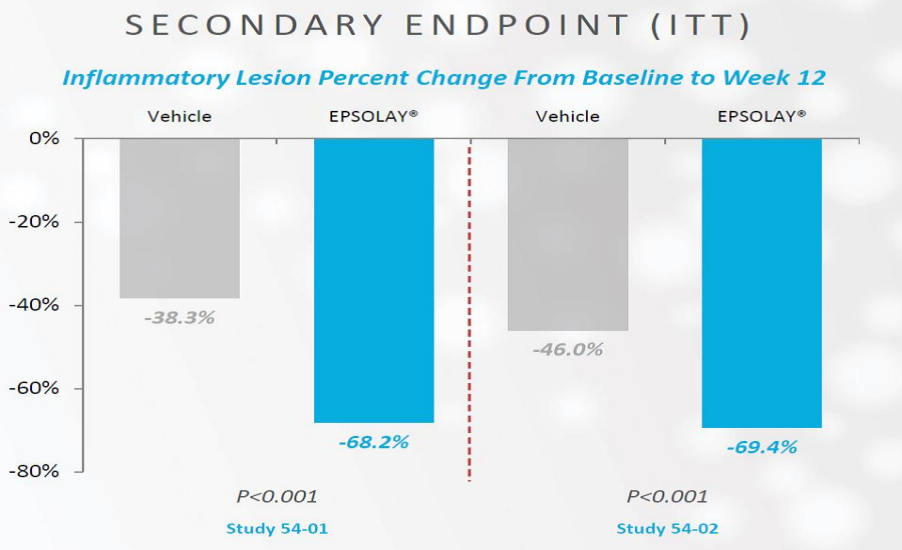
The following chart presents the proportion of subjects in the ITT population in studies SGT 54-01 and SGT 54-02 who achieved a successful improvement in the severity of their disease at week 12, as assessed using the IGA:



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



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



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

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

Long-Term Safety Study Results for Epsolay®

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

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

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

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

SGT-210 for Keratodermas

SGT-210 that we are developing for the treatment of keratoderma, such as PPK, 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, including PPK. 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 profile

SGT-210, SGT-310 and SGT-510 potentially for psoriasis and other medical conditions

We are conducting pre-clinical testing to explore the possible activity of SGT-210, SGT-310, and SGT-510 in various new pharmaceutical indications. Approximately 25 provisional patent applications for these project candidates have been submitted to date, including patent applications covering the use of tapinarof in ophthalmic disorders such as dry eye, uveitis, and blepharitis with or without demodex involvement.

Generic Drug Product Candidates

In addition to our investigational product candidates, we are also currently developing a portfolio of two generic topical dermatological related to four generic drug candidates 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 products. 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 November 1, 2021, we are to unconditionally receive $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 two collaboration agreements with Padagis for the development, manufacturing and commercialization of two generic product candidates. Under such agreements, Padagis will conduct the regulatory (if relevant), scientific, clinical and technical activities necessary to develop the generic product candidates and seek regulatory approval with the FDA for the generic product candidates. If approved by the FDA, Padagis has agreed to commercialize the generic product candidates in the United States. We and Padagis will share the development costs and the gross profits generated from the sales of the generic product candidates, 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 Twyneo®, Epsolay® and our other investigational product candidates, SGT-210, SGT-310, SGT-510 . We seek to protect our intellectual property, core technologies and other know-how, through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others.

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

Our patent portfolio that is directed to Twyneo® Epsolay® and our other investigational product candidates includes 144 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 144 patents and patent applications, 78 are granted patents (11 in the United States and 67 in other countries) and 66 are pending applications (32 in the United States and 34 in other countries).

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

For Epsolay®, we have obtained patents in China, Canada, Japan, Europe, Mexico and the United States (with a term until 2032) covering the composition for topical treatment of rosacea. We have further pending applications for this composition in the United States. 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, Europe (validated in France, Germany, Ireland, Italy, Spain, Switzerland and the United Kingdom) and Japan (with a term until 2028) and pending applications in the United States; and the second patent family has patents granted in Canada, China, Israel, India, Mexico and the United States). We also have 2 granted patents in the United States (with a term until 2040) and 14 patent applications pending covering the methods of use of Epsolay® for the treatment of rosacea.

We have one published international application and 3 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.

For SGT-210, we have 16 pending applications in China, Canada, Japan, Korea, Europe, Mexico and the United States, the refer to methods and compositions of use.

For SGT-310, we have 15 pending applications in China, Canada, Japan, Korea, Europe, Mexico and the United States, that refer to compositions per se, compositions for use, methods of treatments, regimens and kits.

For SGT-510, we have nine pending applications in China, Canada, Japan, Korea, Europe, Mexico and the United States, that refer to refer to compositions per se, dosage forms, methods of treatment, and regimens.

Competition

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

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

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

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

Twyneo® and Epsolay® target the well-established acne and rosacea markets. We expect Twyneo®, and if approved by the FDA, Epsolay®, to compete with current standard-of-care treatments, whether branded, generic or over-the-counter, as well as with new treatments to be approved in the future. The current standard-of-care for acne includes topical anti-bacterial drugs such as benzoyl peroxide that are broadly available over-the-counter, prescription drug products that are based on single retinoid drug products such as Differin, Atralin, Retin-A, Retin-A Micro, Tazorac and Altreno, fixed-dose combinations of benzoyl peroxide and adapalene such as Epiduo and Epiduo Forte, fixed-dose combinations of benzoyl peroxide and clindamycin such as Duac, Benzaclin, Onexton and Acanya, fixed-dose combinations of tretinoin and clindamycin such as Ziana and Veltin, 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 the recently launched Zilxi, as well as oral Oracea (doxycycline embedded in a technology platform). As a fixed-dose combination product candidate, Twyneo® may also compete with drug products utilizing other technologies that can separate two drug substances, such as dual chamber tubes, dual pouches or dual sachets. In addition to these products, our 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, if approved by the FDA, Epsolay®. Pursuant to the agreement, we are entitled to consideration of up to $11 million in upfront payments to us 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 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 other 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 contract manufacturing organizations, or CMOs, or on in-house manufacturing capabilities. As of August 2018, our in-house manufacturing operations have been audited for current good manufacturing, or cGMP, compliance, and were granted a cGMP certification by the Israel Ministry of Health. This certification allowed us to manufacture Twyneo® and its intermediates to support Phase 3 clinical trials. This cGMP certification expired in 2020, and since no other manufacturing for Phase 3 clinical trials is planned at the Company during 2021, the Company and the Israel Ministry of Health have mutually concluded that the cGMP certification will be reassessed and renewed for other products as they reach relevant stages of development. ISO 14001:2015 and ISO 45001:2018certifications continue to be maintained and are due for renewal in May 2024 and March 2021, respectively. For commercial manufacturing of our products, we intend to rely solely on CMOs. It is our policy to have multiple or alternative sources where possible for every service and material we use in our products.

Government Regulation

Regulation by governmental authorities in Israel, the United States and other countries is a significant factor in the development, manufacture and commercialization of our product candidates and in our ongoing research and development activities. Our business is subject to extensive government regulation in Israel for its manufacturing activities involving drug products, drug product intermediates, and drug product active substances to be used in Phase 1 and Phase 2 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.

Unlike NDA products which must be shown to be safe and effective for their intended use, ANDA products must be shown to be the same as, and bioequivalent to, a reference listed drug, or RLD. 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

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

Healthcare Reform

In March 2010, the President of the United States signed the 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. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or 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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, 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. For example, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation. 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®, and if approved by the FDA, Epsolay®.

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 product candidates, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our product candidates, and the sale and marketing of our product candidates, are subject to scrutiny under this law. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

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

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

The Affordable Care Act imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain 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.

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

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

Data Privacy and Security 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 government of Israel through the IIA, for the financing of a portion of our research and development expenditures in Israel.

Under the Innovation Law and the IIA's rules and guidelines, recipients of grants, or Recipient Company(ies), are subject to certain obligations and restrictions with respect to the use of their IIA Funded Know-How, including, the following:

- **Royalty Payment Obligation**. In general, the Recipient Company is obligated to pay the IIA royalties from the revenues generated from the sale of products (and related 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 based on LIBOR (as determined in the IIA's rules and guidelines);

- **Reporting Obligations**. The Innovation Law and the IIA's rules and guidelines impose on the Recipient Company 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);

- **Local Manufacturing Obligation**. Products developed using the IIA grants must, as a general matter, be manufactured in Israel. The Recipient Company is prohibited from manufacturing products developed using these IIA grants outside of the State of Israel without receiving prior approval from the IIA (except for the transfer of less than 10% of the manufacturing capacity in the aggregate which requires only a notice, while the IIA has a right to deny such transfer within 30 days following the receipt of such notice). If the Recipient Company receives approval to manufacture products developed with IIA grants outside of Israel, it will be required (except for certain cases) to pay increased royalties to the IIA, up to 300% of the grant amount plus interest at annual rate based on LIBOR, depending on the manufacturing volume that is performed outside of Israel. The Recipient Company may also be subject to an accelerated royalty repayment rate. A Recipient Company also has the option of declaring in its IIA grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval following the receipt of the grant and avoiding the need to pay increased royalties to the IIA; and

- **IIA Funded Know-How transfer limitation**. Under the Innovation law and the IIA's rules and guidelines, a Recipient Company is prohibited from transferring the IIA Funded Know-How outside of Israel except under limited circumstances, and only 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 interest). The scope of the support received, the royalties that have already paid to the IIA, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which the IIA grants were received and the sale price and the form of transaction will be taken into account in calculating the amount of the payment to the IIA in the event of a transfer of IIA Funded Know-How outside of Israel. A transfer for the purpose of the Innovation Law and the IIA rules means an actual sale of the IIA-funded know-how, or any other transaction which in essence constitutes a transfer of the know-how (such as providing an exclusive license to a foreign entity for R&D purposes, which precludes the IIA funded 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. Upon payment of such redemption fee, the IIA Funded Know-How and the manufacturing rights of the products supported by such IIA funding cease to be subject to the Innovation Law.

  Subject to the IIA's prior approval, a grant recipient may transfer IIA Funded Know-How to another Israeli company. If IIA Funded Know-How is transferred to another Israeli entity, the transfer would still require IIA approval but will not be subject to the payment of the redemption fee (we note that there will be an obligation to pay royalties to the IIA from the income of such sale transaction as part of the royalty payment obligation). In such case, the acquiring company would have to assume all of the selling company's responsibilities towards the IIA as a condition to IIA approval.

- **IIA Funded Know-How license limitation**. The IIA has published certain rules and guidelines with respect to the grant to a foreign entity of the right to use the IIA Funded Know-How for R&D purposes. According to these rules, the grant to a foreign entity of a right to use the IIA Funded Know-How (which does not entirely prevent the IIA funded company from using the Funded Know-How) is subject to receipt of the IIA's prior approval. This approval is subject to payment to the IIA in accordance with the formulas stipulated in these rules (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 rules and will generally be due only upon the receipt of the license fee from the licensee).

  The abovementioned rules 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 restrictions 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. Such restrictions continue to apply even after payment of the full amount of royalties payable pursuant to the grants.

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

The government of Israel does not own intellectual property rights in technology developed with IIA funding and there is no restriction on the export of products manufactured using technology developed with IIA funding. However, the IIA Funded Know-How is subject to transfer of know-how and manufacturing rights restrictions as described above. The IIA's approval is not required for the export of any products resulting from the IIA research or development grants.

We may not receive from the IIA the required approvals for any actual proposed transfer and, if received, we may be required to pay the IIA certain payments calculated according to formulas provided under the IIA's rules and guidelines.

Environmental, Health and Safety Matters

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

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

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

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

Properties

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

Legal Proceedings

We are not subject to any material legal proceedings.

C. Organizational Structure

Not applicable.

D. Property, Plant and Equipment

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

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

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

Overview

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

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

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

On February 12, 2020, we announced positive topline results from our open-label, long-term safety study, evaluating Epsolay® for a treatment duration up to 52 weeks. The study enrolled 547 subjects, all of whom had completed 12 weeks of treatment with Epsolay® or vehicle in the preceding double-blind Phase 3 studies. Patients continued onto open-label treatment with Epsolay once-daily for up to an additional 40 weeks. The safety population of 535 subjects received Epsolay® therapy for an overall period of at least 28 weeks. Of these 535 subjects, 209 subjects completed 52 weeks of treatment with Epsolay®, exceeding the sample size requirements previously defined by the FDA for the Epsolay® one-year safety evaluation. Our NDA for Epsolay® has been accepted for filing by the FDA, which originally assigned a PDUFA goal date of April 26, 2021, which has since been delayed due to COVID-19 related travel restrictions. The FDA conducted a pre-approval inspection of the production site for Epsolay® on February 14, 2022.

Our other investigational product candidates are SGT-210 that we are developing for the treatment of keratoderma, SGT-310 and SGT-510, each a potential treatment of various pharmaceutical indications.

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

In 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, if approved by the FDA, Epsolay®. Pursuant to the agreement, we are entitled to consideration of up to $11 million in upfront payments to us 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 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 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 related to four generic drug candidates. Under the terms of the agreement with Padagis, effective as of November 1, 2021, we are to unconditionally receive $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 agreements, the rights of which were sold to Padagis.

Since our inception, we have incurred significant operating losses. We incurred net losses of $24.6 million and $29.3 million for the years ended December 31, 2019, 2020 and we generated a net profit of $3.2 million for the year ended December 31, 2021, respectively. As of December 31, 2021, we had an accumulated deficit of $178.1 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates from formulation development through pre-clinical development and clinical trials, seek regulatory approval and pursue commercialization of any approved product candidate. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates.

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

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

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

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

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 year ended December 31, 2019 the Company recognized revenues from royalties related to sales of one of the products from this collaboration in the amount of $22.9 million. During the year ended December 31, 2020 the Company recognized revenues from royalties related to sales of one of the products from this collaboration in the amount of $8.7 million. During the year ended December 31, 2021, we generated a total of $31.3 million in revenue, out of which $20.4 million were generated from the sale to Padagis of 10 generic collaborative programs, $3.3 million were generated from our collaboration agreements with Perrigo, with respect to products the rights for which were later sold to Padagis, and $7.5 million were generated from our collaboration agreement with Galderma.

Operating expenses

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

Research and development expenses

Research and development expenses consist principally of:

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

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

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

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

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of the 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,		
	2019	2020	2021
	(in thousands)		
Collaboration Revenues	$ 22,904	$ 8,771	$ 23,772
License Revenues			7,500
Total Revenues	$ 22,904	$ 8,771	31,272
Research and development	40,578	27,913	20,381
General and administrative	8,276	11,091	8,451
OTHER INCOME, net	-	-	524
Total operating income (loss)	(25,950)	(30,233)	2,964
Financial income, net	1,374	943	257
Income (Loss) before income taxes	(24,576)	(29,290)	3,221
Income taxes	33		-
Income (loss) for the year	$ (24,609)	$ (29,290)	$ 3,221

Year ended December 31, 2020 compared to year ended December 31, 2021

Collaboration Revenues

We generated a total of $31.3 million in revenue in 2021, out of which $20.4 million were generated from the sale to Padagis of 10 generic collaborative programs, $3.3 million were generated from our collaboration agreements with Perrigo, with respect to products the rights for which were later sold to Padagis, and $7.5 million were generated from our collaboration agreement with Galderma compared with $8.7 million in 2020. The increase in revenues in 2021 resulted mainly from entering into new agreements.

Research and development expenses

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

	Year Ended December 31,	
	2020	2021
	(in thousands)	
Payroll and related expenses	$ 6,194	$ 5,614
Clinical and preclinical trials expenses	5,526	715
Professional consulting and subcontracted work	12,508	10,776
Other	3,685	3,276
Total research and development expenses	$ 27,913	$ 20,381

Our research and development expenses were $27.9 million for the year ended December 31, 2020 compared to $20.4 million for the year ended December 31, 2021. The decrease of $7.5 million was mainly attributed to a decrease of $4.8 million in clinical trial expenses, mainly related to mainly related to the completion of the clinical trials of Epsolay and Twyneo, a decrease of $0.6 million in payroll and related expenses mainly related to share based compensation expenses.

General and administrative expenses

Our general and administrative expenses were $11.1 million for the year ended December 31, 2020, compared to $8.5 million for the year ended December 31, 2021. The decrease of $2.6 million was mainly attributed to a decrease of $3.0 million in commercialization expenses.

Financial income, net

Our financial income, net, was $0.9 million for the year ended December 31, 2020 compared to $0.3 million for the year ended December 31, 2021.

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

This analysis can be found in Item 5 of the Company's Annual Report on Form 20-F for the year ended December 31, 2020.

JOBS Act

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

B. Liquidity and Capital Resources

Overview

Since our inception, we have devoted substantially all of our resources to developing our product candidates, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing for general and administrative support for these operations. Other than Twyneo®, we do not currently have any approved products.

From inception through December 31, 2021, we have funded our operations primarily through proceeds from our public offerings, the issuance of equity securities to and loans and investments from our controlling shareholder, funding received from the IIA and from amounts received pursuant to past and current collaboration agreements. We automatically converted our outstanding promissory note between us and our controlling shareholder into an aggregate of 5,444,825 ordinary shares immediately prior to the closing of our initial public offering. For a description of the conversion of our shareholder loan agreement, see "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions — Loan Agreements with Our Controlling Shareholder." As of December 31, 2021, our cash and cash equivalents, bank deposits and marketable securities were $43.2 million.

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

From the effective date of the agreement through the issuance date of this report, 41,154 shares were sold under the program for total gross proceeds of approximately $0.5 million, leaving an available balance under the facility of approximately $24.5 million as of the issuance date of this report.

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

	Year Ended December 31,		
	2019	2020	2021
	(in thousands)		
Net cash used in operating activities	$ (22,500)	$ (25,241)	$ (7,691)
Net cash provided by (used in) investing activities	16,024	(2,694)	19,872
Net cash provided by financing activities	10,613	26,457	837
Increase (decrease) in cash and cash equivalents	$ 4,137	$ (1,478)	$ 12,908

Operating Activities

Net cash used in operating activities was $25.2 million during the year ended December 31, 2020 compared to $7.7 million during the year ended December 31, 2021.

Net cash used in operating activities in the year ended December 31, 2021 primarily resulted from our income of $3.2 million during the period, $12.5 million of net changes in working capital and non-cash expenses of $0.7 million share-based compensation expenses and $0.9 million of depreciation of property and equipment.

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

Investing Activities

Net cash used in investing activities was $2.7 million during the year ended December 31, 2020, compared to net cash provided by investing activities of $19.9 million during the year ended December 31, 2021. The 2020 net cash used in investing activities resulted mainly from $19.2 million proceeds from marketable securities, net, offset by investment of $0.5 million in property and equipment and investment of $21.4 million in bank deposits. The 2021 net cash provided by investing activities resulted mainly from $20.1 million proceeds from marketable securities, net.

Financing Activities

Net cash from financing activities was $26.4 million during the year ended December 31, 2020, compared to $0.8 million during the year ended December 31, 2021. The decrease was principally due to our underwritten public offering and private placement in 2020, net of issuance cost, of $26.3 million.

Funding Requirements

Our primary uses of cash have been to fund working capital requirements and research and development. We expect to continue to incur net losses for the foreseeable future as we continue to invest in research and development and seek to obtain regulatory approval for and commercialize our product candidates. We believe that our existing cash resources will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least until the end of 2023, assuming the timely approval of Epsolay®. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our ability to continue as a going concern will depend on our ability to generate positive cash flow from operations and obtain additional financing, both of which are uncertain.

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

- the progress and expenses of our pre-clinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;

- the expenses and timing of obtaining regulatory approval, if any, for our product candidates;
- the expenses of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; 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® with an anticipated launch during the spring of 2022, and, if approved, 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 one or more of our product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. In addition, the terms of any securities we issue in future financings may be more favorable to new investors and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding. If we raise additional funds through collaborations with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to obtain adequate funds on reasonable terms, we will need to curtail operations significantly, including possibly postponing anticipated clinical trials or entering into financing agreements with unattractive terms.

C. Research and Development, Patents and Licenses

For a description of our research and development programs and the amounts that we have incurred over the last two years pursuant to those programs, please see "Item 5. Operating and Financial Review and Prospects — A. Operating Results — Research and Development Expenses"; and "Item 5. Operating and Financial Review and Prospects — A. Operating Results — Year Ended December 31, 2020 compared to Year ended December 31, 2021 - 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, 2021 to December 31, 2021 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, 2021, included elsewhere in this annual report. We believe that the accounting policies and estimates below are critical in order to fully understand and evaluate our financial condition and results of operations. In preparing these consolidated financial statements, our management has made estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods recognized in our financial statements. Actual results may differ from these estimates. As applicable to the consolidated financial statements included in this annual report, the most significant estimates and assumptions relate to the fair value of share-based compensation.

Share-based Compensation

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

Options Valuation

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

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

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	69	Executive Chairman of the Board of Directors
Alon Seri-Levy	60	Chief Executive Officer and Director
Gilad Mamlok	53	Chief Financial Officer
Ofer Toledano	57	Vice President Research and Development
Ofra Levy-Hacham	56	Vice President Clinical and Regulatory Affairs
Karine Neimann	50	Vice President Projects and Planning, Chief Chemist
Itzik Yosef	45	Vice President Operations
Dov Zamir	69	Vice President Special Projects
Nissim Bilman	60	Vice President Quality
Itai Arkin	33	Director
Shmuel Ben Zvi	62	Independent Director
Hani Lerman	49	Director
Yaffa Krindel-Sieradzki	67	Independent Director
Jonathan B. Siegel	48	Independent Director
Ran Gottfried	77	Independent External Director and Lead Independent Director
Jerrold S. Gattegno	69	External and 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 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 Exalenz Bioscience Ltd., a developer of advanced systems for gastrointestinal and liver disorders since 2006, SoniVie Ltd., a company developing systems for the treatment of pulmonary arterial hypertension, Digma Medical, a company developing systems to treat insulin resistance present in type 2 diabetes and other metabolic syndrome diseases, and Valcare Medical, a company developing heart valve devices. From 2005 to 2008, Mr. Moshe Arkin served as the head of generics at Perrigo Company and from 2005 until 2011 as the vice chairman of its board of directors. Prior to joining us, Mr. Moshe Arkin served as a director of cCAM Biotherapeutics Ltd., a company focused on the discovery and development of novel immunotherapies to treat cancer from 2012 until its acquisition in 2015 by Merck & Co., Inc. Mr. Moshe Arkin served as chairman of Agis Industries Ltd. from its inception in 1972 until its acquisition by Perrigo Company in 2005. Mr. Moshe Arkin holds a B.A. in psychology from the Tel Aviv University, Israel.

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

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

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

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

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

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

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

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

Mr. 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.

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

Ms. Hani Lerman became a member of our board of directors immediately following pricing of our initial public offering. Ms. Lerman has served as chief financial officer at Arkin Holdings since 2015. From 2010 until 2014, Ms. Lerman served as chief financial officer of Sansa Security (f/k/a Discretix Technologies), and from 2006 until 2010, she served as chief financial officer of Storwize, which was acquired by IBM in 2010. She 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.

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

Jonathan B. Siegel became a member of our board of directors on September 13, 2018. Mr. Siegel is the founder and CEO of JBS Healthcare Ventures since formation in 2017. In June 2021, he also assumed the role of CEO and Chairman of the board of OPY Acquisition Corp. I, a public Nasdaq-listed company. Previously, he was a partner and healthcare sector head at Kingdon Capital Management from 2011 until 2017. Prior to joining Kingdon, Mr. Siegel was a healthcare portfolio manager at SAC Capital Advisors from 2005 until 2011; an associate director of pharmaceutical and specialty pharmaceutical research at Bear, Stearns & Co.; a pharmaceuticals research associate at Dresdner Kleinwort Wasserstein; and a consultant to the Life Sciences Division of Computer Sciences Corporation. Mr. Siegel has worked as a research associate at the Novartis Center for Immunobiology at Harvard Medical School and as a research assistant at Tufts University School of Medicine. He is also a director at Jaguar Health, Inc., a Nasdaq listed company, and has served on the board of advisors of Vitalis LLC, a private pharmaceutical company, since March 2019 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 is currently a board member and member of the audit and investment, technology and innovation and risk management committees at Shufersal Ltd.

Mr. Jerrold S. Gattegno became a member of our board of directors immediately following the pricing of our initial public offering and serves as an external director under the Companies Law. Mr. Gattegno worked in the New York, Washington D.C. and London offices of Deloitte Touche Tohmatsu Limited, a public accounting firm, from 1973 until 2015, where he served in various senior positions, including as 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.

B. Compensation

The aggregate compensation paid by us to our executive officers and directors for the year ended December 31, 2021 was approximately $3.4 million. This amount includes approximately $0.4 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to officers, and other benefits commonly reimbursed or paid by companies in Israel.

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2021. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2021.

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 2021 monthly average representative U.S. dollar – NIS rate of exchange)					
Alon Seri-Levy / CEO	334	65	72	168	640
Gilad Mamlok / CFO	279	58	15	132	484
Ofer Toledano / VP R&D	219	60	13	95	387
Ofra Levy-Hacham / VP Clinical & RA	162	48	10	66	286
John Vieira / U.S. Head of Commercialization(5)	210	54	(51)	68	281

(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 2021.

(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 2021 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 2019, 2020 and 2021 special bonuses that officers received.

(5) John Viera has ceased being an employee of the Company as of November 2021.

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

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

In addition, 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, and 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.

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

Compensation Policy

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

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

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

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

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

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

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

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

C. Board Practices

Appointment of Directors and Terms of Officers

Our board of directors consists of eight directors, including two external directors, and appointment fulfills the requirements of the Companies Law for the company to have two external directors (see " Item 6. Directors, Senior Management and Employees - C. Board Practices – External Directors"). These two directors, as well as three additional directors, qualify as independent directors under the corporate governance standards of the Nasdaq corporate governance rules and the independence requirements of Rule 10A-3 of the Exchange Act.

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

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

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

- Class I directors consist of Ms. Yaffa Krindel-Sieradzki, Dr. Shmuel Ben Zvi and Mr. Jonathan B. Siegel, who are all independent directors, and their term will expire at our annual general meeting of our shareholders to be held in 2022;
- Class II directors consist of Ms. Hani Lerman and Dr. Alon Seri-Levy, and their term will expire at our annual general meeting of our shareholders to be held in 2023; and
- Class III directors consist of Mr. Itai Arkin and Mr. Moshe Arkin, and their term will expire at our annual general meeting of our shareholders to be held in 2024.

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

Under our amended and restated articles of association, our board of directors may elect new directors if the number of directors is below the maximum provided therein. External directors are elected for an initial term of three years and may be elected for up to two additional three-year terms (or more) under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Companies Law. See "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, Shmuel Ben Zvi and Yaffa Krindel-Sieradzki. Jerrold S. Gattegno serves as Chairman of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq corporate governance rules. Our board of directors has determined that Jerrold S. Gattegno is an audit committee financial expert as defined by SEC rules and has the requisite financial experience as defined by the Nasdaq corporate governance rules.

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

Approval of Transactions with Related Parties

The approval of the audit committee is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. See "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, Shmuel Ben Zvi and Jonathan B. Siegel, assists the board of directors in determining compensation for our directors and officers. Ran Gottfried serves as Chairman of the committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard supervisory board member fees. Although foreign private issuers are not required to meet this heightened standard, our board of directors has determined that all of our expected compensation committee members meet this heightened standard.

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

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

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

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

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

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

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

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

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

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

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

The compensation policy must also include, among others:

- with regards to variable components:
  - with the exception of office holders who report directly to the chief executive officer, determining the variable components on long-term performance basis and on measurable criteria; however, the company may determine that an immaterial part of the variable components of the compensation package of an office holder's shall be awarded based on non-measurable criteria, if such amount is not higher than three monthly salaries per annum, while taking into account such office holder contribution to the company;
  - the ratio between variable and fixed components, as well as the limit of the values of variable components at the time of their grant.

- a condition under which the office holder will return to the company, according to conditions to be set forth in the compensation policy, any amounts paid as part of his or her terms of employment, if such amounts were paid based on information later to be discovered to be wrong, and such information was restated in the company's financial statements;

- the minimum holding or vesting period of variable equity-based components to be set in the terms of office or employment, as applicable, while taking into consideration long-term incentives; and

- a limit to retirement grants.

Corporate Governance Practices

Internal Auditor

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

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

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

Fiduciary Duties of Office Holders

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

- information on the business advisability of a given action brought for his or her approval or performed by virtue of his or her position; and

- all other important information pertaining to such action.

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

- refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;

- refrain from any activity that is competitive with the business of the company;

- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and

- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

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

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

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

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

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

- a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or
- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than two percent (2%) of the voting rights in the company.

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

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

Disclosure of Compensation of Executive Officers

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

Compensation of Directors and Executive Officers

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

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

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

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

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

Duties of Shareholders

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

- an amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

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

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

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

Approval of Private Placements

Under the Companies Law and the regulations promulgated thereunder, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in special circumstances, such as a private placement which is intended to obviate the need to conduct a special tender offer (see "Item 10. Additional Information— Memorandum of Association – Acquisitions under Israeli Law") or a private placement which qualifies as a related party transaction (see "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, 2021, we had 53 employees, all of whom are located in Israel.

	As of December 31,					
	2019		2020		2021	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management	9		9		9	
Research and development and other	52		56		44	

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 February 26, 2021, we had an aggregate of 929,415 ordinary shares available for issuance under the Plan (including ordinary shares underlying outstanding options and restricted share units).

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

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

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

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

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

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

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

Any equity award to an office holder, director or controlling shareholder, whether under the Plan or otherwise, may be subject to further approvals in addition to the approval of the compensation committee as described above. As of December 31, 2021, options to purchase 1,329,604 ordinary shares, at a weighted average exercise price of 5.95 per share, were outstanding under our Plan.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 1, 2022 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, 2022, if any, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ordinary shares beneficially owned is based on 23,127,669ordinary shares outstanding as of March 1, 2022.

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

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

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

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percentage**
5% or greater shareholders		
M. Arkin Dermatology Ltd. (1)	14,432,266	62.40%
Migdal Insurance & Financial Holdings Ltd.(2)	1,239,103	5.36%
Phoenix Holdings Ltd. (3)	2,574,922	11.13%
Directors and executive officers		
Moshe Arkin (1)	14,518,266	62.77%
Alon Seri-Levy (4)	322,202	1.39%
Gilad Mamlok	*	*
Ofer Toledano	*	*
Ofra Levy-Hacham	*	*
Karine Neimann	*	*
Itzik Yosef	*	*
Dubi Zamir	*	*
Nissim Bilman	*	*
Itai Arkin	*	*
Ran Gottfried	*	*
Jerrold S. Gattegno	*	*
Shmuel Ben Zvi	*	*
Hani Lerman	*	*
Yaffa Krindel Sieradzki	*	*
Jonathan Siegel	*	*
All directors and executive officers as a group (17 persons)	15,376,420	66.51%

* Less than 1%.

(1) Based on the Schedule 13D/A filed with the SEC on April 20, 2021, Arkin Dermatology directly owns 14,432,266 ordinary shares. Mr. Moshe Arkin, the chairman of our board of directors, is the sole shareholder and sole director of Arkin Dermatology and may therefore be deemed to be the indirect beneficial owner of the ordinary shares owned directly by Arkin Dermatology. In addition, Mr. Moshe Arkin directly owns 86,000 ordinary shares.

(2) Based on the Schedule 13G/A filed with the SEC on February 2, 2022, 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 11, 2021, the ordinary shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holding Ltd., or the Subsidiaries. The Subsidiaries manage their own funds and/or the funds of others, including for holders of exchange-traded notes or various insurance policies, members of pension or provident funds, unit holders of mutual funds, and portfolio management clients. Each of the Subsidiaries operates under independent management and makes its own independent voting and investment decisions.

(4) Consists of options to purchase 285,188 ordinary shares exercisable within 60 days of March 1, 2022. The exercise price of these options ranges between $1.59 and $11.21 per share and the options expire between March 2025 and May 2028.

Record Holders

As of March 1, 2022, 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, 12,189,697 ordinary shares, representing approximately 52% of the outstanding ordinary shares as of March 1, 2022. The number of record holders in the United States is not representative of the number of beneficial holders nor is it representative of where such beneficial holders are resident since many of these ordinary shares were held by brokers or other nominees.

B. Related Party Transactions

Private Placement with Our Controlling Shareholder

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

Directors and Officers Insurance Policy and Indemnification Agreements

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

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

Registration Rights Agreement

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

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Financial Statements and Other Financial Information

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

Legal Proceedings

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

Dividend Policy

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

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

B. Significant Changes

Except as otherwise disclosed in this annual report, no significant change has occurred since December 31, 2021.

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 April 1, 2022, the last reported closing price of our Ordinary Shares on The Nasdaq Global Market was $7.24 per share.

B. Plan of Distribution

Not applicable.

C. Markets

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

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Registration Number and Purposes of the Company

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

Voting Rights and Conversion

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

Transfer of Shares

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

Liability to Further Capital Calls

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

Election of Directors

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

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

Dividend and Liquidation Rights

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

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

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

Shareholder Meetings

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

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

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

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

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

Voting Rights

Quorum Requirements

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

Vote Requirements

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

Access to Corporate Records

Under the Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our amended and restated articles of association, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting, as set forth in our amended and restated articles of association.

Registration Rights

For a discussion of registration rights we granted to our controlling shareholder in connection with the closing of our initial public offering, please see "Item 7. Major Shareholders and Related Party Transactions – Related Party Transactions — Registration Rights Agreement."

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (a) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser and its controlling shareholder, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any other person acting on their behalf, including relatives and entities under such person's control). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Under the DGCL there are no provisions relating to mandatory tender offers.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described under "Management — Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Transactions").

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value to the parties to the merger and the consideration offered to the shareholders of the company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Anti-Takeover Measures under Israeli Law

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. As of the date of this annual report, no preferred shares are authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "— Voting Rights."

As an Israeli company we are not subject to the provisions of Section 203 of the DGCL, which in general prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior did own, 15% or more of the voting stock of a corporation.

Borrowing Powers

Pursuant to the Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Capital

Our amended and restated articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly adopted by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

Transfer Agent and Registrar

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

C. Material Contracts

For a description of other material agreements, please see "Item 4. Information on the Company – B. Business Overview."

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of certain countries that are considered to be in a state of war with Israel at such time.

E. Taxation

Israeli Tax Considerations and Government Programs

General

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax at the rate of 23% in 2022. However, the effective tax rate payable by a company that derives income from a Benefited Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate.

Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as a company resident in Israel and which was incorporated in Israel of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it and which is located in Israel. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise;
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

Although as of the date of this annual report, we do not have industrial production activities, we may qualify as an Industrial Company in the future and may be eligible for the benefits described above.

Tax Benefits and Grants for Research and Development

Israeli tax law allows, under certain conditions, a tax deduction for expenditures, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research;
- The research and development must be for the promotion of the company; and
- The research and development are carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the financing of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Israeli Tax Ordinance, 1961. Expenditures not so approved are deductible in equal amounts over three years.

From time to time we may apply to the IIA for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets) by "Industrial Enterprises" (as defined under the Investment Law).

Tax Benefits Prior to the 2005 Amendment

An investment program that is implemented in accordance with the provisions of the Investment Law prior to an amendment that became effective in April 2005, or the 2005 Amendment, referred to as an "Approved Enterprise," is entitled to certain benefits. A company that wished to receive benefits as an Approved Enterprise must have received approval from the Investment Center of the Israeli Ministry of Economy and Industry, or the Investment Center. Each certificate of approval for an Approved Enterprise relates to a specific investment program in the Approved Enterprise, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

In general, an Approved Enterprise is entitled to receive a grant from the Government of Israel or an alternative package of tax benefits, known as the alternative benefits track. The tax benefits from any certificate of approval relate only to taxable profits attributable to the specific Approved Enterprise. Income derived from activity that is not integral to the activity of the Approved Enterprise does not enjoy tax benefits.

In addition, a company that has an Approved Enterprise program is eligible for further tax benefits if it qualifies as a Foreign Investors' Company, or FIC, which is a company with a level of foreign investment, as defined in the Investment Law, of more than 25%. The level of foreign investment is measured as the percentage of rights in the company (in terms of shares, rights to profits, voting and appointment of directors), and of combined share and loan capital, that are owned, directly or indirectly, by persons who are not residents of Israel. The determination as to whether a company qualifies as an FIC is made on an annual basis. We are currently not entitled to tax benefits for Approved Enterprise.

Tax Benefits Subsequent to the 2005 Amendment

The 2005 Amendment applies to new investment programs and investment programs commencing after 2004, but does not apply to investment programs approved prior to April 1, 2005. The 2005 Amendment provides that terms and benefits included in any certificate of approval that was granted before the 2005 Amendment became effective (April 1, 2005) will remain subject to the provisions of the Investment Law as in effect on the date of such approval. Pursuant to the 2005 Amendment, the Investment Center will continue to grant Approved Enterprise status to qualifying investments. The 2005 Amendment, however, limits the scope of enterprises that may be approved by the Investment Center by setting criteria for the approval of a facility as an Approved Enterprise, such as provisions generally requiring that at least 25% of the Approved Enterprise's income be derived from exports.

The 2005 Amendment provides that Approved Enterprise status will only be necessary for receiving cash grants. As a result, it was no longer necessary for a company to obtain Approved Enterprise status in order to receive the tax benefits previously available under the alternative benefits track. Rather, a company may claim the tax benefits offered by the Investment Law directly in its tax returns, provided that its facilities meet the criteria for tax benefits set forth in the amendment. Companies are entitled to approach the Israeli Tax Authority for a pre-ruling regarding their eligibility for benefits under the Investment Law, as amended.

In order to receive the tax benefits, the 2005 Amendment states that a company must make an investment which meets all of the conditions, including exceeding a minimum investment amount specified in the Investment Law. Such investment allows a company to receive "Benefited Enterprise" status, and may be made over a period of no more than three years from the end of the year in which the company requested to have the tax benefits apply to its Benefited Enterprise. Where the company requests to apply the tax benefits to an expansion of existing facilities, only the expansion will be considered to be a Benefited Enterprise and the company's effective tax rate will be the weighted average of the applicable rates. In this case, the minimum investment required in order to qualify as a Benefited Enterprise is required to exceed a certain percentage of the value of the company's production assets before the expansion.

The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Benefited Enterprise depend on, among other things, the geographic location in Israel of the Benefited Enterprise. The location will also determine the period for which tax benefits are available. Such tax benefits include an exemption from corporate tax on undistributed income for a period of between two to 10 years, depending on the geographic location of the Benefited Enterprise in Israel, and a reduced corporate tax rate of between 10% and the applicable corporate tax for the remainder of the benefits period, depending on the level of foreign investment in the company in each year. A company qualifying for tax benefits under the 2005 Amendment which pays a dividend out of income derived by its Benefited Enterprise during the tax exemption period will be subject to corporate tax in respect of the gross amount of the dividend at the otherwise applicable corporate tax rate or a lower rate in the case of a qualified FIC which is at least 49% owned by non-Israeli residents. Dividends paid out of income attributed to a Benefited Enterprise are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty.

The benefits available to a Benefited Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations. If a company does not meet these conditions, it may be required to refund the amount of tax benefits, as adjusted by the Israeli consumer price index, and interest, or other monetary penalties.

We applied for tax benefits as a "Benefited Enterprise" with 2012 as a "Year of Election." We may be entitled to tax benefits under this regime once we are profitable for tax purposes and subject to the fulfillment of all the relevant conditions. If we do not meet these conditions, the tax benefits may not be applicable which would result in adverse tax consequences to us. Alternatively, and subject to the fulfillment of all the relevant conditions, we may elect in the future to irrevocably waive the tax benefits available for Benefited Enterprise and claim the tax benefits available to Preferred Enterprise under the 2011 Amendment (as detailed below).

Tax Benefits Under the 2011 Amendment

The Investment Law was significantly amended as of January 1, 2011, or the 2011 Amendment. The 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment.

The 2011 Amendment introduced new tax benefits for income generated by a "Preferred Company" through its "Preferred Enterprise," in accordance with the definition of such term in the Investment Law, which generally means that a "Preferred Company" is an industrial company meeting certain conditions (including a minimum threshold of 25% export).

A Preferred Company is entitled to a reduced flat tax rate with respect to the income attributed to the Preferred Enterprise, at the following rates:

Tax Year	Development Region "A"	Other Areas within Israel
2011 – 2012	10%	15%
2013	7%	12.5%
2014 – 2016	9%	16%
2017 and thereafter	7.5%	16%

Dividends distributed from income which is attributed to a "Preferred Enterprise" will be subject to withholding tax at source at the following rates: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 20% in 2020 (iii) non-Israeli residents — may be reduced down to 4% in 2022, subject to certain conditions under the Investment Law and to a reduced tax rate under the provisions of an applicable double tax treaty.

Under the 2011 Amendment, a company located in Development Region "A" may be entitled to cash grants and the provision of loans under certain conditions, if approved. The rates for grants and loans shall not be fixed, but up to 20% of the amount of the approved investment (may be increased by an additional 4%). In addition, a company owning a Preferred Enterprise under the Grant Track may be entitled also to the tax benefits which are prescribed for a Preferred Company.

The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

We are currently not entitled to tax benefits for a Preferred Enterprise.

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 28, 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 technology company satisfying certain conditions will qualify as 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 Technology Company 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 technology company satisfying certain conditions will qualify as 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 2022.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income —23% for corporations in 2020, and a marginal tax rate of up to 50% for individuals, including an excess tax.

Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares by a non-Israeli shareholder may be exempt under the Israeli Tax Ordinance from Israeli capital gain tax provided that the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed. However, non-Israeli corporations will not be entitled to the foregoing exemption if more than 25% of its means of control are held, directly and indirectly, by Israeli residents, and Israeli residents are entitled to 25% or more of the revenues or profits of the corporation, directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the U.S.-Israel Double Tax Treaty exempts U.S. residents from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding of Israeli tax at source at a rate of 25% if the seller is an individual and at the corporate tax rate (23% in 2022) if the seller is a corporation. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and July 31 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Tax Ordinance and regulations promulgated thereunder, the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

We have never paid cash dividends. A distribution of a dividend by our company from income attributed to a Benefited Enterprise will generally be subject to withholding tax in Israel at a rate of 20% unless a reduced tax rate is provided under an applicable tax treaty. A distribution of a dividend by our company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals — 20%; Israeli resident companies — 0% for a Preferred Enterprise; Non-Israeli residents — 20%, subject to a reduced rate under the provisions of any applicable double tax treaty. A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to withholding tax at a rate of 25%, or 30% if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will not be subject to Israeli tax provided the income from which such dividend is distributed was derived or accrued within Israel.

The Israeli Tax Ordinance provides that a non-Israeli resident (either individual or corporation) is generally subject to Israeli withholding tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12-month period); those rates may be subject to a reduced rate under the provisions of an applicable double tax treaty. Under the U.S.-Israel Double Tax Treaty, the following withholding rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting share capital of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends — the rate is 12.5%, (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate applicable to an Approved Enterprise — the rate is 15% and (iii) in all other cases, the rate is 25%. The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from a business conducted in Israel by the taxpayer, and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Dividends are generally subject to Israeli withholding tax at a rate of 25% so long as the shares are registered with a nominee company (whether or not the recipient is a "Controlling Shareholder," as defined above), unless relief is provided in a treaty between Israel and the shareholder's country of residence and provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% on annual income exceeding NIS 663,240 for 2022, linked to the annual change in the Israeli consumer price index, including, but not limited to income derived from, dividends, interest and capital gains.

Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated and may be restored at any time by administrative action.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Considerations with respect to the Company

The following discussion describes certain material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in our ordinary shares or warrants. This discussion applies only to U.S. Holders that hold our ordinary shares or warrants as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or (the Code, and that have the U.S. dollar as their functional currency.

This discussion is based on the tax laws of the United States, including the Code, as in effect on the date hereof and on U.S. Treasury regulations as in effect or, in some cases, as proposed, on the date hereof, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below. This summary does not address any estate or gift tax consequences, the alternative minimum tax, the Medicare tax on net investment income or any state, local, or non-U.S. tax consequences. The following discussion neither deals with the tax consequences to any particular investor nor describes all of the tax consequences applicable to persons in special tax situations such as:

- banks;
- certain financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;
- traders that elect to mark to market;
- U.S. expatriates;
- tax-exempt entities;
- persons holding our ordinary shares or warrants as part of a straddle, hedging, constructive sale, conversion or integrated transaction;
- persons that actually or constructively (including through the ownership of our warrants) own 10% or more of our share capital (by vote or value);
- persons that are resident or ordinarily resident in or have a permanent establishment in a jurisdiction outside the United States;
- persons who acquired our ordinary shares or warrants pursuant to the exercise of any employee share option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our ordinary shares or warrants being taken into account in an applicable financial statement; or

- pass-through entities, or persons holding our ordinary shares or warrants through pass-through entities.

INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF AN INVESTMENT IN OUR ORDINARY SHARES OR WARRANTS.

The discussion below of the U.S. federal income tax consequences to "U.S. Holders" will apply to you if you are the beneficial owner of our ordinary shares or warrants and you are, for U.S. federal income tax purposes,

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (i) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity or other arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or warrants, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. A person that would be a U.S. Holder if it held our ordinary shares or warrants directly and that is a partner of a partnership holding our ordinary shares or warrants is urged to consult its own tax advisor.

Passive Foreign Investment Company

A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will generally be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for any taxable year if either:

- at least 75% of its gross income for such year is passive income (such as interest income); or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets) during such year is attributable to assets that produce passive income or are held for the production of passive income.

For this purpose, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other entity treated as a corporation for U.S. federal income tax purposes in which we own, directly or indirectly, 25% or more (by value) of the stock.

For our 2019 through 2021 taxable years, we generated revenue under our then collaboration agreement with Perrigo UK Finco Limited Partnership, or Perrigo, for the development of a generic product candidate. In 20201 we sold our rights to this and other generic products and will unconditionally receive further revenue over 24 months in lieu of our share in the collaboration agreements with respect to these products. Starting in 2021, we began generating revenue under our license agreements with Galderma for Twyneo®, and Epsolay®. See "Item 4. Information on the Company – B. Business Overview". Though the application of the relevant rules governing the characterization of the foregoing revenue for purposes of the PFIC income test is uncertain, we intend to take the position that, based on our involvement and management contributions throughout the development process, such revenue is non-passive for PFIC purposes. As a result, assuming we continue to earn substantial revenue from such agreements as anticipated and based on the current and anticipated value and composition of our income and assets, we do not expect that we will be treated as a PFIC for U.S. federal income tax purposes for our current taxable year or for foreseeable future years. However, there are substantial factual and legal ambiguities regarding the nature of the revenue and the application of the relevant PFIC rules, and thus, the determination that such revenue is non-passive is not without doubt, and alternative characterizations are possible.

A separate determination must be made after the close of each taxable year as to whether we were a PFIC for that year. Because the value of our assets for purposes of the PFIC test will generally be determined by reference to the market price of our ordinary shares, our PFIC status may depend in part on the market price of our ordinary shares, which may fluctuate significantly. In addition, there may be certain other ambiguities in applying the PFIC test to us. No rulings from the U.S. Internal Revenue Service, or the IRS, however, have been or will be sought with respect to our status as a PFIC. If the IRS were to assert that, contrary to our expectation, we are a PFIC in the current taxable year or a future year, there would be adverse tax consequences to investors, including those described below. Potential investors are strongly advised to consult their own advisors regarding the consequences to them if we were to be considered a PFIC.

If we are a PFIC for any taxable year during your holding period for our ordinary shares (or under proposed Regulations, our warrants), we generally will continue to be treated as a PFIC with respect to your investment in our ordinary shares or warrants for all succeeding years during which you hold our ordinary shares or warrants, and, although subject to uncertainty, potentially our ordinary shares received upon exercise of such warrants. Certain elections (such as a deemed sale election) may be available under certain circumstances.

For each taxable year that we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any "excess distribution" (as defined below) you receive and any gain you realize from a sale or other disposition (including a pledge) of our ordinary shares or warrants, unless you make a valid "mark-to-market" election as discussed below, which may not be available for the warrants. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period;
- the amount allocated to the current taxable year, and any taxable years in your holding period prior to the first taxable year in which we were a PFIC, will be treated as ordinary income; and
- the amount allocated to each other taxable year will be subject to the highest tax rate in effect for individuals or corporations, as applicable, for each such year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to taxable years prior to the year of disposition or excess distribution cannot be offset by any net operating losses, and gains (but not losses) realized on the sale of our ordinary shares or warrants cannot be treated as capital gains, even if you hold our ordinary shares or warrants as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you may be deemed to own a proportionate interest in such lower-tier PFICs that are directly or indirectly owned by us, and you may be subject to the adverse tax consequences described above with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any excess distribution described above if we receive a distribution from our lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

A U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the tax treatment discussed above. If you make a valid mark-to-market election for our ordinary shares, you will include in income for each year that we are treated as a PFIC with respect to you an amount equal to the excess, if any, of the fair market value of our ordinary shares as of the close of your taxable year over your adjusted basis in such ordinary shares. You will be allowed a deduction for the excess, if any, of the adjusted basis of our ordinary shares over their fair market value as of the close of the taxable year. However, deductions will be allowable only to the extent of any net mark-to-market gains on our ordinary shares included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of our ordinary shares, will be treated as ordinary income. Ordinary loss treatment will also apply to the deductible portion of any mark-to-market loss on our ordinary shares, as well as to any loss realized on the actual sale or disposition of our ordinary shares, to the extent the amount of such loss does not exceed the net mark-to-market gains for such ordinary shares previously included in income. Your basis in our ordinary shares will be adjusted to reflect any such income or loss amounts. If you make a mark-to-market election, any distributions we make would generally be subject to the rules discussed below under "— Taxation of Dividends and Other Distributions on our Ordinary Shares," except the lower rates applicable to qualified dividend income would not apply.

The mark-to-market election is available only for "marketable stock," which is stock that is regularly traded on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations, and may not include our warrants. Our ordinary shares are listed on the Nasdaq Global Market. Because a mark-to-market election cannot be made for equity interests in any lower-tier PFICs we own, you generally will continue to be subject to the PFIC rules with respect to your indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. The Nasdaq Global Market is a qualified exchange, but there can be no assurance that the trading in our ordinary shares will be sufficiently regular to qualify our ordinary shares as marketable stock. You should consult your tax advisor as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Alternatively, if a non-U.S. entity treated as a corporation is a PFIC, a holder of shares in that entity may avoid taxation under the PFIC rules described above regarding excess distributions and recognized gains by making a "qualified electing fund" election to include in income its share of the entity's income on a current basis. However, you may make a qualified electing fund election with respect to your ordinary shares only if we furnish you annually with certain tax information, and we currently do not intend to prepare or provide such information. A qualified electing fund election may not be available for our warrants regardless of whether we provide such information.

A U.S. Holder of a PFIC may be required to file an IRS Form 8621. If we are a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you. You are urged to consult your tax advisor regarding the application of the PFIC rules to an investment in ordinary shares or warrants.

YOU ARE STRONGLY URGED TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT ON YOUR INVESTMENT IN OUR ORDINARY SHARES OR WARRANTS IF WE WERE TO BE CONSIDERED A PFIC AS WELL AS THE APPLICATION OF THE PFIC RULES AND THE POSSIBILITY OF MAKING A MARK-TO-MARKET ELECTION.

Taxation of Dividends and Other Distributions on our Ordinary Shares

Subject to the PFIC rules discussed above, the gross amount of any distributions we make to you (including the amount of any tax withheld) with respect to our ordinary shares generally will be includible in your gross income as dividend income on the date of receipt by the holder, but only to the extent the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). The dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations. To the extent the amount of the distribution exceeds our current and accumulated earnings and profits (as determined under U.S. federal income tax principles), such excess amount will be treated first as a tax-free return of your tax basis in your ordinary shares, and then, to the extent such excess amount exceeds your tax basis in your ordinary shares, as capital gain. We currently do not, and we do not intend to, calculate our earnings and profits under U.S. federal income tax principles. Therefore, you should expect that a distribution will generally be reported as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may be taxed at the lower capital gain rates applicable to "qualified dividend income," provided (i) our ordinary shares are readily tradable on an established securities market in the United States (such as the Nasdaq Global Market), (ii) we are neither a PFIC nor treated as such with respect to you (as discussed above) for either the taxable year in which the dividend was paid or the preceding taxable year, (iii) certain holding period requirements are met and (iv) you are not under an obligation to make related payments with respect to positions in substantially similar or related property.

The amount of any distribution paid in a currency other than U.S. dollars will be equal to the U.S. dollar value of such currency on the date such distribution is includible in your income, regardless of whether the payment is in fact converted into U.S. dollars at that time. The amount of any distribution of property other than cash will be the fair market value of such property on the date of distribution.

Any dividends will constitute foreign source income for foreign tax credit limitation purposes. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by the reduced tax rate applicable to qualified dividend income and divided by the highest tax rate normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to our ordinary shares will generally constitute "passive category income."

If Israeli withholding taxes apply to any dividends paid to you with respect to our ordinary shares, subject to certain conditions and limitations, such withholding taxes may be treated as foreign taxes eligible for credit against your U.S. federal income tax liability. Instead of claiming a credit, you may elect to deduct such taxes in computing taxable income, subject to applicable limitations. If a refund of the tax withheld is available under the applicable laws of Israel or under the Israel-U.S. income tax treaty, or the Treaty, the amount of tax withheld that is refundable will not be eligible for such credit against your U.S. federal income tax liability (and will not be eligible for the deduction against your U.S. federal taxable income). The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor regarding the availability of a foreign tax credit in your particular circumstances, including the effects of the Treaty.

Constructive Dividends on our Ordinary Shares or Warrants

If the exercise price of our warrants is adjusted in certain circumstances (or in certain circumstances, there is a failure to make adjustments or a failure to make adequate adjustments), that adjustment (or failure to adjust) may result in the deemed payment of a taxable dividend to a U.S. Holder of the warrants or our ordinary shares. Any such constructive dividend will be taxable generally as described above under "Taxation of Dividends and Other Distributions on our Ordinary Shares." Generally, a U.S. Holder's tax basis in our ordinary shares or the warrants will be increased to the extent of any such constructive dividend. It is not entirely clear whether a constructive dividend deemed paid to a non-corporate U.S. Holder could be "qualified dividend income" as discussed above under "Taxation of Dividends and Other Distributions on our Ordinary Shares." U.S. Holders should consult their tax advisers regarding the proper U.S. federal income tax treatment of any adjustments to (or failure to adjust or adjust adequately) the exercise price of the warrants.

We are currently required to report the amount of any constructive dividends on our website or to the IRS and to holders not exempt from reporting. The IRS has proposed regulations addressing the amount and timing of constructive dividends, as well as, obligations of withholding agents and filing and notice obligations of issuers in respect of such constructive dividends. If adopted as proposed, the regulations would generally provide that (i) the amount of a constructive dividend is the excess of the fair market value of the right to acquire stock immediately after the exercise price adjustment over the fair market value of the right to acquire stock (after the exercise price adjustment) without the adjustment, (ii) the constructive dividend occurs at the earlier of the date the adjustment occurs under the terms of the instrument and the date of the actual distribution of cash or property that results in the constructive dividend and (iii) we are required to report the amount of any constructive dividends on our website or to the IRS and to all holders (including holders that would otherwise be exempt from reporting). The final regulations will be effective for constructive dividends occurring on or after the date of adoption, but holders and withholding agents may rely on them prior to that date under certain circumstances.

Taxation of Disposition of our Ordinary Shares or Warrants

Subject to the PFIC rules discussed above, upon a sale or other disposition of our ordinary shares or warrants, you will generally recognize capital gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized (including the amount of any tax withheld) and your tax basis in such ordinary shares or warrants. If the consideration you receive for our ordinary shares or warrants is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if our ordinary shares or warrants are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Any gain or loss on the sale or other disposition of our ordinary shares or warrants will generally be treated as U.S. source income or loss and treated as long-term capital gain or loss if your holding period in our ordinary shares or warrants at the time of the disposition exceeds one year. Accordingly, in the event any Israeli tax (including withholding tax) is imposed upon the sale or other disposition, you may not be able to utilize foreign tax credit unless you have foreign source income or gain in the same category from other sources. Long-term capital gain of non-corporate U.S. Holders generally will be subject to U.S. federal income tax at reduced tax rates. The deductibility of capital losses is subject to significant limitations.

Taxation of Exercise or Expiration of our Warrants

In general, you will not be required to recognize income, gain or loss upon exercise of our warrants by payment of the exercise price. Your tax basis in our ordinary shares received upon exercise of our warrants will be equal to the sum of (1) your tax basis in the warrants exchanged therefor and (2) the exercise price of the warrants. Your holding period in our ordinary shares received upon exercise will commence on the day after you exercise the warrants.

If the warrants expire without being exercised, you will recognize a capital loss in an amount equal to your tax basis in the warrants. Such loss will be long-term capital loss if, at the time of the expiration, your holding period in the warrants is more than one year. The deductibility of capital losses is subject to limitations.

Information Reporting and Backup Withholding

Dividend payments (including constructive dividends) with respect to our ordinary shares or warrants and proceeds from the sale, exchange or redemption of our ordinary shares or warrants may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and makes any other required certification or that is otherwise exempt from backup withholding. U.S. Holders that are required to establish their exempt status generally must provide such certification on IRS Form W-9. You should consult your tax advisor regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Information with respect to Foreign Financial Assets

Certain U.S. Holders may be required to report information relating to an interest in our ordinary shares or warrants, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain financial institutions). Penalties can apply if U.S. Holders fail to satisfy such reporting requirements. You should consult your tax advisor regarding the effect, if any, of this requirement on your ownership and disposition of our ordinary shares.

THE SUMMARY OF U.S. FEDERAL INCOME TAX CONSEQUENCES SET OUT ABOVE IS FOR GENERAL INFORMATIONAL PURPOSES ONLY. INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF AN INVESTMENT IN OUR ORDINARY SHARES OR WARRANTS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers, and under those requirements, we file reports with the SEC. Our filings with the SEC are available to the public through the SEC's website at *http://www.sec.gov*.

As a foreign private issuer, we are exempt from the rules under the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act, to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to comply with the informational requirements of the Exchange Act, and, accordingly, file current reports on Form 6-K, annual reports on Form 20-F and other information with the SEC.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail below.

Interest Rate Risk

We do not anticipate undertaking any significant long-term borrowings.

At present, our investments consist primarily of marketable securities and bank deposits. We may be exposed to market price risk because of investments in tradable securities, mainly corporate bonds, held by us and classified in our financial statements as financial assets at fair value through profit or loss. To manage the price risk arising from investments in tradable securities, we invest in marketable securities with high ratings and diversify our investment portfolio. Our investments may also be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. Although a substantial portion of our expenses (mainly salaries and related costs) are denominated in NIS, accounting for almost half of our expenses in the year ended December 31, 2021, 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 2.58% during the fiscal year ended on December 31, 2021. 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, 2021 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, 2021.

(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, 2021 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 Mr. Jerrold S. Gattegno is an audit committee financial expert. Mr. Gattegno is an independent director for the purposes of the Nasdaq Listing Rules.

ITEM 16B. CODE OF ETHICS

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, http://ir.sol-gel.com/corporate-governance/governance-overview.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the aggregate fees billed by our independent registered public accounting firm for professional services.

	Year Ended December 31,	
Services Rendered	**2021**	**2020**
	(U.S. dollars in thousands)	
Audit Fees (1)	192	187
Tax (2)	22	29
Other(3)	1	-
Total	215	216

(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 may not in the future comply with the requirement that a majority of our board of directors consist of independent directors, and we are not required to, and do not intend to comply with the requirement that we have a nominating committee composed entirely of independent directors with a written charter addressing such committee's purpose and responsibilities. A majority of our board of directors currently consists of independent directors. See "Item 6. Directors, Senior Management and Employees — C. Board Practices."

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The financial statements required by this item are found at the end of this annual report, beginning on page F-1.

ITEM 19. EXHIBITS

See Exhibit Index on page 147.

EXHIBIT INDEX

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

Exhibit Number	Exhibit Description
1.1	Amended and Restated Memorandum of Association (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on January 23, 2018).
1.2	Amended and Restated Articles of Association (incorporated by reference to Exhibit 99.1 of Form 6-K/A filed with the Securities and Exchange Commission on August 20, 2018).
2.1	Form of Specimen Share Certificate (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on September 20, 2017).
2.2	Description of Share Capital (incorporated by reference to Exhibit 2.2 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 24, 2020).
4.1	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	Registration Rights Agreement (incorporated by reference to Exhibit 99.2 of Form 6-K filed with the Securities and Exchange Commission on February 6, 2018).
4.5 ∞	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).
4.6∞	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).
4.7∞	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).
4.8∞	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).
4.9∞	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).

4.10∞	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).
4.11∞	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).
4.12∞	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).
4.13∞	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).
4.14	Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 2, 2016 (incorporated by reference to Exhibit 10.12 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.15	Schedule A, as amended, of Promissory Note by and between the Registrant and Moshe Arkin, dated as of June 28, 2017 (incorporated by reference to Exhibit 10.13 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.16	Instrument of Conversion of Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 22, 2017 (incorporated by reference to Exhibit 10.14 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.17	Assignment Agreement between the Registrant and Medicis Pharmaceutical Corporation, dated August 16, 2013 (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on August 29, 2017).
4.18∞	Asset Transfer Agreement and Assignment Deed between Sol-Gel Technologies Ltd. and M. Arkin Dermatology Ltd., dated August 22, 2017 (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1/A filed with the Securities and Exchange Commission on January 30, 2017).
4.19† *	License Agreement between Sol-Gel Technologies Ltd. and Galderma Holding SA, dated June 21, 2021.
4.20† *	License Agreement between Sol-Gel Technologies Ltd. and Galderma Holding SA, dated June 21, 2021.
4.21† *	Supply Agreement between Sol-Gel Technologies Ltd., Galderma Holding SA, and Douglas Manufacturing Limited, dated June 21, 2021.
4.22† *	Termination Agreement between Padagis Israel Pharmaceuticals Ltd, and Sol-Gel Technologies Ltd., dated November 3, 2021.
4.23† *	Termination Agreement between Padagis Israel Pharmaceuticals Ltd, and Sol-Gel Technologies Ltd., dated November 3, 2021.

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
101	The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2021, 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.
∞	Informal translation of the original Hebrew document.

SIGNATURE

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

SOL-GEL TECHNOLOGIES LTD.

By: /s/ Alon Seri-Levy
Name: Alon Seri-Levy
Title: Chief Executive Officer and Director

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

Date: April 4, 2022

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2021

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2021

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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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 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.

Tel-Aviv, Israel
_____, 2022

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

We have served as the Company's auditor since 2000.

Kesselman & Kesselman, 146 Derech Menachem Begin, Tel-Aviv 6492103, Israel,
P.O Box 7187 Tel-Aviv 6107120, Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	December 31	
	2020	2021
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,122	$ 20,085
Bank deposits	21,400	21,448
Marketable securities	21,652	1,709
Receivables from collaborative arrangements	2,153	13,065
Prepaid expenses and other current assets	1,074	800
TOTAL CURRENT ASSETS	53,401	57,107
NON-CURRENT ASSETS:		
Long-term receivables from collaborative arrangements	-	7,402
Restricted long-term deposits and cash	1,293	1,298
Property and equipment, net	1,817	1,051
Operating lease right-of-use assets	1,896	1,501
Funds in respect of employee rights upon retirement	754	830
TOTAL NON-CURRENT ASSETS	5,760	12,082
TOTAL ASSETS	$ 59,161	$ 69,189
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	$ 1,203	$ 766
Other accounts payable	4,088	10,145
Current maturities of operating leases	673	781
TOTAL CURRENT LIABILITIES	5,964	11,692
LONG-TERM LIABILITIES:		
Operating leases liabilities	1,299	810
Liability for employee rights upon retirement	1,049	1,093
TOTAL LONG-TERM LIABILITIES	2,348	1,903
COMMITMENTS (Note 6)		
TOTAL LIABILITIES	8,312	13,595
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.1 par value – authorized: 50,000,000 as of December 31, 2020 and 2021, respectively; issued and outstanding: 23,000,782 and 23,126,804 as of December 31, 2020 and December 31, 2021, respectively	635	638
Additional paid-in capital	231,577	233,098
Accumulated deficit	(181,363)	(178,142)
TOTAL SHAREHOLDERS' EQUITY	50,849	55,594
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 59,161	$ 69,189

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,		
	2019	**2020**	**2021**
COLLABORATION REVENUES	$ 22,904	$ 8,771	$ 23,772
LICENSE REVENUES	-	-	7,500
TOTAL REVENUES	22,904	8,771	31,272
RESEARCH AND DEVELOPMENT EXPENSES	40,578	27,913	20,381
GENERAL AND ADMINISTRATIVE EXPENSES	8,276	11,091	8,451
OTHER INCOME, net	-	-	524
TOTAL OPERATING INCOME (LOSS)	(25,950)	(30,233)	2,964
FINANCIAL INCOME, net	1,374	943	257
INCOME (LOSS) BEFORE INCOME TAXES	(24,576)	(29,290)	3,221
INCOME TAXES	(33)	-	-
NET INCOME (LOSS) FOR THE YEAR	$ (24,609)	$ (29,290)	$ 3,221
BASIC INCOME (LOSS) PER ORDINARY SHARE	$ (1.26)	$ (1.30)	$ 0.14
DILUTED INCOME (LOSS) PER ORDINARY SHARE	(1.26)	(1.30)	0.14
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED INCOME (LOSS) PER SHARE:			
BASIC	19,534,562	22,574,688	23,063,493
DILUTED	19,534,562	22,574,688	23,566,182

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, 2019	18,949,968	520	190,853	(127,464)	63,909
CHANGES DURING 2019:					
Net loss for the year				(24,609)	(24,609)
Vesting of restricted share units	15,332	*	*		-
Issuance of shares through public offering, net of issuance costs	1,437,500	41	10,572		10,613
Share-based compensation			2,552		2,552
BALANCE AS OF DECEMBER 31, 2019	20,402,800	561	203,977	(152,073)	52,465
CHANGES DURING 2020:					
Net loss for the year				(29,290)	(29,290)
Issuance of shares and warrants through public offering, net of issuance costs	2,091,907	61	21,245		21,306
Issuance of shares and warrants through private placement from the controlling shareholder	454,628	13	4,987		5,000
Vesting of restricted share units	23,000	*			
Exercise of options	28,447	*	151		151
Share-based compensation			1,217		1,217
BALANCE AS OF DECEMBER 31, 2020	23,000,782	635	231,577	(181,363)	50,849
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

* Less than 1,000.
The accompanying notes are an integral part of these consolidated financial statements.

SOL-GEL TECHNOLOGIES LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,		
	2019	**2020**	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss) for the year	$ (24,609)	$ (29,290)	$ 3,221
Adjustments required to reconcile net income (loss) to net cash used in operating activities:			
Depreciation	887	946	880
Loss from disposal of property and equipment	-	-	29
Changes in accrued liability for employee rights upon retirement	38	21	(32)
Share-based compensation expenses	2,552	1,217	687
Net changes in operating leases	5	71	14
Changes in fair value of marketable securities	65	138	(125)
Finance expenses, net	50	12	55
Changes in operating asset and liabilities:			
Receivables from collaborative arrangements	(4,120)	1,967	(10,912)
Prepaid expenses and other current assets	1,694	219	274
Accounts payable, accrued expenses and other	938	(542)	5,620
Long-term receivables from collaborative arrangements	-	-	(7,402)
Net cash used in operating activities	(22,500)	(25,241)	(7,691)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(597)	(449)	(143)
Bank deposits	1,000	(21,400)	(48)
Restricted long-term deposits	(10)	(21)	(5)
Investments in marketable securities	(38,702)	(32,322)	(6,716)
Proceeds from sales and maturity of marketable securities	54,333	51,498	26,784
Net cash provided by (used in) investing activities	16,024	(2,694)	19,872
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of shares through ATM, net of issuance costs	-	-	505
Proceeds from exercise of options granted to employees	-	151	332
Proceeds from issuance of shares and warrants through public offering, net of issuance costs	10,613	21,306	-
Net proceeds from issuance of shares and warrants to the controlling shareholder through private placement	-	5,000	-
Net cash provided by financing activities	10,613	26,457	837
EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS	(50)	(12)	(55)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	4,087	(1,490)	12,963
CASH AND CASH EQUIVALENTS AND RESRICTED CASH AT BEGINNING OF THE YEAR	5,675	9,762	8,272
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE YEAR	$ 9,762	$ 8,272	$ 21,235
Cash and Cash equivalents	9,412	7,122	20,085
Restricted cash	350	1,150	1,150
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS	$ 9,762	$ 8,272	$ 21,235
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Recognition of new operating lease ROU and liabilities	$ 1,329	$ 378	$ 253
SUPPLEMENTARY INFORMATION:			
Income taxes paid	$ -	$ 7	$ 34
Interest received	$ 1,600	$ 770	$ 774

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

NOTE 1 — NATURE OF OPERATIONS

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

The Company is a clinical stage specialty pharmaceutical company focused on developing and commercializing topical dermatological drug products. The Company's lead product candidates are based upon its proprietary microencapsulation delivery system, consisting of microcapsules made of precipitated silica. The most advanced investigational drugs in the Company's product pipeline are: (i) Twyneo®, which is developed for the treatment of acne vulgaris and (ii) Epsolay®, a potential treatment for subtype II rosacea. The New Drug Application ("NDA") for Twyneo® was accepted by the U.S. Food and Drug Administration (the "FDA"), which assigned a Prescription Drug User Fee Act ("PDUFA") goal date of August 1, 2021. The NDA for Epsolay® was accepted by the FDA, which assigned a PDUFA goal date of April 26, 2021. On such PDUFA goal date, the Company received confirmation from the FDA that action on the NDA could not be taken since a pre-approval inspection of the production site of Epsolay® still needs to be conducted. On February 18,2022 the FDA conducted a pre-approval inspection of the production site for Epsolay®, currently pending approval by the FDA. 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 8. On July 27, 2021, the Company announced that the FDA approved the drug product, Twyneo®. In addition to the novel product candidates, the Company's products included the 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 two approved generic drug products. Under the new agreement, the company has retained collaboration rights to two generic programs related to four generic drug candidates, see note 7b.

The Company has a wholly owned U.S. subsidiary - Sol-Gel Technologies Inc. (the "Subsidiary"). The Subsidiary supports the Company with regard to marketing, regulatory affairs and business development relating to its products and technology in the U.S.

Since incorporation through December 31, 2021, the Company has an accumulated deficit of approximately $178,142 and its activities have been funded mainly by its shareholders, collaboration revenues and license agreements, see also Notes 7 and 8. The Company expects to continue to incur significant research and development and other costs related to its ongoing operations.

In addition, management is continuing to analyze cash resources and considering raising additional funding from different sources, such as corporate collaborations, public or private equity offerings and/or debt financings, and/or selling shares under the Company's Open Market Sale Agreement with Jefferies LLC. Management expects that the Company's cash and cash equivalents, deposits and marketable securities as of December 31, 2021 will allow the Company to fund its operating plan through at least the next 12 months from the financial statement issuance date.

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. To date, the impact of COVID-19 pandemic has been limited and resulted in delays with respect to pre-approval inspections.

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

NOTE 1 — NATURE OF OPERATIONS (continued)**:**

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

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

a. Use of estimates in the preparation of financial statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results may differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation and the incremental borrowing rate for leases.

b. Functional and presentation currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of the Company and its subsidiary are conducted. The Company's financing has been provided in dollars, revenues are primarily in dollars and a significant part of expenses are incurred in dollars. The financial statements are presented in dollars, which is the Company's functional and presentation currency.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (I) for transactions — exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation) — historical exchange rates. Currency transaction gains and losses are presented in financial income or expenses, as appropriate.

c. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

d. Bank deposits

Bank deposits with original maturity dates of more than three months but less than one year are included in short-term deposits. Such short-term deposits bear interest at an average annual rate of approximately 0.46%-0.82% in 2021. 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.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

e. Marketable securities

Marketable securities consist of debt securities. The Company elected the fair value option to measure and recognize its investments in debt securities in accordance with ASC 825, Financial Instruments as the Company manages its portfolio and evaluates the performance on a fair value basis. Changes in fair value, realized gains and losses on sales of marketable securities, are reflected in the statements of operation as finance expense (income), net.

f. Derivatives and hedging

The Company carries out transactions involving foreign currency exchange derivative financial instruments. The transactions are designed to hedge the Company's exposure in currencies other than the U.S. dollar. The derivative does not 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.

As of December 31, 2021, the Company has $1,150 on the Company's bank account that is restricted in order to secure the hedging transactions. This amount is presented among Restricted long-term deposits and cash.

g. Trade receivables

Trade receivables are initially recognized at the transaction price and subsequently measured at amortized cost less any allowance for expected credit losses.
Starting from January 1, 2020, the Company applies ASU 2016-13 "Financial Instruments Credit Losses Measurement of Credit Losses on Financial Instruments" ("the Standard").

h. Property and equipment

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company's property and equipment are depreciated utilizing the straight-line method on the basis of their estimated useful life.

Annual rates of depreciation are as follows:

	%
Laboratory equipment	10 – 33 (mainly 15 – 25)
Office equipment and furniture	7 – 15
Computers and related equipment	33

Leasehold improvements are amortized utilizing the straight-line method over the shorter of the expected lease term or the estimated useful life of the improvements.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

i. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would then be written down to their estimated fair values.

For the three years ended December 31, 2021, the Company did not recognize an impairment loss for 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 transactions is recognized as an expense over the requisite service period.

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

The Company measures share-based compensation to non-employees in the same manner (except for certain exceptions) as share-based compensation to employees.

The Company has elected to recognize forfeitures as they occur.

k. Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

Acquisitions of in-process research and development product candidate, which are not part of business combination, are recognized as an expense as research and development expenses as incurred.

Grants received from Israel Innovation Authority (hereafter — "IIA"), formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or the OCS are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred. See note 6a(1).

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources its clinical trial activities utilizing external entities such as clinical research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical trials. Clinical trial costs are expensed as incurred.

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, when applicable. At contract inception, the entity assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. 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 7.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

l. Revenue recognition (continued):

Licensing agreements

The Company has identified one performance obligation in The License Agreements: Grant of the license and use of its IP. The Grant of the license and use of its IP performance obligation 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.

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. The transaction price contains 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 commencement date based on the present value of lease payments over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

The Company uses the implicit rate when readily determinable. As the Company's leases do not provide an implicit rate, the Company uses its estimated incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company elected to not separate lease and non-lease components for the leases. The Company elected the practical expedient of the short-term lease recognition exemption for all leases with a term shorter than 12 months.

Additionally, the company applies the portfolio approach to account for operating lease ROU asset and liabilities for certain car leases and incremental borrowing rates.

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 and marketable securities and certain receivables. The Company deposits cash and cash equivalents with highly rated financial institutions (Israeli banks). In addition, all marketable securities carry a high rating or are government insured. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

p. Income (loss) per share

Basic income (loss) per share is computed on the basis of the net income (loss) for the period divided by the weighted average number of ordinary shares outstanding during the period. Diluted income (loss) per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options, restricted shares and warrants, which are included under the treasury stock method when dilutive. The calculation of diluted income (loss) per share does not include 1,260,984, 3,271,507 and 3,397,834 options, restricted shares and warrants for the years ended December 31, 2019, 2020 and 2021, respectively, because their effect would be anti-dilutive.

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.

Due to the short term nature and/or low-risk nature of the Company's cash and cash equivalents, bank deposits, restricted cash, receivables from collaborative arrangements, restricted long-term deposits, accrued expenses (under other account payable), operating leases liabilities and other liabilities, their carrying amounts approximates their fair value.

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

NOTE 3 — MARKETABLE SECURITIES

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

	December 31,	
	2020	2021
Level 2 securities:		
U.S government and agency bonds	$ 4,192	275
Other foreign government bonds	2,006	-
Corporate bonds*	15,454	1,434
Total	$ 21,652	$ 1,709

* Investments in Corporate bonds rated A or higher.

The Company's debt securities are classified within Level 2 because it uses quoted market prices or alternative pricing sources and models utilizing market observable inputs to determine their fair value.
The cost of marketable securities As of December 31, 2021 is $1,734.

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, 2020 and 2021:

	December 31,	
	2020	2021
Balance at beginning of the year	$ 40,966	21,652
Additions	32,322	6,716
Sale or maturity	(51,498)	(26,784)
Changes in fair value during the year	(138)	125
Balance at end of the year	$ 21,652	1,709

As of December 31, 2021, all the Company's debt securities are due within one year.

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

NOTE 4 — PROPERTY AND EQUIPMENT

	December 31	
	2020	2021
Cost:		
Laboratory equipment	$ 3,644	$ 3,588
Office equipment and furniture	265	265
Computers and software	530	357
Leasehold improvements	1,953	1,993
	6,392	6,203
Less:		
Accumulated depreciation and amortization	(4,575)	(5,152)
Property and equipment, net	$ 1,817	$ 1,051

Depreciation and amortization expense totaled $887, $946 and $880 for the years ended December 31, 2019, 2020 and 2021, respectively.

NOTE 5 — EMPLOYEE SEVERANCE BENEFITS

The Company is required to make severance payments upon dismissal of an employee or upon termination of employment in certain circumstances. The severance payment liability to the employees (based upon length of service and the latest monthly salary — one month's salary for each year employed) is recorded on the Company's balance sheet under "Liability for employee rights upon retirement." The liability is recorded as if it was payable at each balance sheet date on an undiscounted basis.

In accordance with the current employment terms starting in August 2014 with all of its employees (Section 14 of the Israeli Severance Pay Law, 1963), the Company makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's retirement benefit obligation. The Company is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the Company balance sheet, as the amounts
funded are not under the control and management of the Company and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plan").

With regard to the period before August 2014, the liability is funded in part from the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the balance sheets under "Funds in respect of employee rights upon retirement." These policies are the Company's assets.

The amounts of severance payment expenses were $402, $428 and $445 for the years ended December 31, 2019, 2020 and 2021, respectively, of which $363, $408 and $404 in the years ended December 2019, 2020 and 2021, respectively, were in respect of the Contribution Plan.

The Company expects to contribute approximately $404 in the year ending December 31, 2022 to insurance companies in connection with its expected severance liabilities for that year.

NOTE 6 — COMMITMENTS :

a. **Royalty Commitments:**

1) The Company is obligated to pay royalties to the IIA on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from the IIA.

Under the specific terms of the funding arrangements with the IIA, royalties of 3.5% to 25% are payable on the sale of products developed with funding received from the IIA, which payments shall not exceed, in the aggregate, 300% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR.

Up to December 31, 2021, 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, 2019, 2020 and 2021). Through December 31, 2021, the Company recorded an accumulated royalty expense of $2,109 as royalties to the IIA with respect to revenue recognized through December 31, 2021($32, $25 and $23 were recorded in 2019, 2020 and 2021 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 sub-license or license of certain patents.

Royalty expenses in immaterial amounts were recorded in 2019, 2020 and 2021 in respect of these agreements.

According to the agreements, the Company may continue commercial use of certain Yissum's patents in connection with the products and subject to the obligation to pay Yissum the royalties and the sub-license fees.

The Company granted rights to a third party for use and commercialization of certain Yissum patents.

b. **Lease Agreements**

The Company leases offices and vehicles under operating leases. For leases with terms greater than 12 months, the Company records right of use assets and lease liabilities at the present value of lease payments over the leases term.

Offices
The Company leases office spaces and research and development facilities under several agreements. These agreements are linked to the change in the Israeli consumer price index and expire in December 2023. These agreements are classified as operating leases and presented under operating lease right-of-use assets and operating leases liabilities. A restricted deposit of $136 has been deposited in order to secure the agreement.

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

NOTE 6 — COMMITMENTS (continued):

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.

Lease Position

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

	As of December 31,	
	2020	2021
Assets		
Operating Leases		
Operating lease right-of-use assets	$ 1,896	$ 1,501
Liabilities		
Current liabilities		
Current maturities of operating leases	$ 673	$ 781
Long-term liabilities		
Non-current operating leases	$ 1,299	$ 810
Weighted Average Remaining Lease Term		
Operating leases	1.29	0.87
Weighted Average Discount Rate		
Operating leases	6.25%	6.13%

Lease Costs

The table below presents certain information related to lease costs of operating leases for the year ended December 31, 2021:

	Year Ended December 31,	
	2020	2021
Operating lease cost:	$ 685	$ 872

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

NOTE 6 — COMMITMENTS (continued):

The table below presents supplemental cash flow information related to leases for the year ended December 31, 2021:

	Year Ended December 31,	
	2020	2021
Cash paid for amounts included in the measurement of leases liabilities:		
Operating cash flows from operating leases	$ 735	$ 843

Undiscounted Cash Flows

The table below reconciles the undiscounted cash flows for each of the first five years and total of the remaining years to the operating lease liabilities recorded on the consolidated balance sheet:

	Operating Leases
For the year ending December 31, 2021	
2022	$ 858
2023	789
2024	30
Total minimum lease payments	1,677
Less: amount of lease payments representing interest	(86)
Present value of future minimum lease payments	1,591
Less: Current maturities of operating leases	781
Long-term operating leases liabilities	810
	$ 1,591

c. In June 2008, the Company entered into a Master Clinical Trial Services Agreement with a third party, which was later amended in April 2017, to retain its services as a clinical research organization for certain product candidate subject to task work orders to be issued by the Company. During 2018, the Company entered into six additional task orders. As consideration for its services the Company will pay a total amount of approximately $14,425 during the term of the engagement and based on achievement of certain milestones, out of which $12,710 were recognized as an expense until December 31, 2021.

d. 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). In November 2021, the Company entered into a new agreement (the "New Agreement") with the Partner, to sell its rights to the Partner in relation to ten generic collaborative agreements between the parties. Under the New Agreement, the Company has retained collaboration rights to two generic programs related to four generic drug candidates. See detailed information in note 7b.

e. In October 2017, the Company entered into a Clinical Development Master Services Agreement with a third party, to retain it as clinical research organization for certain product candidate, subject to task work orders to be issued by the Company. As consideration for its services the Company will pay a total amount of approximately $13,955 during the term of the engagement and based on achievement of certain milestones, out of which $13,430 were recognized as an expense until December 31, 2021.

NOTE 7 — COLLABORATION AGREEMENTS

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

b. In 2016 through 2020, the Company entered into several collaboration agreements mainly with one Partner for the development, manufacturing and commercialization of several generic product candidates. Under the agreements, the Partner is obligated to conduct regulatory, scientific, clinical and technical activities necessary to develop the product and prepare and file ANDA, with the FDA and gain regulatory approval. The Company participates in the development of the product candidates, including participation in joint steering committees and is obligated for sourcing the active pharmaceutical ingredient (API) during the development phase.

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

During the years ended December 31, 2019, 2020 and 2021, the Company recognized collaboration revenues related to sales of products in the U.S. under these agreements in the amounts of $22,775, $8,673 and $3,303, respectively.

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

Under the terms of the New Agreement, effective as of November 1, 2021, the Company will unconditionally receive $21.5 million over 24 months, in lieu of its share in future gross profits for the two approved generic drug products and its potential gross profits for eight unapproved generic programs. The Company received $1,250 as an upfront payment and $20,250 in eight equal quarterly instalments. The New Agreement also provides that effective as of November 1, 2021, the Company will cease paying any outstanding and future operational costs related to these collaborative agreements.

NOTE 8 – LICENSE AGREEMENTS:

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

NOTE 8 – LICENSE AGREEMENTS (continued):

According to the agreement, the Company has an option to regain commercialization rights five years following first commercialization. In the third quarter of 2021, the Company received $7.5 million for Twyneo® and $4 million for Epsolay® of upfront payments, which are refundable if FDA approval for each respective product is not received by December 31, 2021. On July 27, 2021, the Company announced that the FDA approved the Company's first proprietary drug product, Twyneo®. See note 1. Since FDA approval for Epsolay® had not been received as of December 31, 2021, the Company is required to refund the $4 million upfront payment, which is recorded under " Other accounts payable" in the Company's balance sheet. In March 2022, the Company has refunded the $4 million upfront payment to Galderma.

NOTE 9— SHARE CAPITAL

a. Ordinary shares

Rights of the Company's ordinary shares

Each ordinary share is entitled to one vote. The holder of the ordinary shares is also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. Since its inception, the Company has not declared any dividends.

1) On August 12, 2019, the Company completed an underwritten follow-on public offering, in which it issued 1,437,500 ordinary shares, including the full exercise by the underwriters of their option to purchase 187,500 additional ordinary shares, at a public offering price of $8.00 per ordinary share.
The total proceeds received from the offering, net of issuance costs, were approximately $10,613.

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

   In addition, and in parallel to the public offering, the Company signed an agreement for a private placement with its controlling shareholder for an additional investment of approximately $5,000 in consideration of 454,628 ordinary shares and 454,628 warrants to purchase up to 363,702 ordinary shares, at the same terms of the underwritten public offering mentioned above. The private placement agreement was contingent on certain conditions and was approved by the company's shareholders on April 8, 2020. The total proceeds of $5,000 were received in April 2020.

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

   From the effective date of the agreement through the issuance date of this report, 41,154 shares were sold under the program for total gross proceeds of approximately $0.5 million, leaving an available balance under the facility of approximately $24.5 million as of the issuance date of this report.

NOTE 9— 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, may 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.

The Plan is designed to enable the Company to grant awards to purchase Ordinary Shares under various and different tax regimes including, without limitation: pursuant and subject to Section 102 of the Israeli Tax Ordinance and pursuant and subject to Section 3(i) of the Israeli Tax Ordinance and under Internal revenue Code Section 422.

The awards may be exercised after vesting and in accordance with vesting schedules which will be determined by the Board of Directors for each grant. The maximum term of the awards is 10 years. The fair value of each option granted under this Plan is estimated using the Black-Scholes option pricing method. Expected volatility is based on the historical volatility of 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, 2021, 753,578 ordinary shares remain available for future grants under the Plan.

2) **Options grants**

a. Option granted to employees and directors

During the twelve months ended December 31, 2021, the Company granted 248,600 options to employees and directors:

i. In January 2021 and March 2021, the Company granted a total of 20,000 options and 3,600 options, respectively, to several employees to purchase ordinary shares at an exercise price of $10.44 and $9.93 per share, respectively.

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

ii. In February 2021, the Company granted a total of 225,000 options to several directors to purchase ordinary shares at an exercise price of $10.02 per share.

The options vest over a period of 3 years; one third of the options vest on the first anniversary of the vesting commencement date (as described in each agreement) and the rest vest quarterly over the following two years. The options expire on the tenth anniversary of their grant date.

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

NOTE 9 — SHARE CAPITAL (continued):

The fair value of options granted in 2019 and 2021 was $485 and $1,061, respectively. No options were granted in 2020. The underlying data used for computing the fair value of the options are as follows:

	2019	2021
Value of one ordinary share	$6.08-$8.59	$9.56-$10.44
Dividend yield	0%	0%
Expected volatility	74.87%-77.83%	59.52%-70.48%
Risk-free interest rate	1.82%-2.75%	0.55%-1.14%
Expected term	6.11 years	3.25-7 years

The total unrecognized compensation cost of employee options at December 31, 2021 is $376, which is expected to be recognized over a period of 3.17 years.

The following table summarizes the number of options granted to employees under the Plan for the year ended December 31, 2021, and related information:

	Year ended December 31		
	2021		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at the beginning of the year	1,000,894	$ 4.63	6.05
Granted	248,600	$ 10.05	-
Exercised	(65,702)	$ 5.05	-
Expired	(1,350)	$ 5.57	-
Forfeited	(51,413)	$ 7.73	-
Options outstanding at the end of the year	1,131,029	$ 5.64	5.73
Options exercisable at the end of the year	1,030,267	$ 4.42	4.37

b. Option granted to non-employees

The total unrecognized compensation cost of non-employees' options at December 31, 2021 is $1, which is expected to be recognized over a period of 0.23 years.

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

NOTE 9— SHARE CAPITAL (continued)

The following table summarizes the number of options granted to non-employees under the Plan for the year ended December 31, 2021, and related information:

	Year ended December 31		
	2021		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at the beginning of the year	198,575	$ 7.70	6.84
Granted			
Options outstanding at the end of the year	198,575	$ 7.70	5.84
Options exercisable at the end of the year	173,465	$ 7.60	5.83

c. The aggregate intrinsic value of the total outstanding and of total exercisable options as of December 31, 2021 is approximately $3,313 and $3,312, respectively.

d. Restricted Share Units (RSUs) granted to Directors

In February 2018 and September 2018, the board of directors approved and recommended the Company shareholders to approve a total grant of 46,000 and 11,500 RSUs, respectively, to its independent and external directors that vest annually in equal portions over a three-year period. The fair value of shares as of the date of grant was $495 and $105 respectively. As of December 31, 2021, 57,500 RSUs were vested.

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

	Year ended December 31		
	2019	2020	2021
Research and development expenses	$ 1,028	$ 431	$ 33
General and administrative expenses	$ 1,524	$ 786	$ 654
	$ 2,552	$ 1,217	$ 687

NOTE 10 - TAXES ON INCOME

a. Tax rates in Israel

The Company is taxed in accordance with Israeli tax laws. The corporate tax rates applicable to 2019, 2020 and 2021 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, 2021, 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 10- 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, 2021, 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 2016 are considered to be final.

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

NOTE 10 - TAXES ON INCOME (continued)

e. Losses for tax purposes carried forward to future years

As of December 31, 2021, the Company had approximately $170.8 million of net carry forward tax losses which are available to reduce future taxable income with no limited period of use.

f. Deferred income taxes:

	December, 31	
	2020	**2021**
In respect of:		
Net operating loss carry forward	$ 34,835	$ 39,280
Research and development expenses	7,133	5,153
Other	1,085	875
Less – valuation allowance	(43,053)	(45,308)
Net deferred tax assets	$ -	$ -

g. Reconciliation of theoretical tax expenses to actual expenses

Actual tax expenses are in respect of the U.S. subsidiary. The primary reconciling items between the statutory tax rate of the Company and the effective rate are the full valuation allowance of deferred tax assets and nondeductible expenses in relation to the operations in Israel.

h. Roll forward of valuation allowance

Balance at January 1, 2019	$ 26,166
Additions	8,781
Balance at December 31, 2019	$ 34,947
Additions	8,106
Balance at December 31, 2020	$ 43,053
Additions	2,255
Balance at December 31, 2021	$ 45,308

i. Provision for uncertain tax positions

As of December 31, 2020, and 2021, the Company does not have a provision for uncertain tax positions.

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

NOTE 11 — SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Other accounts payables and accruals

	December, 31	
	2020	2021
Accrued expenses	$ 3,250	1,685
Employees payables	812	754
Institutions	26	3,625
Refundable upfront payment	-	4,000
Other	-	81
	$ 4,088	$ 10,145

NOTE 12 — 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 9d.

NOTE 13 — SUBSEQUENT EVENTS

In March 2022, the Company has refunded the $4 million upfront payment to Galderma, See detailed information in note 8.

Exhibit 4.3

COMPENSATION POLICY

SOL-GEL TECHNOLOGIES LTD.

Compensation Policy for Executive Officers and Directors

Adopted October 2, 2017, as amended March 22, 2021

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. The following are the ratios as of the date of the approval of this Compensation Policy:

Position	**Ratio between the Executive Officers Cost and the average Other Employees Cost**	**Ratio between the Executive Officers Cost and the median Other Employees Cost**
CEO	8.12	10.64
Other Executive Officers	3.12	4.16

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

B. Base Salary and Benefits

6. **Base Salary**

6.1. The Base Salary varies between Executive Officers, is individually determined by the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO, also the Company's general meeting of shareholders) and may be considered and adjusted by the Company (subject to the approvals of the abovementioned organs) on a periodically basis, according to, among others, the educational background, prior vocational experience, expertise and qualifications, role, business authorities and responsibilities, past performance and previous compensation arrangements of such Executive Officer, as well as the Company's financial state and cash position and any requirements or restrictions prescribed by any applicable legislation, from time to time. When determining the Base Salary, the Company may also decide to consider, at the sole discretion of the Compensation Committee and the Board and as required, the prevailing pay levels in the relevant market, Base Salary and the total compensation package of comparable Executive Officers in the Company, the proportion between the Executive Officer's compensation package and the salaries of other employees in the Company and specifically the median and average salaries and the effect of such proportions on the work relations in the Company.

7. **Benefits**

7.1. In addition to the Base Salary, the following benefits may be granted to the Executive Officers (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting pf shareholders), in order, among other things, to comply with legal requirements. It shall be clarified, that the list below is an open list and Sol-Gel (subject to the abovementioned required approvals) may grant to its Executive Officers other similar, comparable or customary benefits, subject to the applicable law. In addition, Executive Officers employed outside of Israel may receive other similar, comparable or customary benefits as applicable in the relevant jurisdiction in which they are employed.

- Vacation days in accordance with market practice and the applicable law, up to a cap of 30 days per annum;
- Sick days in accordance with market practice and the applicable law; However, the Company may decide to cover sick days from the first day;
- Convalescence pay according to the applicable law;
- Medical Insurance in accordance with market practice and the applicable law;
- With respect to Executive Officers employed in Israel: monthly remuneration for a study fund ("Keren Hishtalmut"), as allowed by applicable tax law and with reference to Sol-Gel's practice and common market practice;
- Pension and savings – according to local market practices and legislation;
- Disability insurance – the Company may purchase disability insurance, according to applicable legislation.

7.2. Sol-Gel may offer additional benefits to its Executive Officers, including but not limited to: communication, company car and travel benefits, insurances and other benefits (such as newspaper subscriptions, academic and professional studies), etc., including their gross up.

7.3. Sol-Gel may reimburse its Executive Officers for reasonable work-related expenses incurred as part of their activities, including without limitations, meeting participation expenses, reimbursement of business travel, including a daily stipend when traveling and accommodation expenses. Sol-Gel may provide advance payments to its Executive Officers in connection with work-related expenses.

8. **Signing Bonus**

At the discretion of the Compensation Committee and the Board (and with respect to the CEO- also the Company's general meeting of shareholders), Sol-Gel may grant a newly recruited Executive Officer a signing bonus. Such bonus may be granted in cash, equity or a combination of both. The signing bonus will not exceed: (1) 50% of such Executive Officer's annual Base Salary, if the signing bonus is granted in cash; (2) 100% of such Executive Officer's annual Base Salary, if the signing bonus is granted by equity; (3) In case the signing bonus is a combination of cash and equity, its ceiling shall be proportional to the cash and equity components, calculated in accordance with the ratios mentioned in sections (1) and (2) above.

C. Cash Bonuses (Excluding Directors)

The Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may grant cash bonuses to its Executive Officers (excluding directors) on a quarterly or annually basis, or on a shorter or longer period basis, in accordance with the principles detailed below.

9. **Annual Bonuses**

9.1. The annual bonus that may be paid to the Executive Officers for any fiscal year shall not exceed twelve (12) monthly Base Salaries to the CEO, and six (6) monthly Base Salaries to any other Executive Officer.

9.2. CEO

The annual bonus to the CEO will be based mainly on measurable criteria, and with respect to its less significant part shall be determined at the discretion of the Compensation Committee and the Board, in accordance with the following:

Position	Company/Individual Performance Measures	Company's Discretion
CEO	75%-100%	0%-25%

The measurable criteria and their relative weight shall be determined by the Compensation Committee and the Board in respect of each calendar year. These measurable criteria will include, *inter alia*, objectives relating to compliance with the Company's work plans and with various budget objectives, including, *inter alia*, compliance with objectives relating to revenues, expenses, investments, etc., meeting various financial objectives, such as objectives relating to the annual profit (net profit, pre-tax profit, etc.) and the Company's EBITDA, objectives relating to the recruitment and development of professional personnel, objectives relating to raising investments, debt, etc., objectives relating to the Company's business operations and the Company's operations as a company traded on NASDAQ, objectives relating to the realization of the Company's assets, the acquisition of new activities and/or companies and objectives relating to an increase of the return on the Company's assets.

9.3. Other Executive Officers (Excluding CEO and Directors)

The Company may also award (subject to the approvals of the Compensation Committee and the Board) an annual bonus to its Executive Officers, due to their unique contribution to the Company. Such grant will be based, *inter alia*, on measurable criteria, based on the Company's financial results, the scope of the Company's business activity, the CEO's opinion on the contribution of the Executive Officer to the Company, the distribution of the annual bonus over the year, etc. It should be clarified, that the annual bonus may be based in whole or in part on discretion, provided that it does not exceed the ceiling specified in section 9.1 above. The CEO of the Company shall be entitled to determine the abovementioned targets for each such an Executive Officer. Notwithstanding the foregoing, it is hereby clarified, that the grant of annual bonus to an Executive Officer, of up to three Base Salaries, shall be approved by the CEO of the Company.

10. **Special Bonuses**

In addition to the annual bonus, Sol-Gel may grant Executive Officers a special bonus as an award for special achievements (outstanding personal achievement, outstanding personal effort or outstanding Company's performance, such as in connection with mergers and acquisitions, offerings, achieving target budget or business plan under exceptional circumstances and special recognition in case of retirement), at the discretion of the Compensation Committee and the Board (and with respect to the CEO- also the Company's general meeting of shareholders) which shall not exceed six (6) monthly Base Salaries.

11. **Additional Provisions Relating to Cash Bonuses**

11.1. **Pro Rata Payment**

Should the employment or service of the Executive Officer terminate prior to the end of a fiscal year, Sol-Gel may pay the Executive Officer his/her pro-rata share of that fiscal year's bonus, based on the period such Executive Officer was employed by the Company or has served in the Company.

11.2. **Compensation Recovery ("Clawback")**

11.2.2. In the event of an accounting restatement, Sol-Gel shall be entitled to recover from its Executive Officers the bonus compensation in the amount in which such bonus exceeded what would have been paid under the financial statements, as restated ("**Compensation Recovery**"), provided that a claim is made by Sol-Gel prior to the third anniversary of fiscal year end of the restated financial statements.

11.2.3. Notwithstanding the aforesaid, the Compensation Recovery will not be triggered in the following events:

- The financial restatement is required due to changes in the applicable financial reporting standards; or
- The Company (subject to any required approval by the applicable law) has determined that clawback proceedings in the specific case would be impossible, impractical or not commercially or legally efficient; or
- The amount to be paid under the clawback proceedings is less than 10% of the relevant bonus received by the Executive Officer.

11.2.4. It shall be clarified, that Sol-Gel shall not be entitled to Compensation Recovery with respect to equity-based compensation granted to its Executive Officers.

11.3. **Reduction or Postponement**

In the event of the termination of office of an Executive Officer under circumstances in which he/she will not be entitled to severance pay, the Company (subject to the approvals of the Compensation Committee and the Board) may revoke the entitlement of such an Executive Officer to an annual bonus and to all parts of the annual bonus which have not yet been paid to him.

D. Equity-Based Compensation

12. **General and Objectives**

12.1. The Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) may grant from time to time equity-based compensation which will be individually determined and awarded according to, *inter alia*, the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the Executive Officer. Equity-based compensation may also be awarded to the Company's directors, including, for the avoidance of doubt, the Executive Chairman, provided that such directors do not also serve as officers in the Company.

12.2. The main objectives of the equity-based compensation is to enhance the alignment between the Executive Officers' and directors' interests with the long term interests of Sol-Gel and its shareholders, and to strengthen the retention and the motivation of Executive Officers in the medium-to-long term. In addition, since equity-based awards are structured to vest over several years, their incentive value to recipients is aligned with longer-term strategic plans.

12.3. The equity based compensation offered by Sol-Gel is intended to be in a form of options exercisable into shares, restricted shares and/or other equity based awards, such as restricted share units (RSUs), in accordance with the Company's incentive plan in place as may be updated from time to time.[2]

13. **Fair Market Value**

The fair market value of the equity-based compensation for each Executive Officer during a fiscal year, shall not exceed 200% of his/her annual Base Salary, as shall be determined according to acceptable valuation practices at the time of grant.[3]

14. **Taxation Regime**

Subject to any applicable law, Sol-Gel may determine, at the discretion of the Compensation Committee and the Board (and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders), the tax regime under which equity-based compensation may be granted, including a tax regime which will maximize the benefit to the Executive Officers.

15. **Exercise Period**

The exercise price for each option shall not be less than the average closing Company's share price on NASDAQ over the 30 trading days preceding the Board's decision on the grant of the relevant option.

It is hereby clarified, that unless otherwise determined by the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders), and subject to the provisions of any applicable law, the exercise price of restricted shares and restricted share units (RSUs) is zero. In addition, it shall be clarified, that the exercise of restricted shares and RSUs may be subject to the achievement of goals set in advance and approved in accordance with the applicable law.

Options, restricted shares and restricted share units (RSUs) may also be exercised by a method of "Cashless" exercise.

The Board considered the possibility of determining a ceiling for the exercise value of the variable equity components and decided, taking into account the purpose of the equity-based compensation, not to set such a ceiling in this Policy.

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

3 Calculated annually, on a linear basis.

16. **Vesting**

All equity-based incentives granted to Executive Officers and directors shall be subject to vesting periods in order to promote long-term retention of such recipients. Grants to Executive Officers (excluding directors) shall vest gradually over a period of at least two years, while grants to directors shall vest over a period of at least one year. Such grants may be vested on a quarterly, semi-annual or an annual basis, or based on other time periods (which may not be necessarily equal), as determined by the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders). The Company (subject to the abovementioned required approvals) may condition the vesting of part or all of the equity-based incentives, for some or all of its Executive Officers, upon the achievement of predetermined performance goals. The Company (subject to the abovementioned required approvals) may also set terms relating to vesting in connection with an Executive Officer leaving the Company (due to a dismissal, resignation, death or disability).

17. For details regarding ceilings with respect to director's equity-based compensation see section 29 below.

18. **General**

All other terms of the equity awards shall be in accordance with Sol-Gel's incentive plans and other related practices and policies. Accordingly, the Company may (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) extend the period of time for which an award is to remain exercisable and make provisions with respect to the acceleration of the vesting period of any Executive Officer's awards, including, without limitation, in connection with a corporate transaction involving a change of control, subject to any additional approval as may be required by the Companies Law.

E. Retirement and Termination of Service Arrangements (Excluding Directors)

19. **Advanced Notice Period**

19.1. Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may provide each Executive Officer (excluding directors), pursuant to an Executive Officer's employment agreement and according to the Company's decision per each case, a prior notice of termination of up to six (6) months, except for the CEO whose prior notice may be of up to twelve (12) months (the "**Advance Notice Period**"). During the Advance Notice Period, the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her options, restricted shares, RSUs and/or any other equity based awards.

19.2. During the Advance Notice Period, an Executive Officer will be required to keep performing his/her duties pursuant to his/her agreement with the Company, unless the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) has waived the Executive Officer’s services to the Company during the Advance Notice Period and pay the amount payable in lieu of notice, plus the value of benefits.

19.3. In the event of a change of control in the Company, the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may decide to extend the Advance Notice Period as provided in section 19.1 above (and the compensation paid for such Advance Notice Period, accordingly) to up to two times the original Advance Notice Period of the Executive Officer, in accordance with the applicable law as of that time.

20. **Adjustment Period/Retirement Bonus**

In addition to the Advance Notice Period, the Company (subject to the approvals of the Compensation Committee and the Board, and with respect to the CEO- also the Company's general meeting of shareholders) may provide an additional adjustment period/retirement payment that will be determined, among other things, taking into consideration the Executive Officer's seniority in the Company, performance during employment, contribution to Sol-Gel achieving its goals and the circumstances of retirement or termination. The maximum adjustment period/retirement bonus that may be paid to each Executive Officer shall be up to six (6) month Base Salaries and may only be granted to Executive Officers who have served in the Company for at least one year.

21. **Additional Retirement and Termination Benefits**

Sol-Gel may provide additional retirement and terminations benefits and payments as may be required by applicable law (e.g., mandatory severance pay under Israeli labor laws- unless employment/term of service was terminated for cause), or which will be comparable to customary market practices.

F. Exemption, Indemnification and Insurance

22. **Exemption**

Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) may exempt in advance and retroactively its Executive Officers, from any liability to the Company, in whole or in part, for damages in consequence of his or her duty of care vis-a-vis the Company, to the fullest extent permitted by law and subject to the provisions of the Company's Articles of Association.

23. **Indemnification**

Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) may indemnify its Executive Officers to the fullest extent permitted by applicable law and the Company's Articles of Association, for any liability and expense that may be imposed on the Executive Officer, as provided in the Indemnity Agreement between such individuals and Sol-Gel, all subject to applicable law and the Company's Articles of Association.

24. **Insurance**

24.1. Sol-Gel (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) will provide "Directors' and Officers' Liability Insurance" (the "**Insurance Policy**"), as well as a "run off" insurance policy for its Executive Officers as follows:

- The limit of liability of the insurer shall be up to $75 million per event and in the aggregate in the insurance period.
- The Insurance Policy, as well as the limit of liability and the premium for each extension or renewal shall be approved by the Company, which shall determine (subject to the approvals of the Compensation Committee and the Board, and with respect to the Company's directors and CEO- also the Company's general meeting of shareholders) that the sums are reasonable considering Sol-Gel's exposures, the scope of coverage and the market conditions and that the Insurance Policy reflects the current market conditions, and it shall not materially affect the Company's profitability, assets or liabilities.
- The policy will also cover the liability of the controlling shareholders due to their positions as Executive Officers in the Company, from time to time, provided that the coverage terms in this respect do not exceed those of the other Executive Officers in the Company.

G. Arrangements upon Change of Control

25. The following benefits may be granted to the Executive Officers in addition to the benefits applicable in the case of any retirement or termination of service upon a "Change of Control" following of which the employment of the Executive Officer is terminated or adversely adjusted in a material way:

    25.1. Vesting acceleration of outstanding options, restricted shares, restricted share units (RSUs) and/or other equity based awards.

    25.2. Extension of the exercising period of options, restricted shares, restricted share units (RSUs) and/or other equity based awards for Sol-Gel's Executive Officers for a period of up to five (5) years, following the date of termination of employment.

    25.3. An Advance Notice Period, in accordance with section 19.3 above.

    25.4. An Adjustment period/retirement bonus in accordance with section 20 above, of up to twelve (12) months of Employment Cost.

H. Board of Directors Compensation

26. The compensation of the Company's directors shall be in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director) of 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel) of 2000, as such regulations may be amended from time to time, or in accordance with section 27 below, subject to any required approvals by the applicable law.

27. The compensation of the Company's directors (including external directors and independent directors) shall not exceed the following:

    27.1. Base payment of $45,000 per year (the "**Base Payment**");

    27.2. Chairman of the Board- an additional amount of $25,000 per year to the Base Payment;

    27.3. Committee Chairman- an additional amount of $10,000 per year to the Base Payment;

    27.4. Committee member- an additional amount of $5,000 per year to the Base Payment;

28. In addition, the Company may engage with its directors (excluding external and independent directors) for the receipt of consulting services and/or other special services, for a consideration of up to $1,000 per day, plus reasonable expense reimbursement. Such compensation shall be paid for a maximum of 6 days per year for each director.

29. Directors may be granted equity-based compensation in accordance with the applicable principles detailed in section D of this Policy, and subject to the provisions of the Companies Law and the regulations thereunder.[4]

Equity based-compensation granted to the Company's directors, shall not exceed the following amounts (subject to any applicable law):[5]

29.1. Director: $55,000 per year (the "**Equity Compensation**");

29.2. Chairman of the Board- an additional amount of $55,000 per year to the Equity Compensation;

29.3. Committee Chairman- an additional amount of $10,000 per year per year to the Equity Compensation;

29.4. Committee member- an additional amount of $5,000 per year to the Equity Compensation;

30. Sol-Gel's external and independent directors may be entitled to reimbursement of expenses in accordance with the Companies Law and the regulations thereunder.

I. Miscellaneous

31. This Policy is designed solely for the benefit of Sol-Gel. Nothing in this Compensation Policy shall be deemed to grant any of Sol-Gel's Executive Officers or employees or any third party any right or privilege in connection with their employment by the Company and their compensation thereof. Such rights and privileges, to which Executive Officers or employees serving in the Company or that will serve in the Company in the future, are entitled for, shall be governed by the respective personal employment agreements.

32. This Policy is subject to applicable law and is not intended, and should not be interpreted as limiting or derogating from, provisions of applicable law to the extent not permitted, nor should it be interpreted as limiting or derogating from the Company's Articles of Association.

33. This Policy is not intended to affect current agreements nor affect obligating customs (if applicable) between the Company and its Executive Officers as such may exist prior to the approval of this Compensation Policy, subject to any applicable law.

34. In the event of amendments made to the Companies Law or any regulations promulgated thereunder providing relief in connection with Sol-Gel's compensation to its Executive Officers, Sol-Gel may elect to act pursuant to such relief without regard to any contradiction with this Policy.

35. The Company (subject to any required approvals by the applicable law) may determine that none or only part of the payments, benefits and perquisites shall be granted, and is authorized to cancel or suspend a compensation package or part of it.

36. An immaterial change in the terms of office of Executive Officers (excluding directors, a controlling shareholder or a controlling shareholder's relative) during the term of this Compensation Policy, will be subject to the approval of the Company's CEO only (changes in the terms of office of the CEO shall be approved in accordance with the Companies Law). An immaterial change in this matter shall be deemed to be a change that does not exceed 5% of the annual Employment Cost with respect to the employment of such an Executive Officer in the Company, subject to the conditions prescribed in this Compensation Policy.

37. It should be clarified, that the compensation components detailed in this Policy do not relate to various components that the Company may provide to all or part of its employees and/or its Executive Officers, such as: parking spaces, entry permits for its assets, reimbursement for meals and accommodation expenses, vacations, company events, etc.

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

Exhibit 4.19

CERTAIN INFORMATION IDENTIFIED
BY BRACKETED ASTERISKS ([* * *])
HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE
IT IS BOTH NOT MATERIAL AND WOULD BE
COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Execution Copy

LICENSE AGREEMENT

BY AND BETWEEN

GALDERMA HOLDING SA

AND

SOL-GEL TECHNOLOGIES LTD.

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of June 21, 2021 ("**Effective Date**") between Sol-Gel Technologies Ltd., with a principal place of business at 7 Golda Meir St., Ness Ziona 7403620, Israel ("**Sol-Gel**"), and Galderma Holding SA, with a principal place of business at Rue d'Entre-deux-Villes 10, 1814 La Tour-de-Peilz, Switzerland ("**Galderma**"). Sol-Gel and Galderma may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

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

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

WHEREAS, the Parties desire for Sol-Gel to grant such license to Galderma to Manufacture 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 by the applicable Galderma Entity, as applicable.

Section 1.02 "**Affiliate**" means, with respect to a Party, any corporation or other business entity that (directly or indirectly) is controlled by, controls, or is under common control with such entity for so long as such control exists, with "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") meaning (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of or other equity interests in, 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 or cause the direction of the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise. Notwithstanding the foregoing, neither EQT Partners AB nor any other entity listed on **Schedule 1.02 (Excluded Affiliates)** shall be an Affiliate of Galderma for purposes of this Agreement or have any rights or obligations hereunder.

Section 1.03 "**Business Day**" means a day other than (a) a Saturday or a Sunday or (b) a day on which banking institutions in New York City, USA, Zurich, Switzerland, or Tel Aviv, Israel are authorized or required by Law to remain closed.

Section 1.04 "**CMC**" means the chemistry, manufacturing and controls of Licensed Product.

Section 1.05 "**Commercialization**" or "**Commercialize**" means, with respect to a pharmaceutical product, any and all activities directed to the pre-launch, launch, marketing, branding, promotion, advertising, importation, exportation, warehousing, distribution, shipping, handling, pricing, reimbursement approval, offering for sale, sale, or other commercial exploitation of such pharmaceutical product, and interactions with Regulatory Authorities following the Galderma Start Date for such pharmaceutical product regarding the foregoing, including (a) maintaining all Regulatory Approvals following receipt thereof, conducting communications with the applicable Regulatory Authorities following receipt of Regulatory Approval, and performing other regulatory activities following the Galderma Start Date, and (b) seeking any required reimbursement approval and all post-marketing surveillance. Commercialization shall exclude Development, Manufacturing, and performance of Medical Affairs.

Section 1.06 "**Commercially Reasonable Efforts**" means, with respect to Galderma's performance of certain obligations under this Agreement, the carrying out of such obligations using efforts and resources that are **[***]** with respect to the commercialization of products **[***]**.

Section 1.07 "**Confidential Information**" means, subject to **Section 11.02(a)-(d) (Exceptions)**, (a) any Know-How and any technical, scientific, trade, research, manufacturing, business, financial, compliance, marketing, product, supplier, or other confidential or proprietary information that may be disclosed by or on behalf of one Party or any of its Affiliates to the other Party or any of its Affiliates under this Agreement, which information is specifically designated as confidential or would reasonably be understood or expected by the receiving Party to be confidential, regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

Section 1.08 "**Controls**," or "**Controlled**" means, with respect to a Party or any of its Affiliates (as applicable) and any Know-How, Patent Right, Regulatory Documents, or other intellectual property right, such Party's or such of its Affiliates' ownership of or ability or right (other than pursuant to a license granted to such Party or Affiliate under this Agreement) to grant to the other Party or its Affiliates a license, sublicense, or other right 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. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Know-How, Patent Rights, Regulatory Documents, or other intellectual property rights that **[***]** or to which **[***]** did not otherwise **[***]** *unless*, *however*, the Know-How, Patent Rights, Regulatory Documents, or other intellectual property rights **[***]** any such Know-How, Patent Rights, Regulatory Documents, or other intellectual property rights **[***]**, in which case, such Know-How, Patent Rights, Regulatory Documents or other intellectual property rights are "Controlled" **[***]** for purposes of this Agreement.

Section 1.09 "**Cover**", "**Covering**," or "**Covered**" means, with respect to a product (or any component or ingredient thereof), composition, technology, invention, 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 component or ingredient thereof) or composition or the practice of such technology, invention, 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 1.10 "**Develop**" or "**Development**" means, with respect to a given product, internal and external pre-clinical and non-clinical research and clinical development activities reasonably related to the development and submission of information to a Regulatory Authority or otherwise to the research, identification, testing, and validation of an active ingredient, including (a) clinical trials of a pharmaceutical compound or product, investigator sponsored trials, and registry studies; (b) 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 in the Territory (and all activities related thereto); and (c) any activities relating to the development of chemistry, manufacturing, and control data. Development shall include clinical trials and other regulatory activities initiated prior to the Galderma Start Date to the extent necessary to obtain Regulatory Approval (including preparing all Regulatory Filings), but shall exclude Manufacturing, performance of Medical Affairs, and Commercialization.

Section 1.11 "**Dollars**" **or** "**$**" means the legal tender of the U.S.

Section 1.12 "**Drug Approval Application**" means a New Drug Application as defined in the FD&C Act, or an equivalent application filed with any Regulatory Authority in any country other than the United States.

Section 1.13 "**FD&C Act**" means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

Section 1.14 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto having essentially the same function.

Section 1.15 "**Field**" means the treatment, prevention, cure, or amelioration of rosacea in humans.

Section 1.16 "**First Commercial Sale**" means, with respect to a Licensed Product, the first **[***]** sale of the Licensed Product in the Territory by **[***]** to a Third Party after **[***]**. Sales or other distributions for **[***]** shall not be deemed "First Commercial Sale."

Section 1.17 "**Galderma Entity**" means, as applicable, (a) Galderma, or (b) any of Galderma's Affiliates.

Section 1.18 "**Galderma Regulatory Documents**" means Regulatory Documents Controlled by a Galderma Entity **[***]**.

Section 1.19 "**Galderma Start Date**" means the date on which **[***]**

Section 1.20 "**Generic Product**" means, with respect to a Licensed Product, any pharmaceutical product that (a) is an AB rated generic equivalent of the Licensed Product, (b) is approved by **[***]** in the **[***]** in reliance, in whole or in part, on **[***]**, or (c) **[***]**

Section 1.21 "**Governmental Authority**" means any federal, national, multinational, state, provincial, county, city, municipal, local or other government (including any governmental division, subdivision, department, agency, bureau, branch, office, council, court, arbitrational or other tribunal, commission or other government authority of any nature acting under the authority thereof). Governmental Authorities include all Regulatory Authorities.

Section 1.22 "**IND**" means an Investigational New Drug application for submission to the FDA or any equivalent counterpart application in any country other than the United States, including all supplements and amendments thereto.

Section 1.23 "**Know-How**" means proprietary trade secrets, information, know-how, practices, techniques, methods, processes, procedures, inventions, ideas, data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from pre-clinical and non-clinical studies), technology, software, algorithms, drawings, developments, marketing reports, expertise, chemical and biological materials, other materials, formulations, formulae, documents, studies, results, regulatory approvals, regulatory filings and related correspondence (including DMFs), including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and stability and other data, specifications, sourcing information, assays, quality control and testing procedures, formulations, samples, or compositions of matter of any type or kind, in each case of the foregoing whether or not patented or patentable.

Section 1.24 "**Law**" means any law, statute, rule, regulation, order, judgment, standard, ordinance or other pronouncement of any Governmental Authority anywhere in the world.

Section 1.25 "**Licensed Know-How**" means all Know-How owned or Controlled by Sol-Gel or any of its Affiliates at any time during the Term that is **[***]** for the Manufacturing, use, or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product (or its components or ingredients) in the Field in the Territory.

Section 1.26 "**Licensed Patent Rights**" means any Patent Rights owned or Controlled by Sol-Gel or any of Sol-Gel's Affiliates at any time during the Term that Cover **[***]** with respect thereto, in the Territory, including those Patent Rights listed on **Schedule 1.26 (Licensed Patents)**.

Section 1.27 "**Licensed Product**" means a topical prescription product containing a fixed dose of 5% encapsulated benzoyl peroxide as the main active ingredient, as of the Effective Date known and intended to be marketed under the name "Epsolay®."

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

Section 1.29 "**Licensed Trademark**" means the "Epsolay®" word trademark or **[***]**, as further described in **Schedule 1.29 (Licensed Trademark)**.

Section 1.30 "**Manufacture**" or "**Manufacturing**" means, as applicable, all activities associated with, related to or directed to the production, manufacture, formulation, processing, filling, finishing, packaging, labeling, shipping, handling, importing, exporting, holding or storage of pharmaceutical compounds or materials, or any intermediate thereof, including process and formulation development, process qualification and validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture (including placebo and active controls) and analytical development, product characterization, quality assurance and quality control, testing and release. Manufacture shall exclude Development and Commercialization.

Section 1.31 **"Marketing Authorization Holder"** means a Party that possesses in its name, or is designated as the holder of, all Regulatory Approvals for the Licensed Product in the Territory and that is responsible for managing interactions with Regulatory Authorities in the Territory regarding the Licensed Product.

Section 1.32 "**Medical Affairs**" means any and all activities directed to the formulation and performance of (a) post-marketing clinical trials; (b) medical education; (c) communications and liaising with market and key opinion leaders and advisory boards to extent related to medical affairs or clinical guidance for the development of the Licensed Product, including plans to support continuing medical education; (d) publication plans for the Licensed Product; (e) plans to ensure appropriate medical information responses with respect to the Licensed Product; (f) activities performed in connection with patient registries; (g) safety monitoring plans for the Licensed Product; (h) plans and expected activities for field based medical affairs personnel of the Parties for the Licensed Product; (i) other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs; and (j) other comparable medical affairs activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Product; in each case ((a)-(j)), with respect to the Licensed Product in the Territory. Medical Affairs shall exclude Manufacturing, Development, and Commercialization.

Section 1.33 "**Net Sales**" means the **[***]** from any sale **[***]** of Licensed Products in the Territory to **[***]** by Galderma or **[***]** for consideration thereof ("**Gross Sales**"), reduced by the following amounts actually incurred, allowed, accrued, or specifically allocated to or with respect to the Licensed Product, all as calculated in accordance with Accounting Standards, applied consistently with **[***]** standard accounting practices as applied with respect to **[***]**:

(a) **[***]**;

(b) **[***]**

(c) **[***]**

(d) **[***]**

(e) **[***]**

(f) any invoiced amounts from **[***]** that are **[***]** and are **[***]** or its **[***]**, including **[***]**, not to **[***]** for the **[***]**, and *provided* that if any such amounts are later **[***]**, then they will be **[***]** in the **[***]** in which they are **[***]**; and

(g) **[***]**

If non-monetary consideration is received by a Galderma Entity for the Licensed Product in the Territory, Net Sales will be calculated based on **[***]**, as applicable, during the **[***]**, or in the absence of **[***]**, the **[***]** of the **[***]**, assuming an **[***]**, as determined by **[***]**. For the avoidance of doubt, sales of Licensed Product to or among Galderma, its Affiliates, or its sublicensees shall not be included in Net Sales, but all sales of Licensed Product by Galderma, its Affiliates, and its sublicensees to Third Parties shall be included in Net Sales.

Section 1.34 "**Patent Right(s)**" means all rights under any national, regional and international or other patent or patent application, provisional patent or patent application, certificate of inventions, application for certificate of invention or priority patent filing in any jurisdiction or under any international convention or treaty, including any patents issued or issuing in the future on such patent applications, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, revival, restoration, revalidation, renewal, registration, confirmation, division, continuation, or continuation-in-part of any of the foregoing.

Section 1.35 "**[***]**" means the filing or submission of the **[***]** for **[***]**, as such supplement is, will be, or is currently contemplated by **[***]** to be, required to be submitted to applicable Regulatory Authority in the Territory following **[***]** for the Licensed Product in the Territory, subject to **Section 4.01 (Sol-Gel Regulatory Responsibility)**.

Section 1.36 "**Regulatory Approval**" means, with respect to a particular regulatory jurisdiction, an approval, license, registration or authorization granted by any Governmental Authority that provides marketing approval or authorization for the commercial sale or other Commercialization of a product in one or more specified indications in such regulatory jurisdiction, including pricing or reimbursement approval, pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and approval of product labeling. For the avoidance of doubt, approval of a Drug Approval Application constitutes Regulatory Approval.

Section 1.37 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including the United States FDA and any other applicable Governmental Authority in the Territory having jurisdiction over pharmaceutical products.

Section 1.38 "**Regulatory Documents**" means all (a) Regulatory Filings and other applications for Regulatory Approval, registrations, licenses, authorizations, approvals (including Regulatory Approvals) and marketing or regulatory exclusivities made to, received from, or otherwise conducted with a Regulatory Authority for a Licensed Product in a particular country or jurisdiction; (b) correspondence, communications, notifications, reports, or other filings 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.

Section 1.39 "**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, Drug Approval Applications, new drug submissions, clinical trial applications, and other Regulatory Approval and reimbursement approval applications.

Section 1.40 "**Sol-Gel Entity**" means, as applicable, (a) Sol-Gel or (b) any of Sol-Gel's Affiliates.

Section 1.41 "**Sol-Gel Regulatory Documents**" means Regulatory Documents Controlled by a Sol-Gel Entity as of **[***]** that relate to a Licensed Product.

Section 1.42 "**Territory**" means the United States.

Section 1.43 "**Third Party**" means any person, individual, corporation, partnership, limited liability company, trust, unincorporated association, Governmental Authority or other entity or body other than the Parties and their Affiliates.

Section 1.44 "**Trademark**" means any word, name, symbol, color, designation or device, or any combination thereof, that functions as a source identifier or indicia of origin or ownership, including any trademark, trade name, service mark,

service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, and further including the goodwill and activities associated with each of the foregoing.

Section 1.45 "**U.S.**" or "**United States**" means the United States of America, including its districts, territories and possessions.

The following table contains a list of additional terms defined in the corresponding Sections set forth below:

Additional Defined Terms	Section
Additional Term	Section 13.01 (Term)
Alliance Manager	Section 3.07 (Alliance Managers)
Arbitration Request	Section 14.02(a) (Arbitration Request)
Bankrupt Party	Section 13.05(a) (Termination for Bankruptcy and Rights in Bankruptcy)
Breaching Party	Section 13.04 (Termination for Breach)
Breach Notice	Section 13.04 (Termination for Breach)
Claims	Section 12.01 (Indemnification by Sol-Gel)
Commercialization Plan	Section 5.02 (Commercialization Plan)
CMO	Section 6.01 (Manufacture and Supply)
Event of Bankruptcy	Section 13.05(a) (Termination for Bankruptcy and Rights in Bankruptcy)
Executive Officer	Section 14.01 (Executive Officers; Disputes)
FCPA	Section 10.04(b)(i) (Anti-Corruption Compliance)
Galderma Indemnitees	Section 12.01 (Indemnification by Sol-Gel)
Galderma Product Data	Section 4.04 (Galderma Product Data)
Government Official	Section 10.04(a) (Anti-Corruption Provisions)
Gross Sales	Section 1.33 (Definition of "Net Sales")
ICC	Section 14.02 (Arbitration)
Indemnified Party	Section 12.03 (Procedure)
Indemnifying Party	Section 12.03 (Procedure)
Infringement Activity	Section 8.03(a) (Enforcement)
Initial Term	Section 13.01 (Term)
Inventions	Section 8.01(b) (Ownership of Intellectual Property)
Issuing Party	Section 11.04 (Publicity)
JSC	Section 3.01 (General)
Losses	Section 12.01 (Indemnification by Sol-Gel)
Minimum Order Quantities	Section 5.01 (General; Diligence)
Non-Breaching Party	Section 13.04 (Termination for Breach)
Other Covered Party	Section 10.04(a) (Anti-Corruption Provisions)
Other Party	Section 13.05(a) (Termination for Bankruptcy and Rights in Bankruptcy)
Patent Challenge	Section 13.06 (Termination for Patent Challenge)
Payment	Section 7.10(a) (General)
Post-Generic Price	Section 5.01 (General; Diligence)
Public Statement	Section 11.04 (Publicity)
Recipient	Section 11.02 (Exceptions)
Refund Date	Section 7.02 (Possible Refund of Upfront Payment)
Renewal Discussion Period	Section 13.01 (Term)
Representatives	Section 11.01 (Generally)
Residual Knowledge	Section 11.02 (Exceptions)
Right of Reference	Section 4.02(c) (Galderma Regulatory Responsibility)
Rules	Section 14.02 (Arbitration)
Safety Data Exchange Agreement	Section 9.02 (Safety Data Exchange Agreement)
Sell-Off Period	Section 13.07(a)(iii) (Effect of Termination)
Severed Clause	Section 16.03 (Severability)
Shortfall Period	Section 5.01 (General; Diligence)
Shortfall Quantity	Section 5.01 (General; Diligence)
Sol-Gel Indemnitees	Section 12.02 (Indemnification by Galderma)
Sol-Gel Inventions	Section 8.01(c) (Ownership of Intellectual Property)
Sol-Gel Invention Patents	Section 8.01(d) (Ownership of Intellectual Property)
Sol-Gel Product Data	Section 4.03 (Technology Sharing)
Subcontractor	Section 2.03 (Subcontractors)
Supply Agreement	Section 6.01 (Manufacture and Supply)
Term	Section 13.01 (Term)
Withholding Tax Action	Section 7.10(b) (No Withholding Tax)

ARTICLE II

LICENSES

Section 2.01. Grants of Licenses; Limitation.

(a) Subject to the terms and conditions of this Agreement, Sol-Gel and its Affiliates hereby grant to Galderma and Galderma's Affiliates:

(i) an exclusive (including as to Sol-Gel and its Affiliates), royalty-bearing, sublicenseable (solely pursuant to **Section 2.02 (Sublicensing)**), transferable (subject to **Section 15.01 (Assignment)**) license solely during the Term under the Licensed Technology solely to register, have registered (for clarity, only after the Galderma Start Date), use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold, Manufacture, have Manufactured, perform Medical Affairs with respect to, have Medical Affairs performed with respect to, Commercialize, have Commercialized, and otherwise exploit or have exploited the Licensed Product in the Field in the Territory and to import, have imported, export, have exported, Manufacture, and have Manufactured the Licensed Product outside the Territory for Commercialization in the Field in the Territory; and

(ii) an exclusive (including as to Sol-Gel and its Affiliates), sublicenseable (solely pursuant to **Section 2.02 (Sublicensing)**), transferable (subject to **Section 15.01 (Assignment)**) license to use the Licensed Trademark for and in connection with the Licensed Product in the Territory.

(b) Sol-Gel shall not, and shall ensure that its Affiliates do not, either directly or indirectly, knowingly promote, market, distribute, import, sell, or have sold any Licensed Product, including via internet or mail order, into the Territory during the Term. As to the Territory, Sol-Gel shall not, and shall ensure that its Affiliates do not: (i) establish or maintain any branch, warehouse, or distribution facility for any Licensed Product in the Territory for the sale of such Licensed Product in the Territory during the Term, (ii) engage in any advertising or promotional activities relating to any Licensed Product that are directed primarily to customers or other purchasers or users of such Licensed Product located in the Territory during the Term, (iii) solicit orders from any prospective purchaser located in the Territory during the Term, or (iv) sell or distribute Licensed Product to any person who it knows intends to sell such Licensed Product in the Territory during the Term. Notwithstanding the foregoing, in the event that Galderma provides a termination notice to Sol-Gel under **Section 13.03 (Termination for Failure to Receive Regulatory Approval)**, Sol-Gel shall be entitled to perform some or all of the activities set forth in (i) through (iii) above, as part of the transition of rights back to Sol-Gel, subject to the terms of **Section 13.07 (Effect of Termination)**. If Sol-Gel receives any order from a prospective purchaser located in the Territory during the Term, then Sol-Gel shall immediately refer that order to Galderma, and Sol-Gel shall not accept any such orders. Sol-Gel shall not deliver or tender (or cause to be delivered or tendered) Licensed Product into the Territory during the Term.

(c) Galderma shall not, and shall ensure that its Affiliates do not, either directly or indirectly, knowingly promote, market, distribute, sell, or have sold any Licensed Product, including via internet or mail order, outside the Territory during the Term. Galderma shall not, and shall ensure that its Affiliates do not: (i) establish or maintain any branch, warehouse or distribution facility for any Licensed Product in any jurisdictions for the sale of such Licensed Product outside the Territory, (ii) engage in any advertising or promotional activities relating to any Licensed Product that are directed primarily to customers or other purchasers or users of such Licensed Product located outside the Territory, (iii) solicit orders from any prospective purchaser located outside the Territory, or (iv) sell or distribute Licensed Product to any person who it knows intends to sell such Licensed Product outside the Territory. If Galderma receives any order from a prospective purchaser located outside the Territory during the Term, then Galderma shall immediately refer that order to Sol-Gel, and Galderma shall not accept any such orders. Galderma shall not deliver or tender (or cause to be delivered or tendered) Licensed Product outside of the Territory during the Term.

(d) Galderma hereby grants to Sol-Gel a perpetual, irrevocable, non-exclusive, royalty-free, fully paid-up, worldwide license under Galderma's interest in any and all Inventions developed by Galderma during the Term and prior to the effective date of termination of this Agreement in the performance of activities under this Agreement, and all Patent Rights Controlled by Galderma during the Term and prior to the effective date of termination of this Agreement that Cover any such Inventions, in each case, to Develop, Manufacture, perform Medical Affairs with respect to, and Commercialize the Licensed Product (i) outside of the Territory during and after the Term; and (ii) **[***]**.

(e) As between the Parties, all rights not expressly licensed to Galderma and its Affiliates under the Licensed Technology in **Section 2.01(a) (Grants of Licenses; Limitation)** or elsewhere in this Agreement shall be retained by Sol-Gel, including the right to Develop, perform Medical Affairs with respect to, 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.

Section 2.02. **Sublicensing**. Galderma and its Affiliates shall have the right to sublicense the rights and obligations granted to it under **Section 2.01(a)**(i) **(Grants of Licenses; Limitation)** without Sol-Gel's prior written consent to **[***]** and (b) Subcontractors. Notwithstanding the grant of any such sublicense, Galderma will remain responsible for the performance of its obligations hereunder.

Section 2.03. **Subcontractors**. In performing its activities under this Agreement, Galderma may engage Third Party contractors to perform obligations or exercise rights, in each case, of Galderma under this Agreement (each, a "**Subcontractor**") at its sole discretion. Any breach by a Subcontractor of the applicable terms of this Agreement relating to such portions of Galderma's obligations will be deemed a breach by Galderma. The engagement of any Subcontractor in compliance with this **Section 2.03 (Subcontractors)** will not relieve Galderma of its obligations under this Agreement.

ARTICLE III

GOVERNANCE

Section 3.01. **General**. Within **[***]** days following the Effective Date, the Parties shall establish a Joint Steering Committee ("**JSC**") to facilitate discussions, information exchange and coordination of the Parties under this Agreement to the extent relating specifically to matters for which the JSC is responsible pursuant to **Section 3.03 (Joint Steering Committee)**.

Section 3.02. **JSC Materials**. At least **[***]** weeks in advance of each meeting of the JSC held in accordance with **Section 3.06 (Meetings)**, Galderma shall provide the JSC with (a) a summary of **[***]** by **[***]** with respect to the Licensed Product in the Territory since the previous JSC meeting, which summary shall include, for the period since the previous JSC meeting, (i) a reasonably detailed description of **[***]**, (ii) estimates of the **[***]** in each **[***]** during such period, (iii) estimates of the **[***]** or **[***]** for such Licensed Product **[***]**, and (iv) **[***]**, and (b) **[***]**. Such summary **[***]** will be delivered by Galderma to Sol-Gel in a format reasonably determined by Galderma.

Section 3.03. **Joint Steering Committee**.

(a) The JSC shall:

(i) discuss **[***]** of the Licensed Product in the Field in the Territory in relation thereto;

(ii) discuss the summaries of **[***]** activities performed by Galderma hereunder, as such summaries are provided to the JSC pursuant to **Section 3.02 (JSC Materials)**;

(iii) serve as a forum for exchanging information regarding the conduct of the **[***]** of the Licensed Product in the Field in the Territory;

(iv) determine whether to create any additional subcommittee(s) or working group(s) to whom the JSC's responsibilities hereunder may be delegated; and

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

Section 3.04. **Membership**. The JSC shall be composed of **[***]** 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 on the JSC and any replacement of such representatives 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 **[***]** its or its Affiliates' employees, consultants, or advisors as required or useful to discuss the applicable agenda items. The JSC shall appoint a chairperson from among its members who will be responsible for preparing JSC meeting agendas and for presiding over JSC meetings, but who will **[***]**. The first chairperson of the JSC will be a representative of **[***]**. Each chairperson (whether initially appointed or any successor therefor) shall serve a term of no more than **[***]** consecutive **[***]**, 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.

Section 3.05. **Meetings**. The JSC shall hold an initial meeting within **[***]** 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. **Limitations on JSC Authority**. Notwithstanding any provision to the contrary set forth in this Agreement, the **[***]** and shall not **[***]**. For the avoidance of doubt, **[***]**, subject to the terms and conditions of this Agreement relating thereto.

Section 3.07. **Alliance Managers**. Each of the Parties shall appoint a single individual to manage and be a single point of contact with respect to the Development, Medical Affairs, and Commercialization obligations between the Parties under this Agreement (each, an "**Alliance Manager**"). The Alliance Managers may attend any JSC or JSC subcommittee meetings. Each Alliance Manager shall be a non-voting participant in such JSC or JSC subcommittee meetings, unless s/he is also appointed a member of the JSC or such subcommittee; *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 and is within the JSC's responsibilities set forth in **Section 3.03 (Joint Steering Committee)** or otherwise expressly set forth herein. 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. **Sol-Gel Regulatory Responsibility**. Until **[***]**, **[***]** shall have **[***]** with respect to, preparing all Regulatory Filings and conducting communications with the applicable Regulatory Authorities with respect to the Licensed Product, including as necessary to obtain Regulatory Approval for the Licensed Product in the Territory, all at **[***]** cost and expense. Until **[***]**, reasonably in advance of any decision, communication, or filing related to the Licensed Product in the Territory, **[***]**. During the Term, Sol-Gel shall give Galderma reasonable notice of any meeting (whether held in person, by video, by teleconference, or by any other means) with any Regulatory Authority relating to the Licensed Product in the Territory, and Galderma shall have the right to attend, or to have a representative attend on its behalf, any such meeting or any preparatory meeting therefor.

Section 4.02. Galderma Regulatory Responsibility.

(a) Promptly, but no later than **[***]**, **[***]**, Sol-Gel shall transfer and assign to Galderma, **[***]**, all Regulatory Filings and other Regulatory Documents related to the Licensed Product in the Territory or otherwise necessary or reasonably useful to enable Galderma to perform its obligations under this **Section 4.02 (Galderma Regulatory Responsibility)**, and immediately thereafter, Sol-Gel shall designate Galderma as the Marketing Authorization Holder for the Licensed Product in the Territory. **[***]**, Galderma shall thereafter have sole control over, and have decision-making authority with respect to, preparing, obtaining, and maintaining all Regulatory Filings and Regulatory Approvals, conducting communications with the applicable Regulatory Authorities, and performing other regulatory activities and Medical Affairs, in each case, as reasonably useful to perform or support the marketing and Commercialization of the Licensed Product in the Territory, **[***]**

(b) Following the **[***]**, at Galderma's request, Sol-Gel shall **[***]** prepare, complete, and submit the **[***]**. Reasonably in advance of submitting the **[***]**, Sol-Gel will submit the same to Galderma for review and approval, and Sol-Gel will incorporate any comments thereon received from Galderma. Prior to submitting the **[***]**, Sol-Gel must obtain **[***]**. Galderma will reimburse Sol-Gel for out-of-pocket costs reasonably incurred by Sol-Gel to complete and submit the Post-Approval Stability Data Filing.

(c) Upon the **[***]** and as Galderma may reasonably request from time to time thereafter, Sol-Gel shall, in support of Galderma's preparation of any Regulatory Filing with respect to the Licensed Product in the Field in the Territory, provide Galderma access to a complete electronic copy of all (i) Sol-Gel Regulatory Documents, (ii) Regulatory Documents Controlled by any Sol-Gel Entity (including those generated by any of Sol-Gel's sublicensees that are Controlled by Sol-Gel) that are related to the Licensed Product in the Field, and (iii) other information requested by, or reasonably necessary or useful for responding to requests by, Regulatory Authorities in the Territory in connection with Galderma's Regulatory Filings, in each case ((i) – (iii)), solely to the extent Controlled by the Sol-Gel Entities or any of their Third Party sublicensees or licensees for the Licensed Product, and Sol-Gel will obtain the prior written consent of any of the Sol-Gel Entities' Third Party sublicensees or Third Party licensees to the extent necessary to provide to Galderma and its Affiliates any such Sol-Gel Regulatory Documents, Regulatory Documents, or other information. Without limiting the foregoing, Sol-Gel and its Affiliates hereby grant to Galderma a "**Right of Reference**," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including all CMC information as well as data made, collected or otherwise generated in the conduct of any clinical studies for the Licensed Product) included in any Sol-Gel Regulatory Document, or other Regulatory Filing, Regulatory Approval, drug master file, or other regulatory documentation owned or Controlled by Sol-Gel or its Affiliates that relates to the Licensed Product, and Sol-Gel shall provide a signed statement to this effect, if requested by Galderma, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Law recognized outside of the United States).

(d) Except as expressly otherwise provided herein, **[***]** in conducting its regulatory responsibilities and meeting the requirements of applicable Regulatory Authorities as set forth under this **Section 4.02 (Galderma Regulatory Responsibility)**, **[***]** in transferring Regulatory Documentation to Galderma or otherwise assisting Galderma in conducting its regulatory responsibilities under this **Section 4.02 (Galderma Regulatory Responsibility)**. **[***]**.

(e) Following the **[***]**, reasonably in advance of any filing or submission of any application for label expansion related to the Licensed Product in the Territory during the Term, Galderma will submit the same to Sol-Gel for review and discussion, and Galderma will **[***]**. Galderma shall provide Sol-Gel with notice of any changes that Galderma determines to make to the specifications or manufacturing processes for the Licensed Product and shall **[***]** prior to implementing any such change, **[***]**; *provided* that **[***]**. During the Term, Galderma shall give Sol-Gel reasonable notice of any meeting (whether held in person, by video, by teleconference, or by any other means) with any Regulatory Authority relating to such application, and Sol-Gel shall have the right to attend, or to have a representative attend on its behalf, any such meeting or any preparatory meeting therefor.

Section 4.03. **Technology Sharing**. Upon the Galderma Start Date, and thereafter at least **[***]** or more frequently upon Galderma's request, Sol-Gel shall provide to Galderma all data and documents Controlled by any Sol-Gel Entities and related to the Licensed Product that are reasonably necessary or useful for Galderma to Commercialize and perform Medical Affairs with respect to Licensed Product in the Territory or to perform its obligations under **Section 4.02 (Galderma Regulatory Responsibility)**, including Licensed Know-How, regulatory data, and clinical data. Throughout the Term, Sol-Gel shall provide Galderma with updates 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. In addition, at least **[***]** or more frequently upon Galderma's request, Sol-Gel shall make available to Galderma 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 or sublicensees (collectively, the "**Sol-Gel Product Data**"), to the extent (i) such Sol-Gel Product Data are necessary or reasonably useful for any Galderma Entity to Commercialize or perform Medical Affairs with respect to Licensed Product in the Field in the Territory in accordance with this Agreement, or (ii) such Sol-Gel Product Data are required by Regulatory Authority in the Territory in connection with the Commercialization of or performance of Medical Affairs with respect to Licensed Product in the Field in the Territory.

Section 4.04. **Galderma Product Data**. After **[***]**, upon Sol-Gel's reasonable request, Galderma shall make available to Sol-Gel copies of Galderma Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case, that pertain to the Licensed Product and are Controlled by a Galderma Entity or its sub-contractor (collectively, the "**Galderma Product Data**"), to the extent such Galderma Product Data are reasonably necessary for Sol-Gel or its Affiliates or (sub)licensees to exercise Sol-Gel's retained rights. Galderma and its Affiliates hereby grant to Sol-Gel a Right of Reference to, and a right to copy, access, and otherwise use, all information and data included in any Regulatory Filing, Regulatory Approval, drug master file, or other regulatory documentation owned or Controlled by Galderma or its Affiliates that relates to the Licensed Product, and Galderma shall provide a signed statement to this effect, if requested by Sol-Gel, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Law recognized outside of the United States).

Section 4.05. **Generic Products**.

(a) Subject to **Section 4.05(b) (Generic Products)**, Galderma will in no event during the Term, seek Regulatory Approval for or otherwise engage in the Development, Manufacture, or Commercialization of (i) any pharmaceutical product pursuant to Section 505(b)(2) of the U.S. Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)) that uses the Licensed Product as a reference listed drug for the same indication for which the Licensed Product is approved in the Territory; or (ii) subject to **Section 2.02 (Sublicensing)**, any Generic Product, in each case, in the Territory.

(b) Subject to **Section 4.05(a) (Generic Products)**, Sol-Gel and its Affiliates will in no event during the Term launch or Commercialize, or enter into any agreement for the launch or Commercialization by a Third Party of, (i) any pharmaceutical product pursuant to Section 505(b)(2) of the U.S. Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)) that uses the Licensed Product as a reference listed drug for the same indication for which the Licensed Product is approved in the Territory; or (ii) any Generic Product, in each case, in the Territory. Notwithstanding the foregoing, upon Galderma's written request during the Term that the Parties enter into an agreement for Galderma to Commercialize an authorized Generic Product in the Territory, the Parties will discuss such request in good faith and may agree to enter into such an agreement.

ARTICLE V

COMMERCIALIZATION

Section 5.01. **General; Diligence**. **[***]**, and otherwise subject to Sol-Gel's satisfaction of its applicable obligations hereunder that by their nature are necessary for Galderma's Commercialization of the Licensed Product in the Territory (including under **Section 6.01 (Manufacture and Supply)**), Galderma shall use Commercially Reasonable Efforts to **[***]**. Notwithstanding any provision to the contrary set forth in this Agreement, any failure of Galderma to comply with its obligations under this **Section 5.01 (General; Diligence)** with respect to the Licensed Product will be excused to the extent that such failure results solely from Sol-Gel's failure to obtain Regulatory Approval (as applicable) for the Licensed Product in the Territory or otherwise perform its obligations under this Agreement. Except as expressly otherwise provided herein **[***]**.

Section 5.02. **Commercialization Plan**. On or before **[***]** (or at such other time as the Parties may otherwise agree), Galderma shall submit to the JSC to review and discuss a Commercialization plan setting forth for the upcoming calendar year (a) **[***]**, (b) **[***]**, and (c) **[***]** anticipated by Galderma to be undertaken, in each case ((a)-(c)), for the Licensed Products in the Territory (the "**Commercialization Plan**"). During the Term following submission of the initial Commercialization Plan, Galderma will prepare and submit to the JSC **[***]** updates to the Commercialization Plan for review and discussion.

ARTICLE VI

MANUFACTURE AND SUPPLY

Section 6.01. **Manufacture and Supply**. Galderma, **[***]**, shall have sole control over, and decision-making authority with respect to, Manufacturing of the Licensed Products inside or outside the Territory for purposes of Commercialization in the Field in the Territory during the Term. At any time during the Term in Galderma's sole discretion, Galderma shall have the right to, and Sol-Gel shall assist and cooperate with Galderma's efforts to, enter into Third Party manufacture and commercial supply agreements for the Manufacture and supply of Licensed Product during the Term with any contract manufacturing organization(s) **[***]** (each such contract manufacturing organization, a "**CMO**," and each such agreement entered into by Galderma with a CMO, a "**Supply Agreement**"). In such case, upon the request of Galderma, Sol-Gel shall promptly transfer to any applicable CMO all documents, data (including an appropriate set of base reference Manufacturing process data), activities, Licensed Know-How, and other Know-How (including the process for Manufacturing Licensed Product and the analytical testing methodology for the Licensed Product) necessary or reasonably useful for the Manufacture of Licensed Product and to enable such CMO to assume the Manufacturing activities of the Licensed Product for Commercialization in the Territory. In addition, as part of such technology transfer, Sol-Gel will perform analytical testing services as reasonably requested by Galderma or its Affiliate to validate the transferred Manufacturing process. Such activities shall be performed pursuant to reasonable written agreements among Sol-Gel, Galderma, and each such CMO, which agreements shall contain reasonable terms and conditions for the use and confidentiality of such technology. **[***]**.

ARTICLE VII

PAYMENTS

Section 7.01. **Upfront Payment**. Within **[***]** following the Effective Date and receipt of an invoice therefor, Galderma shall pay Sol-Gel a one-time, non-creditable, refundable (solely pursuant to **Section 7.02 (Possible Refund of Upfront Payment)**) upfront payment of **[***]**, by wire transfer in accordance with **Section 7.09 (Methods of Payment)**.

Section 7.02. **Possible Refund of Upfront Payment**. Notwithstanding **Section 7.01 (Upfront Payment)**, in the event that the Licensed Product does not receive Regulatory Approval from the FDA in the Territory on or before **[***]** (the "**Refund Date**"), Sol-Gel will refund to Galderma the upfront payment made under **Section 7.01 (Upfront Payment)** within **[***]** after such Refund Date. For the avoidance of doubt, Galderma shall remain entitled to such refund even in the event that the Licensed Product subsequently receives Regulatory Approval in the Territory following the Refund Date.

Section 7.03. **Regulatory Milestone Payment**. Within **[***]** days following **[***]** in the Territory, and receipt of an invoice therefor, Galderma shall pay Sol-Gel a one-time, non-refundable, non-creditable payment of **[***]**; *provided*, *however*, that Galderma shall not be obligated to make such payment in the event that, following the Refund Date, Galderma has given Sol-Gel notice of termination of this Agreement pursuant to **Section 13.02 (Termination at Will by Galderma)** and Regulatory Approval of the Licensed Product from the FDA in the Territory is received thereafter.

Section 7.04. **Sales Milestone Payments**. Galderma shall pay to Sol-Gel the following one-time payments after the first achievement of aggregate annual Net Sales of Licensed Product in the Territory by Galderma or its Affiliates or sublicensees that meet or exceed the minimum annual Net Sales thresholds set forth below in a given calendar year, which payment shall be made no later than **[***]** after the end of the calendar quarter in which the applicable threshold(s) is (are) met or exceeded:

Annual Net Sales of the Licensed Product in the Territory	**Payment Amount**
Equal to or greater than $**[***]**	$**[***]**
Equal to or greater than $**[***]**	$**[***]**

For clarity, each milestone payment in this **Section 7.04 (Sales Milestone Payments)** shall be payable no more than 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. If more than one of the milestones set forth in the table above are first achieved in a single calendar year, then Galderma shall pay to Sol-Gel in such calendar year all of the payments corresponding to all of the milestones first achieved in such calendar year under this **Section 7.04 (Sales Milestone Payments)**.

Section 7.05. **Royalties**.

(a) Subject to the remainder of this **Section 7.05 (Royalties)**, Galderma shall pay Sol-Gel the following royalties on Net Sales of the Licensed Product in the Territory in each calendar quarter during the Term, **[***]** set forth below during the applicable period during the Term:

[***]	**Royalty Rate for Net Sales of the Licensed Product in the Territory**
[***]	**[***]**
[***]	**[***]**

(b) Notwithstanding the provisions of **Section 7.05(a) (Royalties)**, after the **[***]** to **[***]**, beginning upon the first to occur of (i) the **[***]** by a person that is not a **[***]** and did not **[***]**, in a **[***]** that included any **[***]**; and (ii) **[***]** otherwise determined in accordance with **Section 7.05(a) (Royalties)**.

(c) In the event that **[***]** are) required in its (or their) reasonable judgement to obtain, after the **[***]**, a license under Patent Rights from any Third Party(ies) that would be infringed by **[***]** (or its **[***]**) Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product in the Territory and **[***]** obtains (or such of its **[***]** obtain) such a license, **[***]** may offset, on a calendar quarter-by-calendar quarter basis, **[***]** from the **[***]** otherwise due to **[***]**.

(d) Notwithstanding the foregoing, in no event shall the royalty payments owed by Galderma under this **Section 7.05 (Royalties)** be reduced **[***]** to less than **[***]** of the royalty payment amounts otherwise due to Sol-Gel under **Section 7.05(a) (Royalties)** in any calendar quarter during the Term.

Section 7.06. **Royalty Payments and Reports**.

(a) On a Licensed Product-by-Licensed Product basis, commencing upon the First Commercial Sale of Licensed Product in the Territory and continuing until the expiration of the Term, Galderma agrees to provide **[***]**, each such written report stating for the applicable period the **[***]**). The Parties acknowledge and agree that the monthly sales estimated actuals provided by Galderma to Sol-Gel pursuant to this **Section 7.06(a) (Royalty Payments and Reports)** (a) are **[***]**, (b) are provided to Sol-Gel **[***]**, and (c) are **[***]** by Sol-Gel or to **[***]** in any manner whatsoever. Sol-Gel shall not be permitted to request, and Galderma shall not be required to provide, make, or conduct, **[***]** following delivery thereof.

(b) On a Licensed Product-by-Licensed Product basis, commencing upon the First Commercial Sale of Licensed Product in the Territory and continuing until the expiration of the Term, Galderma agrees to provide quarterly written reports to Sol-Gel within **[***]** after the end of each **[***]**, covering all **[***]** of such **[***]** in the **[***]** by any **[***]**, each such written report stating for the period in question the **[***]** to **Section 7.05 (Royalties)**.

(c) Following delivery of each **[***]** report by Galderma to Sol-Gel pursuant to **Section 7.06(b) (Royalty Payments and Reports)**, Galderma shall make the applicable royalty payment due under **Section 7.05 (Royalties)** for each applicable **[***]** within **[***]** after receipt of an invoice therefor from Sol-Gel. Notwithstanding any provision to the contrary set forth in this Agreement, in any applicable **[***]**, Galderma may **[***]**.

(d) Galderma shall provide written notice to Sol-Gel of the first occurrence of any of the milestones set forth in **Section 7.04 (Sales Milestone Payments)** of this Agreement within **[***]** after **[***]**.

Section 7.07. **Recordkeeping**. Galderma shall keep accurate records as are required and in sufficient detail to determine the Payments due to Sol-Gel under this Agreement in accordance with the Accounting Standards. Galderma shall retain all such books, records, and accounts for a period of at least **[***]** years after the end of the calendar year to which the records relate. Galderma further agrees to permit such books and records to be examined, at **[***]** cost and expense, by an independent accounting firm selected by **[***]** and reasonably acceptable to **[***]** no more than **[***]** to verify any reports and payments delivered under this Agreement during the **[***]** most recently-ended calendar years, upon reasonable written notice (which shall be no less than **[***]** days' prior written notice) and during regular business hours 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 **[***]**, **[***]** during the period 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 the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales invoiced in a currency other than the Dollar), such conversion shall be made into Dollars at the conversion rate existing in the United States (as reported in the *Wall Street Journal*) on the last Business Day of the applicable calendar quarter or, if such rate is unavailable, a substitute therefor reasonably selected by Galderma. 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 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 to Sol-Gel under this Agreement shall be made by Galderma in Dollars by wire transfer to a bank account designated by Sol-Gel. Any refund due to Galderma pursuant to **Section 7.02 (Possible Refund of Upfront Payment)** or other reimbursement of cost and expenses due to Galderma hereunder shall be made by Sol-Gel in Dollars by wire transfer to a bank account designated by Galderma.

Section 7.10. **Taxes**.

(a) **General**. The milestones, royalties and other amounts payable by Galderma 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 **[***]**) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Galderma will deduct or withhold from the Payments any taxes that it is required by applicable Law to deduct or withhold. 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 will deliver to Galderma or the appropriate governmental authority (with the assistance of Galderma 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 Galderma of its obligation to withhold such tax, and Galderma will apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Galderma has received evidence, in a form reasonably satisfactory to Galderma, of Sol-Gel's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least **[***]** prior to the time that the Payments are due. If, in accordance with the foregoing, Galderma withholds any amount, it will pay to Sol-Gel the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Sol-Gel proof of such payment within **[***]** following such payment.

(b) **No Withholding Tax**. Galderma agrees that all Payments will be made by a Galderma Entity with its tax residence in **[***]**, and no withholding taxes shall be required in respect of such Payments. 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) (General)**, the payment by Galderma (in respect of which such deduction or withholding of tax is required to be made) shall be increased by the amount necessary to ensure that Sol-Gel receives an amount equal to the same amount that it would have received had no Withholding Tax Action occurred, whereas such gross-up is limited to the net amount due for such Withholding Tax Action as per the Convention between the Swiss Confederation and the State of Israel for the avoidance of double taxation concerning income tax and wealth tax and on the basis that Sol-Gel is a tax resident of Israel.

Section 7.11. **Invoices**. Any invoice that Sol-Gel delivers to Galderma under this Agreement may be delivered by email to **[***]** (which email address may be changed by Galderma from time to time upon written notice to Sol-Gel), with a hard copy confirmed by mailing to:

Galderma SA

[***]

(which addresses may be changed by Galderma from time to time upon written notice to Sol-Gel).

Section 7.12. **Late Payments**. If a Party 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 such Party from the due date until the date of payment at the **[***]**, as reported by The Wall Street Journal from time to time, **[***]**, or the maximum applicable legal rate, if less. The interest payment shall be due from the **[***]** until the day that the payment was received by such Party; *provided* that, with respect to any *bona fide* disputed payments, **[***]**, calculated from **[***]** through the date **[***]**.

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 Intellectual Property)**, ownership of 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) (Ownership of Intellectual Property)** and subject to **Section 8.01(e) (Ownership of Intellectual Property)**, regardless of inventorship, any and all Inventions, Patent Rights and Know-How that are exclusively directed to the Licensed Product or the composition, use, administration, formulation, or other aspect thereof (and, in each case, not to any other product) and (i) are developed or generated by or on behalf of Sol-Gel or any of its Affiliates, **[***]**, or (ii) improve upon or are derived from Sol-Gel's Confidential Information, the Licensed Technology **[***]**, and all intellectual property rights therein ("**Sol-Gel Inventions**") shall be owned exclusively and solely by Sol-Gel. **[***]**.

(d) Any Patent Rights that Cover or otherwise claim any Sol-Gel Inventions ("**Sol-Gel Invention Patents**") shall be treated for the purposes of this Agreement as part of the Licensed Patent Rights, and any Know-How that is part of the Sol-Gel Inventions shall be treated for the purposes of this Agreement as part of the Licensed Know-How.

(e) Sol-Gel hereby grants to Galderma a perpetual, irrevocable, non-exclusive, sublicenseable (through multiple tiers), royalty-free, transferable (subject to **Section 15.01 (Assignment)**) license under all Sol-Gel Inventions that are developed or generated by or on behalf of Galderma or any of its Affiliates or jointly developed or generated by or on behalf of both Parties (including any Patent Rights that Cover or otherwise claim any such Sol-Gel Inventions) to register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold, and otherwise exploit or have exploited **[***]** (but, for clarity, not the **[***]**).

Section 8.02. **Prosecution of Patent Rights**. Sol-Gel shall be responsible for and have the first right to control the preparation, filing, prosecution, and maintenance of all Licensed Patent Rights (including Sol-Gel Invention Patents) in the Territory in Sol-Gel's name and at its sole cost and expense. Sol-Gel will: (i) instruct such patent counsel to provide Galderma with copies of all proposed filings, submissions, and other substantive correspondences relating to such Licensed Patent Rights in the Territory for Galderma's review and comment, (ii) give Galderma reasonable opportunity to provide, and consider in good faith and incorporate, comments on the preparation, filing, prosecution, and maintenance of the Licensed Patent Rights in the Territory prior to making any such filing, submission, or other substantive correspondence, and (iii) keep Galderma advised of the status of actual and prospective patent filings related to a Licensed Product in the Territory. Subject to the foregoing, 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. If Sol-Gel elects not to continue to seek or maintain, or elects to let lapse, any Licensed Patent Rights, then Sol-Gel will provide Galderma with timely notice and will provide Galderma with a reasonable opportunity to assume responsibility for the continued prosecution and maintenance of such Licensed Patent Rights at its own cost and expense and in the name of Sol-Gel.

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) any of the Licensed Patent Rights, 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, until either Party provides a notice of termination of this Agreement pursuant to any of **Section 13.02 (Termination at Will by Galderma)** through **Section 13.06 (Termination for Patent Challenge**), other than any notice of termination that Galderma disputes, Galderma 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 at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. Galderma will (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 relating thereto), and (ii) reasonably consult with Sol-Gel on such infringement or misappropriation suit. If Galderma notifies Sol-Gel that Galderma will not take steps to enforce the Licensed Patent Rights in the Territory against Infringement Activity, or fails to bring an action 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 taking commercially appropriate steps at its own cost and expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. After the Term and during the Term beginning upon either Party's provision of a notice of termination of this Agreement pursuant to any of **Section 13.02 (Termination at Will by Galderma)** through **Section 13.06 (Termination for Patent Challenge**), other than any notice of termination that Galderma disputes, and at all times thereafter during the period between a Party's provision of such notice of termination and the effective date of such termination, Sol-Gel shall have the sole right, but not the obligation, to resolve any Infringement Activity related to the Licensed Patent Rights at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice.

(c) Any amounts recovered as a result of an action pursuant to **Section 8.03(b) (Enforcement)**, whether by settlement or judgment, shall first be applied to reimbursement of all costs and expenses incurred by each Party in connection with such infringement or misappropriation suit, and the remainder shall be allocated as follows (i) with respect to amounts recovered by Galderma as the enforcing party, **[***]**; and (ii) with respect to amounts recovered by Sol-Gel as the enforcing party, **[***]**.

(d) In any event, at the request and the cost and expense of the Party bringing an infringement or misappropriation action under **Section 8.03(b) (Enforcement)**, the other Party shall provide reasonable assistance in any such action as requested (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) (Enforcement),** 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) (Enforcement)**.

Section 8.04. **Defense of Third Party Infringement and Misappropriation Claims**.

(a) If a Third Party asserts that a Patent Right or other intellectual property right controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement or if a Party becomes aware of a Patent Right or other intellectual property right that might form the basis for such a claim, then 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. At Galderma's request, 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 intellectual property right controlled by such Third Party in the Territory.

(b) Subject to **Section 8.06 (Trademark Enforcement and Defense)**, if a Third Party asserts that a Patent Right or other intellectual property right controlled by it in the Territory is infringed or misappropriated by the Manufacture, use, importation, offer for sale or sale of Licensed Product in the Territory, then Galderma 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. Galderma shall be solely responsible for its defense of such action. Galderma shall keep Sol-Gel reasonably informed regarding such assertion and such defense. Subject to Sol-Gel's indemnification obligations under **Section 12.01 (Indemnification by Sol-Gel)**, Galderma shall bear all costs and expenses incurred in connection with its defense of any such Third Party assertion.

Section 8.05. **Notice of Actions; Settlement**. Galderma 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. **Trademark Enforcement and Defense**.

(a) If either Party becomes aware of any Third Party activity that infringes any of the Licensed Trademark rights, then the Party becoming aware of such activity shall give prompt written notice to the other Party regarding such alleged infringement (collectively, "**Trademark Infringement Activity**").

(b) During the Term, Sol-Gel shall resolve any Trademark Infringement Activity related to the Licensed Trademark anywhere in the world at its own cost and expense, including the filing of an infringement suit using counsel of its own choice; *provided*, *however*, **[***]** Sol-Gel will (i) keep Galderma reasonably informed regarding any such infringement suit (including by providing Galderma with drafts of each filing within a reasonable period before the deadline for such filing and promptly providing Galderma with copies of all final filings and correspondence relating thereto), and (ii) reasonably consult with Galderma on any such infringement suit. Without limiting Sol-Gel's obligations under this **Section 8.06(b) (Trademark Enforcement and Defense)**, if Sol-Gel notifies Galderma that Sol-Gel will not take steps to enforce the Licensed Trademark rights in the Territory against Trademark Infringement Activity, or fails to bring an action to resolve such Trademark 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 Galderma will have the right, but not the obligation, to attempt to resolve such Trademark Infringement Activity by taking commercially appropriate steps at Sol-Gel's sole cost and expense, including the filing of an infringement suit using counsel of Galderma's own choice.

(c) Any amounts recovered by a Party as a result of an action pursuant to **Section 8.06(b) (Trademark Enforcement and Defense)**, whether by settlement or judgment, shall be **[***]**

(d) In any event, at the request and the cost and expense of the Party bringing an infringement action under **Section 8.06(b) (Trademark Enforcement and Defense)**, the other Party shall provide reasonable assistance in any such action as requested (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 8.06(b) (Trademark Enforcement and Defense),** or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in the Licensed Trademark 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 its own expense in any suit or other action instituted by the other Party pursuant to **Section 8.06(b) (Trademark Enforcement and Defense)**.

(e) If a Third Party asserts that a Trademark controlled by it in the Territory is infringed by the use of the Licensed Trademark, then Sol-Gel shall use commercially reasonable efforts to resolve any such claim, whether by obtaining a license from such Third Party or by defending itself and Galderma against such Third Party assertion, *provided* that Galderma shall always have the right to be represented by counsel of its own selection and its own expense in any such suit or other action. Galderma shall keep Sol-Gel reasonably informed regarding such assertion and such defense. Subject to Sol-Gel's indemnification obligations under **Section 12.01 (Indemnification by Sol-Gel)**, Galderma shall bear all costs and expenses incurred in connection with its defense of any such Third Party assertion.

Section 8.07. **Orange Book Listings.** During the Term, **[***]** shall have the right, at its sole discretion, to decide whether to list with the applicable regulatory authorities within the Territory any applicable patent of the Licensed Patent Rights covering any Licensed Product. Such listings may include so-called "Orange Book" listings required under the Hatch-Waxman Act or any similar statutory or regulatory requirement in the Territory. At least **[***]** days prior to any submission of a patent within the Licensed Patent Rights covering any Licensed Product in the Orange Book, **[***]** shall notify **[***]** of the Licensed Patent Rights that it intends to so list in the Orange Book. Upon **[***]** reasonable written request, **[***]** will list any additional Licensed Patent Rights with respect to the Licensed Products in the Orange Book at **[***]** cost and expense. **[***]** shall have the right, at its sole discretion, to decide whether to list with the applicable Regulatory Authorities any applicable Patent Rights **[***]** Covering any Licensed Product.

ARTICLE IX

ADVERSE DRUG EVENTS AND REPORTS

Section 9.01. **Adverse Event Reporting**. 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 Alliance Managers of any Adverse Event (as such term will be defined in the Safety Data Exchange Agreement) received by it in sufficient detail, and shall provide the Alliance Managers 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 (Adverse Event Reporting)**) and each Galderma Entity to comply with any and all regulatory requirements imposed upon it. The Party that holds the applicable Regulatory Filing(s) in the Territory shall be responsible for reporting Adverse Events related to the Licensed Product in the Territory 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.

Section 9.02. **Safety Data Exchange Agreement**. Within **[***]** days after the Effective Date (unless otherwise agreed by the Parties), the Parties shall enter into an agreement setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as the receipt, investigation, sharing, exchange and reporting of safety data, product complaints, product recalls, adverse events and any other information related to the safety of the Licensed Product (the "**Safety Data Exchange Agreement**"), which Safety Data Exchange Agreement may be an amendment to an already existing agreement between the Parties regarding the exchange of such safety data for another product. The Safety Data Exchange Agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other safety information, and Licensed Product quality and Licensed Product complaints involving adverse events, sufficient to permit each Party and its Affiliates and sublicensees to comply with their respective 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. In the event of any inconsistency between the provisions of the Safety Data Exchange Agreement and the provisions of this Agreement, the terms of the Safety Data Exchange Agreement shall govern with respect to patient safety matters.

ARTICLE X

REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section 10.01. **Mutual Representations and Warranties**. Each of Galderma 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 or organized, 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 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 this Agreement and the performance of its obligations hereunder; and (iii) this 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 prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement;

(d) 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;

(e) none of such Party's employees, consultants or contractors 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 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.; and

(f) it 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.

Section 10.02. **Mutual Covenants**. Each of Galderma and Sol-Gel hereby covenants to the other Party that:

(a) it will not knowingly 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 upon such Party's becoming aware that 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 that 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 or licenses granted by it to the other Party hereunder; and

(c) it will comply with all applicable Laws in all material respects 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 Galderma that as of the Effective Date:

(a) Sol-Gel solely owns or Controls the entire right, title, and interest in and to the Licensed Technology and the Licensed Trademark free and clear of any mortgages, pledges, liens, security interests, options, conditional and installment sale agreements, encumbrances, charges, or claims of any kind;

(b) neither Sol-Gel nor its Affiliates own or hold rights to any Patents Rights, Know-How, Regulatory Filings, or other Regulatory Documents related to the Licensed Product in the Territory or that are otherwise necessary, or reasonably useful, to enable Galderma to perform its obligations hereunder, in each case, that Sol-Gel or its Affiliates do not Control;

(c) 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 that are inconsistent with the rights or licenses granted to Galderma under this Agreement;

(d) there are no amounts that will be required to be paid to a Third Party as a result of Galderma's Manufacture or Commercialization of, or performance of Medical Affairs with respect to, Licensed Product that arise out of any agreement to which Sol-Gel or any of its Affiliates is a party;

(e) **Schedule 1.26 (Licensed Patents)** contains a list of all Patent Rights owned, Controlled, or otherwise held for use by Sol-Gel as of the Effective Date that are necessary or reasonably useful to Manufacture, Commercialize, or perform Medical Affairs with respect to the Licensed Product in the Field in the Territory;

(f) all of the issued Patent Rights on **Schedule 1.26 (Licensed Patents)** 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;

(g) the Licensed Patent Rights are being diligently prosecuted in the respective patent offices in the Territory in accordance with applicable Law, and the Licensed Patent Rights have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment;

(h) Sol-Gel and its Affiliates have complied in all material respects with all applicable Laws in connection with the prosecution of the Licensed Patent Rights, including the duty of candor owed to any patent office pursuant to such Laws;

(i) to Sol-Gel's knowledge, there has been no past, and there currently is no pending, claim, action, or proceeding challenging the validity or enforceability of any of the Licensed Patent Rights listed in **Schedule 1.26 (Licensed Patents)** or the Licensed Trademark or alleging that the Development, Manufacture, or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product or its ingredients infringes or misappropriates any patent rights or other intellectual property rights of any Third Party;

(j) neither Sol-Gel nor any of its Affiliates has received any written notification from a Third Party, and Sol-Gel has no knowledge, that the research, development, manufacture, use, sale, offer for sale, distribution, importation, exportation, commercialization, performance of medical affairs with respect to, or other exploitation of Licensed Product in the Territory has infringed or misappropriated, or would infringe or misappropriate, any Patent Right, Know-How or other intellectual property right owned or controlled by such Third Party;

(k) to Sol-Gel's knowledge, no Third Party has infringed or misappropriated, or is currently infringing or misappropriating or threatening to infringe or misappropriate, any of the Licensed Technology;

(l) Sol-Gel and its Affiliates have 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 (except for any such notice that would not have a material effect on the Licensed Product in the Territory and that was delivered so recently before the Effective Date so as to not afford a reasonable opportunity for Sol-Gel's management to have become aware of such notice before the Effective Date);

(m) Sol-Gel has furnished or made available to Galderma or its agents or representatives (i) all information requested by Galderma in writing, (ii) all **[***]** data existing as of the Effective Date that Sol-Gel deems in its reasonable discretion to be material, and (iii) all **[***]** that Sol-Gel deems in its reasonable discretion to be material, in each case ((i) through (iii)), concerning the Licensed Product or the Licensed Technology. To Sol-Gel's knowledge, all such information, data, **[***]** is accurate, complete, and true in all material respects at the time of disclosure to Galderma;

(n) to Sol-Gel's knowledge, there is no existing scientific fact or circumstance that would materially adversely affect the safety, efficacy, or market performance of the Licensed Product and that Sol-Gel has not communicated to Galderma; and

(o) Sol-Gel has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of the Licensed Know-How, and to Sol-Gel's knowledge, no Third Party has any Licensed Know-How in its possession or control that is not subject to continuing obligations of confidentiality owed to Sol-Gel or any of its Affiliates, and to Sol-Gel's knowledge, no breach of such confidentiality has been committed by any Third Party.

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 else 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 each case, 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 Galderma) other Galderma Entities, agrees to comply with all applicable anti-corruption Laws, including the Foreign Corrupt Practices Act of 1977, as amended from time to time ("**FCPA**") and all anti-corruption Laws of the Territory.

(ii) 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 Galderma) no other Galderma 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.

(iii) Each Party shall, in all cases, refrain from engaging in any activities or conduct that would cause the other Party to be in violation of the FCPA or any applicable anti-bribery Laws. To the extent allowed by applicable Law, if a Party 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 the FCPA or any applicable anti-bribery Law, then it shall first obtain the prior written approval of the other Party, which will not be unreasonably withheld, and to the extent approved, shall provide such information, data or documentation in accordance with such other Party's written instructions.

(iv) Each Party 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 the other Party under this Agreement or otherwise, or (ii) any other development during the Term that in any way makes inaccurate or incomplete the representations, warranties, or certifications of such Party hereunder given or made as of the date hereof or at any time during the Term, relating to the FCPA, such Party will immediately advise such other Party in writing of such knowledge or suspicion and the entire basis known to such Party therefor.

(v) Notwithstanding any other provisions contained in this Agreement, each Party agrees that full disclosure of information relating to a possible violation of the FCPA or the existence and terms of this Agreement, including the compensation provisions hereof, may be made at any time and for any reason to the U.S. government and its agencies, and to whomsoever the other Party determines has a legitimate need to know.

Section 10.05. **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EITHER PARTY TO THE OTHER PARTY 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 NON-INFRINGEMENT 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, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING SHALL NOT LIMIT (A) **[***]**, (B) **[***]** OR (C) **[***]**

ARTICLE XI

CONFIDENTIALITY

Section 11.01. **Generally**. During the Term and for a period of **[***]** thereafter, each Party (a) shall maintain in confidence all Confidential Information furnished to it by the other Party or any of the other Party's Affiliates; (b) shall not use such Confidential Information for any purpose except to fulfill its obligations or exercise its rights under this Agreement; and (c) shall not disclose such Confidential Information to anyone other than those of its Affiliates, directors, investors, **[***]**, subcontractors, prospective subcontractors, employees, consultants, financial or legal advisors, or other agents or contractors acting on its behalf in connection with this Agreement (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 Confidential Information from the other Party (or any of such Party's Affiliates) comply with the obligations set forth in this **ARTICLE XI (Confidentiality)** and (ii) be responsible for any breach of such obligations by any of its Representatives who receive from such Party (whether directly or indirectly through its Affiliates or other Representatives) any of the Confidential Information received from the other Party (or any of such Party's Affiliates). Without limiting the foregoing, Galderma shall not, during the Term or **[***]** thereafter, use Confidential Information of Sol-Gel in connection with **[***]**

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 enters the public domain or becomes publicly available, in each case, other than as a result of any disclosure by the Recipient or any of its Representatives in breach of this Agreement; (b) was lawfully known by the Recipient or any of its Representatives (as can be reasonably demonstrated) prior to the date of disclosure to the Recipient or any of its Representatives by the disclosing Party or any of its Affiliates pursuant to this Agreement; (c) is or was received by or made available to the Recipient or any of its Representatives on an unrestricted basis from a Third Party that the Recipient reasonably believed was rightfully in possession of such information and not under a duty of confidentiality to the disclosing Party or any of its Affiliates with respect to such information; or (d) is or was independently developed by or for the Recipient or any of its Representatives without reference to or reliance on the Confidential Information of the other Party or any of its Affiliates (as can be reasonably demonstrated). Notwithstanding any provision to the contrary set forth in this Agreement, "Confidential Information" will not include any knowledge, technique, experience, or Know-How that is retained in the unaided memory of the Recipient or any of its authorized Representatives after having access to such Confidential Information ("**Residual Knowledge**"). Any use made by the Recipient or its Representatives of any such Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

Section 11.03. **Permitted Disclosures**. Notwithstanding any other provision to the contrary set forth in 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 request or order of a court or other Governmental Authority, including the rules and regulations promulgated by the Securities and Exchange 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 or Nasdaq; (c) is made: (i) **[***]**; or (d) is made 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 under this subsection (d) 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 reasonable efforts to obtain confidential treatment of such information. If a Recipient is required to disclose Confidential Information pursuant to **Section 11.03(a) (Permitted Disclosures)** or **Section 11.03(b) (Permitted Disclosures)**, then prior to any such 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, and in the event of the disclosing Party's failure to obtain such protective order, the Recipient shall only disclose that information which is legally required to be disclosed.

Section 11.04. **Publicity**. The Parties will issue a joint press release in connection with this Agreement in substantially the form attached hereto as **Schedule 11.04 (Press Release)**. The Parties recognize that each Party may from time to time desire to issue other press releases and make other public statements or public disclosures in respect of this Agreement, including the Development or Commercialization of, or performance of Medical Affairs with respect to, Licensed Product in the Territory during the Term (each, a "**Public Statement**"). If a Party desires to make a Public Statement (an "**Issuing Party**"), then it shall provide the other Party a copy of such Public Statement at least **[***]** prior to the date it desires to make such public disclosure. An Issuing Party shall not issue a Public Statement without the other Party's prior written approval, which advance approval shall not be unreasonably withheld, conditioned or delayed. Once the form of any Public Statement has been approved in accordance with this **Section 11.04** (**Publicity**), then the Issuing Party may appropriately communicate information contained in such permitted Public Statement. 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 11.03 (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 or Nasdaq, *provided* that such statement or disclosure is made in accordance with **Section 11.03 (Permitted Disclosures)**.

Section 11.05. Publications.

(a) **General**. Sol-Gel acknowledges Galderma's interest in publishing certain key results of Galderma's Commercialization of Licensed Product in the Field in the Territory. Galderma 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)**, **Section 11.04 (Publicity)**, or **Section 11.05(b) (Top-Level Data Subset Readouts)**, if Galderma wishes to make a publication or public presentation with respect to its Commercialization of Licensed Product in the Field in the Territory, then Galderma shall deliver to Sol-Gel a copy of the proposed written publication or presentation at least **[***]** prior to submission for publication or presentation. Galderma will redact all of Sol-Gel's Confidential Information if requested by Sol-Gel. If Sol-Gel requests a delay in publication or presentation in order to protect patentable information, then Galderma shall delay submission or presentation for a reasonable period of time (but no longer than **[***]**, except as the Parties may otherwise agree) to enable Sol-Gel to file patent applications protecting Sol-Gel's rights in such information.

(b) **Top-Level Data Subset Readouts**. Notwithstanding any provision to the contrary set forth in this Agreement, Galderma may publish in its promotional materials readouts of the top-level results of any analysis by Galderma of various subsets of data from clinical study reports involving the Licensed Product **[***]**; *provided* that such publication does not, in Galderma's good faith belief, **[***]** that would be (i) **[***]** or (ii) **[***]**. For the avoidance of doubt, this **Section 11.05(b) (Top-Level Data Subset Readouts)** shall not be construed to permit Galderma to publish the detailed clinical study report upon which such top-level results are based **[***]**.

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 & INSURANCE

Section 12.01. Indemnification by Sol-Gel. Sol-Gel shall indemnify, hold harmless, and defend any Galderma Entity and any of their sublicensees and their respective directors, officers, and employees (the "**Galderma Indemnitees**") from and against any and all 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**") incurred in connection with any and all Third Party suits, claims, actions or demands ("**Claims**") to the extent that such Claims arise out of (a) any breach of this Agreement by Sol-Gel or its Affiliates, (b) the Development, Manufacture, or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product anywhere in the world by or on behalf of any Sol-Gel Entity or their sublicensees, or (c) the gross negligence, fraud, or willful misconduct of any Sol-Gel Indemnitee in connection with the performance of this Agreement. Notwithstanding the foregoing, Sol-Gel shall not have any obligation to indemnify the Galderma Indemnitees to the extent that the applicable Claims or Losses arise out of any activities set forth in **Section 12.02 (Indemnification by Galderma)** for which Galderma is obligated to indemnify Sol-Gel or any other Sol-Gel Indemnitees.

Section 12.02. **Indemnification by Galderma**. Galderma shall indemnify, hold harmless and defend any Sol-Gel Entity and any of their sublicensees, and their respective directors, officers, and employees (the "**Sol-Gel Indemnitees**") from and against any and all Losses incurred in connection with any and all Claims to the extent that such Claims arise out of (a) any breach of this Agreement by Galderma or its Affiliates, (b) the Manufacture or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product in the Territory by or on behalf of any Galderma Entity, or (c) the gross negligence, fraud, or willful misconduct of any Galderma Indemnitee in connection with the performance of this Agreement. Notwithstanding the foregoing, Galderma shall not have any obligation to indemnify the Sol-Gel Indemnitees to the extent that the applicable Claims or Losses arise out of any activities set forth in **Section 12.01 (Indemnification by Sol-Gel)** for which Sol-Gel is obligated to indemnify Galderma or any other Galderma Indemnitees.

Section 12.03. **Procedure**. In the event of a claim by a Third Party against a Galderma Indemnitee or a 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, *provided* that no delay on the part of the Indemnified Party in giving such notice shall relieve the Indemnifying Party of any indemnification obligation unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby, and the Indemnifying Party, without admission of the other Party's fault, shall undertake and solely manage and control, at its sole expense and with counsel of its own choosing, the defense of the claim and its settlement. The Indemnified Party shall reasonably cooperate with the Indemnifying Party with respect to such defense and settlement. The Indemnified Party may, at its option and its sole cost 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**. Galderma and Sol-Gel each represent and warrant that they currently have, and will maintain during the Term, adequate insurances at their own expense and in accordance with usual industry standards to support their respective liabilities and obligations assumed under, arising out of, and in connection with, this Agreement. Galderma and Sol-Gel agree that such insurance may be provided by way of self-insurance to the same extent without violation or breach of the foregoing.

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 expire upon the fifth (5th) anniversary of the First Commercial Sale of Licensed Product in the Territory (the "**Initial Term**"). Notwithstanding the foregoing, the Parties may renew the term by written agreement of the Parties. At Galderma's request, during the **[***] [***]** period immediately preceding the **[***]** anniversary of the First Commercial Sale of Licensed Product in the Territory (or at such other time, or for such longer period of time, as the Parties may otherwise agree) (the "**Renewal Discussion Period**"), the Parties will engage in exclusive, good faith discussions regarding the renewal of this Agreement for additional term(s) (each, an "**Additional Term**" and together with the Initial Term, the "**Term**"), and until the conclusion of such Renewal Discussion Period, Sol-Gel shall not discuss with any Third Party the terms on which Sol-Gel might grant rights to Commercialize the Licensed Product in the Field in the Territory.

Section 13.02. **Termination at Will by Galderma**. At any time during the Term, Galderma may terminate this Agreement for any or no reason upon giving **[***]** notice to Sol-Gel. Should Galderma exercise such termination right prior to the Refund Date, it will not be entitled to a refund of any amounts previously paid to Sol-Gel pursuant to **Section 7.01 (Upfront Payment)**.

Section 13.03. **Termination for Failure to Receive Regulatory Approval**. In the event that the Licensed Product does not receive Regulatory Approval from the FDA in the Territory on or before March 31, 2022, Galderma may, in its sole discretion, terminate this Agreement immediately upon delivery of written notice to Sol-Gel no later than thirty (30) days after such date.

Section 13.04. **Termination for Breach**. Subject to the terms and conditions of this **Section 13.04 (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 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 material breaches, the Breaching Party shall have a period of **[***]** days after such Breach Notice is provided to cure such breach, *provided* that if the Breaching Party demonstrates good faith efforts to execute a plan reasonably calculated to cure such breach within **[***]** days thereafter, then such cure period shall be extended by an additional **[***]** days. If a material breach for which a Breach Notice is provided is not cured within the applicable period set forth above, then the Non-Breaching Party may, at its election, terminate this Agreement upon written notice to the Breaching Party. If a Non-Breaching Party provides a Breach Notice to the Breaching Party pursuant to this **Section 13.04** (**Termination for Breach**) and the Breaching Party disputes the existence of a material breach in good faith, then the Breaching Party may refer such dispute to the dispute resolution process set forth in **ARTICLE XIV (Dispute Resolution; Governing Law)**. The **[***]** day cure period set forth in this **Section 13.04 (Termination for Breach)** shall be tolled during the pendency of such dispute, and all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder during such pendency.

Section 13.05. **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, then the other Party (the "**Other Party**") shall have, in addition to all other legal and equitable rights and remedies available to such Other Party, the option to terminate this Agreement upon 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, then, 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 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 Galderma 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 rights 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 13.06. **Termination for Patent Challenge**. Except to the extent the following is unenforceable under applicable Law, Sol-Gel shall have the right to terminate this Agreement in its entirety upon written notice to Galderma in the event that any Galderma Entity, individually or in association with any other person or entity, directly or indirectly, commences or continues to participate in a legal action challenging the validity, enforceability, or scope of any of the Licensed Patent Rights set forth on **Schedule 1.26 (Licensed Patents)** (a "**Patent Challenge**") **[***]**. Notwithstanding any provision to the contrary set forth herein, this **Section 13.06 (Termination for Patent Challenge)** will not apply to, and Sol-Gel may not terminate this Agreement with respect to, (a) any affirmative defense or other validity, enforceability, or non-infringement challenge with respect to a Licensed Patent Right, whether in the same action or in any other agency or forum of competent jurisdiction, advanced by a Galderma Entity in response to any claim or action for patent infringement with respect to such Licensed Patent Right brought in the first instance by or on behalf of a Sol-Gel Entity or any Third Party designated by a Sol-Gel Entity to initiate such claim or action; (b) any claim or proceeding that would otherwise be a Patent Challenge hereunder to the extent commenced by a Third Party that after the Effective Date becomes an Affiliate of Galderma during the Term as a result of a change of control, merger, or acquisition of, with, or by Galderma, *provided* that such claim or proceeding commenced prior to the closing of such change of control, merger, or acquisition; (c) any Patent Challenge that is commenced by a sublicensee of Galderma hereunder if Galderma (i) causes such Patent Challenge to be withdrawn, terminated, or dismissed (or in the case of *ex-parte* proceedings, multi-party proceedings or other Patent Challenges in which Galderma does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge) or (ii) terminates such sublicensee's sublicense to the Licensed Patent Right(s) being challenged by the sublicensee, in each case ((i) and (ii)) within ninety (90) days after Sol-Gel's notice to Galderma under this **Section 13.06 (Termination for Patent Challenge)**; (d) any Patent Challenge required to be commenced pursuant to a government order or applicable Law; or (e) the provision of documents or testimony in response to any court order in a valid legal process.

Section 13.07. Effect of Termination.

(a) In the event of expiration or termination of this Agreement for any reason:

(i) all license grants in this agreement from Sol-Gel to Galderma shall terminate, except to the extent necessary for Galderma to exercise its rights and perform its obligations under this **Section 13.07 (Effect of Termination)**;

(ii) Galderma shall, in advance of and effective as of the effective date of termination, assign and transfer to Sol-Gel all Galderma Product Data, Regulatory Approvals, Regulatory Documents and Trademarks in its Control relating to the Licensed Product in the Territory, except to the extent necessary for Galderma to perform its continuing obligations under this Agreement until the effective date of such termination or to exercise its rights and perform its obligations under this **Section 13.07 (Effect of Termination)**;

(iii) **[***]**, any then-existing inventory of Licensed Product in Galderma's (and its Affiliates' and sublicensees') possession, **[***]** of such Licensed Product; *provided*, *however*, that in case of termination of this Agreement by Galderma pursuant to **Section 13.04 (Termination for Breach)**, **[***]**, all then-existing inventory of Licensed Product in Galderma's (and its Affiliates' and sublicensees') possession **[***]** of such Licensed Product inventory. Notwithstanding any provision to the contrary set forth in this Agreement, with respect to any inventory of the Licensed Product that **[***]** upon expiration or termination of this Agreement pursuant to this **Section 13.07(a)(iii) (Effect of Termination)**, for a period of **[***]** following any expiration or termination of this Agreement (as applicable) ("**[***] Period**"), Galderma shall be **[***]**. Upon the conclusion of such **[***]** Period, Sol-Gel shall, at its option, either (a) extend the **[***]** Period by **[***]** by providing prompt written notice to Galderma, or (b) **[***]**, all then-existing inventory of the Licensed Product in Galderma's (and its Affiliates' and sublicensees') possession **[***]** remaining at such time, **[***]**; *provided* that if, following the conclusion of such Sell-Off Period, Sol-Gel has given notice to Galderma that it intends to **[***]** pursuant to the foregoing clause (b), then such **[***]** Period will be automatically further extended until **[***]**;

(iv) at Sol-Gel's request, (a) any existing agreements between Galderma or its Affiliates and any Third Party **[***]**, and (b) all of Galderma's and its Affiliates' rights, title and interests therein and thereto, shall at Sol-Gel's option be terminated or assigned and transferred to Sol-Gel or its designee, in each case, to the extent freely terminable, assignable or transferable (as applicable) without liability or monetary damages pursuant to the terms thereof (and for any such agreement that by its terms cannot be so assigned, Galderma shall reasonably cooperate with Sol-Gel to seek the transfer of the benefits of such agreement to Sol-Gel);

(v) upon Sol-Gel's written request, Galderma shall, where freely assignable, assign all contract manufacturing, research service, or other vendor agreements related solely to the Licensed Product to Sol-Gel, or, where such agreements are not freely assignable, reasonably cooperate with Sol-Gel to seek the transfer of the benefits of such agreements to Sol-Gel;

(vi) subject to the remainder of this **Section 13.07(a)(vi) (Effect of Termination)**, in the event of expiration of this Agreement or termination of this Agreement by Sol-Gel pursuant to **Section 13.04 (Termination for Breach)** or by Galderma pursuant to **Section 13.02 (Termination at Will by Galderma)**, if Galderma, either itself or through one of its Affiliates, has exercised its right to assume the Manufacture of Licensed Product for Commercialization in the Territory pursuant to **Section 2.01(a)(i) (Grants of Licenses; Limitation)** (and not through one or more CMOs), then, at Sol-Gel's request, Galderma shall Manufacture and supply to Sol-Gel (or its Affiliate or other designee) Licensed Product for Commercialization in the Field in the Territory for a period not to exceed **[***]** following such expiration or termination, subject to terms to be agreed upon by the Parties as of the effective date of such expiration or termination. If Sol-Gel requests that Galderma Manufacture and supply Licensed Product following expiration or termination of this Agreement in accordance with this **Section 13.07(a)(vi) (Effect of Termination)**, then all licenses granted to Galderma by Sol-Gel under this Agreement will survive on a non-exclusive basis to the extent necessary for Galderma to satisfy its Manufacture and supply obligations under this **Section 13.07(a)(vi) (Effect of Termination)**, and except as the Parties may otherwise agree, **[***]**;

(vii) unless this Agreement is terminated by Galderma for Sol-Gel's material breach of this Agreement pursuant to **Section 13.04 (Termination for Breach)**, Galderma shall remain responsible for all its non-cancellable Third Party obligations incurred with respect to the Licensed Product, except for any such obligations assigned to and assumed by Sol-Gel pursuant to **Section 13.07(a)(iv) (Effect of Termination)** or **Section 13.07(a)(v) (Effect of Termination)**; and

(viii) Galderma shall cooperate with Sol-Gel and provide reasonable assistance in effecting the efficient transfer of regulatory and commercial responsibility for the Licensed Product in the Territory to Sol-Gel and to ensure a smooth transition while minimizing interruptions and delays in the conduct of such transition.

Galderma shall perform its obligations under this **Section 13.07 (Effect of Termination)** at its own cost and expense, except in the event that this Agreement is terminated by Galderma pursuant to **Section 13.04 (Termination for Breach)**, in which case Sol-Gel shall be responsible for such costs and expenses.

Section 13.08. **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), **Section 8.01 (Ownership of Intellectual Property)**, **Section 8.02 (Prosecution of Patent Rights)**, **Section 8.03 (Enforcement)**, **Section 8.04 (Defense of Third Party Infringement and Misappropriation Claims)**, **Section 8.06 (Trademark Enforcement and Defense)**, **Section 10.05 (Disclaimer)**, **Section 10.06 (Limitation of Liability)**, **ARTICLE XI (Confidentiality)**, **Section 12.01 (Indemnification by Sol-Gel)**, **Section 12.02 (Indemnification by Galderma)**, **Section 12.03 (Procedure)**, **Section 12.04 (Insurance)**, **Section 13.07 (Effect of Termination)**, **Section 13.08 (Survival; Accrued Rights)**, **Section 14.03 (Choice of Law)**, **Section 14.04 (Language)**, 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 occurring prior to such expiration or termination.

ARTICLE XIV

DISPUTE RESOLUTION; GOVERNING LAW

Section 14.01. **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, if a dispute arises between the Parties under this Agreement, then the Parties shall refer such dispute to the Executive Officers, who shall attempt in good faith to resolve such dispute. If the Executive Officers are unable to resolve such dispute within **[***]** days after such dispute has been referred to them under this **Section 14.01 (Executive Officers; Disputes)**, then such dispute shall be referred to the dispute resolution process set forth in **Section 14.02 (Arbitration)**.

Section 14.02. **Arbitration**. Subject to **Section 14.02(d) (Intellectual Property Disputes)**, 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 **Section 14.01 (Executive Officers; Disputes)** shall be referred to and finally resolved by binding arbitration administered by the ICC International Court of Arbitration ("**ICC**"), in accordance with the then-current rules of the ICC (the "**Rules**"), which rules are deemed to be incorporated by reference into this **Section 14.02 (Arbitration)**, in the manner described below; *provided* that, prior to commencing arbitration or other legal proceedings with respect to any disputes, claims or controversies in connection with this Agreement, the Executive Officers of both Parties shall discuss in good faith such disputes, claims or controversies for at least **[***]** pursuant to **Section 14.01 (Executive Officers; Disputes)**.

(a) **Arbitration Request**. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, then 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 **[***]** after the receipt of an Arbitration Request, the other Party may, by written notice, add additional issues for resolution by providing written notice thereof to the Party that originally issues the Arbitration Request.

(c) **General Arbitration Procedure for Disputes**. The seat of arbitration will be in New York, New York, and the arbitration will be conducted in the English language. No Party will challenge the jurisdiction or venue provisions as provided in this Agreement. The arbitration will be conducted by a single arbitrator, who will be appointed according to the Rules or by mutual agreement of the Parties and who 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 and permitted assigns. 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 arbitrator and the ICC, and each Party shall bear the costs and fees of its 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 such 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, then any arbitrator 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 the other provision of **Section 14.02 (Arbitration)**, 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 14.03. **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 laws of the State of New York, exclusive of and without regard to its conflicts of laws principles; *provided*, *however*, that any dispute between the Parties hereunder relating to inventorship shall be resolved based on an independent inventorship analysis under the United States patent law. This Agreement shall not be governed by the provisions of the United Nations Convention on Contracts for the International Sale of Goods.

Section 14.04. **Language**. This Agreement has been prepared and executed in the English language, and the English language shall control its interpretation in all respects. 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

Section 15.01. **Assignment**.

(a) Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by either Party (and, for these purposes, a merger, sale of assets, operation of law or other similar transaction shall be deemed an assignment) without the prior written consent of the other Party. Notwithstanding the foregoing, a Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (i) an Affiliate or (ii) a Third Party that acquires, by or otherwise in connection with, a merger, sale of assets or otherwise, all or substantially all of the business of such assigning Party to which the subject matter of this Agreement relates; *provided* that the assignee agrees in writing to assume all of such assigning Party's obligations under this Agreement. A Party assigning this Agreement in accordance with this paragraph will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned.

(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 in, interrupted in or prevented from the performance of any of its obligations hereunder by reason of force majeure, which may include any act of God, fire, flood, earthquake, storm, war (declared or undeclared), failure of plant or machinery, public disaster, epidemic, pandemic, spread of infectious disease, quarantine, state of emergency, act of terrorism, insurrection, riot, government act, order, ordinance, guideline or other similar action, strike or labor differences (other than strikes or labor disturbances involving a Party's own employees), or a CMO's failure to supply Licensed Product to Galderma as a result of any of the foregoing reasons, in each case outside of such Party's reasonable control (each a "**Force Majeure**"), then such Party shall not be liable to the other Party therefor nor be deemed to have defaulted under or breached this Agreement as a result thereof, 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. **[***]**. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to **[***]** or cessation of activities in response to **[***]**. The Party invoking the force majeure rights of this **Section 16.01 (Force Majeure**) must notify the other Party of the Force Majeure by courier or overnight dispatch (*e.g.*, Federal Express) promptly following both the first and last days of the Force Majeure unless the Force Majeure renders such notification impossible or commercially impracticable, in which case notification will be made as soon as commercially practicable. While the Force Majeure circumstance continues, the affected Party will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances, and will provide to the other Party on a monthly basis, or more frequently if requested by the other Party, written summaries of its mitigation efforts and its estimates of when normal performance under this Agreement will be able to resume. If the delay resulting from the Force Majeure exceeds **[***]**, then 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; Amendments**. 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 Galderma 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 Galderma 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 held 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**"), then it is 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. **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, 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, 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 such recitals, Schedules or Exhibits, the terms of the body of this Agreement shall control unless such recital, Schedule or Exhibit expressly states the intent of the Parties that such terms and conditions shall supersede the terms of the body of this Agreement; (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, Exhibits 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) any reference herein to any person will be construed to include the person's successors and assigns; (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; (m) the word "year" means any consecutive twelve (12) month period, unless otherwise specified; (n) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or"; and (o) nothing in this Agreement shall require or be construed or interpreted to require a Party to violate any applicable Law.

Section 16.05. **Notices**. Except as expressly otherwise provided herein, any notice required or permitted to be given under this Agreement shall be in writing and shall be delivered by internationally recognized express courier or delivery service, or sent by facsimile or email and confirmed by registered or certified mailing, postage prepaid, return receipt requested, and in each case, addressed 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 7403620
Israel
Attn: **[***]**

With a copy to (which shall not constitute notice for purposes of this Agreement):

[***]

If to Galderma:

Galderma SA
Rue d'Entre-deux-Villes 10
1814 La Tour-de-Peilz
Switzerland
Attn: General Counsel

With a copy to (which shall not constitute notice for purposes of this Agreement):

[***]

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 16.06. **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 and the legal relationship between the Parties shall not constitute a partnership, joint venture or agency, including for all tax purposes. 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 16.07. **No Waiver**. No waiver of a term, condition, covenant or provision of this Agreement shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term, condition, covenant or provision. Except as may be expressly set forth herein, 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, conditions, 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 or similar breach or default by the other Party, and any single or partial exercise of any particular right by a Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

Section 16.08. **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 applicable Law or in equity.

Section 16.09. **No Third Party Beneficiary Rights**. This Agreement is not intended to and shall not be construed to give any Third Party any interest, rights or remedies (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 Galderma Indemnitees and (b) to the extent provided in **Section 12.02 (Indemnification by Galderma)**, the Sol-Gel Indemnitees.

Section 16.10. **Performance by Affiliates**. Subject to **Section 7.09 (Methods of Payment)**, either Party may use one or more of its Affiliates to perform its obligations and duties and exercise its rights hereunder; *provided* that each Party shall cause such of its Affiliates to comply with the provisions of this Agreement in connection with such performance or exercise and shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

Section 16.11. **Further Assurances and Actions**. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary to consummate or implement expeditiously the express purposes and intent contemplated by this Agreement.

Section 16.12. **Counterparts**. This Agreement may be executed in one or more counterparts, all of which taken together shall be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format ("**PDF**") sent by electronic mail. In addition, PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a PDF signature by any Party will constitute due execution and delivery of this Agreement.

[*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:
Name:
Title:

GALDERMA HOLDING SA

By:
Name:
Title:

By:
Name:
Title:

[Signature Page to Epsolay License Agreement]

Schedule 1.02

[***]

Schedule 1.26

Licensed Patents
[***]

Schedule 1.29

[***]

[***]

Schedule 5.01

Minimum Order Quantities
[***]

Schedule 11.04

Press Release

[***]

Exhibit 4.20

CERTAIN INFORMATION IDENTIFIED
BY BRACKETED ASTERISKS ([* * *])
HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE
IT IS BOTH NOT MATERIAL AND WOULD BE
COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Execution Copy

LICENSE AGREEMENT

BY AND BETWEEN

GALDERMA HOLDING SA

AND

SOL-GEL TECHNOLOGIES LTD.

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") is made and entered into as of June 21, 2021 ("**Effective Date**") between Sol-Gel Technologies Ltd., with a principal place of business at 7 Golda Meir St., Ness Ziona 7403620, Israel ("**Sol-Gel**"), and Galderma Holding SA, with a principal place of business at Rue d'Entre-deux-Villes 10, 1814 La Tour-de-Peilz, Switzerland ("**Galderma**"). Sol-Gel and Galderma may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

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

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

WHEREAS, the Parties desire for Sol-Gel to grant such license to Galderma to Manufacture 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 by the applicable Galderma Entity, as applicable.

Section 1.02 "**Affiliate**" means, with respect to a Party, any corporation or other business entity that (directly or indirectly) is controlled by, controls, or is under common control with such entity for so long as such control exists, with "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") meaning (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of or other equity interests in, 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 or cause the direction of the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise. Notwithstanding the foregoing, neither EQT Partners AB nor any other entity listed on **Schedule 1.02 (Excluded Affiliates)** shall be an Affiliate of Galderma for purposes of this Agreement or have any rights or obligations hereunder.

Section 1.03 "**Business Day**" means a day other than (a) a Saturday or a Sunday or (b) a day on which banking institutions in New York City, USA, Zurich, Switzerland, or Tel Aviv, Israel are authorized or required by Law to remain closed.

Section 1.04 "**CMC**" means the chemistry, Manufacturing and controls of Licensed Product.

Section 1.05 "**CMO**" means **[***]**.

Section 1.06 "**Commercialization**" **or** "**Commercialize**" means, with respect to a pharmaceutical product, any and all activities directed to the pre-launch, launch, marketing, branding, promotion, advertising, importation, exportation, warehousing, distribution, shipping, handling, pricing, reimbursement approval, offering for sale, sale, or other commercial exploitation of such pharmaceutical product, and interactions with Regulatory Authorities following the Galderma Start Date for such pharmaceutical product regarding the foregoing, including (a) maintaining all Regulatory Approvals following receipt thereof, conducting communications with the applicable Regulatory Authorities following receipt of Regulatory Approval, and performing other regulatory activities following the Galderma Start Date, and (b) seeking any required reimbursement approval and all post-marketing surveillance. Commercialization shall exclude Development, Manufacturing, and performance of Medical Affairs.

Section 1.07 "**Commercially Reasonable Efforts**" means, with respect to Galderma's performance of certain obligations under this Agreement, the carrying out of such obligations using efforts and resources that are **[***]** with respect to the Commercialization of products **[***]**.

Section 1.08 "**Confidential Information**" means, subject to **Section 11.02(a)-(d) (Exceptions)**, (a) any Know-How and any technical, scientific, trade, research, manufacturing, business, financial, compliance, marketing, product, supplier, or other confidential or proprietary information that may be disclosed by or on behalf of one Party or any of its Affiliates to the other Party or any of its Affiliates under this Agreement, which information is specifically designated as confidential or would reasonably be understood or expected by the receiving Party to be confidential, regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

Section 1.09 "**Controls**," or "**Controlled**" means, with respect to a Party or any of its Affiliates (as applicable) and any Know-How, Patent Right, Regulatory Documents, or other intellectual property right, such Party's or such of its Affiliates' ownership of or ability or right (other than pursuant to a license granted to such Party or Affiliate under this Agreement) to grant to the other Party or its Affiliates a license, sublicense, or other right 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. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Know-How, Patent Rights, Regulatory Documents, or other intellectual property rights that **[***]** or to which **[***]** did not otherwise **[***]**; unless, however, the Know-How, Patent Rights, Regulatory Documents, or other intellectual property rights **[***]** any such Know-How, Patent Rights, Regulatory Documents, or other intellectual property rights **[***]**, in which case, such Know-How, Patent Rights, Regulatory Documents or other intellectual property rights are "Controlled" **[***]** for purposes of this Agreement.

Section 1.10 "**Cover**", "**Covering**," or "**Covered**" means, with respect to a product (or any component or ingredient thereof), composition, technology, invention, 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 component or ingredient thereof) or composition or the practice of such technology, invention, 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 1.11 "**Develop**" or "**Development**" means, with respect to a given product, internal and external pre-clinical and non-clinical research and clinical development activities reasonably related to the development and submission of information to a Regulatory Authority or otherwise to the research, identification, testing, and validation of an active ingredient, including (a) clinical trials of a pharmaceutical compound or product, investigator sponsored trials, and registry studies; (b) 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 in the Territory (and all activities related thereto); and (c) any activities relating to the development of chemistry, manufacturing, and control data. Development shall include clinical trials and other regulatory activities initiated prior to the Galderma Start Date to the extent necessary to obtain Regulatory Approval (including preparing all Regulatory Filings) and to prepare, complete, and submit the Post-Approval Stability Data Filing, but shall exclude Manufacturing, performance of Medical Affairs, and Commercialization.

Section 1.12 "**Dollars**" **or** "**$**" means the legal tender of the U.S.

Section 1.13 "**Douglas**" means Douglas Manufacturing Limited.

Section 1.14 "**Drug Approval Application**" means a New Drug Application as defined in the FD&C Act, or an equivalent application filed with any Regulatory Authority in any country other than the United States.

Section 1.15 **[***]** means **[***]**

Section 1.16 "**FD&C Act**" means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

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

Section 1.18 "**Field**" means the treatment, prevention, cure, or amelioration of Acne vulgaris in humans.

Section 1.19 "**First Commercial Sale**" means, with respect to a Licensed Product, the first **[***]** sale of the Licensed Product in the Territory by **[***]** for **[***]** to a Third Party after **[***]**. Sales or other distributions for **[***]** shall not be deemed "First Commercial Sale."

Section 1.20 "**Galderma Entity**" means, as applicable, (a) Galderma, or (b) any of Galderma's Affiliates.

Section 1.21 "**Galderma Regulatory Documents**" means Regulatory Documents Controlled by a Galderma Entity **[***]**.

Section 1.22 "**Galderma Start Date**" means the date on which **[***]**.

Section 1.23 "**Generic Product**" means, with respect to a Licensed Product, any pharmaceutical product that (a) is an AB rated generic equivalent of the Licensed Product, (b) is approved by **[***]** in the **[***]** in reliance, in whole or in part, on **[***]**, or (c) **[***]**.

Section 1.24 "**Governmental Authority**" means any federal, national, multinational, state, provincial, county, city, municipal, local or other government (including any governmental division, subdivision, department, agency, bureau, branch, office, council, court, arbitrational or other tribunal, commission or other government authority of any nature acting under the authority thereof). Governmental Authorities include all Regulatory Authorities.

Section 1.25 "**IND**" means an Investigational New Drug application for submission to the FDA or any equivalent counterpart application in any country other than the United States, including all supplements and amendments thereto.

Section 1.26 "**Know-How**" means proprietary trade secrets, information, know-how, practices, techniques, methods, processes, procedures, inventions, ideas, data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from pre-clinical and non-clinical studies), technology, software, algorithms, drawings, developments, marketing reports, expertise, chemical and biological materials, other materials, formulations, formulae, documents, studies, results, regulatory approvals, regulatory filings and related correspondence (including DMFs), including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and stability and other data, specifications, sourcing information, assays, quality control and testing procedures, formulations, samples, or compositions of matter of any type or kind, in each case of the foregoing whether or not patented or patentable.

Section 1.27 "**Law**" means any law, statute, rule, regulation, order, judgment, standard, ordinance or other pronouncement of any Governmental Authority anywhere in the world.

Section 1.28 "**Licensed Know-How**" means all Know-How owned or Controlled by Sol-Gel or any of its Affiliates at any time during the Term that is **[***]** for the Manufacturing, use, or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product (or its components or ingredients) in the Field in the Territory.

Section 1.29 "**Licensed Patent Rights**" means any Patent Rights owned or Controlled by Sol-Gel or any of Sol-Gel's Affiliates at any time during the Term that Cover **[***]** with respect thereto, in the Territory, including those Patent Rights listed on **Schedule 1.29 (Licensed Patents)**.

Section 1.30 "**Licensed Product**" means a topical prescription product containing an antibiotic-free, fixed dose combination of microencapsulated tretinoin 0.1% and microencapsulated benzoyl peroxide 3% as the main active ingredients, as of the Effective Date, known and intended to be marketed under the name "Twyneo®."

Section 1.31 "**Licensed Technology**" means the Licensed Patent Rights and the Licensed Know-How.

Section 1.32 "**Licensed Trademark**" means the "Twyneo®" word trademark **[***]**, as further described in **Schedule 1.32 (Licensed Trademark)**.

Section 1.33 "**Manufacture**" or "**Manufacturing**" means, as applicable, all activities associated with, related to or directed to the production, manufacture, formulation, processing, filling, finishing, packaging, labeling, shipping, handling, importing, exporting, holding or storage of pharmaceutical compounds or materials, or any intermediate thereof, including process and formulation development, process qualification and validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture (including placebo and active controls) and analytical development, product characterization, quality assurance and quality control, testing and release. Manufacture shall exclude Development and Commercialization.

Section 1.34 **"Marketing Authorization Holder"** means a Party that possesses in its name, or is designated as the holder of, all Regulatory Approvals for the Licensed Product in the Territory and that is responsible for managing interactions with Regulatory Authorities in the Territory regarding the Licensed Product.

Section 1.35 "**Medical Affairs**" means any and all activities directed to the formulation and performance of (a) post-marketing clinical trials; (b) medical education; (c) communications and liaising with market and key opinion leaders and advisory boards to extent related to medical affairs or clinical guidance for the development of the Licensed Product, including plans to support continuing medical education; (d) publication plans for the Licensed Product; (e) plans to ensure appropriate medical information responses with respect to the Licensed Product; (f) activities performed in connection with patient registries; (g) safety monitoring plans for the Licensed Product; (h) plans and expected activities for field based medical affairs personnel of the Parties for the Licensed Product; (i) other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs; and (j) other comparable medical affairs activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Product; in each case ((a)-(j)), with respect to the Licensed Product in the Territory. Medical Affairs shall exclude Manufacturing, Development, and Commercialization.

Section 1.36 "**Net Sales**" means the **[***]** from any sale **[***]** of Licensed Products in the Territory to **[***]** by Galderma or **[***]** for consideration thereof ("**Gross Sales**"), reduced by the following amounts actually incurred, allowed, accrued, or specifically allocated to or with respect to the Licensed Product, all as calculated in accordance with Accounting Standards, applied consistently with **[***]** standard accounting practices as applied with respect to **[***]**:

(a) **[***]**;

(b) **[***]**

(c) **[***]**;

(d) **[***]**

(e) **[***]**;

(f) any invoiced amounts from **[***]** that are **[***]** and are **[***]** or its **[***]**, including **[***]**, not to **[***]**, and *provided* that if any such amounts are later **[***]**, then they will be **[***]** in the **[***]** in which they are **[***]**; and

(g) **[***]**.

If non-monetary consideration is received by a Galderma Entity for the Licensed Product in the Territory, Net Sales will be calculated based on **[***]**, as applicable, during the **[***]**, or in the absence of **[***]**, the **[***]** of the **[***]**, assuming an **[***]**, as determined by **[***]**. For the avoidance of doubt, sales of Licensed Product to or among Galderma, its Affiliates, or its sublicensees shall not be included in Net Sales, but all sales of Licensed Product by Galderma, its Affiliates, and its sublicensees to Third Parties shall be included in Net Sales.

Section 1.37 "**Patent Right(s)**" means all rights under any national, regional and international or other patent or patent application, provisional patent or patent application, certificate of inventions, application for certificate of invention or priority patent filing in any jurisdiction or under any international convention or treaty, including any patents issued or issuing in the future on such patent applications, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, revival, restoration, revalidation, renewal, registration, confirmation, division, continuation, or continuation-in-part of any of the foregoing.

Section 1.38 "**[***]**" means the filing or submission of the **[***]** for **[***]**, as such supplement is, will be, or is currently contemplated by **[***]** to be, required to be submitted to applicable Regulatory Authority in the Territory immediately following **[***]** for the Licensed Product in the Territory, subject to **Section 4.01 (Sol-Gel Regulatory Responsibility)**.

Section 1.39 "**Regulatory Approval**" means, with respect to a particular regulatory jurisdiction, an approval, license, registration or authorization granted by any Governmental Authority that provides marketing approval or authorization for the commercial sale or other Commercialization of a product in one or more specified indications in such regulatory jurisdiction, including pricing or reimbursement approval, pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and approval of product labeling. For the avoidance of doubt, approval of a Drug Approval Application constitutes Regulatory Approval.

Section 1.40 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including the United States FDA and any other applicable Governmental Authority in the Territory having jurisdiction over pharmaceutical products.

Section 1.41 "**Regulatory Documents**" means all (a) Regulatory Filings and other applications for Regulatory Approval, registrations, licenses, authorizations, approvals (including Regulatory Approvals) and marketing or regulatory exclusivities made to, received from, or otherwise conducted with a Regulatory Authority for a Licensed Product in a particular country or jurisdiction; (b) correspondence, communications, notifications, reports, or other filings 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.

Section 1.42 "**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, Drug Approval Applications, new drug submissions, clinical trial applications, and other Regulatory Approval and reimbursement approval applications.

Section 1.43 "**Sol-Gel Entity**" means, as applicable, (a) Sol-Gel or (b) any of Sol-Gel's Affiliates.

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

Section 1.45 "**Territory**" means the United States.

Section 1.46 "**Third Party**" means any person, individual, corporation, partnership, limited liability company, trust, unincorporated association, Governmental Authority or other entity or body other than the Parties and their Affiliates.

Section 1.47 "**Trademark**" means any word, name, symbol, color, designation or device, or any combination thereof, that functions as a source identifier or indicia of origin or ownership, including any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, and further including the goodwill and activities associated with each of the foregoing.

Section 1.48 "**U.S.**" or "**United States**" means the United States of America, including its districts, territories and possessions.

The following table contains a list of additional terms defined in the corresponding Sections set forth below:

Additional Defined Terms	**Section**
Additional Term	Section 13.01 (Term)
Alliance Manager	Section 3.07 (Alliance Managers)
Arbitration Request	Section 14.02(a) (Arbitration Request)
[***]	Section 6.02 (**[***]**)
Bankrupt Party	Section 13.05(a) (Termination for Bankruptcy and Rights in Bankruptcy)
Breaching Party	Section 13.04 (Termination for Breach)
Breach Notice	Section 13.04 (Termination for Breach)
Claims	Section 12.01 (Indemnification by Sol-Gel)
Commercialization Plan	Section 5.02 (Commercialization Plan)
[***]	Section 5.01 (General; Diligence)
Douglas Supply Agreement	Section 6.01 (Manufacture and Supply)
Event of Bankruptcy	Section 13.05(a) (Termination for Bankruptcy and Rights in Bankruptcy)
Executive Officer	Section 14.01 (Executive Officers; Disputes)
FCPA	Section 10.04(b)(i) (Anti-Corruption Compliance)
Galderma Indemnitees	Section 12.01 (Indemnification by Sol-Gel)
Galderma Product Data	Section 4.04 (Galderma Product Data)
Government Official	Section 10.04(a) (Anti-Corruption Provisions)
Gross Sales	Section 1.36 (Definition of "Net Sales")
ICC	Section 14.02 (Arbitration)
Indemnified Party	Section 12.03 (Procedure)
Indemnifying Party	Section 12.03 (Procedure)
Infringement Activity	Section 8.03(a) (Enforcement)
Initial Term	Section 13.01 (Term)
Inventions	Section 8.01(b) (Ownership of Intellectual Property)
Issuing Party	Section 11.04 (Publicity)
JSC	Section 3.01 (General)
Losses	Section 12.01 (Indemnification by Sol-Gel)
Minimum Order Quantities	Section 5.01 (General; Diligence)
Non-Breaching Party	Section 13.04 (Termination for Breach)
Other Covered Party	Section 10.04(a) (Anti-Corruption Provisions)
Other Party	Section 13.05(a) (Termination for Bankruptcy and Rights in Bankruptcy)
Patent Challenge	Section 13.06 (Termination for Patent Challenge)
Payment	Section 7.10(a) (General)
Post-Generic Price	Section 5.01 (General; Diligence)
Public Statement	Section 11.04 (Publicity)
Quality Agreement	Section 6.03 (Quality Agreement)
Recipient	Section 11.02 (Exceptions)
Refund Date	Section 7.02 (Possible Refund of Upfront Payment)
Renewal Discussion Period	Section 13.01 (Term)
Representatives	Section 11.01 (Generally)
Residual Knowledge	Section 11.02 (Exceptions)
Right of Reference	Section 4.02(b) (Galderma Regulatory Responsibility)
Rules	Section 14.02 (Arbitration)
Safety Data Exchange Agreement	Section 9.02 (Safety Data Exchange Agreement)
Sell-Off Period	Section 13.07(a)(iii) (Effect of Termination)
Severed Clause	Section 16.03 (Severability)
Shortfall Period	Section 5.01 (General; Diligence)
Shortfall Quantity	Section 5.01 (General; Diligence)
Sol-Gel Indemnitees	Section 12.02 (Indemnification by Galderma)
Sol-Gel Inventions	Section 8.01(c) (Ownership of Intellectual Property)
Sol-Gel Invention Patents	Section 8.01(d) (Ownership of Intellectual Property)
Sol-Gel Product Data	Section 4.03 (Technology Sharing)
Subcontractor	Section 2.03 (Subcontractors)
[***]	**[***]**
Term	Section 13.01 (Term)

Withholding Tax Action	Section 7.10(b) (No Withholding Tax)

ARTICLE II

LICENSES

Section 2.01. Grants of Licenses; Limitation.

(a) Subject to the terms and conditions of this Agreement, Sol-Gel and its Affiliates hereby grant to Galderma and Galderma's Affiliates:

(i) **[***]**, an exclusive (including as to Sol-Gel and its Affiliates), royalty-bearing, sublicenseable (solely pursuant to **Section 2.02 (Sublicensing)**), transferable (subject to **Section 15.01 (Assignment)**) license solely during the Term under the Licensed Technology solely to register, have registered (for clarity, only after the Galderma Start Date), use, have used, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold, perform Medical Affairs with respect to, have Medical Affairs performed with respect to, Commercialize, have Commercialized, and otherwise exploit or have exploited the Licensed Product in the Field in the Territory and to import, have imported, export, have exported, have Manufactured the Licensed Product outside the Territory for Commercialization in the Field in the Territory; and

(ii) an exclusive (including as to Sol-Gel and its Affiliates), sublicenseable (solely pursuant to **Section 2.02 (Sublicensing)**), transferable (subject to **Section 15.01 (Assignment)**) license to use the Licensed Trademark for and in connection with the Licensed Product in the Territory.

(b) Sol-Gel shall not, and shall ensure that its Affiliates do not, either directly or indirectly, knowingly promote, market, distribute, import, sell, or have sold any Licensed Product, including via internet or mail order, into the Territory during the Term. As to the Territory, Sol-Gel shall not, and shall ensure that its Affiliates do not: (i) establish or maintain any branch, warehouse, or distribution facility for any Licensed Product in the Territory for the sale of such Licensed Product in the Territory during the Term, (ii) engage in any advertising or promotional activities relating to any Licensed Product that are directed primarily to customers or other purchasers or users of such Licensed Product located in the Territory during the Term, (iii) solicit orders from any prospective purchaser located in the Territory during the Term, or (iv) sell or distribute Licensed Product to any person who it knows intends to sell such Licensed Product in the Territory during the Term. Notwithstanding the foregoing, in the event that Galderma provides a termination notice to Sol-Gel under **Section 13.03 (Termination for Failure to Receive Regulatory Approval)**, Sol-Gel shall be entitled to perform some or all of the activities set forth in (i) through (iii) above, as part of the transition of rights back to Sol-Gel, subject to the terms of **Section 13.07 (Effect of Termination)**. If Sol-Gel receives any order from a prospective purchaser located in the Territory during the Term, then Sol-Gel shall immediately refer that order to Galderma, and Sol-Gel shall not accept any such orders. Sol-Gel shall not deliver or tender (or cause to be delivered or tendered) Licensed Product into the Territory during the Term.

(c) Galderma shall not, and shall ensure that its Affiliates do not, either directly or indirectly, knowingly promote, market, distribute, sell, or have sold any Licensed Product, including via internet or mail order, outside the Territory during the Term. Galderma shall not, and shall ensure that its Affiliates do not: (i) establish or maintain any branch, warehouse or distribution facility for any Licensed Product in any jurisdictions for the sale of such Licensed Product outside the Territory, (ii) engage in any advertising or promotional activities relating to any Licensed Product that are directed primarily to customers or other purchasers or users of such Licensed Product located outside the Territory, (iii) solicit orders from any prospective purchaser located outside the Territory, or (iv) sell or distribute Licensed Product to any person who it knows intends to sell such Licensed Product outside the Territory. If Galderma receives any order from a prospective purchaser located outside the Territory during the Term, then Galderma shall immediately refer that order to Sol-Gel, and Galderma shall not accept any such orders. Galderma shall not deliver or tender (or cause to be delivered or tendered) Licensed Product outside of the Territory during the Term.

(d) Galderma hereby grants to Sol-Gel a perpetual, irrevocable, non-exclusive, royalty-free, fully paid-up, worldwide license under Galderma's interest in any and all Inventions developed by Galderma during the Term and prior to the effective date of termination of this Agreement in the performance of activities under this Agreement, and all Patent Rights Controlled by Galderma during the Term and prior to the effective date of termination of this Agreement that Cover any such Inventions, in each case, to Develop, Manufacture, perform Medical Affairs with respect to, and Commercialize the Licensed Products (i) outside of the Territory during and after the Term; and (ii) **[***]**.

(e) As between the Parties, all rights not expressly licensed to Galderma and its Affiliates under the Licensed Technology in **Section 2.01(a) (Grants of Licenses; Limitation)** or elsewhere in this Agreement shall be retained by Sol-Gel, including the right to Develop, perform Medical Affairs with respect to, 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.

Section 2.02. **Sublicensing**. Galderma and its Affiliates shall have the right to sublicense the rights and obligations granted to it under **Section 2.01(a)(i) (Grants of Licenses; Limitation) [***]** and (b) **[***]**. Notwithstanding the grant of any such sublicense, Galderma will remain responsible for the performance of its obligations hereunder.

Section 2.03. **Subcontractors**. In performing its activities under this Agreement, Galderma may engage Third Party contractors to perform obligations or exercise rights, in each case, of Galderma under this Agreement (each, a "**Subcontractor**") at its sole discretion. Any breach by a Subcontractor of the applicable terms of this Agreement relating to such portions of Galderma's obligations will be deemed a breach by Galderma. The engagement of any Subcontractor in compliance with this **Section 2.03 (Subcontractors)** will not relieve Galderma of its obligations under this Agreement.

ARTICLE III

GOVERNANCE

Section 3.01. **General**. Within **[***]** days following the Effective Date, the Parties shall establish a Joint Steering Committee ("**JSC**") to facilitate discussions, information exchange and coordination of the Parties under this Agreement to the extent relating specifically to matters for which the JSC is responsible pursuant to **Section 3.03 (Joint Steering Committee)**.

Section 3.02. **JSC Materials**. At least **[***]** weeks in advance of each meeting of the JSC held in accordance with **Section 3.06 (Meetings)**, Galderma shall provide the JSC with (a) a summary of **[***]** by **[***]** with respect to the Licensed Product in the Territory since the previous JSC meeting, which summary shall include, for the period since the previous JSC meeting, (i) a reasonably detailed description of **[***]**, (ii) estimates of the **[***]** in each **[***]** during such period, (iii) estimates of the **[***]** or **[***]** for such Licensed Product **[***]**, and (iv) **[***]**, and (b) **[***]**. Such summary **[***]** will be delivered by Galderma to Sol-Gel in a format reasonably determined by Galderma.

Section 3.03. **Joint Steering Committee**.

(a) The JSC shall:

(i) discuss **[***]** of the Licensed Product in the Field in the Territory in relation thereto;

(ii) discuss the summaries of **[***]** activities performed by Galderma hereunder, as such summaries are provided to the JSC pursuant to **Section 3.02 (JSC Materials)**;

(iii) serve as a forum for exchanging information regarding the conduct of the **[***]** of the Licensed Product in the Field in the Territory;

(iv) determine whether to create any additional subcommittee(s) or working group(s) to whom the JSC's responsibilities hereunder may be delegated; and

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

Section 3.04. **Membership**. The JSC shall be composed of **[***]** 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 on the JSC and any replacement of such representatives 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 **[***]** its or its Affiliates' employees, consultants, or advisors as required or useful to discuss the applicable agenda items. The JSC shall appoint a chairperson from among its members who will be responsible for preparing JSC meeting agendas and for presiding over JSC meetings, but who will **[***]**. The first chairperson of the JSC will be a representative of **[***]**. Each chairperson (whether initially appointed or any successor therefor) shall serve a term of no more than **[***]** consecutive **[***]**, 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.

Section 3.05. **Meetings**. The JSC shall hold an initial meeting within **[***]** 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. **Limitations on JSC Authority**. Notwithstanding any provision to the contrary set forth in this Agreement, the **[***]** and shall not **[***]**. For the avoidance of doubt, **[***]**, subject to the terms and conditions of this Agreement relating thereto.

Section 3.07. **Alliance Managers**. Each of the Parties shall appoint a single individual to manage and be a single point of contact with respect to the Development, Medical Affairs, and Commercialization obligations between the Parties under this Agreement (each, an "**Alliance Manager**"). The Alliance Managers may attend any JSC or JSC subcommittee meetings. Each Alliance Manager shall be a non-voting participant in such JSC or JSC subcommittee meetings, unless s/he is also appointed a member of the JSC or such subcommittee; *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 and is within the JSC's responsibilities set forth in **Section 3.03 (Joint Steering Committee)** or otherwise expressly set forth herein. 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. **Sol-Gel Regulatory Responsibility**. Until **[***]**, **[***]** shall have **[***]** with respect to, preparing all Regulatory Filings and conducting communications with the applicable Regulatory Authorities with respect to the Licensed Product, including as necessary to obtain Regulatory Approval for the Licensed Product in the Territory and to submit the **[***]**, all at **[***]** cost and expense, except that **[***]**. Until **[***]**, reasonably in advance of any decision, communication, or filing related to the Licensed Product in the Territory, **[***]**. During the Term, Sol-Gel shall give Galderma reasonable notice of any meeting (whether held in person, by video, by teleconference, or by any other means) with any Regulatory Authority relating to the Licensed Product in the Territory, and Galderma shall have the right to attend, or to have a representative attend on its behalf, any such meeting or any preparatory meeting therefor.

Section 4.02. **Galderma Regulatory Responsibility**.

(a) Promptly, but no later than **[***]**, after the date on which **[***]**, Sol-Gel shall transfer and assign to Galderma, **[***]**, all Regulatory Filings and other Regulatory Documents related to the Licensed Product in the Territory or otherwise necessary or reasonably useful to enable Galderma to perform its obligations under this **Section 4.02 (Galderma Regulatory Responsibility)**, and immediately thereafter, Sol-Gel shall designate Galderma as the Marketing Authorization Holder for the Licensed Product in the Territory. **[***]**, Galderma shall thereafter have sole control over, and have decision-making authority with respect to, preparing, obtaining, and maintaining all Regulatory Filings and Regulatory Approvals, conducting communications with the applicable Regulatory Authorities, and performing other regulatory activities and Medical Affairs, in each case, as reasonably useful to perform or support the marketing and Commercialization of the Licensed Product in the Territory, **[***]**. Without limiting the foregoing, Galderma shall be responsible for **[***]**.

(b) Upon the **[***]** and as Galderma may reasonably request from time to time thereafter, Sol-Gel shall, in support of Galderma's preparation of any Regulatory Filing with respect to the Licensed Product in the Field in the Territory, provide Galderma access to a complete electronic copy of all (i) Sol-Gel Regulatory Documents, (ii) Regulatory Documents Controlled by any Sol-Gel Entity (including those generated by any of Sol-Gel's sublicensees that are Controlled by Sol-Gel) that are related to the Licensed Product in the Field, and (iii) other information requested by, or reasonably necessary or useful for responding to requests by, Regulatory Authorities in the Territory in connection with Galderma's Regulatory Filings, in each case ((i) – (iii)), solely to the extent Controlled by the Sol-Gel Entities or any of their Third Party sublicensees or licensees for the Licensed Product, and Sol-Gel will obtain the prior written consent of any of the Sol-Gel Entities' Third Party sublicensees or Third Party licensees to the extent necessary to provide to Galderma and its Affiliates any such Sol-Gel Regulatory Documents, Regulatory Documents, or other information. Without limiting the foregoing, Sol-Gel and its Affiliates hereby grant to Galderma a "**Right of Reference**," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including all CMC information as well as data made, collected or otherwise generated in the conduct of any clinical studies for the Licensed Product) included in any Sol-Gel Regulatory Document, or other Regulatory Filing, Regulatory Approval, drug master file, or other regulatory documentation owned or Controlled by Sol-Gel or its Affiliates that relates to the Licensed Product, and Sol-Gel shall provide a signed statement to this effect, if requested by Galderma, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Law recognized outside of the United States).

(c) Except as expressly otherwise provided herein, **[***]** in conducting its regulatory responsibilities and meeting the requirements of applicable Regulatory Authorities as set forth under this **Section 4.02 (Galderma Regulatory Responsibility)**, and will **[***]** in transferring Regulatory Documentation to Galderma or otherwise assisting Galderma in conducting its regulatory responsibilities under this **Section 4.02 (Galderma Regulatory Responsibility)**.

(d) Following the **[***]**, reasonably in advance of any filing or submission of any application for label expansion related to the Licensed Product in the Territory during the Term, Galderma will submit the same to Sol-Gel for review and discussion, and Galderma will **[***]**. Galderma shall provide Sol-Gel with notice of any changes that Galderma determines to make to the specifications or manufacturing processes for the Licensed Product and shall **[***]** prior to implementing any such change**[***]**; *provided* that **[***]**. During the Term, Galderma shall give Sol-Gel reasonable notice of any meeting (whether held in person, by video, by teleconference, or by any other means) with any Regulatory Authority relating to such application, and Sol-Gel shall have the right to attend, or to have a representative attend on its behalf, any such meeting or any preparatory meeting therefor.

Section 4.03. **Technology Sharing**. Upon the Galderma Start Date, and thereafter at least **[***]** or more frequently upon Galderma's request, Sol-Gel shall provide to Galderma all data and documents Controlled by any Sol-Gel Entities and related to the Licensed Product that are reasonably necessary or useful for Galderma to Commercialize and perform Medical Affairs with respect to Licensed Product in the Territory or to perform its obligations under **Section 4.02 (Galderma Regulatory Responsibility)**, including Licensed Know-How, regulatory data, and clinical data. Throughout the Term, Sol-Gel shall provide Galderma with updates 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. In addition, at least **[***]** or more frequently upon Galderma's request, Sol-Gel shall make available to Galderma 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 or sublicensees (collectively, the "**Sol-Gel Product Data**"), to the extent (i) such Sol-Gel Product Data are necessary or reasonably useful for any Galderma Entity to Commercialize or perform Medical Affairs with respect to Licensed Product in the Field in the Territory in accordance with this Agreement, or (ii) such Sol-Gel Product Data are required by Regulatory Authority in the Territory in connection with the Commercialization of or performance of Medical Affairs with respect to Licensed Product in the Field in the Territory.

Section 4.04. **Galderma Product Data**. After **[***]**, upon Sol-Gel's reasonable request, Galderma shall make available to Sol-Gel copies of Galderma Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case, that pertain to the Licensed Product and are Controlled by a Galderma Entity or its sub-contractor (collectively, the "**Galderma Product Data**"), to the extent such Galderma Product Data are reasonably necessary for Sol-Gel or its Affiliates or (sub)licensees to exercise Sol-Gel's retained rights. Galderma and its Affiliates hereby grant to Sol-Gel a Right of Reference to, and a right to copy, access, and otherwise use, all information and data included in any Regulatory Filing, Regulatory Approval, drug master file, or other regulatory documentation owned or Controlled by Galderma or its Affiliates that relates to the Licensed Product, and Galderma shall provide a signed statement to this effect, if requested by Sol-Gel, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Law recognized outside of the United States).

Section 4.05. **Generic Products**.

(a) Subject to **Section 4.05(b) (Generic Products)**, Galderma will in no event during the Term, seek Regulatory Approval for or otherwise engage in the Development, Manufacture, or Commercialization of (i) any pharmaceutical product pursuant to Section 505(b)(2) of the U.S. Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)) that uses the Licensed Product as a reference listed drug for the same indication for which the Licensed Product is approved in the Territory; or (ii) subject to **Section 2.02 (Sublicensing)**, any Generic Product, in each case, in the Territory.

(b) Subject to **Section 4.05(a) (Generic Products)**, Sol-Gel and its Affiliates will in no event during the Term launch or Commercialize, or enter into any agreement for the launch or Commercialization by a Third Party of, (i) any pharmaceutical product pursuant to Section 505(b)(2) of the U.S. Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)) that uses the Licensed Product as a reference listed drug for the same indication for which the Licensed Product is approved in the Territory; or (ii) any Generic Product, in each case, in the Territory. Notwithstanding the foregoing, upon Galderma's written request during the Term that the Parties enter into an agreement for Galderma to Commercialize an authorized Generic Product in the Territory, the Parties will discuss such request in good faith and may agree to enter into such an agreement.

ARTICLE V

COMMERCIALIZATION

Section 5.01. **General; Diligence**. **[***]**, and otherwise subject to Sol-Gel's satisfaction of its applicable obligations hereunder that by their nature are necessary for Galderma's Commercialization of the Licensed Product in the Territory (including under **Section 6.01 (Manufacture and Supply)** and **Section 6.02 ([***])**), Galderma shall use Commercially Reasonable Efforts to Commercialize Licensed Product in the Territory for use in the Field, which efforts shall include **[***]**. **[***]**. Notwithstanding any provision to the contrary set forth in this Agreement, any failure of Galderma to comply with its obligations under this **Section 5.01 (General; Diligence)** with respect to the Licensed Product will be excused to the extent that such failure results solely from (a) **[***]**, or (b) **[***]**.

Section 5.02. **Commercialization Plan**. On or before **[***]** (or at such other time as the Parties may otherwise agree, including if the Parties determine that **[***]**), Galderma shall submit to the JSC to review and discuss a Commercialization plan setting forth for the upcoming calendar year (a) a **[***]**, (b) **[***]**, and (c) **[***]** anticipated by Galderma to be undertaken, in each case ((a)-(c)), for the Licensed Products in the Territory (the "**Commercialization Plan**"). During the Term following submission of the initial Commercialization Plan, Galderma will prepare and submit to the JSC **[***]** updates to the Commercialization Plan for review and discussion.

ARTICLE VI

MANUFACTURE AND SUPPLY

Section 6.01. **Manufacture and Supply**.

(a) Galderma, **[***]**, shall have sole control over, and decision-making authority with respect to, Manufacturing of the Licensed Products inside or outside the Territory for purposes of Commercialization in the Field in the Territory during the Term. As of or prior to the Effective Date, the Parties have entered into a Third Party manufacturing and commercial supply agreement with Douglas, attached hereto as **Schedule 6.01 (Douglas Supply Agreement)**, pursuant to which Douglas shall Manufacture and supply to Galderma Licensed Product during the Term of this Agreement (so long as Galderma is a party thereto, such agreement, together with any amendment or successor agreement thereto, the "**Douglas Supply Agreement**"). Upon Galderma's reasonable request, Sol-Gel shall assist and cooperate with Galderma's efforts to **[***]**, pursuant to which **[***]**. **[***]**.

(b) Solely with respect to all orders of Licensed Product that Galderma submits to Douglas under the Douglas Supply Agreement prior to **[***]**.

Section 6.02. **[***]**

Section 6.03. **Quality Agreement**. Galderma and **[***]** CMO will enter into a quality agreement for Commercial supply of the Licensed Product to Galderma (**[***]**, a "**Quality Agreement**") concurrently with the entry into **[***]** Supply Agreement.

ARTICLE VII

PAYMENTS

Section 7.01. **Upfront Payment**. Within **[***]** following the Effective Date and receipt of an invoice therefor, Galderma shall pay Sol-Gel a one-time, non-creditable, refundable (solely pursuant to **Section 7.02 (Possible Refund of Upfront Payment)**) upfront payment of **[***]**, by wire transfer in accordance with **Section 7.09 (Methods of Payment)**.

Section 7.02. **Possible Refund of Upfront Payment**. Notwithstanding **Section 7.01 (Upfront Payment)**, in the event that the Licensed Product does not receive Regulatory Approval from the FDA in the Territory on or before **[***]** (the "**Refund Date**"), Sol-Gel will refund to Galderma the upfront payment made under **Section 7.01 (Upfront Payment)** within **[***]** after such Refund Date. For the avoidance of doubt, Galderma shall remain entitled to such refund even in the event that the Licensed Product subsequently receives Regulatory Approval in the Territory following the Refund Date.

Section 7.03. **Regulatory Milestone Payment**. Within **[***]** days following **[***]** in the Territory, and receipt of an invoice therefor, Galderma shall pay Sol-Gel a one-time, non-refundable, non-creditable payment of **[***]**; *provided*, *however*, that Galderma shall not be obligated to make such payment in the event that, following the Refund Date, Galderma has given Sol-Gel notice of termination of this Agreement pursuant to **Section 13.02 (Termination at Will by Galderma)** and Regulatory Approval of the Licensed Product from the FDA in the Territory is received thereafter.

Section 7.04. **Sales Milestone Payments**. Galderma shall pay to Sol-Gel the following one-time payments after the first achievement of aggregate annual Net Sales of Licensed Product in the Territory by Galderma or its Affiliates or sublicensees that meet or exceed the minimum annual Net Sales thresholds set forth below in a given calendar year, which payment shall be made no later than **[***]** after the end of the calendar quarter in which the applicable threshold(s) is (are) met or exceeded:

Annual Net Sales of the Licensed Product in the Territory	**Payment Amount**
Equal to or greater than $**[***]**	$**[***]**
Equal to or greater than $**[***]**	$**[***]**
Equal to or greater than $**[***]**	$**[***]**

For clarity, each milestone payment in this **Section 7.04 (Sales Milestone Payments)** shall be payable no more than 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. If more than one of the milestones set forth in the table above are first achieved in a single calendar year, then Galderma shall pay to Sol-Gel in such calendar year all of the payments corresponding to all of the milestones first achieved in such calendar year under this **Section 7.04 (Sales Milestone Payments)**.

Section 7.05. **Royalties**.

(a) Subject to the remainder of this **Section 7.05 (Royalties)**, Galderma shall pay Sol-Gel the following royalties on Net Sales of the Licensed Product in the Territory in each calendar quarter during the Term, **[***]** set forth below during the applicable period during the Term:

[***]	**Royalty Rate for Net Sales of the Licensed Product in the Territory**
[***]	**[***]**
[***]	**[***]**

(b) Notwithstanding the provisions of **Section 7.05(a) (Royalties)**, after the **[***]** to **[***]**, beginning upon the first to occur of (i) the **[***]** by a person that is not a **[***]** and did not **[***]**, or a **[***]**, in a **[***]** that included any **[***]**; and (ii) a **[***]** otherwise determined in accordance with **Section 7.05(a) (Royalties)**.

(c) In the event that **[***]** are) required in its (or their) reasonable judgement to obtain, after the **[***]**, a license under Patent Rights from any Third Party(ies) that would be infringed by **[***]** (or its **[***]**) Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product in the Territory and **[***]** obtains (or such of its **[***]** obtain) such a license, **[***]** may offset, on a calendar quarter-by-calendar quarter basis, **[***]** from the **[***]** otherwise due to **[***]**.

(d) Notwithstanding the foregoing, in no event shall the royalty payments owed by Galderma under this **Section 7.05 (Royalties)** be reduced **[***]** to less than **[***]** of the royalty payment amounts otherwise due to Sol-Gel under **Section 7.05(a) (Royalties)** in any calendar quarter during the Term.

Section 7.06. **Royalty Payments and Reports**.

(a) On a Licensed Product-by-Licensed Product basis, commencing upon the First Commercial Sale of Licensed Product in the Territory and continuing until the expiration of the Term, Galderma agrees to provide **[***]**, each such written report stating for the applicable period the **[***]**). The Parties acknowledge and agree that the **[***]** provided by Galderma to Sol-Gel pursuant to this **Section 7.06(a) (Royalty Payments and Reports)** (a) are **[***]**, (b) are provided to Sol-Gel **[***]**, and (c) are **[***]** by Sol-Gel or to **[***]** in any manner whatsoever. Sol-Gel shall not be permitted to request, and Galderma shall not be required to provide, make, or conduct, **[***]** following delivery thereof.

(b) On a Licensed Product-by-Licensed Product basis, commencing upon the First Commercial Sale of Licensed Product in the Territory and continuing until the expiration of the Term, Galderma agrees to provide quarterly written reports to Sol-Gel within **[***]** after the end of each **[***]**, covering all **[***]** of such **[***]**in the **[***]** by any **[***]**, each such written report stating for the period in question the **[***]** to **Section 7.05 (Royalties)**.

(c) Following delivery of each **[***]** report by Galderma to Sol-Gel pursuant to **Section 7.06(b) (Royalty Payments and Reports)**, Galderma shall make the applicable royalty payment due under **Section 7.05 (Royalties)** for each applicable **[***]** within **[***]** after receipt of an invoice therefor from Sol-Gel; *provided*, *however*, that, with respect to **[***]** pursuant to **Section 6.01(b) (Manufacture and Supply)**. Notwithstanding any provision to the contrary set forth in this Agreement, in any applicable **[***]**, Galderma may **[***]**.

(d) Galderma shall provide written notice to Sol-Gel of the first occurrence of any of the milestones set forth in **Section 7.04 (Sales Milestone Payments)** of this Agreement within **[***]** after **[***]**.

Section 7.07. **Recordkeeping**. Galderma shall keep accurate records as are required and in sufficient detail to determine the Payments due to Sol-Gel under this Agreement in accordance with the Accounting Standards. Galderma shall retain all such books, records, and accounts for a period of at least **[***]** years after the end of the calendar year to which the records relate. Galderma further agrees to permit such books and records to be examined, at **[***]** cost and expense, by an independent accounting firm selected by **[***]** and reasonably acceptable to **[***]** no more than **[***]** to verify any reports and payments delivered under this Agreement during the **[***]** most recently-ended calendar years, upon reasonable written notice (which shall be no less than **[***]** days' prior written notice) and during regular business hours 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 **[***]** during the period 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 the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales invoiced in a currency other than the Dollar), such conversion shall be made into Dollars at the conversion rate existing in the United States (as reported in the *Wall Street Journal*) on the last Business Day of the applicable calendar quarter or, if such rate is unavailable, a substitute therefor reasonably selected by Galderma. 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 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 to Sol-Gel under this Agreement shall be made by Galderma in Dollars by wire transfer to a bank account designated by Sol-Gel. Any refund due to Galderma pursuant to **Section 7.02 (Possible Refund of Upfront Payment)** or other reimbursement of cost and expenses due to Galderma hereunder shall be made by Sol-Gel in Dollars by wire transfer to a bank account designated by Galderma.

Section 7.10. **Taxes**.

(a) **General**. The milestones, royalties and other amounts payable by Galderma 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 **[***]**) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Galderma will deduct or withhold from the Payments any taxes that it is required by applicable Law to deduct or withhold. 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 will deliver to Galderma or the appropriate governmental authority (with the assistance of Galderma 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 Galderma of its obligation to withhold such tax, and Galderma will apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Galderma has received evidence, in a form reasonably satisfactory to Galderma, of Sol-Gel's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least **[***]** prior to the time that the Payments are due. If, in accordance with the foregoing, Galderma withholds any amount, it will pay to Sol-Gel the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Sol-Gel proof of such payment within **[***]** following such payment.

(b) **No Withholding Tax**. Galderma agrees that all Payments will be made by a Galderma Entity with its tax residence in **[***]**, and no withholding taxes shall be required in respect of such Payments. 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) (General)**, the payment by Galderma (in respect of which such deduction or withholding of tax is required to be made) shall be increased by the amount necessary to ensure that Sol-Gel receives an amount equal to the same amount that it would have received had no Withholding Tax Action occurred, whereas such gross-up is limited to the net amount due for such Withholding Tax Action as per the Convention between the Swiss Confederation and the State of Israel for the avoidance of double taxation concerning income tax and wealth tax and on the basis that Sol-Gel is a tax resident of Israel.

Section 7.11. **Invoices**. Any invoice that Sol-Gel delivers to Galderma under this Agreement may be delivered by email to **[***]** (which email address may be changed by Galderma from time to time upon written notice to Sol-Gel), with a hard copy confirmed by mailing to:

Galderma SA

[***]

(which addresses may be changed by Galderma from time to time upon written notice to Sol-Gel).

Section 7.12. **Late Payments**. If a Party 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 such Party from the due date until the date of payment at the **[***]**, as reported by The Wall Street Journal from time to time, **[***]**, or the maximum applicable legal rate, if less. The interest payment shall be due from the **[***]** until the day that the payment was received by such Party; *provided* that, with respect to any *bona fide* disputed payments, **[***]**, calculated from **[***]** through the date **[***]**.

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 Intellectual Property)**, ownership of 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) (Ownership of Intellectual Property)** and subject to **Section 8.01(e) (Ownership of Intellectual Property)**, regardless of inventorship, any and all Inventions, Patent Rights and Know-How that are exclusively directed to the Licensed Product or the composition, use, administration, formulation, or other aspect thereof (and, in each case, not to any other product) and (i) are developed or generated by or on behalf of Sol-Gel or any of its Affiliates, **[***]**, or (ii) improve upon or are derived from Sol-Gel's Confidential Information, the Licensed Technology **[***]**, and all intellectual property rights therein ("**Sol-Gel Inventions**") shall be owned exclusively and solely by Sol-Gel. **[***]**

(d) Any Patent Rights that Cover or otherwise claim any Sol-Gel Inventions ("**Sol-Gel Invention Patents**") shall be treated for the purposes of this Agreement as part of the Licensed Patent Rights, and any Know-How that is part of the Sol-Gel Inventions shall be treated for the purposes of this Agreement as part of the Licensed Know-How.

(e) Sol-Gel hereby grants to Galderma a perpetual, irrevocable, non-exclusive, sublicenseable (through multiple tiers), royalty-free, transferable (subject to **Section 15.01 (Assignment)**) license under all Sol-Gel Inventions that are developed or generated by or on behalf of Galderma or any of its Affiliates or jointly developed or generated by or on behalf of both Parties (including any Patent Rights that Cover or otherwise claim any such Sol-Gel Inventions) to register, have registered, use, have used, make, have made, import, have imported, export, have exported, market, have marketed, distribute, have distributed, sell, have sold, and otherwise exploit or have exploited **[***]** (but, for clarity, not the **[***]**).

Section 8.02. **Prosecution of Patent Rights**. Sol-Gel shall be responsible for and have the first right to control the preparation, filing, prosecution, and maintenance of all Licensed Patent Rights (including Sol-Gel Invention Patents) in the Territory in Sol-Gel's name and at its sole cost and expense. Sol-Gel will: (i) instruct such patent counsel to provide Galderma with copies of all proposed filings, submissions, and other substantive correspondences relating to such Licensed Patent Rights in the Territory for Galderma's review and comment, (ii) give Galderma reasonable opportunity to provide, and consider in good faith and incorporate, comments on the preparation, filing, prosecution, and maintenance of the Licensed Patent Rights in the Territory prior to making any such filing, submission, or other substantive correspondence, and (iii) keep Galderma advised of the status of actual and prospective patent filings related to a Licensed Product in the Territory. Subject to the foregoing, 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. If Sol-Gel elects not to continue to seek or maintain, or elects to let lapse, any Licensed Patent Rights, then Sol-Gel will provide Galderma with timely notice and will provide Galderma with a reasonable opportunity to assume responsibility for the continued prosecution and maintenance of such Licensed Patent Rights at its own cost and expense and in the name of Sol-Gel.

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) any of the Licensed Patent Rights, 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, until either Party provides a notice of termination of this Agreement pursuant to any of **Section 13.02 (Termination at Will by Galderma)** through **Section 13.06 (Termination for Patent Challenge**), other than any notice of termination that Galderma disputes, Galderma 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 at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. Galderma will (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 relating thereto), and (ii) reasonably consult with Sol-Gel on such infringement or misappropriation suit. If Galderma notifies Sol-Gel that Galderma will not take steps to enforce the Licensed Patent Rights in the Territory against Infringement Activity, or fails to bring an action 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 taking commercially appropriate steps at its own cost and expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. After the Term and during the Term beginning upon either Party's provision of a notice of termination of this Agreement pursuant to any of **Section 13.02 (Termination at Will by Galderma)** through **Section 13.06 (Termination for Patent Challenge**), other than any notice of termination that Galderma disputes, and at all times thereafter during the period between a Party's provision of such notice of termination and the effective date of such termination, Sol-Gel shall have the sole right, but not the obligation, to resolve any Infringement Activity related to the Licensed Patent Rights at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice.

(c) Any amounts recovered as a result of an action pursuant to **Section 8.03(b) (Enforcement)**, whether by settlement or judgment, shall first be applied to reimbursement of all costs and expenses incurred by each Party in connection with such infringement or misappropriation suit, and the remainder shall be allocated as follows (i) with respect to amounts recovered by Galderma as the enforcing party, **[***]**; and (ii) with respect to amounts recovered by Sol-Gel as the enforcing party, **[***]**.

(d) In any event, at the request and the cost and expense of the Party bringing an infringement or misappropriation action under **Section 8.03(b) (Enforcement)**, the other Party shall provide reasonable assistance in any such action as requested (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) (Enforcement),** 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) (Enforcement)**.

Section 8.04. **Defense of Third Party Infringement and Misappropriation Claims**.

(a) If a Third Party asserts that a Patent Right or other intellectual property right Controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement or if a Party becomes aware of a Patent Right or other intellectual property right that might form the basis for such a claim, then 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. At Galderma's request, 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 intellectual property right controlled by such Third Party in the Territory.

(b) Subject to **Section 8.06 (Trademark Enforcement and Defense)**, if a Third Party asserts that a Patent Right or other intellectual property right Controlled by it in the Territory is infringed or misappropriated by the Manufacture, use, importation, offer for sale or sale of Licensed Product in the Territory, then Galderma 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. Galderma shall be solely responsible for its defense of such action. Galderma shall keep Sol-Gel reasonably informed regarding such assertion and such defense. Subject to Sol-Gel's indemnification obligations under **Section 12.01 (Indemnification by Sol-Gel)**, Galderma shall bear all costs and expenses incurred in connection with its defense of any such Third Party assertion.

Section 8.05. **Notice of Actions; Settlement**. Galderma 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. **Trademark Enforcement and Defense**.

(a) If either Party becomes aware of any Third Party activity that infringes any of the Licensed Trademark rights, then the Party becoming aware of such activity shall give prompt written notice to the other Party regarding such alleged infringement (collectively, "**Trademark Infringement Activity**").

(b) During the Term, Sol-Gel shall resolve any Trademark Infringement Activity related to the Licensed Trademark anywhere in the world at its own cost and expense, including the filing of an infringement suit using counsel of its own choice; *provided*, *however*, **[***]**. Sol-Gel will (i) keep Galderma reasonably informed regarding any such infringement suit (including by providing Galderma with drafts of each filing within a reasonable period before the deadline for such filing and promptly providing Galderma with copies of all final filings and correspondence relating thereto), and (ii) reasonably consult with Galderma on any such infringement suit. Without limiting Sol-Gel's obligations under this **Section 8.06(b) (Trademark Enforcement and Defense)**, if Sol-Gel notifies Galderma that Sol-Gel will not take steps to enforce the Licensed Trademark rights in the Territory against Trademark Infringement Activity, or fails to bring an action to resolve such Trademark 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 Galderma will have the right, but not the obligation, to attempt to resolve such Trademark Infringement Activity by taking commercially appropriate steps at Sol-Gel's sole cost and expense, including the filing of an infringement suit using counsel of Galderma's own choice.

(c) Any amounts recovered by a Party as a result of an action pursuant to **Section 8.06(b) (Trademark Enforcement and Defense)**, whether by settlement or judgment, shall be **[***]**.

(d) In any event, at the request and the cost and expense of the Party bringing an infringement action under **Section 8.06(b) (Trademark Enforcement and Defense)**, the other Party shall provide reasonable assistance in any such action as requested (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 8.06(b) (Trademark Enforcement and Defense),** or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in the Licensed Trademark 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 its own expense in any suit or other action instituted by the other Party pursuant to **Section 8.06(b) (Trademark Enforcement and Defense)**.

(e) If a Third Party asserts that a Trademark Controlled by it in the Territory is infringed by the use of the Licensed Trademark, then Sol-Gel shall use commercially reasonable efforts to resolve any such claim, whether by obtaining a license from such Third Party or by defending itself and Galderma against such Third Party assertion, *provided* that Galderma shall always have the right to be represented by counsel of its own selection and its own expense in any such suit or other action. Galderma shall keep Sol-Gel reasonably informed regarding such assertion and such defense. Subject to Sol-Gel's indemnification obligations under **Section 12.01 (Indemnification by Sol-Gel)**, Galderma shall bear all costs and expenses incurred in connection with its defense of any such Third Party assertion.

Section 8.07. **Orange Book Listings.** During the Term, **[***]**, **[***]** shall have the right, at its sole discretion, to decide whether to list with the applicable regulatory authorities within the Territory any applicable patent of the Licensed Patent Rights covering any Licensed Product. Such listings may include so-called "Orange Book" listings required under the Hatch-Waxman Act or any similar statutory or regulatory requirement in the Territory. At least **[***]** days prior to any submission of a patent within the Licensed Patent Rights covering any Licensed Product in the Orange Book, **[***]** shall notify **[***]** of the Licensed Patent Rights that it intends to so list in the Orange Book. Upon **[***]** reasonable written request, **[***]** will list any additional Licensed Patent Rights with respect to the Licensed Products in the Orange Book at **[***]** cost and expense. **[***]**, **[***]** shall have the right, at its sole discretion, to decide whether to list with the applicable Regulatory Authorities any applicable Patent Rights **[***]** Covering any Licensed Product.

ARTICLE IX

ADVERSE DRUG EVENTS AND REPORTS

Section 9.01. **Adverse Event Reporting**. 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 Alliance Managers of any Adverse Event (as such term will be defined in the Safety Data Exchange Agreement) received by it in sufficient detail, and shall provide the Alliance Managers 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 (Adverse Event Reporting))** and each Galderma Entity to comply with any and all regulatory requirements imposed upon it. The Party that holds the applicable Regulatory Filing(s) in the Territory shall be responsible for reporting Adverse Events related to the Licensed Product in the Territory 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.

Section 9.02. **Safety Data Exchange Agreement**. Within **[***]** days after the Effective Date (unless otherwise agreed by the Parties), the Parties shall enter into an agreement setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as the receipt, investigation, sharing, exchange and reporting of safety data, product complaints, product recalls, adverse events and any other information related to the safety of the Licensed Product (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 safety information, and Licensed Product quality and Licensed Product complaints involving adverse events, sufficient to permit each Party and its Affiliates and sublicensees to comply with their respective 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. In the event of any inconsistency between the provisions of the Safety Data Exchange Agreement and the provisions of this Agreement, the terms of the Safety Data Exchange Agreement shall govern with respect to patient safety matters.

ARTICLE X

REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section 10.01. **Mutual Representations and Warranties**. Each of Galderma 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 or organized, 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 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 this Agreement and the performance of its obligations hereunder; and (iii) this 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 prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement;

(d) 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;

(e) none of such Party's employees, consultants or contractors 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 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.; and

(f) it 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.

Section 10.02. **Mutual Covenants**. Each of Galderma and Sol-Gel hereby covenants to the other Party that:

(a) it will not knowingly 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 upon such Party's becoming aware that 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 that 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 or licenses granted by it to the other Party hereunder; and

(c) it will comply with all applicable Laws in all material respects 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 Galderma that as of the Effective Date:

(a) Sol-Gel solely owns or Controls the entire right, title, and interest in and to the Licensed Technology and the Licensed Trademark free and clear of any mortgages, pledges, liens, security interests, options, conditional and installment sale agreements, encumbrances, charges, or claims of any kind;

(b) neither Sol-Gel nor its Affiliates own or hold rights to any Patents Rights, Know-How, Regulatory Filings, or other Regulatory Documents related to the Licensed Product in the Territory or that are otherwise necessary, or reasonably useful, to enable Galderma to perform its obligations hereunder, in each case, that Sol-Gel or its Affiliates do not Control;

(c) 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 that are inconsistent with the rights or licenses granted to Galderma under this Agreement;

(d) there are no amounts that will be required to be paid to a Third Party as a result of Galderma's Manufacture or Commercialization of, or performance of Medical Affairs with respect to, Licensed Product that arise out of any agreement to which Sol-Gel or any of its Affiliates is a party, except for any existing agreements between Sol-Gel and its CMOs, as applicable;

(e) **Schedule 1.29 (Licensed Patents)** contains a list of all Patent Rights owned, Controlled, or otherwise held for use by Sol-Gel as of the Effective Date that are necessary or reasonably useful to Manufacture, Commercialize, or perform Medical Affairs with respect to the Licensed Product in the Field in the Territory;

(f) all of the issued Patent Rights on **Schedule 1.29 (Licensed Patents)** 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;

(g) the Licensed Patent Rights are being diligently prosecuted in the respective patent offices in the Territory in accordance with applicable Law, and the Licensed Patent Rights have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment;

(h) Sol-Gel and its Affiliates have complied in all material respects with all applicable Laws in connection with the prosecution of the Licensed Patent Rights, including the duty of candor owed to any patent office pursuant to such Laws;

(i) to Sol-Gel's knowledge, there has been no past, and there currently is no pending, claim, action, or proceeding challenging the validity or enforceability of any of the Licensed Patent Rights listed in **Schedule 1.29 (Licensed Patents)** or the Licensed Trademark or alleging that the Development, Manufacture, or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product or its ingredients infringes or misappropriates any patent rights or other intellectual property rights of any Third Party;

(j) neither Sol-Gel nor any of its Affiliates has received any written notification from a Third Party, and Sol-Gel has no knowledge, that the research, development, manufacture, use, sale, offer for sale, distribution, importation, exportation, commercialization, performance of medical affairs with respect to, or other exploitation of Licensed Product in the Territory has infringed or misappropriated, or would infringe or misappropriate, any Patent Right, Know-How or other intellectual property right owned or Controlled by such Third Party;

(k) to Sol-Gel's knowledge, no Third Party has infringed or misappropriated, or is currently infringing or misappropriating or threatening to infringe or misappropriate, any of the Licensed Technology;

(l) Sol-Gel and its Affiliates have 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 (except for any such notice that would not have a material effect on the Licensed Product in the Territory and that was delivered so recently before the Effective Date so as to not afford a reasonable opportunity for Sol-Gel's management to have become aware of such notice before the Effective Date);

(m) Sol-Gel has furnished or made available to Galderma or its agents or representatives (i) all information requested by Galderma in writing, (ii) all **[***]** data existing as of the Effective Date that Sol-Gel deems in its reasonable discretion to be material, and (iii) all **[***]** that Sol-Gel deems in its reasonable discretion to be material, in each case ((i) through (iii)), concerning the Licensed Product or the Licensed Technology. To Sol-Gel's knowledge, all such information, data, **[***]** is accurate, complete, and true in all material respects at the time of disclosure to Galderma;

(n) to Sol-Gel's knowledge, there is no existing scientific fact or circumstance that would materially adversely affect the safety, efficacy, or market performance of the Licensed Product and that Sol-Gel has not communicated to Galderma; and

(o) Sol-Gel has taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of the Licensed Know-How, and to Sol-Gel's knowledge, no Third Party has any Licensed Know-How in its possession or Control that is not subject to continuing obligations of confidentiality owed to Sol-Gel or any of its Affiliates, and to Sol-Gel's knowledge, no breach of such confidentiality has been committed by any Third Party.

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 else 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 each case, 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 Galderma) other Galderma Entities, agrees to comply with all applicable anti-corruption Laws, including the Foreign Corrupt Practices Act of 1977, as amended from time to time ("**FCPA**") and all anti-corruption Laws of the Territory.

(ii) 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 Galderma) no other Galderma 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.

(iii) Each Party shall, in all cases, refrain from engaging in any activities or conduct that would cause the other Party to be in violation of the FCPA or any applicable anti-bribery Laws. To the extent allowed by applicable Law, if a Party 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 the FCPA or any applicable anti-bribery Law, then it shall first obtain the prior written approval of the other Party, which will not be unreasonably withheld, and to the extent approved, shall provide such information, data or documentation in accordance with such other Party's written instructions.

(iv) Each Party 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 the other Party under this Agreement or otherwise, or (ii) any other development during the Term that in any way makes inaccurate or incomplete the representations, warranties, or certifications of such Party hereunder given or made as of the date hereof or at any time during the Term, relating to the FCPA, such Party will immediately advise such other Party in writing of such knowledge or suspicion and the entire basis known to such Party therefor.

(v) Notwithstanding any other provisions contained in this Agreement, each Party agrees that full disclosure of information relating to a possible violation of the FCPA or the existence and terms of this Agreement, including the compensation provisions hereof, may be made at any time and for any reason to the U.S. government and its agencies, and to whomsoever the other Party determines has a legitimate need to know.

Section 10.05. **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EITHER PARTY TO THE OTHER PARTY 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 NON-INFRINGEMENT 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, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING SHALL NOT LIMIT (A) **[***]**, (B) **[***]** OR (C) **[***]**.

ARTICLE XI

CONFIDENTIALITY

Section 11.01. **Generally**. During the Term and for a period of **[***]** thereafter, each Party (a) shall maintain in confidence all Confidential Information furnished to it by the other Party or any of the other Party's Affiliates; (b) shall not use such Confidential Information for any purpose except to fulfill its obligations or exercise its rights under this Agreement; and (c) shall not disclose such Confidential Information to anyone other than those of its Affiliates, directors, investors, **[***]**, subcontractors, prospective subcontractors, employees, consultants, financial or legal advisors, or other agents or contractors acting on its behalf in connection with this Agreement (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 Confidential Information from the other Party (or any of such Party's Affiliates) comply with the obligations set forth in this **ARTICLE XI (Confidentiality)** and (ii) be responsible for any breach of such obligations by any of its Representatives who receive from such Party (whether directly or indirectly through its Affiliates or other Representatives) any of the Confidential Information received from the other Party (or any of such Party's Affiliates). Without limiting the foregoing, Galderma shall not, during the Term or **[***]** thereafter, use Confidential Information of Sol-Gel in connection with **[***]**.

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 enters the public domain or becomes publicly available, in each case, other than as a result of any disclosure by the Recipient or any of its Representatives in breach of this Agreement; (b) was lawfully known by the Recipient or any of its Representatives (as can be reasonably demonstrated) prior to the date of disclosure to the Recipient or any of its Representatives by the disclosing Party or any of its Affiliates pursuant to this Agreement; (c) is or was received by or made available to the Recipient or any of its Representatives on an unrestricted basis from a Third Party that the Recipient reasonably believed was rightfully in possession of such information and not under a duty of confidentiality to the disclosing Party or any of its Affiliates with respect to such information; or (d) is or was independently developed by or for the Recipient or any of its Representatives without reference to or reliance on the Confidential Information of the other Party or any of its Affiliates (as can be reasonably demonstrated). Notwithstanding any provision to the contrary set forth in this Agreement, "Confidential Information" will not include any knowledge, technique, experience, or Know-How that is retained in the unaided memory of the Recipient or any of its authorized Representatives after having access to such Confidential Information ("**Residual Knowledge**"). Any use made by the Recipient or its Representatives of any such Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

Section 11.03. **Permitted Disclosures**. Notwithstanding any other provision to the contrary set forth in 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 request or order of a court or other Governmental Authority, including the rules and regulations promulgated by the Securities and Exchange 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 or Nasdaq; (c) is made: (i) **[***]**; or (d) is made 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 under this subsection (d) 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 reasonable efforts to obtain confidential treatment of such information. If a Recipient is required to disclose Confidential Information pursuant to **Section 11.03(a) (Permitted Disclosures)** or **Section 11.03(b) (Permitted Disclosures)**, then prior to any such 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, and in the event of the disclosing Party's failure to obtain such protective order, the Recipient shall only disclose that information which is legally required to be disclosed.

Section 11.04. **Publicity**. The Parties will issue a joint press release in connection with this Agreement in substantially the form attached hereto as **Schedule 11.04 (Press Release)**. The Parties recognize that each Party may from time to time desire to issue other press releases and make other public statements or public disclosures in respect of this Agreement, including the Development or Commercialization of, or performance of Medical Affairs with respect to, Licensed Product in the Territory during the Term (each, a "**Public Statement**"). If a Party desires to make a Public Statement (an "**Issuing Party**"), then it shall provide the other Party a copy of such Public Statement at least **[***]** prior to the date it desires to make such public disclosure. An Issuing Party shall not issue a Public Statement without the other Party's prior written approval, which advance approval shall not be unreasonably withheld, conditioned or delayed. Once the form of any Public Statement has been approved in accordance with this **Section 11.04** (**Publicity**), then the Issuing Party may appropriately communicate information contained in such permitted Public Statement. 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 11.03 (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 or Nasdaq, *provided* that such statement or disclosure is made in accordance with **Section 11.03 (Permitted Disclosures)**.

Section 11.05. Publications.

(a) **General**. Sol-Gel acknowledges Galderma's interest in publishing certain key results of Galderma's Commercialization of Licensed Product in the Field in the Territory. Galderma 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)**, **Section 11.04 (Publicity)**, or **Section 11.05(b) (Top-Level Data Subset Readouts)**, if Galderma wishes to make a publication or public presentation with respect to its Commercialization of Licensed Product in the Field in the Territory, then Galderma shall deliver to Sol-Gel a copy of the proposed written publication or presentation at least **[***]** prior to submission for publication or presentation. Galderma will redact all of Sol-Gel's Confidential Information if requested by Sol-Gel. If Sol-Gel requests a delay in publication or presentation in order to protect patentable information, then Galderma shall delay submission or presentation for a reasonable period of time (but no longer than **[***]**, except as the Parties may otherwise agree) to enable Sol-Gel to file patent applications protecting Sol-Gel's rights in such information.

(b) **Top-Level Data Subset Readouts**. Notwithstanding any provision to the contrary set forth in this Agreement, Galderma may publish in its promotional materials readouts of the top-level results of any analysis by Galderma of various subsets of data from clinical study reports involving the Licensed Product **[***]**; *provided* that such publication does not, in Galderma's good faith belief, **[***]** that would be (i) **[***]** or (ii) **[***]**. For the avoidance of doubt, this **Section 11.05(b) (Top-Level Data Subset Readouts)** shall not be construed to permit Galderma to publish the detailed clinical study report upon which such top-level results are based **[***]**.

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 & INSURANCE

Section 12.01. **Indemnification by Sol-Gel**. Sol-Gel shall indemnify, hold harmless, and defend any Galderma Entity, and their respective directors, officers, and employees (the "**Galderma Indemnitees**") from and against any and all 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**") incurred in connection with any and all Third Party suits, claims, actions, or demands ("**Claims**") to the extent that such Claims arise out of (a) any breach of this Agreement by Sol-Gel or its Affiliates, (b) the Development, Manufacture, or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product anywhere in the world by or on behalf of any Sol-Gel Entity or their sublicensees, including Licensed Product Manufactured by **[***]** under the **[***]** Supply Agreement to the extent that **[***]** Supply Agreement, or (c) the gross negligence, fraud, or willful misconduct of any Sol-Gel Indemnitee in connection with the performance of this Agreement. Notwithstanding the foregoing, Sol-Gel shall not have any obligation to indemnify the Galderma Indemnitees to the extent that the applicable Claims or Losses arise out of any activities set forth in **Section 12.02 (Indemnification by Galderma)** for which Galderma is obligated to indemnify Sol-Gel or any other Sol-Gel Indemnitees.

Section 12.02. **Indemnification by Galderma**. Galderma shall indemnify, hold harmless and defend any Sol-Gel Entity and any of their sublicensees, and their respective directors, officers, and employees (the "**Sol-Gel Indemnitees**") from and against any and all Losses incurred in connection with any and all Claims to the extent that such Claims arise out of (a) any breach of this Agreement by Galderma or its Affiliates, (b) the Manufacture or Commercialization of, or performance of Medical Affairs with respect to, the Licensed Product in the Territory by or on behalf of any Galderma Entity, or (c) the gross negligence, fraud, or willful misconduct of any Galderma Indemnitee in connection with the performance of this Agreement. Notwithstanding the foregoing, Galderma shall not have any obligation to indemnify the Sol-Gel Indemnitees to the extent that the applicable Claims or Losses arise out of any activities set forth in **Section 12.01 (Indemnification by Sol-Gel)** for which Sol-Gel is obligated to indemnify Galderma or any other Galderma Indemnitees.

Section 12.03. **Procedure**. In the event of a claim by a Third Party against a Galderma Indemnitee or a 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, *provided* that no delay on the part of the Indemnified Party in giving such notice shall relieve the Indemnifying Party of any indemnification obligation unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby, and the Indemnifying Party, without admission of the other Party's fault, shall undertake and solely manage and control, at its sole expense and with counsel of its own choosing, the defense of the claim and its settlement. The Indemnified Party shall reasonably cooperate with the Indemnifying Party with respect to such defense and settlement. The Indemnified Party may, at its option and its sole cost 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**. Galderma and Sol-Gel each represent and warrant that they currently have, and will maintain during the Term, adequate insurances at their own expense and in accordance with usual industry standards to support their respective liabilities and obligations assumed under, arising out of, and in connection with, this Agreement. Galderma and Sol-Gel agree that such insurance may be provided by way of self-insurance to the same extent without violation or breach of the foregoing.

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 expire upon the fifth (5th) anniversary of the First Commercial Sale of Licensed Product in the Territory (the "**Initial Term**"). Notwithstanding the foregoing, the Parties may renew the term by written agreement of the Parties. At Galderma's request, during the **[***]** period immediately preceding the **[***]** anniversary of the First Commercial Sale of Licensed Product in the Territory (or at such other time, or for such longer period of time, as the Parties may otherwise agree) (the "**Renewal Discussion Period**"), the Parties will engage in exclusive, good faith discussions regarding the renewal of this Agreement for additional term(s) (each, an "**Additional Term**" and together with the Initial Term, the "**Term**"), and until the conclusion of such Renewal Discussion Period, Sol-Gel shall not discuss with any Third Party the terms on which Sol-Gel might grant rights to Commercialize the Licensed Product in the Field in the Territory.

Section 13.02. **Termination at Will by Galderma**. At any time during the Term, Galderma may terminate this Agreement for any or no reason upon giving **[***]** notice to Sol-Gel. Should Galderma exercise such termination right prior to the Refund Date, it will not be entitled to a refund of any amounts previously paid to Sol-Gel pursuant to **Section 7.01 (Upfront Payment)**.

Section 13.03. **Termination for Failure to Receive Regulatory Approval**. In the event that the Licensed Product does not receive Regulatory Approval from the FDA in the Territory on or before **[***]**, Galderma may, in its sole discretion, terminate this Agreement immediately upon delivery of written notice to Sol-Gel no later than **[***]** after such date.

Section 13.04. **Termination for Breach**. Subject to the terms and conditions of this **Section 13.04 (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 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 material breaches, the Breaching Party shall have a period of **[***]** days after such Breach Notice is provided to cure such breach, *provided* that if the Breaching Party demonstrates good faith efforts to execute a plan reasonably calculated to cure such breach within **[***]** days thereafter, then such cure period shall be extended by an additional **[***]** days. If a material breach for which a Breach Notice is provided is not cured within the applicable period set forth above, then the Non-Breaching Party may, at its election, terminate this Agreement upon written notice to the Breaching Party. If a Non-Breaching Party provides a Breach Notice to the Breaching Party pursuant to this **Section 13.04** (**Termination for Breach**) and the Breaching Party disputes the existence of a material breach in good faith, then the Breaching Party may refer such dispute to the dispute resolution process set forth in **ARTICLE XIV (Dispute Resolution; Governing Law)**. The **[***]** day cure period set forth in this **Section 13.04 (Termination for Breach)** shall be tolled during the pendency of such dispute, and all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder during such pendency.

Section 13.05. 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, then the other Party (the "**Other Party**") shall have, in addition to all other legal and equitable rights and remedies available to such Other Party, the option to terminate this Agreement upon 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, then, 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 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 Galderma 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 rights 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 13.06. **Termination for Patent Challenge**. Except to the extent the following is unenforceable under applicable Law, Sol-Gel shall have the right to terminate this Agreement in its entirety upon written notice to Galderma in the event that any Galderma Entity, individually or in association with any other person or entity, directly or indirectly, commences or continues to participate in a legal action challenging the validity, enforceability, or scope of any of the Licensed Patent Rights set forth on **Schedule 1.29 (Licensed Patents)** (a "Patent Challenge") **[***]**. Notwithstanding any provision to the contrary set forth herein, this **Section 13.06 (Termination for Patent Challenge)** will not apply to, and Sol-Gel may not terminate this Agreement with respect to, (a) any affirmative defense or other validity, enforceability, or non-infringement challenge with respect to a Licensed Patent Right, whether in the same action or in any other agency or forum of competent jurisdiction, advanced by a Galderma Entity in response to any claim or action for patent infringement with respect to such Licensed Patent Right brought in the first instance by or on behalf of a Sol-Gel Entity or any Third Party designated by a Sol-Gel Entity to initiate such claim or action; (b) any claim or proceeding that would otherwise be a Patent Challenge hereunder to the extent commenced by a Third Party that after the Effective Date becomes an Affiliate of Galderma during the Term as a result of a change of control, merger, or acquisition of, with, or by Galderma, *provided* that such claim or proceeding commenced prior to the closing of such change of control, merger, or acquisition; (c) any Patent Challenge that is commenced by a sublicensee of Galderma hereunder if Galderma (i) causes such Patent Challenge to be withdrawn, terminated, or dismissed (or in the case of *ex-parte* proceedings, multi-party proceedings or other Patent Challenges in which Galderma does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge) or (ii) terminates such sublicensee's sublicense to the Licensed Patent Right(s) being challenged by the sublicensee, in each case ((i) and (ii)) within ninety (90) days after Sol-Gel's notice to Galderma under this **Section 13.06 (Termination for Patent Challenge)**; (d) any Patent Challenge required to be commenced pursuant to a government order or applicable Law; or (e) the provision of documents or testimony in response to any court order in a valid legal process.

Section 13.07. **Effect of Termination**.

(a) In the event of expiration or termination of this Agreement for any reason:

(i) all license grants in this agreement from Sol-Gel to Galderma shall terminate, except to the extent necessary for Galderma to exercise its rights and perform its obligations under this **Section 13.07 (Effect of Termination)**;

(ii) Galderma shall, in advance of and effective as of the effective date of termination, assign and transfer to Sol-Gel all Galderma Product Data, Regulatory Approvals, Regulatory Documents and Trademarks in its Control relating to the Licensed Product in the Territory, except to the extent necessary for Galderma to perform its continuing obligations under this Agreement until the effective date of such termination or to exercise its rights and perform its obligations under this **Section 13.07 (Effect of Termination)**;

(iii) **[***]**, any then-existing inventory of Licensed Product in Galderma's (and its Affiliates' and sublicensees') possession, **[***]** of such Licensed Product; *provided*, *however*, that in case of termination of this Agreement by Galderma pursuant to **Section 13.04 (Termination for Breach)**, **[***]**, all then-existing inventory of the Licensed Product in Galderma's (and its Affiliates' and sublicensees') possession **[***]**, **[***]** of such Licensed Product inventory. Notwithstanding any provision to the contrary set forth in this Agreement, with respect to any inventory of the Licensed Product that **[***]** upon expiration or termination of this Agreement pursuant to this **Section 13.07(a)(iii) (Effect of Termination)**, for a period **[***]** following any expiration or termination of this Agreement (as applicable) ("**[***] Period**"), Galderma shall be **[***]**. Upon the conclusion of such **[***]** Period, Sol-Gel shall, at its option, either (a) extend the **[***]** Period by **[***]** by providing prompt written notice to Galderma, or (b) **[***]**, all then-existing inventory of the Licensed Product in Galderma's (and its Affiliates' and sublicensees') possession **[***]** remaining at such time, **[***]**; *provided* that if, following the conclusion of such **[***]** Period, Sol-Gel has given notice to Galderma that it intends to **[***]** pursuant to the foregoing clause (b), then such **[***]** Period will be automatically further extended until **[***]**;

(iv) at Sol-Gel's request, (a) any existing agreements between Galderma or its Affiliates and any Third Party **[***]**, and (b) all of Galderma's and its Affiliates' rights, title and interests therein and thereto, shall at Sol-Gel's option be terminated or assigned and transferred to Sol-Gel or its designee, in each case, to the extent freely terminable, assignable or transferable (as applicable) without liability or monetary damages pursuant to the terms thereof (and for any such agreement that by its terms cannot be so assigned, Galderma shall reasonably cooperate with Sol-Gel to seek the transfer of the benefits of such agreement to Sol-Gel);

(v) upon Sol-Gel's written request, Galderma shall, where freely assignable, assign all contract manufacturing, research service, or other vendor agreements related solely to the Licensed Product to Sol-Gel, or, where such agreements are not freely assignable, reasonably cooperate with Sol-Gel to seek the transfer of the benefits of such agreements to Sol-Gel;

(vi) unless this Agreement is terminated by Galderma for Sol-Gel's material breach of this Agreement pursuant to **Section 13.04 (Termination for Breach)**, Galderma shall remain responsible for all its non-cancellable Third Party obligations incurred with respect to the Licensed Product, except for any such obligations assigned to and assumed by Sol-Gel pursuant to **Section 13.07(a)(iv) (Effect of Termination)** or **Section 13.07(a)(v) (Effect of Termination)**; and

(vii) Galderma shall cooperate with Sol-Gel and provide reasonable assistance in effecting the efficient transfer of regulatory and commercial responsibility for the Licensed Products in the Territory to Sol-Gel and to ensure a smooth transition while minimizing interruptions and delays in the conduct of such transition.

Galderma shall perform its obligations under this **Section 13.07 (Effect of Termination)** at its own cost and expense, except in the event that this Agreement is terminated by Galderma pursuant to **Section 13.04 (Termination for Breach)**, in which case Sol-Gel shall be responsible for such costs and expenses.

Section 13.08. **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), **Section 8.01 (Ownership of Intellectual Property)**, **Section 8.02 (Prosecution of Patent Rights), Section 8.03 (Enforcement), Section 8.04 (Defense of Third Party Infringement and Misappropriation Claims)**, **Section 8.06 (Trademark Enforcement and Defense)**, **Section 10.05 (Disclaimer), Section 10.06 (Limitation of Liability)**, **ARTICLE XI (Confidentiality)**, **Section 12.01 (Indemnification by Sol-Gel), Section 12.02 (Indemnification by Galderma), Section 12.03 (Procedure)**, **Section 12.04 (Insurance), Section 13.07 (Effect of Termination)**, **Section 13.08 (Survival; Accrued Rights)**, **Section 14.03 (Choice of Law)**, **Section 14.04 (Language)**, 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 occurring prior to such expiration or termination.

ARTICLE XIV

DISPUTE RESOLUTION; GOVERNING LAW

Section 14.01. **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, if a dispute arises between the Parties under this Agreement, then the Parties shall refer such dispute to the Executive Officers, who shall attempt in good faith to resolve such dispute. If the Executive Officers are unable to resolve such dispute within **[***]** days after such dispute has been referred to them under this **Section 14.01 (Executive Officers; Disputes)**, then such dispute shall be referred to the dispute resolution process set forth in **Section 14.02 (Arbitration)**.

Section 14.02. **Arbitration**. Subject to **Section 14.02(d) (Intellectual Property Disputes)**, 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 **Section 14.01 (Executive Officers; Disputes)** shall be referred to and finally resolved by binding arbitration administered by the ICC International Court of Arbitration ("**ICC**"), in accordance with the then-current rules of the ICC (the "**Rules**"), which rules are deemed to be incorporated by reference into this **Section 14.02 (Arbitration)**, in the manner described below; *provided* that, prior to commencing arbitration or other legal proceedings with respect to any disputes, claims or controversies in connection with this Agreement, the Executive Officers of both Parties shall discuss in good faith such disputes, claims or controversies for at least **[***]** pursuant to **Section 14.01 (Executive Officers; Disputes)**.

(a) **Arbitration Request**. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, then 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 **[***]** after the receipt of an Arbitration Request, the other Party may, by written notice, add additional issues for resolution by providing written notice thereof to the Party that originally issues the Arbitration Request.

(c) **General Arbitration Procedure for Disputes**. The seat of arbitration will be in New York, New York, and the arbitration will be conducted in the English language. No Party will challenge the jurisdiction or venue provisions as provided in this Agreement. The arbitration will be conducted by a single arbitrator, who will be appointed according to the Rules or by mutual agreement of the Parties and who 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 and permitted assigns. 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 arbitrator and the ICC, and each Party shall bear the costs and fees of its 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 such 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, then any arbitrator 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 the other provision of **Section 14.02 (Arbitration)**, 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 14.03. **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 laws of the State of New York, exclusive of and without regard to its conflicts of laws principles; *provided*, *however*, that any dispute between the Parties hereunder relating to inventorship shall be resolved based on an independent inventorship analysis under the United States patent law. This Agreement shall not be governed by the provisions of the United Nations Convention on Contracts for the International Sale of Goods.

Section 14.04. **Language**. This Agreement has been prepared and executed in the English language, and the English language shall control its interpretation in all respects. 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

Section 15.01. **Assignment**.

(a) Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by either Party (and, for these purposes, a merger, sale of assets, operation of law or other similar transaction shall be deemed an assignment) without the prior written consent of the other Party. Notwithstanding the foregoing, a Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (i) an Affiliate or (ii) a Third Party that acquires, by or otherwise in connection with, a merger, sale of assets or otherwise, all or substantially all of the business of such assigning Party to which the subject matter of this Agreement relates; *provided* that the assignee agrees in writing to assume all of such assigning Party's obligations under this Agreement. A Party assigning this Agreement in accordance with this paragraph will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned.

(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 in, interrupted in or prevented from the performance of any of its obligations hereunder by reason of force majeure, which may include any act of God, fire, flood, earthquake, storm, war (declared or undeclared), failure of plant or machinery, CMO Supply Failure, public disaster, epidemic, pandemic, spread of infectious disease, quarantine, state of emergency, act of terrorism, insurrection, riot, government act, order, ordinance, guideline or other similar action, or strike or labor differences (other than strikes or labor disturbances involving a Party's own employees), in each case outside of such Party's reasonable control (each a "**Force Majeure**"), then such Party shall not be liable to the other Party therefor nor be deemed to have defaulted under or breached this Agreement as a result thereof, 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. **[***]**. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to **[***]**, or cessation of activities in response to **[***]**. The Party invoking the force majeure rights of this **Section 16.01 (Force Majeure**) must notify the other Party of the Force Majeure by courier or overnight dispatch (*e.g.*, Federal Express) promptly following both the first and last days of the Force Majeure unless the Force Majeure renders such notification impossible or commercially impracticable, in which case notification will be made as soon as commercially practicable. While the Force Majeure circumstance continues, the affected Party will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances, and will provide to the other Party on a monthly basis, or more frequently if requested by the other Party, written summaries of its mitigation efforts and its estimates of when normal performance under this Agreement will be able to resume. If the delay resulting from the Force Majeure exceeds **[***]**, then 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; Amendments**. 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 Galderma 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 Galderma 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 held 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**"), then it is 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. **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, 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, 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 such recitals, Schedules or Exhibits, the terms of the body of this Agreement shall control unless such recital, Schedule or Exhibit expressly states the intent of the Parties that such terms and conditions shall supersede the terms of the body of this Agreement; (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, Exhibits 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) any reference herein to any person will be construed to include the person's successors and assigns; (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; (m) the word "year" means any consecutive twelve (12) month period, unless otherwise specified; (n) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or"; and (o) nothing in this Agreement shall require or be construed or interpreted to require a Party to violate any applicable Law.

Section 16.05. **Notices**. Except as expressly otherwise provided herein, any notice required or permitted to be given under this Agreement shall be in writing and shall be delivered by internationally recognized express courier or delivery service, or sent by facsimile or email and confirmed by registered or certified mailing, postage prepaid, return receipt requested, and in each case, addressed 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 7403620
Israel
Attn: **[***]**
With a copy to (which shall not constitute notice for purposes of this Agreement):

[***]

If to Galderma:

Galderma SA
Rue d'Entre-deux-Villes 10
1814 La Tour-de-Peilz
Switzerland
Attn: General Counsel

With a copy to (which shall not constitute notice for purposes of this Agreement):

[***]

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 16.06. **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 and the legal relationship between the Parties shall not constitute a partnership, joint venture or agency, including for all tax purposes. 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 16.07. **No Waiver**. No waiver of a term, condition, covenant or provision of this Agreement shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term, condition, covenant or provision. Except as may be expressly set forth herein, 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, conditions, 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 or similar breach or default by the other Party, and any single or partial exercise of any particular right by a Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

Section 16.08. **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 applicable Law or in equity.

Section 16.09. **No Third Party Beneficiary Rights**. This Agreement is not intended to and shall not be construed to give any Third Party any interest, rights or remedies (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 Galderma Indemnitees and (b) to the extent provided in **Section 12.02 (Indemnification by Galderma)**, the Sol-Gel Indemnitees.

Section 16.10. **Performance by Affiliates**. Subject to **Section 7.09 (Methods of Payment)**, either Party may use one or more of its Affiliates to perform its obligations and duties and exercise its rights hereunder; *provided* that each Party shall cause such of its Affiliates to comply with the provisions of this Agreement in connection with such performance or exercise and shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

Section 16.11. **Further Assurances and Actions**. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary to consummate or implement expeditiously the express purposes and intent contemplated by this Agreement.

Section 16.12. **Counterparts**. This Agreement may be executed in one or more counterparts, all of which taken together shall be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format ("**PDF**") sent by electronic mail. In addition, PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a PDF signature by any Party will constitute due execution and delivery of this Agreement.

[*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:
Name:
Title:

GALDERMA HOLDING SA

By:
Name:
Title:

By:
Name:
Title:

[Signature Page to Twyneo License Agreement]

Schedule 1.02

Excluded Affiliates

[***]

Schedule 1.29

Licensed Patents

[***]

Schedule 1.32

Licensed Trademark

[***]

Schedule 5.01

Minimum Order Quantities

[***]

Schedule 6.01

Douglas Supply Agreement

[***]

Schedule 11.04

Press Release

[***]

Exhibit 4.21

CERTAIN INFORMATION IDENTIFIED
BY BRACKETED ASTERISKS ([* * *])
HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE
IT IS BOTH NOT MATERIAL AND WOULD BE
COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Contract Manufacturing Agreement

DOUGLAS MANUFACTURING LIMITED

SOL-GEL TECHNOLOGIES LIMITED

GALDERMA SA

May 28, 2021

AGREEMENT DETAILS

Parties	**DOUGLAS MANUFACTURING LIMITED** ("**Douglas**") **SOL-GEL TECHNOLOGIES LIMITED** ("**Sol-Gel**") **GALDERMA SA** ("**Galderma**")	
Douglas contact details	Address	Corner of Central Park Drive and Te Pai Place, Lincoln, Auckland 0610, New Zealand
	Email address	**[***]**
	Contact number	+64 9 822 5510
	Contact person	Tony Clark, General Manager DML
Sol-Gel contact details	Address	Golda Meir 7, Ness Ziona, Israel
	Email address	**[***]**
	Contact number	**[***]**
	Contact person	**[***]** CFO
Galderma contact details	Address	Rue d'Entre-deux-Villes 10, 1814 La Tour-de-Peilz, Switzerland
	Email address	**[***]**
	Contact number	**[***]**
	Contact person	**[***]** VP Operations

Commencement Date	The date of the last signature of this agreement.
Customer	Galderma, or following any termination of this Agreement by Galderma pursuant to clause 16 (Termination), Sol-Gel or its designated Affiliate or licensee, in accordance with clause 16.5 (Effect of Termination as to Galderma).
Products, Lead Time and Additional Services	As set out in Schedule 1.
Components	All Materials (as set out in Schedule 3), ingredients, consumables, Secondary Packaging, and other components and materials that are incorporated into or used to produce Product. The term Components includes Critical Components and Exclusive Components.
Territory	The United States of America, including its districts, territories, possessions and protectorates, such as Puerto Rico.
Manner of Delivery	Either **[***]** or **[***]** approved for the Product.
Initial Term	The initial term of this Agreement shall commence on the Commencement Date and shall continue until the third (3rd) anniversary of the First Commercial Sale (unless sooner terminated under clause 16 (Termination)).
Renewal Term (if any)	At Sol-Gel's and the Customer's option, Sol-Gel and the Customer may renew this Agreement for an additional period following the Initial Term so that the entire Term of the Agreement shall expire on the fifth (5th) anniversary of the First Commercial Sale, by providing Douglas written notice of its intent to renew no less than **[***]** prior to the end of the Initial Term, pursuant to clause 2.2 (Renewal Term). As between Sol-Gel and the Customer, Sol-Gel's consent to renew the Agreement shall not be unreasonably withheld, delayed, or conditioned, and good faith discussions on the subject shall take place beginning no later than **[***]** prior to the end of the Initial Term, which discussions shall include the **[***]**, taking into account the circumstances at the time of such renewal.
Prices	The Prices for manufacturing and supplying the Products, as set out in Schedule 1 (subject the Price adjustment clauses contained in clause 8.1 (Price for Manufacturing Services)).
Payment	Payments shall be made by the Customer within **[***]** after the date of an undisputed invoice issued by Douglas in accordance with clause 9.2 (Invoicing) and the other terms of this Agreement. Payment shall be made by way of electronic transfer to the bank account nominated by Douglas.
Currency in which moneys payable under this Agreement	USD

DOUGLAS MANUFACTURING LIMITED by:

Signature

Name

Position

Date

SOL-GEL TECHNOLOGIES LIMITED by:

Signature

Name

Position

Date

GALDERMA SA by:

Signature

Name

Position

Date

GALDERMA SA by:

Signature

Name

Position

Date

Contents

TERMS AND CONDITIONS

1. Interpretation

1.1. **Definitions:** In this Agreement:

"**Additional Fee**" shall mean the additional **[***]** due to Douglas from **[***]**, and from **[***]**, in the amount set forth in Schedule 1.

"**Additional Services**" means the additional services listed at Schedule 1.

"**Additional Service Pricing**" has the meaning given to that term at Schedule 1.

"**Affiliate**" means, in relation to a Party, any person who controls, or is controlled by, or is under common control with, that Party.

"**Agreement**" means this Contract Manufacturing Agreement.

"**Applicable Laws**" means all laws, regulations, statutes, codes of conduct and industry standards applicable to the Manufacture, supply, and/or sale of the Licensed Product or the Parties' performance of other activities under this Agreement.

"**Approved Manufacturer**" means the approved Material manufacturers set forth on Schedule 3.

"**Approved Manufacturer List**" has the meaning given to that term in clause 3.1.2 (Components).

"**Authority**" means any governmental authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether international, supranational, federal, state, provincial, county or municipal.

"**Batch**" means a defined quantity of Product, during a defined cycle of Manufacture, and which is identified by a unique production number.

"**Business Day**" means Monday to Friday except for any day in either New Zealand, Switzerland or the United States that is a public or statutory holiday.

"**Claims**" has the meaning given to that term in clause 19.1 (Indemnification by Douglas).

"**Commencement Date**" has the meaning given to this term at the front of the agreement**.**

"**Commitment**" has the meaning given to that term in clause 6.1 (Forecasts).

"**Components**" has the meaning given to this term at the front of the agreement.

"**Confidential Information**" shall mean all written information and data or verbal information or information obtained during on-site visits that is specifically designated as confidential or by its nature would reasonably be understood or expected by the receiving Party to be confidential, provided by the Parties to each other under this Agreement or with respect to the Products (including any information concerning the financial position of any Party and its business, sales and technical operations or any information concerning the customers or suppliers of any Party, and the terms of this Agreement and the Technical Quality Agreement), except any portion thereof that:

(a) is known to the receiving Party, as evidenced by the receiving Party's written records, before receipt thereof under this Agreement;

(b) is independently developed by the receiving Party prior to receipt of the Confidential Information, either under this Agreement, the License Agreement or the Service Development Agreement, as evidenced by written records of the receiving Party;

(c) is disclosed to the receiving Party by a third person who has a right to make such disclosure; or

(d) is or becomes part of the public domain through no fault of the receiving Party.

"**Continuous Improvements**" has the meaning given to it in clause 3.1.4 (Continuous Improvement).

"**Critical Components**" means any Components that are **[***]**, as identified in Schedule 3.

"**Current Good Manufacturing Practices**" or the letters "**GMP**" or "**cGMP**" means current good manufacturing practice and standards as provided for (and as amended from time to time) in European Community Directive 2003/94/EC (Principles and guidelines of good manufacturing practice for medicinal products for human use) and in the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 C.F.R. Parts 210 and 211) or any similar laws, rules, or regulations or directives promulgated by any applicable Regulatory Authority as applicable to the activities contemplated under this Agreement, including as applicable in the country where the Product will be actually Manufactured by Douglas or the country in which any API or other Component is produced, marketed, distributed, made available, used or sold, for methods to be used in, and the facilities or controls to be used for, the Manufacture, processing, testing, packaging, labelling, handling or storage of a product to assure that it is safe, and has the identity and strength and meets the quality and purity characteristics that it purports, or is represented, to possess. For clarity, in case of any contradictions between the governing laws and regulations applicable to different countries the principals adopted by the U.S. Code of Federal Regulations Title 21 (21 C.F.R. Parts 210 and 211) shall govern.

"**Customer**" has the meaning given to this term at the front of the agreement**.**

"**Delivery Date**" has the meaning given to that term in clause 6.2 (Purchase Orders).

"**Dispute**" has the meaning given to that term in clause 22.2.1 (Dispute Resolution).

"**Douglas Indemnitees**" has the meaning given to that term in clause 19.2 (Indemnification by Customer).

"**Equipment**" means the equipment listed in Schedule 2.

"**Exclusive Components**" means any Components that are unique to any Product (i.e. that Douglas does not procure for any other customer or drug product), as identified in Schedule 3, which may be amended from time to time to add to, delete from or alter the status of such Components as agreed. In the event that any such Components are no longer unique to the Products, such Components shall no longer be defined as Exclusive Components.

"**Exclusive Vendors**" means any vendors that are unique to the Product such as exclusive storage providers and exclusive external testing laboratories.

"[***]" means **[***]** (as amended from time to time).

"**Facility**" means the facility operated by Douglas located at **[***]** as defined in the site master file, or any other facility approved by the Customer in writing from time to time.

"**FDA**" means the United States Food and Drug Administration or any successor thereto.

"**Firm Order**" has the meaning given to that term in clause 6.3 (Acceptance of Orders).

"**First Commercial Sale**" means the first bona fide sale of a Product in the Territory by the Customer or its Affiliates or sublicensees for **[***]** to a Third Party **[***]** . Sales or other distribution for **[***]**, or (e) similar purposes shall not be deemed "First Commercial Sale."

"**Force Majeure Event**" has the meaning given to that term in clause 18.1 (Force Majeure).

"**Generic Processes**" has the meaning given to that term in clause 15.7 (Generic Improvements).

"**ICC**" has the meaning given to that term in clause 22.2.1 (Dispute Resolution).

"**ICC Rules**" has the meaning given to that term in clause 22.2.1 (Dispute Resolution).

"**Incremental Order Quantity**" means the incremental order quantities relating to each Product as set out in Schedule 1.

"**Indemnified Party**" has the meaning given to that term in clause 19.5 (Procedure).

"**Indemnifying Party**" has the meaning given to that term in clause 19.5 (Procedure).

"**Initial Term**" has the meaning given to that term in clause 2.1 (Initial Term)**.**

"**Intellectual Property**" means all intellectual property rights and other proprietary rights in any jurisdiction throughout the world including: (i) inventions, trade secrets, know-how and other confidential or proprietary information, (ii) works of authorship and copyrights, (iii) trademarks, (iv) data, results and reports related to any clinical trial involving a Product, whether published or unpublished, (v) any additions, advances, changes, derivatives, improvements, enhancements, refinements or modifications made to any of the foregoing, and (vi) all other intellectual property; in each case, including any registrations, applications for registration, or other embodiments of any of the foregoing (e.g., patents, patent applications, patent disclosures, and any divisions, continuations, continuations-in-part, reissues, extensions, or re-examinations thereof), and including any and all rights, title, and interests therein and thereto.

"**Inventory**" means all stocks and inventories of Components, Product and work-in-process Product that, at a particular time, have been purchased or produced and are held or maintained by Douglas in accordance with this Agreement, including any excess material purchased by reason of vendor minimum purchase requirements and any long lead time material.

"**Latent Defect**" means any non-conformity that causes Product to be non-conforming with the Specifications and that could not reasonably be detected by visual inspection or the Methods of Analysis used to characterise the Product at the time of release.

"**Lead Time**" means the minimum required period of time between the date when a Purchase Order is placed and the Delivery Date set out in the Purchase Order of the Products, as specified at Schedule 1.

"**License Agreement**" has the meaning given to that term in clause 16.4 (Termination for Expiration or Termination of License Agreement).

"**Licensed Rights**" means all rights in and to the formula, technology, techniques (both patented and non-patented), know-how, methods, Confidential Information, designs, and Intellectual Property owned or controlled by Sol-Gel or any of its Affiliates relating to the Products and the Methods of Analysis, or otherwise necessary or useful for the Manufacture of Products.

"**Long Term Forecast**" has the meaning given to that term in clause 6.1 (Forecasts).

"**Losses**" has the meaning given to that term in clause 19.1 (Indemnification by Douglas).

"**Manufacturing License**" has the meaning ascribed to it in clause 3.3 (Use of Licensed Rights and Quality Information).

"**Manufacture**" or "**Manufacturing**" means, as applicable, all activities associated with, related to, directed to, or involved in the production of the Product, including the purchase, receipt, and use of Materials and Components, the preparation, formulation, processing, production, manufacturing, filling, packaging (primary and secondary), component assembly, finishing, serialization, testing, analysis, as well as finished product or stability testing, labelling, holding, storage, handling, and release of the Product and the Materials or intermediate thereof, including process qualification and validation, and commercial manufacture and analytical development, quality assurance and quality control, and the handling, storage and disposal of any residues or wastes generated thereby**. "Manufactured**" has a correlative meaning.

"**Marketing Approval**" means all approvals, licenses, registrations, authorizations or clearances of any Regulatory Authority necessary for the Manufacture, commercialization, distribution, marketing, offer for sale, use, importation into, storage, and commercial sale in the Territory of the Product Manufactured by Douglas at the Facility**.**

"**Materials**" means all APIs, excipients, and primary packaging as set out in Schedule 3.

"**Methods of Analysis**" means the methods of analysis for the Product as agreed in writing between the Parties.

"**Modifications**" has the meaning given to that term in clause 11.1 (Changes by Douglas).

"**Non-Conforming Materials**" means the Materials that do not comply or conform with the Sol-Gel Specifications and **[***]**.

"**Other Equipment**" means equipment used in the performance of the Services, but that are not listed in Schedule 2.

"**Parties**" has the meaning given to that term at the front of this Agreement.

"**Patent Infringement Termination**" has the meaning given to that term in clause 16.3 (Termination for Regulatory Action or Claim of Infringement).

"**Patent Rights**" means all patent and patent application rights throughout the world in respect of any technology or techniques relating to the Manufacture of the Products and any patent granted pursuant to such applications (including without limitation those patent applications and registrations specified at the front of this Agreement (if any), as amended from time to time in accordance with this Agreement), and any further patent applications made by, and patents granted to Sol-Gel at any time during the Term in respect of or relating to the Products.

"**Person**" means any natural person, corporation, general partnership, limited partnership, limited liability company, limited liability partnership proprietorship, other business organization, trust, union, association or Authority.

"**Preferential Use**" has the meaning given to that term in Schedule 2.

"**Preliminary Specifications**" has the meaning given to this term in clause 4.2 (Specifications).

"**Prices**" has the meaning given to that term at the front of this Agreement.

"**Products**" means the products set out in Schedule 1, as amended from time to time in accordance with this Agreement.

"**Purchase Order**" has the meaning given to that term in clause 6.2 (Purchase Orders).

"**Quality Information**" means quality information relating in any way to the Manufacture of the Products, and to the use of any equipment and techniques relating to the Products, including any such information provided by Sol-Gel to Douglas prior to the Commencement Date and any such information that may be further provided by the Customer, or by Sol-Gel at the Customer's request, to Douglas from time to time to enable Douglas to Manufacture the Products at the Facility.

"**Recall**" means any action in the Territory (a) by the Customer to recover title to or possession of, or to issue a field alert or field correction with respect to, quantities of Product sold or shipped to Third Parties, including any voluntary withdrawal of Product from the market, or (b) by any Regulatory Authority to recall, withdraw from the market, order any corrective action, or otherwise detain or destroy any Product.

"**Regulatory Authorities**" means any U.S. federal, state, local or other non-U.S. governmental or regulatory body, court or arbitrator, including FDA and authorities appointed under the Drugs and Cosmetics Act, 1940, for the time being in force, as well as any other health regulatory authorities having jurisdiction over any activities contemplated by the Parties in the Territory.

"**Regulatory Requirements**" means any and all applicable U.S. federal, state, and local, or non-U.S. and New Zealand laws, legal and regulatory standards, procedures, protocols, guidelines, guidances, and requirements or requests of any Regulatory Authority having jurisdiction over the Product or the Manufacture thereof or any other activities contemplated by this Agreement. Regulatory Requirements shall include the applicable provisions of the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and Current Good Manufacturing Practices.

"**Renewal Term**" has the meaning given to that term in clause 2.2 (Renewal Term)**.**

"**Required Regulatory Change**" has the meaning given to this term in clause 11.3 (Changes Required by Authority).

"**Rolling Forecast**" has the meaning given to that term in clause 6.1 (Forecasts).

"**Secondary Packaging**" means all secondary packaging for the Product, including labels, inserts, cartons, shippers, and dividers.

"**Service Development Agreement**" has the meaning given to that term in clause 2.3 (Existing Relationship).

"**Services**" means the Manufacturing and supply of Products to the Customer. The term Services excludes any Additional Services.

"**Sol-Gel IP**" has the meaning given to that term in clause 15.1 (Rights of Sol-Gel).

"**Sol-Gel Specifications**" means specifications required by Sol-Gel in relation to **[***]**, in addition to the specifications that **[***]**, as set out in Schedule 3, which may be amended by the Customer and Sol-Gel upon agreement in writing from time to time, provided that as between Sol-Gel and Customer, if Customer requests Sol-Gel to approve a change in the Sol-Gel Specifications, then Sol-Gel's consent to such change shall not be unreasonably withheld, delayed, or conditioned.

"**Specifications**" means the mastered specifications for the Products (document numbers **[***]**), including specifications relating to the raw materials (**[***]**), the formula, techniques and method of Manufacture (document numbers **[***]**). The Specifications may be amended by the Customer and Sol-Gel upon agreement in writing from time to time, provided that as between Sol-Gel and the Customer, if the Customer requests Sol-Gel to approve a change in the Specifications, then Sol-Gel's consent to such change shall not be unreasonably withheld, delayed, or conditioned.

"**Subcontractor**" has the meaning given to it in clause 3.4.2.1 (Subcontractors).

"**Technical Quality Agreement**" means the quality agreement between Douglas and the Customer annexed to this Agreement as Annexure 1, as may be updated by Douglas and the Customer from time to time.

"**Term**" has the meaning given to that term in clause 2.2 (Renewal Term)**.**

"**Territory**" has the meaning given to this term at the front of the agreement**.**

"**Third Party**" means any Person that is not a Party to this Agreement or an Affiliate of a Party to this Agreement.

"**Third Party Claim**" has the meaning given to it in clause 15.3 (Indemnity).

All other capitalised terms shall have the meaning given to them at the front of this Agreement.

1.2. **Interpretation:** In this Agreement, unless the context otherwise requires:

(a) "control" includes where one or more Persons, directly or indirectly, whether by the legal or beneficial ownership of shares, securities or other equity, the possession of voting power, by contract, trust, or otherwise:

(i) has the power to appoint or remove the majority of the members of the governing body of the Person concerned;

(ii) controls or has the power to control the affairs or policies of the person concerned; or

(iii) is in a position to derive more than 50% of the benefit of the existence or activities of the Person concerned;

(b) the word "year" means any consecutive twelve (12) month period, unless otherwise specified;

(c) the singular includes the plural and vice versa and pronouns cover all genders;

(d) 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;

(e) unless otherwise provided, references to clauses and Schedules are references to clauses and Schedules in this Agreement;

(f) the Schedules to this Agreement, and the terms and conditions incorporated in such Schedules, shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such Schedules and the terms and conditions incorporated in such Schedules, *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 Schedules, the terms of the body of this Agreement shall control unless such Schedule expressly states the intent of the Parties that such terms and conditions shall supersede the terms of the body of this Agreement;

(g) 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;

(h) "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;

(i) headings are to be ignored in construing this Agreement;

(j) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or";

(k) 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;

(l) "including" and its derivatives (such as include and includes) means, whether or not capitalized in this Agreement, "including, but not limited to" and "including without limitation";

(m) references to any law, statute, or Regulatory Requirement shall mean such law, statue, or Regulatory Requirement as in effect as of the relevant time, including any then-current modification of, amendment to, re-enactment of, or successor to, such law, statute, or Regulatory Requirement, and all legislation, orders, rules, and regulations issued under that statute or passed or made in substitution for the same;

(n) this Agreement shall be construed as if the Parties drafted it jointly, and shall not be construed against any Party as principal drafter; and

(o) nothing in this Agreement shall require or be construed or interpreted to require a Party to violate any Applicable Law or Regulatory Requirement.

2. Term

2.1 **Initial Term:** The initial term of this Agreement shall commence on the Commencement Date and shall continue until the third (3rd) anniversary of the First Commercial Sale (unless sooner terminated under clause 16 (Termination)) (the "**Initial Term**").

2.2 **Renewal Term**: At Sol-Gel's and the Customer's option, Sol-Gel and the Customer may renew this Agreement for an additional period following the Initial Term so that the entire Term of the Agreement shall expire on the fifth (5th) anniversary of the First Commercial Sale of Product (as such option is exercised by the Customer, the "**Renewal Term**") by providing Douglas written notice of its intent to renew no less than **[***]** prior to the end of the Initial Term. As between Sol-Gel and the Customer, Sol-Gel's consent to renew the Agreement shall not be unreasonably withheld, delayed, or conditioned, and good faith discussions on the subject shall take place beginning no later than **[***]** prior to the end of the Initial Term, which discussions shall include the **[***]**, taking into account the circumstances of such renewal. The "**Term**" of this Agreement shall include the Initial Term and, as applicable, the Renewal Term (unless sooner terminated under clause 16 (Termination).

2.3 **Existing Relationship**: Douglas and Sol-Gel entered into a Service Development Agreement dated **[***]**, as amended on **[***]**, pursuant to which Douglas provided development services to Sol-Gel relating to the Products. This Agreement replaces the Service Development Agreement dated **[***]** (as amended) (the "**Service Development Agreement**"), except that any provisions of the Service Development Agreement that are intended to survive its expiry or termination shall do so and the entering into of this Agreement shall not preclude or override any liability of either Douglas or Sol-Gel that arose pursuant to the Service Development Agreement prior to the Commencement Date of this Agreement, including any obligation to make any payment. Notwithstanding any provision to the contrary set forth in this Agreement, Galderma, not having been party to the Service Development Agreement, shall not be bound by, or have any responsibility or liability with respect to, the Service Development Agreement in any manner whatsoever, including any surviving terms thereof.

3. Services

3.1 **Manufacturing Services:**

3.1.1 **Arrangement:** In consideration of the Customer's payment of the Prices due under, and the other terms and conditions of, this Agreement, Douglas shall perform the Services during the Term at the Facility in order to Manufacture and supply Product to the Customer for sale in the Territory pursuant to Purchase Orders issued by the Customer in accordance with clause 6.2 (Purchase Orders). Douglas shall perform the Services in accordance with the Specifications, the Sol-Gel Specifications, this Agreement, and the Technical Quality Agreement.

3.1.2 **Components:** Douglas shall purchase all Components as required by the Specifications. A list of manufacturers and Materials approved by Sol-Gel and the Customer for the Materials to be used in Product Manufacturing is set forth at Schedule 3 (the "**Approved Manufacturer List"**), which list may be amended from time to time upon agreement of Sol-Gel and the Customer, provided that as between Sol-Gel and the Customer, if Customer requests Sol-Gel to approve an amendment to the Approved Manufacturer List, then Sol-Gel's approval of such amendment shall not be unreasonably withheld, delayed, or conditioned. Douglas shall not use any Material or engage any manufacturer to supply a Material unless it is on the Approved Manufacturer List or approved in advance upon agreement of Sol-Gel and the Customer, provided that as between Sol-Gel and Customer, if Customer requests Sol-Gel to approve a Material or a manufacturer to supply a Material, then Sol-Gel's approval of such Material or manufacturer shall not be unreasonably withheld, delayed, or conditioned. Douglas shall be responsible for conducting an assessment and quality qualification of any newly proposed Material manufacturer and shall provide to the Customer a good faith qualification report detailing such qualification findings (where such assessment and quality qualification shall be conducted, and such qualification report shall be prepared and provided, at Douglas's sole cost, unless the newly proposed Material manufacturer would be an Exclusive Vendor, in which case Douglas shall invoice Customer in accordance with the rates set out in Schedule 1 for such audit).

3.1.3 **Technical Quality Agreement:** The parties shall enter into a Technical Quality Agreement on or about the date of this Agreement.

3.1.4 **Non-Conforming Product**: Douglas is not liable for any costs relating to (A) **[***]** or (B) **[***]**. As between the Parties, **[***]** shall bear the costs directly relating to the **[***]** other than as a result of the foregoing causes ((i)-(iv)), but will not be liable for any costs related to **[***]**. For the avoidance of doubt, **[***]** shall not be liable for the costs of **[***]** prior to or at the time of delivery by Douglas.

3.1.5 **Continuous Improvement:** Douglas shall use commercially reasonable efforts to ensure continuous improvements of the processing performance regarding the Product at the Facility ("**Continuous Improvements"**) in order to ensure efficient production, thereby generating potential savings that could be shared with Sol-Gel through a reduction in Prices payable by the Customer pursuant to clause 8.1.5 (Adjustment of Price Due to Continuous Improvements).

3.1.6 **Facility Requirements**: Douglas shall Manufacture the Product only at the Facility.

3.1.7 **Performance of Services and Other Obligations:** Douglas, on behalf of itself and its Affiliates, covenants that:

3.1.7.1 to Douglas's knowledge, Douglas's performance of its obligations under this Agreement, including its provision of the Services, shall not infringe or otherwise violate any Intellectual Property rights of any Third Party, except to the extent such infringement or violation is a result of Douglas's **[***]**;

3.1.7.2 Douglas shall provide the Services and the Additional Services in strict accordance with this Agreement, the Technical Quality Agreement, the Specifications, Applicable Laws (including cGMPs), and the Regulatory Requirements;

3.1.7.3 during the Term, the Facility shall remain cGMP-compliant;

3.1.7.4 Douglas shall not allow any liens, charges, encumbrances and security interests to be registered against the Product;

3.1.7.5 Douglas shall maintain throughout the Term all necessary approvals, licenses, authorizations, registrations, exemptions, consents, and permits from any Regulatory Authority or other Third Party in order to Manufacture the Product hereunder, except for the Marketing Approvals which is the responsibility of **[***]** and the responsibility of **[***]**; and

3.1.7.6 Douglas shall perform the Services and Additional Services with diligence, and in a professional manner, in accordance with the practices and professional standards used in well-managed operations performing services similar to the Services and Additional Services.

3.1.8 **Covenants of Sol-Gel and the Customer:**

3.1.8.1 Sol-Gel, on behalf of itself and its Affiliates, covenants that the Specifications, Sol-Gel Specifications, the Quality Information, and the manufacturing process or instructions that it provides to Douglas hereunder are currently and **[***]**) (i) will be correct in all material respects ; and (ii) ,), contain sufficient information to enable Douglas to comply with its obligations under this Agreement, and do not and will not infringe or otherwise violate any Intellectual Property rights of any Third Party. For clarity this covenant under clause 3.1.8 shall not diminish or modify Douglas' and Customer's rights to receive the remedies set forth in clause 15.6 with respect to any Third Party Claim.

3.1.8.2 The Customer, on behalf of itself and its Affiliates, covenants that at all times during the Term ([***]), the Specifications, Sol-Gel Specifications, the Quality Information and the manufacturing process or instructions that it provides to Douglas hereunder will be correct in all material respects and will not infringe or otherwise violate any Intellectual Property rights of any Third Party.

3.2 **Other Services:**

3.2.1 **Additional Products and Territories:** Additional products and countries may be added to this Agreement upon the written agreement of Douglas, the Customer, and Sol-Gel.

3.2.2 **Product Related Services:** In addition to the Services, Douglas shall perform any Additional Services in connection with Product as Douglas and the Customer may agree in writing from time to time. Such written agreement shall specify the scope, timing, parameters (including protocols, if applicable), fees payable by the Customer, and other matters pertinent to the Additional Services. To the extent Douglas and the Customer have agreed any such matters as of the Commencement Date, they are set out in Schedule 1. The terms and conditions of this Agreement shall govern the provision and receipt of any Additional Services.

3.2.3 **Storage**: Excluding retains and/or stability samples, and unless otherwise agreed by the Parties:

3.2.3.1 the Customer agrees to pay, according to the fees set out in Schedule 1, for (a) the storage of any bulk, in process, packaged Product (other than the process validation Batches) released by Douglas and stored by Douglas longer than **[***]** thereafter; and (b) any **[***]** stored by Douglas longer than **[***]** (other than **[***]**); and

3.2.3.2 Sol-Gel agrees to pay, according to the fees set out in Schedule 1, for the storage of (a) any bulk, in process, packaged Product which is part of the **[***]** stored by Douglas longer than **[***]** days; (b) any Materials stored by Douglas longer **[***]** (which was **[***]**); and (c) Equipment owned by Sol-Gel that is unused by Douglas for longer than **[***]**.

3.3 **Use of Licensed Rights and Quality Information:** Sol-Gel hereby grants Douglas, a non-exclusive, time limited, non-sublicensable, non-transferable, royalty free right to use the Licensed Rights and any of its Quality Information for the sole purpose of providing the Services to the Customer and Sol-Gel with respect to the Products during the Term strictly in the manner permitted under this Agreement (the "**Manufacturing License"**). After the expiry or termination of this Agreement, the Manufacturing License shall terminate and all rights hereby granted to Douglas under the Licensed Rights and the Quality Information shall revert to Sol-Gel and Douglas shall not use, purport to use or permit to be used any of the Licensed Rights or Quality Information for any purpose whatsoever.

3.4 **Customer Relationship Management and Subcontractors:**

3.4.1 **Customer Relationship Management**: Douglas shall provide relationship management through its customer relationship management team. In order to continue to develop and foster the relationship between Douglas and the Customer, Douglas will sponsor **[***]** relationship meetings with the Customer during which the Douglas and the Customer will discuss, at the Customer's request, such topics as market insights, forward forecasts, supply chain performance, quality and relationship management. The Parties agree that any issues arising during the Term that are not appropriate to be discussed at such relationship meetings will be escalated within the respective Parties for resolution.

3.4.2 **Subcontractors**:

3.4.2.1 Except as set forth in this clause 3.4.2 (Subcontractors), Douglas shall not subcontract any of its manufacturing, packing, storage and testing obligations under this Agreement to any Affiliate, Third Party entity or other Person (a "**Subcontractor**") without the Customer's prior written consent, which consent shall not be unreasonably withheld or delayed.

3.4.2.2 Notwithstanding any such prior written consent given by the Customer pursuant to clause 3.4.2.1 (Subcontractors), if Douglas subcontracts the performance of its obligations under this Agreement (as permitted), then (i) Douglas will be and remain primarily liable for any acts and omissions of any Subcontractors; (ii) such subcontracting will not relieve Douglas of its obligations or limit Sol-Gel's or the Customer's rights to pursue any remedies directly against Douglas under this Agreement, including for breaches committed by Subcontractors; and (iii) Douglas shall include in any such subcontract (to the extent applicable) terms relating to **[***]** that are no less protective of the Customer and Sol-Gel than the terms of this Agreement. Douglas shall ensure Subcontractors do not further subcontract obligations without prior approval from both the Customer and Douglas.

4. Obligations of the Parties

4.1 **Table of Responsibilities:** During the Term, Sol-Gel, Douglas, and the Customer shall perform the obligations under this Agreement and in accordance with the allocated responsibilities that are set forth in the Table of Responsibilities in the Technical Quality Agreement. In order to facilitate such performance, Douglas shall communicate directly with Sol-Gel and the Customer (as applicable), and respond in a timely manner to Sol-Gel's and the Customer's queries and requests.

4.2 **Specifications:** On or prior to the Commencement Date, Sol-Gel has provided Douglas with a preliminary copy of the Specifications pertaining to Product, including **[***]** with **[***]**, which are attached hereto as Schedule 5 (the "**Preliminary Specifications**"). Prior to the Customer placing its first Purchase Order, Sol-Gel and the Customer will provide Douglas with originally executed copies of final Specifications and any other Product-related information reasonably requested by Douglas in connection with the Services or the Additional Services. If such final Specifications are different from the Preliminary Specifications, clause 8.1.4 (Price Adjustments Due to Technical Changes) shall apply. Thereafter, the Customer may revise the Specifications from time to time, subject to clause 8.1.4 (Price Adjustments Due to Technical Changes).

4.3 **Non-Conforming Materials**: All costs associated with Non-Conforming Materials are the responsibility of **[***]**, including but not limited to write-offs, disposal and resupply. For clarity **[***]** shall not be liable to **[***]** for **[***]** that is caused solely due to Non-Conforming Materials. Douglas shall not be liable to Sol-Gel or the Customer for **[***]** that is caused solely due to Non-Conforming Materials.

4.4 **Materials that do not conform**: All costs associated with Materials that do not comply or conform with the **[***]** are the responsibility of **[***]**.

4.5 **Packaging:** The Customer shall be solely responsible for the choice of packaging and the development of all artwork and labelling in connection with Product packaging, including all associated content and intellectual property matters. Following receipt of Marketing Approval for the Product in the Territory, the Customer may, at its cost (including the destruction of obsolete packaging), make changes to Product packaging subject to clause 8.1.4 (Price Adjustments Due to Technical Changes). The Customer shall use commercially reasonable efforts to provide at least **[***]** notice to Douglas of any such change and Douglas shall use commercially reasonable efforts to implement such change within the required timeframe.

4.6 **Changes to Artwork after Firm Order:** If agreed to in writing by Douglas (which agreement shall not be unreasonably withheld, delayed, or conditioned, and shall be granted if required by the FDA or any other applicable Regulatory Authority or Authority), the Customer may (**[***]**)) change packaging artwork after the placement of a Firm Order. If **[***]** agrees to such change, the Delivery Date(s) for such Product (if less than **[***]** from the date that such change is agreed to by Douglas) will be revised to **[***]** from the date that such change is agreed to by Douglas.

4.7 **Quality Control; Safety:** As between the Parties under this Agreement, the Customer shall have sole responsibility for the release of Product to the market and for collecting and responding to customer complaints. Prior to the Commencement Date (or the commencement date of the applicable amendment to this agreement, in the case of Products added to this agreement after the Commencement Date), Sol-Gel shall have provided Douglas with all environmental, health and safety information relating to the Products, including safety data sheets. Sol-Gel or the Customer, as appropriate, shall promptly provide Douglas any updates to such documentation that become available to them or, where relevant, at least within **[***]** from the date of revision or date first supplied to Douglas.

4.8 **Product Discontinuation:** The Customer and Sol-Gel shall use commercially reasonable efforts to provide at least **[***]** advance notice to Douglas if it intends to discontinue sale of, or otherwise withdraw from the market, any Product in all of the Territory. If Customer discontinues sale of, or otherwise withdraws from the market, a Product in all of the Territory under this clause 4.8 (Product Discontinuation), the provisions of clause 17.1 (Consequences Arising) shall apply in respect of the discontinued Product. If the result of such discontinuation or withdrawal is that there are no longer any Products covered by this Agreement then clause 16.6 (Termination for Discontinuation) shall apply.

4.9 **Access to Quality Information**: Subject to compliance by Douglas with its obligations relating to confidentiality set out in clause 21.1 (Confidentiality), Sol-Gel and the Customer shall each provide Douglas with such access to the Quality Information within its respective possession or control as is necessary to enable Douglas to Manufacture the Products in accordance with the terms of this Agreement.

4.10 **Other Information and Assistance:** Subject to any obligations of confidentiality, Sol-Gel shall provide Douglas and Customer with such other information (including any know-how and other information contained in the Licensed Rights) and assistance as Douglas or Customer may reasonably request from time to time to enable Douglas to perform the Services, the Additional Services, and Douglas's other obligations under this Agreement.

5. Registration:

5.1 **Registration:** Sol-Gel shall register the Products with the appropriate Regulatory Authorities within the Territory, all such Product registrations to be at the cost of **[***]** and to be **[***]**. In such circumstances:

5.1.1 Douglas shall provide Sol-Gel, the Customer, and any Regulatory Authorities directly involved in the registration of the Products with such reasonable assistance and information, as well as access to the Facility (upon reasonable notice during normal business hours), as is necessary to enable Sol-Gel to obtain and to enable the Customer to maintain registration of the Products. For the avoidance of doubt, the assistance provided by Douglas does not include **[***]**. Such assistance will be classed as Additional Services;

5.1.2 Sol-Gel with respect to the registration of the Product, and the Customer with respect to the maintenance of the registration of the Product, agrees **[***]**; and

5.1.3 Sol-Gel shall provide Douglas with copies of any registration certificates or other evidence received upon registration of any of the Products, as well as any other information and documentation relating to the registration of the Products that Douglas may reasonably request from time to time.

6. Forecasting and Purchase Orders

6.1 **Forecasts:** On or before the Commencement Date (or at such other time as Douglas and the Customer may otherwise agree) the Customer shall provide Douglas with a written, non-binding **[***]** forecast of the volume of each Product that the Customer anticipates it will require Douglas to supply during each **[***]** ("**Long Term Forecast"**) (updated quarterly). The Customer shall provide Douglas with an **[***]** forecast ("**Rolling Forecast**") (a) on or before the **[***]** thereafter on a rolling basis and (b) **[***]** with respect to the quantities of Product specified therein **[***]**. The Customer shall place orders for Services against the Rolling Forecast as specified in clause 6.2 (Purchase Orders).

6.2 **Purchase Orders:** From time to time as provided in this clause 6.2 (Purchase Orders), the Customer shall submit to Douglas a binding, non-cancellable purchase order for Services identifying:

(a) an order number;

(b) the Product(s) to be Manufactured;

(c) the number of Batches of such Product(s);

(d) the Customer's requested delivery date for each Batch, which shall be at least **[***]** following the date on which the Purchase Order was placed (the "**Delivery Date**");

(e) the approved Douglas printed packaging code for each Batch (if new printed packaging is required, the Purchase Order must clearly indicate that new packaging is to be used), provided that in the event that the Customer fails to identify such printed packaging code, the validity of such Purchase Order shall not be affected and Douglas shall package the ordered Product in accordance with the printed packaging code most recently identified in a prior Purchase Order submitted to Douglas by the Customer; and

(f) any other elements necessary to ensure the timely production and delivery of Product

(each, a "**Purchase Order**"). Concurrently with the submission of each Rolling Forecast, the Customer shall submit a Purchase Order for all portions of the Commitment not already ordered.

6.3 **Acceptance of Orders**: Any Purchase Order that is within the amounts of Product forecasted in the applicable **[***]** of the Rolling Forecast submitted by the Customer within the **[***]** (each, a "**Firm Order**"). [***]. Without limiting Douglas's obligation to fill each Purchase Order in accordance with this Agreement, Douglas shall promptly notify the Customer if it is unable to fill a Purchase Order. Any such notice shall indicate **[***]**.

6.4 **Cancelation or Change of Orders**: **[***]**.

6.5 **Terms of Acceptance**: If there is any inconsistency between the terms of this Agreement and any Purchase Order submitted by the Customer (whether in writing, verbally or by Electronic Data Interchange (EDI)) or any other arrangement between the Customer and Douglas, **[***]** prevail unless otherwise agreed in writing between the Customer and Douglas.

6.6 **Rejection; Excess Volume:** Douglas may reject any Purchase Order without penalty or liability to the Customer if and to the extent:

(a) **[***]**; or

(b) the Purchase Order is not given in accordance with this Agreement.

Notwithstanding the foregoing, Douglas shall use commercially reasonable efforts to accept any Purchase Order for, and to supply the Customer with, **[***]**.

6.7 **Partial Batches**:

Except as otherwise agreed by the Customer and Douglas, the Customer shall not submit to Douglas any Purchase Order that includes **[***]**) for such Product set forth Schedule 1. For the avoidance of doubt, the Customer shall be required to order **[***]**.

7. Procurement

7.1 **Reliance on Forecast:** The Customer understands and acknowledges that Douglas will rely on the **[***]** to procure the Inventory necessary for Douglas to fulfil its obligations to supply Product under this agreement. Accordingly, the Customer **[***]**.

7.2 **Critical Components and Exclusive Components:** Set forth in Schedule 3 is a list of Critical Components and Exclusive Components that Douglas expects to be required to purchase in accordance with clause 7.1 (Reliance on Forecast) and from Approved Manufacturers pursuant to clause 3.1.2 (Components). The Customer shall **[***]**.

7.3 **Audits: [***]** shall be responsible for assessing and qualifying all vendors. **[***]** shall bear the costs of assessing and qualifying Exclusive Vendors.

7.4 **Delays**: Douglas shall not be liable for any delay in delivery of Product if **[***]**. In the event of any such delay, **[***]**.

8. Pricing and Payment

8.1 **Price for Manufacturing Services**

8.1.1 **Initial Price**: The Prices set out in Schedule 1 are the Prices for the performance of the Services and are valid **[***]**.

8.1.2 **[***] Price Adjustment: [***]** the Prices shall be adjusted to reflect inflation or deflation based on the documented changes in **[***]** costs so as to pass on to the Customer the actual cost or savings of any increase or decrease in such costs. Douglas shall provide in writing to the Customer at least **[***]** prior to the end of **[***]** its proposed updated Prices for **[***]**, with appropriate supporting documentation. At the Customer's request, Douglas and the Customer shall discuss the proposed Price adjustments in good faith **[***]**. If Douglas and the Customer are unable to agree to an appropriate Price adjustment within such **[***]** period, then Douglas and the Customer shall refer the matter to **[***]**, who shall attempt in good faith to reach agreement on an appropriate Price adjustment within **[***]** after such matter is referred to **[***]** under this clause 8.1.2 (Renewal Term Price Adjustment). Such revised Price shall be effective with respect to any Product delivered by Douglas following **[***]**, as applicable.

8.1.3 **Hardship Price Adjustments**: During the Term, the Price shall be adjusted in accordance with this clause 8.1.3 (Hardship Price Adjustments) to reflect extraordinary increases or decreases in **[***]** costs due to market conditions. An extraordinary change shall be deemed to have occurred if either:

(g) the cost of a given **[***]** increases or decreases by **[***]** or more of the cost for that **[***]** upon which the most recent Price was based; or

(h) such increase or decrease referred to in (a) above results in an increase or decrease in the **[***]**.

Douglas shall promptly notify the Customer and Sol-Gel of any such extraordinary increase or decrease and provide in writing to the Customer and Sol-Gel a proposal for the adjusted Prices, with appropriate supporting documentation. At the Customer's request, Douglas and the Customer shall discuss the proposed Price adjustments in good faith for up to **[***]**. If Douglas and the Customer are unable to agree to an appropriate Price adjustment within such **[***]** period, then Douglas and the Customer shall refer such matter to **[***]**, who shall attempt in good faith to reach agreement on an appropriate Price adjustment within **[***]** after such matter is referred to **[***]** under this clause 8.1.3 (Hardship Price Adjustments).

8.1.4 **Price Adjustments Due to Technical Changes:** Amendments to **[***]** requested by a Party will be implemented only following **[***]**, and are subject to the Customer and Douglas reaching agreement on appropriate revisions to the Prices and any other impacted fees under this Agreement and on a timeframe for implementation by Douglas. If the Parties agree to proceed with such amendment and the Customer accepts a proposed Price revision, then: the Parties shall memorialise the amendment in writing (and where the amendment is to **[***]** shall provide Douglas with originally executed copies of such revised **[***]**), Douglas shall implement the proposed amendment on the agreed timeframe, and the revised Prices shall apply only to Products that are Manufactured under the amended **[***]**, as applicable.

8.1.5 **Adjustment of Price Due to Continuous Improvements:** The Prices of the Products shall be reduced on an equitable basis to reflect process savings resulting from initiatives implemented pursuant to clause 3.1.4 (Continuous Improvement).

8.2 **Supplemental Charges**

8.2.1 **[***]:** Sol-Gel shall pay **[***]**, and either Sol-Gel or the Customer shall pay **[***]** set forth at Schedule 1.

8.2.2 **Taxes:** All payment amounts within this Agreement are **[***]** of any applicable GST, duties, levies, and other taxes. If the Customer is required by or under any laws or regulations to make any withholding or deduction, **[***]**, provided, however, that, in regard to **[***]**. Each Party shall comply with reasonable request of the other Party to take any proper actions that may minimise any withholding obligation.

8.2.3 **[***]:** Douglas shall have the right to charge **[***]**.

8.2.4 **[***] Fees:** Douglas shall have the right to pass through **[***]**. Such pro rata share of the fees to be supported by appropriate documentation.

8.2.5 **[***]:**

8.2.5.1 Douglas reserves the right to charge **[***].**

8.2.5.2 **[***]** will be charged to the Customer at Douglas's then-current standard rates.

8.2.6 **Pre-Validation Batches: [***]** shall order by written request to Douglas, and Douglas shall Manufacture, any pre-validation Batches **[***]**. **[***]** shall be responsible for the cost of each pre-validation Batch produced under this Agreement and requested in writing by **[***]**, and any Batch Manufactured following: **[***]**; provided, that the foregoing shall not apply to the extent **[***]**. Douglas and Sol-Gel shall cooperate in good faith to determine and resolve any problems **[***]**.

8.3 **Liability for Additional Services:** Douglas shall invoice the Customer for any Additional Services as have been pre-approved in writing by the Customer in accordance with clause 9.2 (Invoicing). Douglas shall, if requested by the Customer, provide evidence that such costs for Additional Services were incurred by Douglas.

9. Invoicing and Payment

9.1 **Payment by the Customer and Sol-Gel:** In consideration of Douglas's performance of the Services, the Customer and Sol-Gel shall pay Douglas the Prices, fees for Additional Services, and all other amounts owing to Douglas by the Customer or Sol-Gel (as applicable) pursuant to this Agreement. For the avoidance of doubt, Additional Services shall be subject to prior written agreement in order to be payable. A Table of Financial Responsibilities is outlined in Schedule 4, such table is provided for convenience purposes only and is not intended to modify the obligations specifically set forth in the Agreement.

9.2 **Invoicing:** Douglas shall invoice the Customer for the Prices owing to Douglas by the Customer for each Batch following quality release and delivery of such Batch to the Customer in accordance with this Agreement. Douglas shall invoice the Customer or Sol-Gel (as applicable) for all other amounts owing to Douglas by the Customer or Sol-Gel (as applicable) pursuant to this Agreement as and when earned or accrued.

9.3 **Disputed Invoices**: If the Customer or Sol-Gel in good faith disputes the accuracy of any invoice, the Customer shall, **[***]** after receipt of the invoice, give notice of that fact to Douglas. Such notice shall state the basis of the dispute and give relevant supporting details. The Customer shall pay the undisputed portion of the invoice in accordance with clause 9.4 (Payment of Invoices) and may withhold payment of the portion disputed. Douglas and the Customer shall discuss and attempt to resolve such dispute in good faith. If Douglas and the Customer do not resolve the dispute within **[***]** of the date of the notice, the dispute shall be determined in accordance with the dispute resolution process set forth in clause 22.2.1 (Dispute Resolution).

9.4 **Payment of Invoices**: The Customer and Sol-Gel shall pay all amounts invoiced under clause 9.2 (Invoicing), to the extent not subject to a good faith dispute under clause 9.3 (Disputed Invoices), within **[***]** of its receipt of such invoice from Douglas. Payment shall be made by way of electronic transfer to the bank account nominated by Douglas.

9.5 **Payments overdue**: Without prejudice to Douglas' rights and remedies in respect of any payment default, if the Customer or Sol-Gel (as applicable) fails to make any undisputed payment under this Agreement on the due date for payment, **[***]**.

10. Delivery

10.1 **Terms of Delivery**: Delivery shall be made by Douglas in the manner specified, and to the destination nominated, at the front of this Agreement. As between Sol-Gel and the Customer, Customer shall be responsible for acceptance of Product delivered by Douglas.

10.2 **Late Delivery**:

10.2.1 If Douglas is unable or anticipates that it may not be able to meet the Delivery Date requested by the Customer for any Batch of Product, Douglas shall notify the Customer of such anticipated delay in writing as soon as reasonably practicable following its determination of such anticipated delay and shall provide the Customer an alternative delivery date, which alternative delivery date shall be as soon as practicable after the requested Delivery Date.

10.2.2 In the event of delivery delayed after the Delivery Date in a Firm Order, **[***]** provided that, the delay is not caused by:

[***].

10.3 **Risk**: Risk of any loss or damage of or to the Products shall pass to the Customer on delivery to the nominated delivery destination in accordance with clause 10.1 (Terms of Delivery).

11. Manufacturing Modifications

11.1 **Changes by Douglas:** Douglas shall not make any changes to **[***]** ("**Modifications**"), without requesting such change in writing and obtaining the prior written consent of each of Sol-Gel and the Customer; provided that as between Sol-Gel and Customer, if Customer requests Sol-Gel to approve such changes, then Sol-Gel's consent to such change shall not be unreasonably withheld, delayed, or conditioned.

11.2 **Changes Required by the Customer and Sol-Gel:** Either the Customer or Sol-Gel may request Modifications, on which the Customer and Sol-Gel have agreed in writing prior to such request being made, by submitting a request to Douglas setting out a full description of the changes proposed, provided that as between Sol-Gel and Customer, if Customer requests Sol-Gel to approve a Modification request, then Sol-Gel's consent to such request shall not be unreasonably withheld, delayed, or conditioned. Where such a request is made:

(a) if the requested Modifications would not affect **[***]**; or

(b) if the requested Modifications would affect **[***]** shall apply with respect to such Modifications.

If any Modifications requested under this clause are **[***]**.

[***] shall purchase from Douglas any Inventory rendered obsolete as a result of such amendment, and that cannot reasonably be used by Douglas for any other products manufactured by Douglas.

11.3 **Changes Required by Authority**. If an Authority requests or requires, or takes any action that requires, any Modification or a change in the Facility or otherwise with respect to the Product (a "**Required Regulatory Change**"), then Douglas and the Customer shall meet and discuss an implementation plan for such Required Change and use all commercially reasonable efforts to accommodate such Required Regulatory Change to meet the Authority's requirements. **[***]**. Without limiting any other obligation under this Agreement, Douglas agrees to promptly forward to Sol-Gel and the Customer copies of any written communication received by Douglas from the Authority that may affect the Manufacture or supply of the Product as contemplated herein. Additionally, Douglas will provide a reasonable summary of any potential consequences of such communication.

11.4 **Modifications**: Any Modification shall:

(a) be recorded in writing;

(b) be signed by all Parties (except to the extent Sol-Gel's consent is expressly stated in this Agreement to not be required);

(c) take effect from such date as Douglas is reasonably able to implement the relevant Modifications **[***]**; and

(d) comply with the Technical Quality Agreement.

12. Warranties

12.1 **Warranties by Douglas**: Douglas on behalf of itself and its Affiliates, represents and warrants that:

12.1.1 to Douglas's knowledge, it or one of its Affiliates owns or has the right to use, any Intellectual Property rights used in the performance of the Services, except for any Intellectual Property rights that are the subject of the Manufacturing License;

12.1.2 to Douglas's knowledge, its performance of its obligations under this Agreement, including its provision of the Services, shall not infringe or otherwise violate any Intellectual Property rights of any Third Party, except to the extent such infringement or violation is a result of Douglas's adherence to the Specifications or the Sol-Gel Specifications or Douglas's exercise of the rights granted to it under the Manufacturing License;

12.1.3 the Facility is cGMP-compliant;

12.1.4 Douglas has not had any facility, including the Facility, subject to a Regulatory Authority shutdown or import or export prohibition (including by the FDA), nor within the last three (3) years received any Warning Letters, Untitled Letters, or similar correspondence (that would affect its ability to comply with its obligations under this Agreement) from a Regulatory Authority alleging or asserting noncompliance with Regulatory Requirements;

12.1.5 it is qualified and capable of performing the Services and the Additional Services in accordance with this Agreement and has the resources, know-how, and capabilities and the skill, experience, and reputation of its management and staff required to perform the Services and the Additional Services in accordance with this Agreement;

12.1.6 Douglas has obtained prior to the Commencement Date, and currently maintains, all necessary approvals, licenses, authorizations, registrations, exemptions, consents, and permits from any Regulatory Authority or other Third Party in order to Manufacture the Product hereunder, except for the Marketing Approvals, which is the responsibility of Sol-Gel to obtain and the responsibility of the Customer to maintain; and

12.1.7 Neither Douglas nor any of its employees or agents used to perform any of its obligations under this Agreement is or has been or are in the process of being, (i) debarred under 21 U.S.C. § 335a(a) or (ii) excluded from participation in the Medicare program, any state Medicaid program or any other health care program. Furthermore, neither Douglas nor any of its employees or agents used to perform any of its obligations under this Agreement has been convicted of an offense under (x) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval or suspension, or (y) any other law cited in any comparable law as a ground for debarment, denial of approval or suspension.

Douglas shall notify the Customer and Sol-Gel immediately upon learning of any circumstance that would render it in breach of this clause 12.1.7 (Warranties by Douglas) or any other representation or warranty made by it under this clause 12.1 (Warranties by Douglas).

12.2 **Warranties by Sol-Gel**: Sol-Gel on behalf of itself and its Affiliates, represents and warrants that:

12.2.1 it or one of its Affiliates owns or has the right to use, all the Licensed Rights (and any Intellectual Property rights contained therein) and any other Intellectual Property rights that are the subject of the Manufacturing License; and

12.2.2 the Specifications, Sol-Gel Specifications, the Quality Information, and the manufacturing process or instructions that it provides to Douglas hereunder are currently and will be **[***]**, (i) correct in all material respects and; (ii) contain sufficient information to enable Douglas to comply with its obligations under this Agreement, and do not and will not infringe or otherwise violate any Intellectual Property rights of any Third Party. For clarity this warranty under clause 12.2.2 shall not diminish or modify Douglas' and Customer's rights to receive the remedies set forth in clause 15.6 with respect to any Third Party Claim.

12.3 **Warranties by Customer:** The Customer, on behalf of itself and its Affiliates, represents and warrants that at all times during the Term **[***]** the Specifications, Sol-Gel Specifications, the Quality Information and the manufacturing process or instructions that it provides to Douglas hereunder will be correct in all material respects and will not infringe or otherwise violate any Intellectual Property rights of any Third Party.

12.4 **Warranties by Each Party**: Each Party hereby represents and warrants to the other Party on behalf of itself and its Affiliates as follows:

12.4.1 it (i) is a corporation duly organized, validly existing and in good standing under the laws of the state or country in which it is incorporated or organized and duly qualified and in good standing under the laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, (ii) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted, (iii) is in compliance with all requirements of Applicable Laws and regulations relevant to such Party's ability to perform its obligations under this Agreement, and (iv) is in compliance with its certificate of incorporation and by-laws;

12.4.2 it (i) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, without any violation of its certificate of incorporation or by-laws, (ii) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (iii) has duly executed and delivered this Agreement on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

12.4.3 all necessary consents, approvals and authorisations of all Authorities and other persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby and the performance of its obligations hereunder have been obtained or shall be applied for at the appropriate time; and

12.4.4 the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws or regulations of any Authority or any contractual obligation of such Party, and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party.

12.5 **Limitation on Warranties**: Except as expressly set forth in this Agreement, no Party accepts any liability for any representations, warranties or undertakings, whether express or implied, as to any matter relating to the Products or their Manufacture or as to the merchantability of the Products or otherwise.

12.6 **Breach of Warranty by Douglas**: Following a **[***]**, the Customer may test the Product delivered by Douglas in accordance with the Specifications using the Methods of Analysis. If the analysis of any Product performed by or for the Customer differs from Douglas's analysis of the same Batch and indicates that the Product does not meet the Specifications, then the Customer shall advise Douglas within **[***]** of the analysis. In the case of a Latent Defect, then the Customer shall advise Douglas **[***]** of its discovery of such Latent Defect but in no event after **[***]**. The Parties agree that **[***]**. Douglas and the Customer agree to consult with each other in order to explain and resolve the discrepancy between each other's determination regarding a Product's conformity with the Specifications. If, after good faith attempts by Douglas and the Customer to do so, such consultation does not resolve the discrepancy, **[***]** shall repeat the applicable Methods of Analysis on representative samples from such Batch provided by or for the Customer. The costs of **[***]**. If Douglas and the Customer agree or **[***]** determines that the Products do not comply with the warranties contained in clause 12.1 (Warranties by Douglas) at the time of delivery to the Customer then, **[***]**. Except for remedies available to the Customer under clause 19.1 (Indemnification by Douglas), this shall constitute the sole remedy of the Customer in respect of such breach, with Douglas having no further liability to the Customer under this Agreement or otherwise.

If notice of non-conforming Product is not given to Douglas within the times specified herein, then **[***]**.

12.7 **Breach of Warranty by Sol-Gel or Customer**: If Sol-Gel or the Customer fails to comply with any of its obligations under clause 12.2 (Warranties by Sol-Gel) or clause 12.3 (Warranties by Customer) then **[***]** as a result of Sol-Gel's non-compliance, then Sol-Gel shall perform commercially reasonable efforts to cure such non-compliance with the cooperation of the Customer, provided that if Sol-Gel fails to perform commercially reasonable efforts to cure such non-compliance **[***]**. If Customer exercises its right set forth in the foregoing clause (i) **[***]**. For clarity the performance by Sol-Gel of any of the remedies set forth in clause 15.6 will be considered a commercially reasonable effort to cure a breach that is related to a Third Party Claim.

13. Equipment

13.1 **Ownership of Equipment**: The ownership of the Equipment used in the performance of the Services is as specified in Schedule 2.

13.2 **Maintenance of Equipment**: The Equipment shall be qualified and maintained at the cost of the Party specified at Schedule 2.

13.3 **Other Equipment**: Except as specified below and as the Parties may agree in writing from time to time, **[***]** shall provide at its cost all Other Equipment needed to perform the Services. Any Other Equipment required to be dedicated to the Customer may be either:

(a) purchased by **[***]** at **[***]**'s actual cost (to be reimbursed by **[***]**) plus a [**[***]**; or

(b) purchased **[***]**.

13.4 **Replacement**: Where any of the Equipment owned by Sol-Gel as set out in Schedule 2 requires replacing (as determined by **[***]** in its sole discretion), **[***]** shall be responsible for the replacement of such Equipment, the cost of procuring such replacement Equipment and any costs associated with transitioning to the replacement Equipment.

13.5 **Liability**: Douglas shall not be liable for any loss of, or damage to, any Equipment owned by Sol-Gel, **[***]**.

14. Insurance:

14.1 Each Party shall, at its own cost and expense, obtain and maintain in full force insurance during the term of this Agreement (and if such insurance policy is on a claims made basis, then for additional **[***]**), necessary to cover its obligations under this Agreement. In no event, however, shall any Party carry insurance in amounts less than the following for each type specified or as otherwise might be required by Applicable Law or regulation:

14.1.1 (**[***]**.

14.2 **[***]** shall insure the Equipment and Products while at the Douglas premises, against All-Risk including: theft and/or burglary and natural perils (including coverage for earth movement) and also for an extreme change of temperature in respect of Products held in controlled environment due to machinery breakdown and/or failure of electronic or electrical system or apparatus, (a) in an amount equal to **[***]** and; (b) in an amount equal to **[***]**, subject to the following additional conditions:

14.2.1 Douglas and the Customer shall coordinate in advance the **[***]**.

14.3 Each Party shall furnish upon request, certificates of insurance for the above noted insurance Policies to the other Party within **[***]** days after the request by the other Party. The above described insurance policies will be issued by insurer with an S&P Rating of at least **[***]**, or equivalent internationally licensed insurer description, however **[***]** is anyway agreed.

14.4 The issuance of any such insurance policy will not constitute an approval that the above insurance is in accordance with the provisions of this Agreement and will not impose any liability on either Party; nor will it be considered as reducing either Party's liability under this Agreement and under any Applicable Law.

14.5 The coverage of the insurance policies set forth above shall be by the prevailing legal system including but not limited to the law, custom and jurisdiction in the country/state where the claim is served, anywhere in the world.

14.6 **Product Recalls**: Douglas and the Customer shall promptly notify each other by telephone (confirmed by written notice) of any information of which it becomes aware that might affect the safety, efficacy or marketability of any Product or that could reasonably be expected to result in a Recall. The conduct of and regulatory filings for any Recall shall be controlled, implemented and made by **[***]**, and **[***]** will cooperate in such Recall as reasonably requested by the **[***]**, having regard to all Applicable Laws and Regulatory Requirements. **[***]** shall provide **[***]** with a reasonably detailed description of those portions of any proposed submission to any Authority in respect of any Recall that could reasonably be expected to **[***]**, and shall consider in good faith any comments from **[***]**. **[***]** shall bear the cost of any Recall and reimburse **[***]** for the reasonable expenses incurred by **[***]** in connection with any Recall, unless such Recall **[***]**. In this case and subject to clause 19.6 (Consequential Damages), **[***]** will reimburse **[***]** reasonable, actual and documented out-of-pocket expenses of conducting such Recall and bear the expenses incurred by **[***]** in connection with such Recall. For clarity, **[***]**.

15. Intellectual Property Rights

15.1 **Rights of Sol-Gel**: Douglas acknowledges and agrees that, as between Douglas and Sol-Gel, all right, title and interest in and to the Licensed Rights and the Quality Information including the formulation, manufacturing process of the Product, artwork and labelling, and the application or submission for Marketing Approval (including the Sol-Gel NDA), and the Marketing Approval, and any improvements to the foregoing (whether conceived, developed or reduced to practice by Douglas or Sol-Gel but subject to clause 15.7 (Generic Improvements)) (collectively, the "**Sol-Gel IP**") shall belong to and remain with Sol-Gel as its absolute property. Douglas hereby assigns to Sol-Gel, without additional consideration to Douglas, the entire right, title and interest in and to the Sol-Gel IP. Douglas waives all moral rights, to the maximum extent allowed by Applicable Laws, in all documents prepared by Douglas and provided to or for the benefit of Sol-Gel hereunder. Douglas shall not at any time challenge the validity of any of Sol-Gel's rights in respect of the same.

15.2 **Rights of Douglas**: The Customer shall not at any time use the name "Douglas Pharmaceuticals" or "Douglas Manufacturing" or any trade marks or trade names owned by Douglas or its Affiliates or any trade marks or trade names similar thereto on or in connection with the Products or otherwise, except (a) as expressly permitted by this Agreement, (b) with the prior written consent of Douglas, or (c) as required to comply with Applicable Law or Regulatory Requirements (including, for example, if Douglas is required by Applicable Law or Regulatory Requirements to be identified as the manufacturer on Product packaging).

15.3 **Indemnity**: Without limiting anything contained in clause 15.1 (Rights of Sol-Gel), Sol-Gel shall indemnify Douglas and its Affiliates and hold it and its Affiliates harmless from and against all liability, claims, loss, damage, costs and expenses (whether direct or indirect, and including all reasonable legal, accounting and other professional fees) awarded against, suffered or incurred by Douglas or its Affiliates arising out of or in connection with any claim that the Manufacture of the Products according to the Specifications or the sale or use of the Products infringes the Intellectual Property rights of any Third Party (**"Third Party Claim"**).

15.4 **Indemnity Offered Regardless of Institution of Proceedings:** The indemnity referred to in clause 15.3 (Indemnity) will be granted whether or not legal proceedings are instituted and, if such proceedings are instituted, irrespective of the means, manner or nature of any settlement, compromise or determination.

15.5 **Third Party Claim**: In relation to any Third Party Claim:

(a) if either Party becomes aware of a Third Party Claim, it shall immediately inform the other Party;

(b) Sol-Gel shall at its own cost and expense, conduct or settle all negotiations and litigation resulting from such claim; and

(c) Douglas shall afford all reasonable assistance with such negotiations and litigation, provided that Sol-Gel shall reimburse Douglas for its staff costs and all other expenses incurred in providing such assistance.

15.6 **Remedies**: If at any time Douglas is enjoined by a court of competent jurisdiction from Manufacturing, holding or selling any Products as a result of any Third Party Claim or if it is at any time established to Douglas's satisfaction upon due investigation that the Manufacture of the Products infringes any Intellectual Property rights of any Third Party, Sol-Gel will at its discretion:

(a) obtain on behalf of Douglas the right to continue manufacturing, holding or selling those Products which are the subject of a third party claim;

(b) at Sol-Gel's expense, modify the Specifications, Components or the Products, or any packaging of the Products, so that they become non-infringing (and make any consequent Modifications to this Agreement in accordance with clause 11 (Manufacturing Modifications) where so required), provided that any non-Material Component that is so modified shall thereafter be treated as a "Material" (as defined hereunder); or

(c) if (a) and (b) are not reasonably available and solely with the prior written consent of the Customer, terminate this Agreement.

[***]

15.7 **Generic Improvements**: Where Douglas, in the course of exercising its obligations under this Agreement, develops any manufacturing processes which are generic in nature and not related specifically to the Product, the Licensed Rights or the Quality Information, Douglas shall be the absolute owner of all Intellectual Property in and to such improvements and modifications, with ownership to arise as from the time of creation or discovery of such improvements or modifications (the "**Generic Processes**"). Douglas hereby grants the Customer a non-exclusive, perpetual, irrevocable, worldwide, transferable, royalty free license (with the rights to grant sublicenses) to use the Generic Processes for the purposes of developing, manufacturing, and commercializing the Product. Douglas shall provide written documentation of the Generic Processes to the Customer upon request.

15.8 **Further Assurances**: Except as specifically set forth herein, the Parties expressly acknowledge and agree that neither intends to convey any rights, licenses, assignments or grants to the other, by implication, estoppel or otherwise, as a result of this Agreement. Nothing in this Agreement shall be construed as conveying any rights, license, assignments, or grants (implied or mandated by law, equity or otherwise) in any Party's Intellectual Property rights, the Quality Information or the Licensed Rights, including any know-how, statutory or non-statutory rights, and in any other drug or pharmaceutical product besides the Product. The Parties shall execute and deliver such further documents and take such further actions as may be necessary or appropriate to effectuate more fully this Agreement and to carry out the business contemplated by this Agreement, including any Intellectual Property licenses or assignments, grants or powers-of-attorney, as may be commercially reasonable and required.

16. Termination

16.1 **Termination by the Customer or Douglas**: The Customer and Douglas may each, without prejudice to any of its other rights or remedies, terminate this Agreement immediately in whole (or, in the case of subsection (a), in part insofar as it applies to those Products affected) if:

(a) another Party fails to comply with any of the material terms of this Agreement and does not remedy such breach (if the same is capable of remedy) within **[***]** of receipt of a written notice from the terminating Party requiring remedy;

(b) another Party enters into any composition or arrangement with its creditors (except a voluntary solvent restructure);

(c) a resolution is passed or an application is made for the liquidation of another Party;

(d) a receiver or statutory or official manager is appointed over all or any of another Party's assets; or

(e) it has a right to do so pursuant to clause 18.3 (Termination for Continuing Force Majeure).

16.2 **Termination by Sol-Gel**: Subject to the Customer's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned, Sol-Gel may, without prejudice to any of its other rights or remedies, terminate this Agreement immediately upon written notice to Douglas and the Customer if Douglas breaches its obligations under clauses 3.3 (Use of Licensed Rights and Quality Information), 15 (Intellectual Property Rights), or 21 (Confidentiality).

16.3 **Termination for Regulatory Action or Claim of Infringement**: The Customer may terminate its rights, obligations, and interests in and under this Agreement immediately upon written notice to Sol-Gel and Douglas, if (a) any Regulatory Authority takes any action, or makes a statement, the result of which is to prohibit, inhibit, or restrict the Manufacture, storage, importation, sale, offer for sale, or use of the Product, or that otherwise prohibits, inhibits, or restricts Douglas's use of the Facility, or (b) any claim is made that the Manufacture, storage, importation, sale, offer for sale, or use of the Product, infringes any patent or other Intellectual Property or any other proprietary or protected right of any Third Party ("**Patent Infringement Termination**"). **[***]**.

16.4 **Termination for Expiration or Termination of License Agreement**: Galderma's rights, obligations, and interests in and under this Agreement shall immediately terminate upon the expiration or termination of that certain License Agreement, entered into by and between Sol-Gel and Galderma on or around the date of this Agreement (the "**License Agreement**"), in which case this Agreement shall remain in effect between Sol-Gel and Douglas and clause 16.5 (Effect of Termination as to Galderma) shall apply.

16.5 **Effect of Termination as to Galderma**: If this Agreement is terminated under clause 16.4 (Termination for Expiration or Termination of License Agreement), then Galderma's rights, obligations, and interests in and under this Agreement shall immediately terminate upon the effective date of such termination, and all rights and obligations of the Customer hereunder shall immediately and automatically vest in Sol-Gel or its designated Affiliate or licensee.

16.6 **Termination for Discontinuation**: This Agreement shall automatically terminate if, as a result of the Customer exercising its right to discontinue a Product under clause 4.8 (Product Discontinuation), there are no other Products covered by this Agreement, and in such event clause 17 (Effect of Termination) shall apply.

17. Effect of Termination

17.1 **Consequences Arising**: Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to any Party prior to such expiration or termination.

17.1.1 Upon expiration or termination of this Agreement:

(a) **Amounts Owing**: No Party shall be released from liability for any of its payment obligations that have accrued under this Agreement as of the effective date of such expiration or termination;

(b) **Work in Process:** At the Customer's election, Douglas shall either (i) complete any Product that is a work in process, which Product shall be subject to clause 17.1(c) (Product), or (ii) cease such work and transfer such work in process into storage containers, which work in process shall be subject to clause 17.1(d) (Inventory); it being understood that if the Customer fails to timely make such an election or if termination is by Douglas under clause 16.1 (Termination by the Customer or Douglas), clause (ii) above shall automatically apply;

(c) **Product:** The Customer shall take delivery of and pay for, at the Price in effect at the time, all completed, undelivered Product that Douglas has produced pursuant to a Firm Order;

(d) **Inventory:** Except in the event of termination of this Agreement **[***]**, the Customer shall purchase all Inventory **[***]** then in stock or that is later delivered by a Third Party vendor pursuant to purchases of Inventory in accordance with clause 7.1 (Reliance on Forecast) and shall reimburse Douglas for **[***]**. Notwithstanding the foregoing, in the event that this Agreement is terminated **[***]**.

(e) **Returns:** Douglas shall return to the Customer all Inventory paid for by the Customer pursuant to clause 17.1(d) (Inventory) above in accordance with applicable instructions for storage and handling;

(f) **Equipment:** Douglas shall return to Sol-Gel all Equipment owned by Sol-Gel (as specified in Schedule 2);

(g) **Stability:** At the Customer's election, Douglas shall either (i) continue to perform any ongoing stability testing or (ii) ship the stability samples to the Customer, or any Third Party as the Customer informs in writing; it being understood that if the Customer fails to timely make such an election or if termination is by Douglas under clause 16.1 (Termination by the Customer or Douglas), clause (ii) (of this paragraph (g)) shall automatically apply;

(h) **Records**: Douglas shall deliver to the Customer any and all copies (whether in digital form or hard copy) of any information and records held by it relating to the Products, the Specifications, the Licensed Rights or the Quality Information provided to Douglas by the Customer, except that Douglas may retain one copy for its records solely for the purposes of complying with Applicable Law or Regulatory Requirement or demonstrating its compliance with this Agreement or the Technical Quality Agreement; and

(i) **Assistance**: Douglas and Sol-Gel shall provide reasonable assistance and support necessary to transition the Manufacture and supply of Product to the Customer or a Third Party designated by the Customer, including the provision of reasonable services, information and instruction regarding such methods and production necessary to enable the Customer or such Third Party to perform the Manufacturing of the Product.

17.1.2 Any costs reasonably incurred by Douglas to comply with its obligations under clause 17.1.1, including shipping and related expenses, shall be borne by **[***]**. Any Services performed by Douglas as referred to in this clause that are Additional Services shall be charged at the rate set out in Schedule 1.

17.1.3 Any out-of-pocket costs reasonably incurred by Sol-Gel to comply with its obligations under clause 17.1(i) (Assistance), including shipping and related expenses, shall be borne by **[***]**.

17.1.4 In lieu of taking possession of any of the materials described in this clause 17.1 (Consequences Arising), the Customer may direct Douglas to destroy such items, which Douglas shall cause to be done at **[***]**.

17.2 **Survival:** The expiry or termination of this Agreement shall not operate so as to affect any of clauses 13 (Equipment), 14 (Insurance), 15 (Intellectual Property Rights), 16 (Termination), 17 (Effect of Termination), 19 (Liability and Indemnity), 21 (Confidentiality) or 22 (General) or any other provision of this Agreement which is intended to continue after such expiry or termination.

18. Force Majeure

18.1 **Force Majeure:** The performance by either Party of any obligation on its part to be performed hereunder (other than an obligation to pay money or issue credit hereunder) shall be excused if and to the extent that such Party is unable to perform any of its obligations under this Agreement due to: flood, strike, or other labour disturbance, riot, fire, earthquake, volcanic activity, natural occurrence of any kind, accident, act of God or of public enemy, war, embargo, injunction, epidemic, pandemic or restraint of government (whether or not now or threatened, including the unexpected loss of regulatory approval or import bans), or any cause preventing such performance, whether similar or dissimilar to the foregoing, that is beyond the reasonable control of the Party bound by such covenant or obligation ("**Force Majeure Event**").

18.2 **Endeavours to Cure:** The Party affected by a Force Majeure Event referred to in clause 18.1 (Force Majeure) shall notify the other Parties of the Force Majeure Event in writing promptly following the commencement and conclusion of the Force Majeure Event and use all reasonable endeavours to eliminate, cure, or overcome any such causes and to resume performance of all of its obligations under this Agreement as soon as is reasonably practicable.

18.3 **Termination for Continuing Force Majeure:** During the Force Majeure Event, the Parties shall in good faith discuss how to proceed**,** but if the Force Majeure Event continues to prevent the affected Party from performing its material obligations for more than **[***]**, then the unaffected Party may immediately terminate this Agreement by giving written notice to the Party that has been prevented from performing; **[***]**.

19. Liability and Indemnity

19.1 **Indemnification by Douglas:** Douglas shall defend, indemnify and hold harmless Sol-Gel, the Customer, and their respective Affiliates, licensees, sublicensees, directors, officers, employees, and agents from and against any and all damages, losses, liabilities, expenses, and costs (including reasonable attorneys' fees and expenses) (excluding consequential loss or damage) ("**Losses**") they may suffer as a result of any Third Party claims, demands, suits, judgments or administrative or judicial orders ("**Claims**") to the extent arising out of (i) the negligence or wilful misconduct of Douglas Indemnitees or Subcontractors; (ii) any breach by Douglas of this Agreement, the Technical Quality Agreement, or the representations, warranties or covenants hereunder or thereunder; or (iii) any failure by Douglas Indemnitees or Subcontractors to comply with any Specifications, Regulatory Requirements, or Applicable Laws, regulation or order (including cGMPs, environmental laws, regulations and orders); *provided that* Douglas shall have no obligation under this clause 19.1 (Indemnification by Douglas) to the extent such Losses arise out of or are a result of any of the matters:

19.1.1 in clauses 19.2.1(i) to (v); or

19.1.2 in clauses 19.3(i) to (iii).

19.2 **Indemnity by Customer**: Customer shall defend, indemnify and hold harmless:

19.2.1 Douglas, its Affiliates, directors, officers, employees and agents ("**Douglas Indemnitees**") from and against any and all Losses they may suffer as a result of any Claims to the extent arising out of (i) any breach by the Customer of this Agreement, the Technical Quality Agreement, or the representations, warranties or covenants hereunder or thereunder; (ii) the negligence or wilful misconduct of the Customer, its Affiliates, licensees, sublicensees, directors, officers, employees, agents ("**Customer Indemnitees**"); (iii) **[***]**; (iv) any sale, marketing, or distribution of the Product by the Customer in the Territory; or (v) any failure by Customer Indemnitees or distributors to comply with any Regulatory Requirements, or other Applicable Laws, regulations or orders (including environmental laws, regulations and orders), provided that Customer shall have no obligation under this clause 19.2.1 to the extent that such Losses arise out of or are a result of any of the matters in clauses 19.1(i) to (iii) (Indemnification by Douglas);

19.2.2 Sol-Gel and its Affiliates, directors, officers, employees and agents from and against any and all Losses they may suffer as a result of any Claims to the extent arising out of (i) the Customer's breach of this Agreement, the Technical Quality Agreement, or the representations, warranties or covenants hereunder or thereunder; (ii) the negligence or willful misconduct of the Customer or its Affiliates, sublicensees or distributors; or (iii) any failure by the Customer to comply with any Applicable Laws, regulations or orders (including environmental laws, regulations and orders), provided that Customer shall have no obligation hereunder to the extent that such Losses circumstances due to which Douglas is obligated to indemnify in accordance with clause 19.1 (Indemnification by Douglas) or are a result of any acts or omissions of Sol-Gel or its Affiliates, including any such acts or omissions giving rise to circumstances due to which Sol-Gel is obligated to indemnify in accordance with clause 19.3 (Indemnity by Sol-Gel).

19.3 **Indemnity by Sol-Gel**: Sol-Gel shall defend, indemnify and hold harmless the Douglas Indemnitees from and against any and all Losses they may suffer as a result of any Claims to the extent arising out of (i) Sol-Gel's breach of this Agreement, or the representations, warranties or covenants provided by Sol-Gel hereunder; (ii) the negligence or wilful misconduct of the Sol-Gel (or its Affiliates); or (iii) any failure by the Sol-Gel to comply with any Applicable Laws. Sol-Gel shall also defend, indemnify, and hold harmless the Customer Indemnitees and Douglas Indemnitees from and against any and all Losses they may suffer as a result of any Claims to the extent arising out of any injury or other harm to a Third Party that is caused by Product that is manufactured in accordance with the Specifications. Provided that Sol-Gel shall have no obligation hereunder to the extent that such Losses are a result of circumstances due to which Douglas is obligated to indemnify in accordance with clause 19.1 (Indemnification by Douglas), or a result of circumstances due to which Customer is obligated to indemnify in accordance with clause 19.2 (Indemnification by Customer).

19.4 **Mitigation**: Each of the Parties must take reasonable steps to mitigate any claim for any Losses (including those for which the parties are indemnified under this clause 19.

19.5 **Procedure:** In the event that any claim is asserted against any Party hereto, or any Party hereto is made a Party defendant in any action or proceeding, and such claim, action or proceeding involves a matter which is subject to a claim for indemnification under this clause 19 (Liability and Indemnity), then such Party (an "**Indemnified Party**") shall promptly give written notice to the other Party (the "**Indemnifying Party**") of such claim, action or proceeding, provided that the failure to give such notice shall not excuse the Indemnifying Party from its indemnity obligations hereunder unless the Indemnifying Party is materially prejudiced by such failure. The Indemnified Party shall cooperate fully with the Indemnifying Party throughout the pendency of the claim, lawsuit or liability, and the Indemnifying Party shall have complete control over the conduct and disposition of the claim, lawsuit, or liability including the retention of legal counsel engaged to handle such matter provided, however, that, (a) the Indemnifying Party shall, without the written consent of the Indemnified Party, which shall not be unreasonably withheld, as part of any settlement (i) admit to liability on the part of the Indemnified Party; (ii) agree to an injunction against the Indemnified Party; or (iii) settle any matter in a manner that separately apportions fault to the Indemnified Party and (b) the Indemnified Party shall be entitled to participate in any such action, suit or proceeding with counsel of its own choice, but as its own expense. If the Indemnifying Party fails to assume the defence within a reasonable time, the Indemnified Party may assume such defence and the reasonable fees and expenses of its attorneys will be covered by the Indemnifying Party pursuant to the indemnity provisions provided for herein. An Indemnified Party shall be liable for any costs resulting from any settlement made by an Indemnifying Party without the prior consent of the Indemnified Party to such settlement, which consent shall not be unreasonably withheld or delayed.

19.6 **Consequential Damages**: Except with respect to breaches of clause 21 (Confidentiality) or as otherwise expressly provided for in this Agreement, no Party shall be liable to another Party for any indirect or consequential loss or damages (whether in contract or in tort, including negligence), including loss or damages comprising, or resulting from, loss of business or loss of profit, however caused.

19.7 **LIMITATION OF LIABILITY**: THE MAXIMUM AGGREGATE LIABILITY OF DOUGLAS TO CUSTOMER AND/OR SOL-GEL, EXCEPT WITH RESPECT TO **[***]**, IN RESPECT OF CLAIMS UNDER OR IN CONNECTION WITH THIS AGREEMENT IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE SHALL BE LIMITED TO:

[***],

PROVIDED THAT THESE LIMITS DO NOT APPLY TO **[***]**

19.8 **LIMITATION OF LIABILITY RELATING TO INDEMNITY**: DOUGLAS' MAXIMUM AGGREGATE LIABILITY UNDER ANY AND ALL CLAIMS OF WHATEVER NATURE ARISING UNDER OR IN CONNECTION WITH CLAUSE 19.1 (INDEMNIFICATION BY DOUGLAS) WILL NOT EXCEED **[***]**.

20. Compliance, Quality and Environmental

20.1 **Technical Quality Agreement**: Annexed to and forming part of this Agreement is a copy of the Technical Quality Agreement between Douglas and the Customer, pursuant to which various roles and responsibilities are designated as assigned to one or the other of the Parties.

20.2 **Prevailing Terms**: Nothing in this clause 20 (Compliance, Quality and Environmental) or the Technical Quality Agreement shall be read or construed as limiting, restricting or modifying the other provisions of this Agreement. In the event of any conflict or contradiction between the terms of the Technical Quality Agreement and the terms of this Agreement, the terms of this Agreement shall prevail in relation to non-quality matters but the terms of the Technical Quality Agreement shall prevail in relation to any quality matters.

20.3 **Compliance with Law and Permits:**

20.3.1 Douglas shall perform its obligations under this Agreement and conduct its Manufacturing operations hereunder in a safe and prudent manner, including in order to ensure the quality, safety and efficacy of the product in compliance with the Specifications, all applicable Regulatory Requirements (including, but not limited to, GMPs and all Applicable Laws and regulations regarding occupational safety and health, public safety and health, environmental protection, and disposal of wastes), and in compliance with all applicable provisions of this Agreement, and the Technical Quality Agreement. Douglas shall obtain and maintain all necessary permits, licenses, authorizations, registrations, exemptions, and approvals for its activities contemplated by this Agreement at its sole cost.

20.3.2 Prior to receipt of Marketing Approval for the Products in the Territory, Sol-Gel shall have sole responsibility for communications with Regulatory Authorities relating to Marketing Approval for the Product to establish and maintain the Facility as an approved facility to Manufacture the Product. Following receipt of Marketing Approval for the Products in the Territory, the Customer shall have such responsibility. Douglas agrees to cooperate with such efforts to the extent reasonably requested by Sol-Gel and the Customer, as applicable.

20.4 **Environmental, Occupational Health and Safety**: Within **[***]** of the Commencement Date, Douglas shall, at the Customer's cost, undergo a SEDEX audit. Douglas shall report to the Customer as soon as possible after any of the following incidents related to the Manufacturing operations hereunder occurs:

20.4.1 any fatalities or prosecutions from Work Safe New Zealand;

20.4.2 property damage that may hinder or impact supply of Products;

20.4.3 any material observations from inspections by any environmental protection agency or Work Safe New Zealand; or

20.4.4 requests for information, notices of violations or other significant governmental and safety agency communications relating to environmental, occupational health and safety compliance.

DOUGLAS SHALL BE SOLELY RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LAWS IN RELATION TO ENVIRONMENTAL, OCCUPATIONAL HEALTH AND SAFETY MATTERS PERTAINING TO MANUFACTURING OPERATIONS PERFORMED HEREUNDER INCLUDING FOR DISPOSAL OF HAZARDOUS WASTE AND RESIDUES.

21. Confidentiality

21.1 **Confidentiality**: During the Term, each Party may discover, receive, or otherwise acquire, whether directly or indirectly, Confidential Information of the other Party or its Affiliates. Each Party shall treat as confidential, and not use or disclose to any person or Third Party, Confidential Information of the other Party or its Affiliates except as set forth herein.

21.2 **Non-Disclosure of Confidential Information**: The receiving Party shall (i) use the Confidential Information of the other Party or its Affiliates solely for purposes of this Agreement; and (ii) shall disclose Confidential Information of the other Party or its Affiliates only to those Persons and Third Parties who are required to know this information in order to perform such Party's obligations under this Agreement, and provided that such Persons and Third Parties are subject to confidentiality undertakings at least as stringent as those contained in this Agreement. Prior to disclosure of Confidential Information to a Person or Third Party as may be permitted under subpart (ii) hereof, the receiving Party shall obtain from any such Person or Third Party a legally enforceable written agreement not to disclose the other Party's Confidential Information or use such Confidential Information for any purposes other than those contemplated by this Agreement. Each such confidentiality agreement shall be at least as protective of the disclosing Party's rights as the terms and conditions of this clause 21 (Confidentiality). Each Party shall take all commercially reasonable actions to protect the other Party's or its Affiliates' Confidential Information from disclosure or misappropriation (but in no event shall such Party use less than the degree of care is uses to protect its own Confidential Information). Upon request, each Party shall provide to the other evidence of any confidentiality agreement required under this paragraph.

21.3 **Non-Disclosure of Agreement:** Each Party shall be permitted to disclose the terms and conditions of this Agreement **[***]** under written confidentiality agreements at least as protective of the disclosing Party's rights as the terms and conditions of this clause 21 (Confidentiality).

21.4 **Exceptions**: The confidentiality obligations of the receiving Party under this clause 21 (Confidentiality) shall not apply solely to the extent that any information is required to be publicly disclosed pursuant to a governmental or judicial requirement or other requirement of law, but only after notifying the Party owning such Confidential Information of such requirement and, if requested by the owning Party, using reasonable efforts to minimise such disclosure and to obtain confidential treatment for all or relevant portions of the Confidential Information to be disclosed.

21.5 **Injunctive Relief; Specific Performance**: The Parties hereto acknowledge and agree that a breach of this clause 21 (Confidentiality) could give rise to irreparable harm for which money damages would not be an adequate remedy and accordingly the Parties agree that, in addition to any other remedies, each Party shall be entitled to seek preliminary or injunctive relief and to enforce the terms of this clause 21 (Confidentiality) by a decree of specific performance.

22. General

22.1 **Notices**: Every notice or other communication for the purposes of this Agreement shall be in writing and may be given by delivery to the physical address of the relevant Party or sending it by email to the email address of the relevant Party, set out at the front of this Agreement, or such other address or email address as one Party may have notified in writing to the other Party. A notice given by email, is not deemed received unless (if receipt is disputed) the Party giving notice produces a printed copy of the email which evidences that the email was sent to the email address of the Party given notice.

22.2 **Dispute Resolution**:

22.2.1 In the event of any controversy, dispute or difference arising out of this Agreement ("**Dispute**"), except as otherwise set forth in this Agreement, the Parties agree to submit any such Dispute to settlement proceedings under the Mediation Rules of the International Chamber of Commerce ("**ICC**"). If the Dispute has not been settled pursuant to the Mediation Rules within **[***]** days following the filing of a request for Mediation or within such other period as the Parties may agree in writing, such Dispute shall be finally settled under the Rules of Arbitration of the ICC (the "**ICC Rules**") by one or more arbitrators appointed in accordance with such ICC Rules. The place for arbitration shall be New York City (assuming it is then reasonably feasible for both Parties to participate in New York in light of any applicable travel-related restrictions or, if not, then by video conference as mutually agreed or as consistent with applicable ICC procedures), and proceedings shall be conducted in the English language. The award shall be final and binding on both Parties, and the Parties hereby waive the right of appeal to any court for amendment or modification of the arbitrators' award.

22.2.2 Notwithstanding anything to the contrary in this Agreement, each Party, at its option, may obtain in any court of competent jurisdiction any injunctive relief, including preliminary injunctions, against conduct or threatened conduct for which no adequate remedy at law may be available or which may cause such Party irreparable harm.

22.2.3 Before either Party initiates any mediation or arbitration proceeding under clause 22.2.2 (Dispute Resolution), the Dispute will first be referred to the chief operations officers or other appropriate officers of the Parties. Such officers shall take all reasonable steps to attempt to resolve the matter within **[***]** of the date of referral.

22.3 **Counterparts:** This Agreement may be executed in two or more counterparts, each of which is deemed an original and all of which constitute one and the same agreement. This Agreement will be effective upon the exchange (including electronic exchange of scanned copies) of executed signature pages. Each Party consents to this Agreement (including any counterpart of it) being signed and delivered in electronic form in accordance with the Contract and Commercial Law Act 2017.

22.4 **Governing Law**: This Agreement is governed by the laws of New York and the Parties submit to the non-exclusive jurisdiction of the courts of New York. Each Party agrees that it will not object to the choice of New York law or arbitration in New York City in any proceeding to adjudicate a dispute under this Agreement.

22.5 **Waiver**: No delay, failure or forbearance by a Party in enforcing against the other any provision of this Agreement will be a waiver, or in any way prejudice any right, of that Party.

22.6 **Severance**: If any provision of this Agreement is or becomes unenforceable, illegal or invalid for any reason it shall be deemed to be severed from this agreement without affecting the validity of the remainder of this Agreement and shall not affect the enforceability, legality, validity or application of any other provision of this Agreement.

22.7 **No Assignment**: This Agreement is not assignable by any Party without obtaining the prior written consent of the other Parties, such consent not to be unreasonably withheld; provided, however, that Sol-Gel and the Customer may assign or delegate its rights or duties to any Affiliate or in connection with any merger, change of control, or transfer or sale (including by means of exclusive license) of all or substantially all of the assets to which this Agreement relates or other similar transaction. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefits of, the Parties hereto and their respective permitted successors and assigns. In the event of an assignment of this Agreement by Sol-Gel due to merger, change of control, or transfer or sale (including by means of exclusive license) of all or substantially all of the assets to which this Agreement relates or other similar transaction, **[***]**

22.8 **International Sale of Goods:** The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to the supply of any Products pursuant to this Agreement.

22.9 **Relationship of the Parties**: Douglas's relationship with Sol-Gel and the Customer during the Term shall be that of an independent contractor. None of the Parties has the power to assume or create any obligation on behalf of the other Parties except as expressly provided in this Agreement. Sol-Gel, Douglas, and the Customer are not partners or joint venturers. No Party shall be responsible for the compensation, payroll-related taxes, workers' compensation, accident or health insurance or other benefits of employees of the other Parties. All contracts and other obligations undertaken by a Party shall be undertaken by such Party on its own behalf and shall not involve any financial or other responsibility on the part of the other Parties.

22.10 **Cumulative Remedies**. Except as otherwise expressly provided herein, the remedies accorded the Parties under this Agreement are cumulative and in addition to those provided by law, in equity or elsewhere in this Agreement.

SCHEDULE 1 – PRODUCT LIST, BATCH SIZES, PRICING, LEAD TIME AND ADDITIONAL SERVICES

[***]

SCHEDULE 2 – EQUIPMENT

[***]

SCHEDULE 3 – MATERIALS

[***]

SCHEDULE 4 – TABLE OF FINANCIAL RESPONSIBILITIES [1]

[***]

[1] This table is provided for convenience purposes only and is not intended to revise or add to any of the obligations set forth in Supply Agreement.

Exhibit 4.22

CERTAIN INFORMATION IDENTIFIED
BY BRACKETED ASTERISKS ([* * *])
HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE
IT IS BOTH NOT MATERIAL AND WOULD BE
COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

TERMINATION AGREEMENT

This Termination Agreement ("**Agreement**") is entered into as of November 3, 2021 ("**Effective Date**"), between Padagis Israel Pharmaceuticals Ltd, a limited liability company organized in Israel ("**Padagis**"), and Sol-Gel Technologies Ltd., a limited liability company organized in Israel ("**Sol-Gel**"). Padagis and Sol-Gel are individually referred to as a "**Party**" and collectively referred to as the "**Parties**. "

Background

A. Perrigo Israel Pharmaceuticals Ltd. ("**Perrigo Israel**") or Perrigo UK Finco Limited Partnership ("**Perrigo UK**") (collectively "**Perrigo**") and Sol-Gel entered into the agreements set forth in Exhibit A (collectively, the "**Development Agreements**"). Pursuant to the transaction between Perrigo and Padagis, LLC (f/k/a Vesta Pharma LLC), Perrigo Israel was sold to Padagis LLC, and renamed Padagis Israel Pharmaceuticals Ltd. Pursuant to the same transaction, Development Agreements entered into by Perrigo UK were assigned to Padagis.

B. The Parties desire to terminate the Development Agreements upon the terms set forth in this Agreement.

Accordingly, Padagis and Sol-Gel agree as follows:

1. Terms used in this Agreement and not otherwise defined shall have the respective meaning ascribed to them under the Development Agreements.

2. Termination of Development Agreements.

(a) The Parties hereby terminate the Development Agreements and each of their respective rights and obligations under the Development Agreements without further liability or obligation whatsoever, including, without limitation, Padagis's obligation to pay Sol-Gel profit sharing payments and Sol-Gel's responsibility for certain development obligations and costs.

(b) Notwithstanding Section 1(a) above, nothing in this Agreement will affect (i) either Party's rights under a Development Agreement with respect to claims arising out of events occurring prior to the Effective Date; (ii) either Party's right to receive all payments owed or accrued to it under the Development Agreements for periods prior to th e Effective Date; (iii) Padagis's ownership of assets transferred to it pursuant to the Development Agreements and any intellectual property license granted to Padagis by Sol-Gel pursuant to the Development Agreements; (iv) any provision in all Development Agreements other than the Development and Commercialization Agreement between Perrigo Israel Pharmaceuticals Ltd. k/n/a Padagis and Sol-Gel Technologies Ltd. dated as of **[***]** that expressly survive termination pursuant to the terms of the applicable Development Agreement, provided however that (1) Sol-Gel shall have no obligations under the Development Agreements with respect to **[***]**; (2) Sol-Gel's obligation to indemnify Padagis under the indemnification provisions in the Development Agreements shall apply solely to claims arising out of events occurring prior to the Effective Date; and (v) no provision in the **[***]** shall survive the termination of such agreement. To the extent there is any conflict between the terms of this Agreement and the Development Agreements, this Agreement shall control.

(c) Within **[***]** days after the Effective Date, the Parties will true-up all payments that were owed or accrued to the Parties under the Development Agreements prior to the Effective Date that have not already been paid. Such payments shall be made in accordance with the Development Agreements.

3. Consideration. As consideration for the agreements set forth herein, Padagis will pay Sol-Gel $**[***]** in the aggregate payable in **[***]** installments of **[***]** on each **[***]** until paid in full. The initial payment will be made as of the Effective Date.

4. Representations and Warranties. Each Party represents and warrants to the other Party that such Party has the necessary power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary action of such Party. This Agreement constitutes the legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

5. Covenant not to Compete. For a period of the later of: (a) **[***]** after the Effective Date and (b) **[***]** after the launch date with respect to any Product under the Development Agreements that has not been launched as of the Effective Date, without the prior written consent of Padagis, Sol-Gel will not directly or indirectly, and will cause its affiliates not to, promote, market, sell, distribute, develop, commercialize, or manufacture (or enter into any arrangement with any person or entity to develop, commercialize, or manufacture) any generic pharmaceutical product that competes with any Product. In addition to any other rights or remedies provided by this Agreement, Padagis will have the right to injunctive or other equitable relief to restrain any breach or threatened breach or otherwise to specifically enforce the provisions of this Section. Padagis acknowledges and agrees that money damages would be an inadequate remedy to compensate for the breach of this Section. Padagis and Sol-Gel intend all provisions of this Section to be enforced to the fullest extent permitted by applicable legal requirements. If any provision or term of this Section is held to be illegal, invalid, or unenforceable under present or future applicable legal requirements of any jurisdiction, such provision will be fully severable, and this Section will be construed and enforced in such jurisdiction as if such illegal, invalid or unenforceable provision were never a part hereof, and the remaining provisions will remain in full force in such jurisdiction and will not be affected by the illegal, invalid, or unenforceable provision, or by its severance. Without limiting the generality of the foregoing, if a court or arbitrator of any competent jurisdiction should determine that any of the restrictions contained in this Section are unreasonable in terms of scope, duration, geographic area or otherwise, such provision will be reformed in such jurisdiction to the extent necessary such that such restriction will be rendered enforceable to the fullest extent permitted by applicable legal requirements.

6. Assignment and License.

(a) Sol-Gel hereby irrevocably and unconditionally sells, assigns, conveys, transfers and grants to Padagis, as of the Effective Date, Sol-Gel's entire right, title and interest in and to the Assigned Sol-Gel Intellectual Property, the same to be held and enjoyed by Padagis for its own use and benefit, and for the use and benefit of its affiliates, successors, assigns, or legal representatives, as fully and entirely as the same would have been held and enjoyed by Sol-Gel if this Agreement had not been executed.

(b) The transfer, assignment and sale under Section (a) above shall be deemed to include the right to register and/or apply for registration of the Assigned Sol-Gel Intellectual Property in Padagis' own name in appropriate registries throughout the world, including without limitation all rights to publish cautionary notices reserving ownership of the Assigned Sol-Gel Intellectual Property.

(c) In the event that any assignment under this Agreement may be ineffective or incomplete as a result of any moral rights, artists' rights, or any other similar rights worldwide ("**Moral Rights**"), Sol-Gel hereby irrevocably and unconditionally transfers and assigns to Padagis any and all Moral Rights that Sol-Gel may have in or with respect to the Assigned Sol-Gel Intellectual Property. To the extent that Sol-Gel cannot transfer and assign such Moral Rights to Padagis, Sol-Gel hereby waives and agrees never to assert such Moral Rights against Padagis or any of its licensees. If Sol-Gel has any Assigned Sol-Gel Intellectual Property that cannot be assigned to Padagis or waived by Sol- Gel, then Sol-Gel unconditionally and irrevocably grants to Padagis during the term of such rights, an exclusive, irrevocable, perpetual, worldwide, fully-paid and royalty-free license (subject to Sol-Gel's license set forth in (d) below), with rights to transfer, sublicense and assign in any way or manner including throughout multiple tiers of sublicensees, to use, reproduce, modify, create derivative works of, perform, display, distribute directly and indirectly, and otherwise exploit such Assigned Sol-Gel Intellectual Property by all means now known or later developed, and to make, have made, sell, offer to sell, lease, offer to lease and import products and services that contain or embody such Assigned Sol- Gel Intellectual Property, all whether by itself or through others.

(d) Padagis hereby grants to Sol-Gel a non-exclusive, worldwide, fully-paid, royalty-free, transferable, irrevocable license under the Assigned Sol-Gel Intellectual Property, with the right to sublicense (through multiple tiers of sublicensees), to develop, manufacture and commercialize any product other than the Products.

(e) For the purposes of this Agreement, "**Assigned Sol-Gel Intellectual Property**" means the Sol-Gel Intellectual Property as such term is defined in any of the Development Agreements.

7. Miscellaneous Provisions.

(a) *Entire Agreement*. This Agreement and the Development Agreements contain the entire agreement among the Parties with respect to the subject matter hereof and supersedes all prior oral and written agreements, memoranda and undertakings among the Parties with regard to such subject matter.

(b) *Counterparts.* This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which taken together will constitute one and the same Agreement. Such counterparts may also be executed electronically (including by DocuSign) and will be deemed as effective as an original.

(c) *Successors*. This Agreement will be binding upon and inure to the benefit of each of the Parties, including all of their subsidiaries, parent companies, affiliates, officers, directors, attorneys, partners, firms, agents, employees, servants, affiliates, executors, administrators, trustees, receivers, assigns, beneficiaries, successors, predecessors and other representatives.

(e) *Amendment*. No amendment or modification of this Agreement will be binding unless executed in writing by all the Parties hereto.

(f) *Applicable Law*. This Agreement is made in, is governed by and shall be construed in accordance with the laws of the State of New York and the laws of the United States of America applicable therein, without regard to principles of conflicts of laws.

(h) *Validity*. If any provision of this Agreement is determined to be illegal, against public order or otherwise unenforceable, it shall not in any way defeat, invalidate or render unenforceable any other provision of this Agreement and each such provision shall at all times be considered separate and severable in this Agreement.

(i) *Notices and Deliveries.* Any notice, request, delivery, approval, authorization, consent or other communication required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered personally, sent by overnight courier or mailed by registered or certified mail (return receipt requested), postage prepaid, to the other Party at the addresses first set forth below or at such other addresses (or to such other person) as any Party may designate by notice to the other Party hereunder:

If to Sol-Gel: Sol-Gel Technologies Ltd.
Weizmann Science Park
7 Golda Meir St.
Ness Ziona 7403650, Israel
Attn: **[***]**
E-mail: **[***]**

If to Padagis: Padagis Israel Pharmaceuticals Ltd
1251 Lincoln Road
Allegan, Michigan 49010
Attn: **[***]**
E-mail **[***]**

Any notice, request, delivery, approval, authorization, consent or other communication as aforesaid shall be deemed to have been effectively delivered and received if mailed, to have been received three business days after being deposited in the mails, postage prepaid, if delivered personally, to have been delivered and received on the date of such delivery and if sent by e-mail, upon receipt by the sender Party of an acknowledgment of receipt (including an automatically-generated e-mailed read receipt); provided, however, that if such date is not a business day, then it shall be deemed to have been delivered and received on the business day next following such delivery.

The Parties have executed this Termination Agreement as of the date first written above.

PADAGIS ISRAEL PHARMACEUTICALS LTD

x

SOL-GEL TECHNOLOGIES LTD.

EXHIBIT A
DEVELOPMENT AGREEMENTS

[* * *]

Exhibit 4.23

CERTAIN INFORMATION IDENTIFIED
BY BRACKETED ASTERISKS ([* * *])
HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE
IT IS BOTH NOT MATERIAL AND WOULD BE
COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

TERMINATION AGREEMENT
([***])

This Termination Agreement ("**Agreement**") is entered into as of November 3, 2021 ("**Effective Date**"), between Padagis Israel Pharmaceuticals Ltd, a limited liability company organized in Israel ("**Padagis**"), and Sol-Gel Technologies Ltd., a limited liability company organized in Israel ("**Sol-Gel**"). Padagis and Sol-Gel are individually referred to as a "**Party**" and collectively referred to as the "**Parties**. "

Background

A. Perrigo Israel Pharmaceuticals Ltd. ("**Perrigo**") and Sol-Gel entered into the agreement set forth in Exhibit A (the "**Development Agreement**"). Pursuant to the transaction between Perrigo and Vesta Pharma LLC, Perrigo was sold to Padagis, LLC (f/k/a Vesta Pharma LLC), and renamed Padagis Israel Pharmaceuticals Ltd ("**Padagis Israel**").

B. The Parties desire to terminate the Development Agreement upon the terms set forth in this Agreement.

Accordingly, Padagis and Sol-Gel agree as follows:

1. Terms used in this Agreement and not otherwise defined shall have the meaning ascribed to them under the Development Agreement.

2. Termination of Development Agreement.

(a) **[***]**.

(b) The Parties hereby terminate the Development Agreement and each of their respective rights and obligations under the Development Agreement without further liability or obligation whatsoever, including, without limitation, Padagis's obligation to pay Sol-Gel profit sharing payments and Sol-Gel's responsibility for certain development obligations and costs.

(c) Notwithstanding Section 1(b) above, nothing in this Agreement will affect (i) either Party's rights under a Development Agreement with respect to claims arising out of events occurring prior to the Effective Date; (ii) either Party's right to receive all payments owed or accrued to it under the Development Agreement for periods prior to the Effective Date; (iii) Padagis's ownership of assets transferred to it pursuant to the Development Agreement and any intellectual property license granted to Padagis by Sol-Gel pursuant to the Development Agreement; and (iv) any provision in the Development Agreement that expressly survive termination pursuant to the terms of the applicable Development Agreement provided however that (1) Sol-Gel shall have no obligations under the Development Agreement with respect to Recalls of Products, the Sol-Gel Intellectual Property and/or IP Litigation and Settlement; and (2) Sol-Gel's obligation to indemnify Padagis under the indemnification provisions in the Development Agreement shall apply solely to claims arising out of events occurring prior to the Effective Date. To the extent there is any conflict between the terms of this Agreement and the Development Agreement, this Agreement shall control.

(d) Within **[***]** days after the Effective Date, the Parties will true-up all payments that were owed or accrued to the Parties under the Development Agreement prior to the Effective Date that have not already been paid. Such payments shall be made in accordance with the Development Agreement.

3. Consideration. As consideration for the agreements set forth herein, Padagis will pay Sol-Gel **[***]** in the aggregate payable in **[***]** installments of **[***]** on each **[***]** until paid in full. The initial payment will be made as of the Effective Date.

4. Representations and Warranties. Each Party represents and warrants to the other Party that such Party has the necessary power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary action of such Party. This Agreement constitutes the legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

5. Covenant not to Compete. For a period beginning on the Effective Date and ending **[***]** years after the launch date of the Product under the Development Agreement, without the prior written consent of Padagis, Sol-Gel will not directly or indirectly, and will cause its affiliates not to, promote, market, sell, distribute, develop, commercialize, or manufacture (or enter into any arrangement with any person or entity to develop, commercialize, or manufacture) any generic pharmaceutical product that competes with the Product. In addition to any other rights or remedies provided by this Agreement, Padagis will have the right to injunctive or other equitable relief to restrain any breach or threatened breach or otherwise to specifically enforce the provisions of this Section. Padagis acknowledges and agrees that money damages would be an inadequate remedy to compensate for the breach of this Section. Padagis and Sol-Gel intend all provisions of this Section to be enforced to the fullest extent permitted by applicable legal requirements. If any provision or term of this Section is held to be illegal, invalid, or unenforceable under present or future applicable legal requirements of any jurisdiction, such provision will be fully severable, and this Section will be construed and enforced in such jurisdiction as if such illegal, invalid or unenforceable provision were never a part hereof, and the remaining provisions will remain in full force in such jurisdiction and will not be affected by the illegal, invalid, or unenforceable provision, or by its severance. Without limiting the generality of the foregoing, if a court or arbitrator of any competent jurisdiction should determine that any of the restrictions contained in this Section are unreasonable in terms of scope, duration, geographic area or otherwise, such provision will be reformed in such jurisdiction to the extent necessary such that such restriction will be rendered enforceable to the fullest extent permitted by applicable legal requirements.

6. Assignment and License.

(a) Sol-Gel hereby irrevocably and unconditionally sells, assigns, conveys, transfers and grants to Padagis, as of the Effective Date, Sol-Gel's entire right, title and interest in and to the Assigned Sol-Gel Intellectual Property, the same to be held and enjoyed by Padagis for its own use and benefit, and for the use and benefit of its affiliates, successors, assigns, or legal representatives, as fully and entirely as the same would have been held and enjoyed by Sol-Gel if this Agreement had not been executed.

(b) The transfer, assignment and sale under Section (a) above shall be deemed to include the right to register and/or apply for registration of the Assigned Sol-Gel Intellectual Property in Padagis' own name in appropriate registries throughout the world, including without limitation all rights to publish cautionary notices reserving ownership of the Assigned Sol-Gel Intellectual Property.

(c) In the event that any assignment under this Agreement may be ineffective or incomplete as a result of any moral rights, artists' rights, or any other similar rights worldwide ("**Moral Rights**"), Sol-Gel hereby irrevocably and unconditionally transfers and assigns to Padagis any and all Moral Rights that Sol-Gel may have in or with respect to the Assigned Sol-Gel Intellectual Property.

To the extent that Sol-Gel cannot transfer and assign such Moral Rights to Padagis, Sol-Gel hereby waives and agrees never to assert such Moral Rights against Padagis or any of its licensees. If Sol-Gel has any Assigned Sol-Gel Intellectual Property that cannot be assigned to Padagis or waived by Sol-Gel, then Sol-Gel unconditionally and irrevocably grants to Padagis during the term of such rights, an exclusive, irrevocable, perpetual, worldwide, fully-paid and royalty-free license (subject to Sol-Gel's license set forth in (d) below), with rights to transfer, sublicense and assign in any way or manner including throughout multiple tiers of sublicensees, to use, reproduce, modify, create derivative works of, perform, display, distribute directly and indirectly, and otherwise exploit such Assigned Sol-Gel Intellectual Property by all means now known or later developed, and to make, have made, sell, offer to sell, lease, offer to lease and import products and services that contain or embody such Assigned Sol-Gel Intellectual Property, all whether by itself or through others.

(d) Padagis hereby grants to Sol-Gel a non-exclusive, worldwide, fully-paid, royalty-free, transferable, irrevocable license under the assigned Assigned Sol-Gel Intellectual Property, with the right to sublicense (through multiple tiers of sublicensees), to develop, manufacture and commercialize any product other than the Product.

(e) For the purposes of this Agreement, "**Assigned Sol-Gel Intellectual Property**" means the Sol-Gel Intellectual Property as such term is defined in the Development Agreement.

7. **[***]**.

(a) Sol-Gel and **[***]**. ("**[***]**") are parties to the agreements set forth in Exhibit B (the "**[***] Agreements**").

(b) Sol-Gel hereby grants, transfers and assigns to Padagis and Padagis's successors and assigns all of Sol-Gel's right, title and interest in and to the **[***]** Agreements. Padagis accepts the assignment of the **[***]** Agreements and hereby assumes Sol-Gel's obligations and liabilities under the **[***]** Agreements that arise from and after the Effective Date and agrees to be bound by all of the terms and provisions of the **[***]** Agreements as if Padagis were a party thereto. Padagis shall not be liable for any of Sol-Gel's liabilities and obligations under the **[***]** Agreements that arose prior to the Effective Date or that relate to Sol-Gel's acts or omissions prior to the Effective Date (including any breach of the **[***]** Agreements). Sol-Gel shall not be liable for any of Padagis' liabilities and obligations under the **[***]** Agreements that arose following the Effective Date or that relate to Padagis' acts or omissions following the Effective Date (including any breach of the **[***]** Agreements).

(c) Sol-Gel hereby represents and warrants that: (i) it has provided Padagis with true and complete copies of the **[***]** Agreements and all amendments thereto; (ii) Sol-Gel and **[***]** are in compliance with the terms of the **[***]** Agreements and have not breached the terms of the **[***]** Agreements, (iii) Sol-Gel has performed all of its obligations (including all payment obligations) pursuant to the terms of the **[***]** Agreements.

(d) Simultaneously with the execution of this Agreement, Sol-Gel will deliver to Padagis **[***]**'s consent to the assignment of the **[***]** Agreements to Padagis, which consent will be in a form and substance reasonably satisfactory to Padagis.

(e) Sol-Gel hereby transfers all of its right, title and interest in and to the equipment set forth in Exhibit C to Padagis, free and clear of all liens and encumbrances.Miscellaneous Provisions.

(a) *Entire Agreement*. This Agreement and the Development Agreement contain the entire agreement among the Parties with respect to the subject matter hereof and supersedes all prior oral and written agreements, memoranda and undertakings among the Parties with regard to such subject matter.

(b) *Counterparts*. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which taken together will constitute one and the same Agreement. Such counterparts may also be executed electronically (including by DocuSign) and will be deemed as effective as an original.

(c) *Successors*. This Agreement will be binding upon and inure to the benefit of each of the Parties, including all of their subsidiaries, parent companies, affiliates, officers, directors, attorneys, partners, firms, agents, employees, servants, affiliates, executors, administrators, trustees, receivers, assigns, beneficiaries, successors, predecessors and other representatives.

(e) *Amendment*. No amendment or modification of this Agreement will be binding unless executed in writing by all the Parties hereto.

(f) *Applicable Law*. This Agreement is made in, is governed by and shall be construed in accordance with the laws of the State of New York and the laws of the United States of America applicable therein, without regard to principles of conflicts of laws.

(h) *Validity.* If any provision of this Agreement is determined to be illegal, against public order or otherwise unenforceable, it shall not in any way defeat, invalidate or render unenforceable any other provision of this Agreement and each such provision shall at all times be considered separate and severable in this Agreement.

(i) *Notices and Deliveries*. Any notice, request, delivery, approval, authorization, consent or other communication required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered personally, sent by overnight courier or mailed by registered or certified mail (return receipt requested), postage prepaid, to the other Party at the addresses first set forth below or at such other addresses (or to such other person) as any Party may designate by notice to the other Party hereunder:

If to Sol-Gel: Sol-Gel Technologies Ltd.
Weizmann Science Park
7 Golda Meir St.
Ness Ziona 7403650, Israel
Attn: **[***]**
E-mail: **[***]**

If to Padagis: Padagis US LLC
1251 Lincoln Road
Allegan, Michigan 49010
Attn: **[***]**
E-mail **[***]**

Any notice, request, delivery, approval, authorization, consent or other communication as aforesaid shall be deemed to have been effectively delivered and received if mailed, to have been received three business days after being deposited in the mails, postage prepaid, if delivered personally, to have been delivered and received on the date of such delivery and if sent by e-mail, upon receipt by the sender Party of an acknowledgment of receipt (including an automatically-generated e-mailed read receipt); provided, however, that if such date is not a business day, then it shall be deemed to have been delivered and received on the business day next following such delivery.

* * *

The Parties have executed this Termination Agreement as of the date first written above.

PADAGIS ISRAEL PHARMACEUTICALS LTD
Its

SOL-GEL TECHNOLOGIES LTD.
Its

November 3, 2021

By _____

EXHIBIT A
DEVELOPMENT AGREEMENT

[***]

EXHIIBIT B
[***] AGREEMENTS

[***]

EXHIBIT C
EQUIPMENT

[***]

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: April 4, 2022

/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: April 4, 2022

/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, 2021 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: April 4, 2022

/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, 2021 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: April 4, 2022

/s/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-223915) and Form F-3 (No. 333-230564) of Sol-Gel Technologies Ltd. of our report dated April 4, 2022 relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
April 4, 2022

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited