

As confidentially submitted to the Securities and Exchange Commission on June 6, 2017

Registration No. 333-

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

**Form F-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**Sol-Gel Technologies Ltd.**

(Exact Name of Registrant as Specified in its Charter)

**State of Israel**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**Not Applicable**  
(I.R.S. Employer Identification No.)

**Sol-Gel Technologies Ltd.**  
**7 Golda Meir St., Weizmann Science Park**  
**Ness Ziona, 7403648, Israel**  
**Tel: +972-8-931-3433**

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after effectiveness of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933. 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 7(a)(2)(B) of the Securities Act. ☐

**CALCULATION OF REGISTRATION FEE**

<b>Title of each Class of Securities to be Registered</b>	<b>Proposed Maximum Aggregate Offering Price (1)(2)</b>	<b>Amount of Registration Fee (3)</b>
Ordinary shares, par value NIS 0.1 per share	\$	\$

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Includes ordinary shares that the underwriters may purchase pursuant to their option to purchase additional ordinary shares.
- (3) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated , 2017

## Preliminary Prospectus

## Shares



## Ordinary Shares

This is an initial public offering of ordinary shares of Sol-Gel Technologies Ltd.

No public market currently exists for our ordinary shares. The initial public offering price is expected to be between \$ and \$ per share.

We intend to apply to list our ordinary shares on The NASDAQ Global Market under the symbol "SLGL".

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 and will be subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company and a Foreign Private Issuer."

Upon the closing of this offering, we will be a "controlled company" within the meaning of NASDAQ's corporate governance listing standards.

**Investing in our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page 11 of this prospectus for a discussion of information that should be considered in connection with an investment in our ordinary shares.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	Per share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions (1)	\$	\$
Proceeds to us (before expenses)	\$	\$

(1) We refer to "Underwriting" beginning on page [•] for additional information regarding underwriting compensation.

We have granted a 30-day option to the underwriters to purchase up to additional ordinary shares solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers in the offering on or about , 2017.

The date of this prospectus is , 2017

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Neither we nor any of the underwriters have authorized anyone to provide information different from that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus prepared by us or on our behalf. When you make a decision about whether to invest in our ordinary shares, you should not rely upon any information other than the information in this prospectus and any free writing prospectus prepared by us or on our behalf. Neither the delivery of this prospectus nor the sale of our ordinary shares means that information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or solicitation of an offer to buy these ordinary shares in any circumstances under which the offer or solicitation is unlawful.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

## PROSPECTUS SUMMARY

*This summary does not contain all of the information you should consider before investing in our ordinary shares. You should read this summary together with the more detailed information appearing in this prospectus, including “Risk Factors,” “Selected Historical Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business” and our financial statements and the related notes included at the end of this prospectus, before making an investment in our ordinary shares. 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 prospectus are translated using the rate of NIS 3.845 and NIS 3.902 to \$1.00, based on the exchange rates reported by the Bank of Israel on December 31, 2016 and 2015, respectively.*

### Our Company

We are a clinical stage specialty pharmaceutical company developing both branded and generic topical dermatological drug products. Our strategy is to establish ourselves as a pure-play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases, including products utilizing our proprietary microencapsulation delivery system. Our management team has extensive experience in product development and commercialization, having served in prominent roles at several leading pharmaceutical and medical dermatology companies.

Our four branded product candidates are: VERED, for the treatment of rosacea, TWIN and SIRS-T, for the treatment of acne vulgaris, or acne, and E-06 for the treatment of symptomatic interdigital tinea pedis. VERED, TWIN and SIRS-T are based upon our proprietary microencapsulation delivery system. Subject to an End of Phase II meeting to be scheduled with the U.S. Food and Drug Administration, or FDA, we expect to commence two pivotal Phase III clinical trials for VERED in the United States in the first half of 2018 and expect to report top-line data in the first half of 2019. In May 2016, we initiated a Phase II clinical trial for TWIN in the United States, and we expect to report top-line data in mid-2017. We intend to use the data from this trial to support the commencement of pivotal Phase III trials for both TWIN and SIRS-T. In September 2016, we commenced a Phase II clinical trial for E-06 for the treatment of symptomatic interdigital tinea pedis, a fungal infection between the toes accompanied by stinging and burning and expect to report top-line data from this trial in the second half of 2017. We plan to develop our current branded product candidates under the 505(b)(2) regulatory pathway of the FDA.

In addition to these branded drug product candidates, our product pipeline also includes the generic product candidate ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which is being developed in collaboration Perrigo UK Finco Limited Partnership, or Perrigo UK. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016.

Our microencapsulation delivery system is based on silica and is formed around the active substances using our proprietary ‘sol-gel’ processes. Each ‘sol-gel’ process starts from silica precursor(s). These precursor(s) polymerize under controlled conditions to form colloidal silica particles, which constitutes the “sol” that continue interacting until a silica shell, which constitutes the “gel,” is constructed around the active substances.

### Overview of Our Product Candidates

VERED is an innovative topical formulation containing 5% encapsulated benzoyl peroxide, or E-BPO, that we are developing for the treatment of rosacea. If approved, we expect VERED to be the first product containing encapsulated benzoyl peroxide for the treatment of rosacea. We believe VERED, if approved, has the potential to redefine the standard of care for the treatment of rosacea, a chronic skin disorder characterized by facial redness and inflammatory lesions. According to the U.S. National Rosacea Society, approximately 16 million people in the United States are affected by rosacea. According to a study we commissioned, approximately 4.8 million people in the United States experience subtype II symptoms and physicians estimate that they treat only 20% of the U.S. rosacea population. The topical drugs approved by the FDA to treat subtype II rosacea generated aggregate revenues of approximately \$420 million in the United States for the 12 months ended June 30, 2015. We evaluated VERED in a double blind, randomized, dose-ranging Phase II clinical trial involving 92 adult patients at ten centers in the United States. Based on the results of this trial, VERED has demonstrated statistically significant improvements compared to the control vehicle group in achieving the IGA success co-primary endpoint ( $p=0.0013$ ) and in reducing papulopustular-lesions based on the percentage change in the inflammatory lesion count from baseline at week 12 ( $p=0.02$ ). VERED has also shown to be well tolerated and its safety profile is similar to that of vehicle. Subject to an End of Phase II meeting to be scheduled with the FDA, we expect to commence two pivotal Phase III clinical trials for VERED in the United States in the first half of 2018 and expect to report top-line data in the first half of 2019.

TWIN is a novel, non-antibiotic topical cream formulation that we are developing for the treatment of acne. Acne is one of the three most prevalent skin conditions in the world and is the most commonly treated skin disorder in the United States. According to the American Academy of Dermatology, acne affects approximately 40 to 50 million people in the United States alone, of which approximately 10% are treated with prescription medications. The North American market for topical prescription drugs for acne was estimated to be approximately \$1.7 billion for the 12 months ended June 30, 2015. The leading topical drug product for 2015 was Epiduo, a fixed-dose combination of benzoyl peroxide and adapalene. TWIN is under development as a fixed-dose combination of benzoyl peroxide and tretinoin. These active substances have been separately encapsulated in silica using our proprietary technology. In nonclinical stability tests, encapsulation stabilized tretinoin in the presence of benzoyl peroxide, and in nonclinical skin irritation studies conducted in minipigs, it reduced irritation and improved the tolerability for TWIN. We believe that reduced irritation will enhance patient compliance. We initiated a Phase II clinical trial for TWIN in the United States in May 2016, and we expect to report top-line data in the mid-2017.

We are also developing SIRS-T, a topical cream containing encapsulated tretinoin for the treatment of acne. The topical tretinoin drugs most commonly used to treat acne generated aggregate revenues of approximately \$529 million in the United States for the 12 months ended June 30, 2015. While fixed-dose combination drugs like Onexton, Ziana and Epiduo are most commonly used as first-line treatments in cases of moderate and severe acne and as second-line treatments in cases of mild acne, antiseptics, such as benzoyl peroxide, or retinoids, such as tretinoin or adapalene, are used as first-line treatment in cases of mild acne. We believe that a more tolerable tretinoin drug product will improve patient compliance. We intend to leverage data from the ongoing TWIN Phase II clinical trial, which is evaluating two different concentrations of encapsulated tretinoin. We plan to request an End of Phase II meeting with the FDA for both TWIN and SIRS-T following the completion of the ongoing Phase II trial for TWIN.

E-06 is a fixed-dose combination of an antifungal drug substance and a mid-potency steroid that is being developed for the treatment of symptomatic interdigital tinea pedis. The incidence rate of interdigital tinea pedis in the U.S. population is estimated to be approximately 3% to 10%, and we believe approximately 20% of that population seeks treatment. The ultimate goal of treatment is to eradicate the infection, which is generally accomplished through use of a topical antifungal agent. Until the infection is eradicated, the involved cutaneous tissues can remain

inflamed and painful. Most forms of inflammation can be reduced or eliminated by the use of steroids. E-06 is designed to treat the underlying fungal infection as well as to rapidly relieve inflammation, which we believe will improve patient comfort and compliance. In September 2016, we commenced a Phase II clinical trial for E-06, with top-line data expected in the second half of 2017.

In addition to these branded drug product candidates, our product pipeline also includes the generic product candidate ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which is being developed in collaboration with Perrigo UK. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016.

The following table summarizes the development pipeline for our branded and generic product candidates:

Product Candidate	Indication	Status	Upcoming Milestone
VERED	Papulopustular (subtype II) rosacea	Preparing for Phase III clinical trial	Initiate pivotal Phase III clinical trials first half of 2018
TWIN	Acne vulgaris	Phase II clinical trial ongoing	Top-line Phase II clinical trial results mid-2017
SIRS-T	Acne vulgaris	Preparing for Phase III clinical trial	Initiate Phase III clinical trials second half of 2018
E-06	Symptomatic interdigital tinea pedis	Phase II clinical trial ongoing	Top-line Phase II clinical trial results second half of 2017
Ivermectin cream, 1%	Papulopustular (subtype II) rosacea	Bioequivalence study ongoing	ANDA submission upon study completion

### Our Strengths

We believe we are well positioned to develop and commercialize treatments for skin diseases based on the following.

- Diversified clinical stage product pipeline.* We are currently conducting a Phase II clinical trial for TWIN in acne, for which we expect to report top-line data in mid-2017, and a Phase II trial for E-06 in tinea pedis, for which we expect to report top-line data in the second half of 2017. We are also scheduled to commence two pivotal Phase III trials for VERED in rosacea in the first half of 2018. Subject to an End of Phase II meeting we expect to schedule with the FDA, we intend to commence pivotal Phase III clinical trials for SIRS-T in the second half of 2018 based on the results of our ongoing TWIN Phase II clinical trial. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016 and we expect to submit an abbreviated new drug application, or ANDA, to the FDA after completion of this study.
- Expertise in generic drug development and commercialization.* We have an established collaboration with Perrigo UK to develop ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea. Our intellectual property and formulation teams also have considerable expertise in the identification and development of generic dermatological products and continue to identify new opportunities to expand our pipeline of generic product candidates. Furthermore, Mr. Moshe (Mori) Arkin, who serves as the chairman of our board of directors, has substantial experience leading companies focused on the development and commercialization of generic drugs.

- *Proprietary microencapsulation drug delivery system.* Our silica-based delivery system is designed to improve the tolerability of topical dermatological drug products by entrapping drug substances in porous silica microcapsules, thereby creating a protective barrier between the drug substance and the skin and controlling the release rate of the entrapped substance. This delivery system is designed to substantially improve the stability of topical fixed-dose combinations of non-compatible drug substances, allowing us to produce stable fixed-dose combinations of active ingredients that have been well tolerated in the clinical trials we have conducted to date.
- *Experienced management team.* Our executive management team has extensive experience in the development and commercialization of dermatology drug products. Mr. Moshe (Mori) Arkin, who serves as the chairman of our board of directors, has held leadership roles in several innovative and generic drug companies. Mr. Arkin was the chairman of Agis Industries Ltd., expanding it into becoming a leading pharmaceutical company in the United States until its acquisition by Perrigo Company where he served as vice chairman. Our chief executive officer, Alon Seri-Levy, has considerable experience in the field of drug development and computer-aided drug design.
- *Efficient FDA regulatory pathway.* We expect the review process for our branded product candidates to be conducted according to the FDA's 505(b)(2) regulatory pathway, which permits us to rely upon the FDA's previous findings of safety and efficacy of an approved product. Silica, which forms the basis of our proprietary microencapsulation delivery system, is an inorganic inert excipient already approved by the FDA as a safe excipient in other topical drug products.
- *Barriers to entry for competing products.* We have developed an in-depth understanding of the critical chemical and physical parameters affecting the release rate of active pharmaceutical ingredients from microcapsules made of silica. This complex understanding is essential to obtain a desired, well-defined, controlled-release profile for each drug candidate and in order to maintain it to support commercial scale production. In addition to our patent portfolio, we have considerable proprietary know-how that permits us to employ our proprietary process to produce a silica-based delivery system with a well-defined, controlled-release profile of the drug candidate. If any of VERED, TWIN or SIRS-T are approved for marketing, we believe that our patent portfolio, combined with our know-how, will create a barrier to entry for generic drugs with comparable and bioequivalent release profiles.

#### **Our Strategy**

Our strategy is to establish ourselves as a pure-play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases, including products utilizing our proprietary microencapsulation delivery system. To achieve this objective, the key elements of our strategy are:

- *Complete development of our branded and generic product candidates.* We intend to advance our branded and generic product candidates through clinical development and obtain regulatory approvals. In certain cases, we will collaborate with pharmaceutical partners in order to expedite this process.
- *Expand our diversified pipeline.* We intend to expand our portfolio of branded product candidates to also include new chemical entities that may address additional skin conditions. We will focus on skin conditions where we believe there is a need for improved drug therapies.

- *Improve efficacy and tolerability of existing drugs.* We intend to continue to identify new opportunities to apply our proprietary delivery system to other drug substances in order to improve efficacy and tolerability of additional approved topical drug products, with a goal of improving patient comfort, compliance and quality of life.
- *Maximize commercial potential of our product candidates.* We intend to independently commercialize our product candidates in the United States, if approved. In other markets, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.
- *Expand and protect our intellectual property.* We intend to expand and protect our intellectual property in the areas of silica-based delivery systems, encapsulation processes and drug formulations in order to maintain a defensible and valuable intellectual property portfolio.

#### **Risks Associated with our Business**

Investing in our ordinary shares involves risks. You should carefully consider the risks described in “Risk Factors” beginning on page [11](#) before making a decision to invest in our ordinary shares. The following is a summary of some of the principal risks we face:

- we have incurred significant losses since our inception and we expect to incur losses over the next several years and may never achieve or maintain profitability;
- our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern;
- even if this offering is successful, we will need substantial additional funding to meet our financial obligations and to pursue our business objectives and 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;
- our ability to complete the development of our product candidates and to meet our development timelines;
- we rely, and expect to continue to rely, on third parties to conduct our clinical trials and manufacture our product candidates for clinical testing, and those third parties may not perform satisfactorily, which could delay our product development activities;
- our ability to obtain and maintain regulatory approvals for our product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained;
- our ability to commercialize our product candidates;
- our ability to obtain and maintain adequate protection of our intellectual property;
- the possibility that we may face third party claims of intellectual property infringement;
- acceptance of our product candidates by healthcare professionals and patients;
- we will face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do; and
- loss or retirement of key executives and research scientists.



### **Our Controlling Shareholder**

As of the date of this prospectus, M.Arkin Dermatology Ltd., or Arkin Dermatology, owns 100% of our ordinary shares. Mr. Moshe Arkin, the chairman of our board of directors, owns 100% of the share capital of Arkin Dermatology. Upon completion of this offering, Arkin Dermatology will own approximately % of our ordinary shares. For more information see “Principal Shareholders.”

### **Corporate Information**

We were incorporated under the laws of the State of Israel on October 28, 1997. Our principal executive offices are located at Weizmann Science Park, 7 Golda Meir St., Ness Ziona, Israel 7403650, and our telephone number is +972 (8) 931-3433. Our website address is <http://www.sol-gel.com>. The information contained therein or connected thereto shall not be deemed to be incorporated into this prospectus or the registration statement of which it forms a part.

### **Implications of Being an Emerging Growth Company and a Foreign Private Issuer**

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act. As such, we are eligible, for up to five years, to take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include:

- the option to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- we are not required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis); and
- we are not required to submit certain executive compensation matters to shareholder advisory votes, such as “say-on-pay,” “say-on-frequency” and “say-on-golden parachutes;” and we are not required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of this offering or such earlier time that we no longer qualify as an emerging growth company. As a result, the information we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act, for complying with new or revised accounting standards. Accordingly, as an emerging growth company, we have elected to utilize this exemption and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion; (ii) the last day of the fiscal year following the fifth anniversary of the date of this offering; (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if

the aggregate market value of our ordinary shares that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during any three-year period.

Upon the closing of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, for as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specific information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

<b>The Offering</b>	
Ordinary shares offered by us	ordinary shares (or      ordinary shares if the underwriters exercise their option to purchase additional ordinary shares in full).
Ordinary shares to be outstanding after this offering	ordinary shares (or      ordinary shares if the underwriters exercise their option to purchase additional ordinary shares in full).
Option to purchase additional ordinary shares	We have granted the underwriters an option to purchase up to      additional ordinary shares from us within 30 days of the date of this prospectus.
Use of proceeds	<p>We estimate that we will receive net proceeds from this offering of approximately \$      million, or approximately \$      million if the underwriters exercise their option to purchase additional ordinary shares in full, based on an assumed initial public offering price of \$      per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering to fund our planned clinical trials of our branded product candidates, VERED, TWIN, SIRS-T and E-06, as well as our generic product candidate, Ivermectin cream, 1%. The remaining proceeds will be used for other research and development activities, as well as for working capital and general corporate purposes. See “Use of Proceeds” for additional information.</p>
Risk factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our ordinary shares.
Controlled company	Because Arkin Dermatology will own more than 50% of the voting power of our outstanding voting share capital following the completion of this offering, we may avail ourselves of the “controlled company” exemptions under the rules of the NASDAQ.
Proposed NASDAQ Global Market symbol	“SLGL”
<p>The number of ordinary shares to be outstanding after this offering is based on 3,494,579 ordinary shares outstanding as of February 28, 2017, and excludes the following:</p> <ul style="list-style-type: none"> <li>• 253,768 ordinary shares issuable upon the exercise of options to purchase ordinary shares outstanding under our 2014 Share Incentive Plan, at a weighted average exercise price of \$2.86 per share; and</li> <li>• an additional 95,690 ordinary shares reserved for future issuance under our 2014 Share Incentive Plan.</li> </ul>	

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- an assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- no exercise by the underwriters of their over-allotment option to purchase up to      additional ordinary shares from us;
- the adoption and effectiveness of our amended and restated articles of association, which will occur immediately prior to the closing of this offering; and
- a      for      share split of our ordinary shares by means of a bonus share issuance of      ordinary shares for each ordinary share outstanding, which was effected on      .

### SUMMARY FINANCIAL DATA

The following tables present our summary statement of operations for the years ended December 31, 2015 and 2016 and our summary balance sheet data as of December 31, 2016. Our summary statement of operations for the years ended December 31, 2015 and 2016 and our summary balance sheet data as of December 31, 2016 have been derived from our audited financial statements included elsewhere in this prospectus. We prepare our financial statements in accordance with U.S. Generally Accepted Accounting Principles, or U.S. GAAP. Our historical results are not necessarily indicative of results to be expected in any future periods. You should read this summary financial data together with “Selected Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31	
	2015	2016
	(in thousands, except share and per share data )	
Statement of Operations Data:		
Research and development expenses	\$ 7,184	\$ 17,023
General and administrative expenses	2,463	3,733
Total operating loss	9,647	20,756
Financial expenses, net	13	15
Loss for the year	\$ 9,660	\$ 20,771
Basic and diluted loss per ordinary share (1)	\$ 2.76	\$ 5.94
Weighted average number of ordinary shares outstanding – basic and diluted	3,494,579	3,494,579

- (1) Basic loss per ordinary share and diluted loss per ordinary share are the same because outstanding options would be anti-dilutive due to our net losses in these periods.

	As of December 31, 2016	
	Actual	As Adjusted (1)
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	\$ 7,001	\$
Total assets	10,985	
Total liabilities	42,322	
Accumulated deficit	(63,693)	
Total capital deficiency	(31,337)	

- (1) The as adjusted balance sheet data give effect to the issuance and sale of ordinary shares by us in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the as adjusted amount of each of cash and cash equivalents, total assets and total shareholders’ equity by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. This as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

## RISK FACTORS

*Investment in our ordinary shares involves a high degree of risk. You should carefully consider the risks described below and all other information contained in this prospectus before you decide to buy our ordinary shares. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment.*

### Risks Related to Our Business and Industry

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

We are a clinical stage pharmaceutical company with a limited operating history. We have incurred net losses since our formation in 1997. In particular, we incurred net losses of \$9.7 million in 2015 and \$20.8 in 2016. As of December 31, 2016, we had an accumulated deficit of \$63.7 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur net losses for the foreseeable future, as we continue to invest in research and development and seek to obtain regulatory approval and commercialization of our product candidates. The extent of our future operating losses and the timing of becoming profitable are highly uncertain, and we may never achieve or sustain profitability. We anticipate that our expenses will increase substantially as we:

- initiate and conduct the Phase III clinical trials and long term safety studies for VERED, TWIN, SIRS-T and E-06, which we refer to collectively as our branded product candidates, and continue the research and development of future branded product candidates;
- continue the development, bioequivalence and other studies required for ANDA submissions for our generic product candidate ivermectin cream, 1% and other generic product candidates;
- seek to enhance our technology platform;
- seek regulatory approvals for any product candidate that successfully completes clinical development;
- potentially establish a sales, marketing and distribution infrastructure and commercial manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- obtain freedom to operate for our technologies and product candidates;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our transition to a public company; 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.

To date, we have financed our operations primarily through private placements of equity securities and loans from our controlling shareholder. We have devoted a significant portion of our financial resources and efforts to developing our product candidates and conducting nonclinical studies and our clinical trials for VERED, TWIN, SIRS-T, E-06, and ivermectin cream, 1%. We have not completed development of any of our product candidates. 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 nonclinical 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 product royalties or product sales, 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.

***Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.***

We have not commercialized any products or generated any revenue from our product candidates. Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, for the year ended December 31, 2016, our independent registered public accounting firm has issued its report on our financial statements and has expressed substantial doubt about our ability to continue as a going concern. We have no current source of revenue to sustain our present activities other than the loans extended to us from time to time by our controlling shareholder, and we do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve, and we successfully commercialize, our product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations, such as the proceeds from this offering. The perception that we might be unable to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

***Even if this offering is successful, we will need substantial additional funding to meet our financial obligations and 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 nonclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we commence our Phase III clinical trials for VERED, seek marketing approval for VERED and advance our other branded product candidates, including TWIN, SIRS-T and E-06. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for VERED or any other product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. We expect that our existing cash, cash equivalents and investments, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements

through at least the next . 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 progress and results of our pivotal Phase III clinical trials for VERED for the treatment of rosacea, that we plan to commence in the first half of 2018;
- the progress and results of our Phase II clinical trials for TWIN and E-06 for the treatment of acne and symptomatic interdigital tinea pedis, respectively;
- the scope, progress, results and costs of development, laboratory testing and clinical trials for our other product candidates, including SIRS-T for the treatment of acne;
- the cost of manufacturing clinical supplies and exhibition batches of our product candidates;
- the costs, timing and outcome of regulatory review of any of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims by third parties that we are infringing upon their intellectual property rights;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the extent to which we acquire or invest in businesses, product candidates and technologies, including entering into licensing or collaboration arrangements for any of our product candidates.

If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

We have invested a majority of our efforts and financial resources in the research and development of VERED for the treatment of rosacea, TWIN and SIRS-T for the treatment of acne and E-06 for the treatment of symptomatic interdigital tinea pedis. We are currently investing a majority of our efforts and resources to bring VERED to a position to commence a Phase III clinical trial in the United States during the first half of 2018, to provide support for our ongoing TWIN Phase II clinical trial in the United States which commenced in May 2016 and to provide ongoing support for the E-06 Phase II clinical trial in the United States, which commenced in September 2016. The success of our business depends largely on our ability to fund, execute and complete the development of, obtain regulatory approval for and successfully commercialize our branded product candidates in the United States market in a timely manner.

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

We currently do not have any product candidates that have obtained regulatory approval for sale in the United States or any other country, and we cannot guarantee that we will ever obtain such approvals to market our product candidates. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize our product



candidates in the United States without first obtaining regulatory approval to market each product candidate from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities.

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

Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval is never guaranteed. Upon submission of an NDA, 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 approval, the FDA may require that we conduct additional clinical trials or nonclinical studies, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than 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 foreign regulatory approval could require additional chemical manufacturing control data, nonclinical studies or clinical trials, which could be costly and time consuming. Obtaining foreign regulatory approval may include all of the risks associated with obtaining FDA approval.

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

Market perceptions of our business are very important to us, especially market perceptions of the safety and quality of our product candidates. If any of our product candidates, if they are approved, or similar products that other companies distribute, or third-party products from which our product candidates are derived are subject to market withdrawal or recall or are proven to be, or are claimed to be, harmful to consumers, it could have a material adverse effect on our business.

Because our business is dependent on market perceptions, negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to be resulting 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 can call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other costly risk management programs such as the need for a patient registry.

***We have focused much of our efforts, to date, on the research and development of our product candidates, rather than their commercialization and therefore we have a limited operating history in the dermatological prescription drug space which may make it difficult to evaluate the success of our business to date and to assess our future viability.***

We have a limited operating history in the dermatological prescription drug space and have focused much of our efforts, to date, on the research and development of our product candidates, rather than their commercialization. As such, 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:

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

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

***Raising additional capital may cause dilution to our shareholders, including purchasers of ordinary shares in this offering, 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 drug 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 will be able to generate revenues from our operations in the future, our revenues and operating income could fluctuate significantly.***

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

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

- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- the ability of our product license partner(s) to secure regulatory approval, gain market share, sales volume, and sales milestone levels;
- timing of revenue recognition related to our alliance and 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.

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

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

**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 generic products and the submission of new drug applications under the Section 505(b)(2) regulatory pathway is expensive, time consuming and has an inherently uncertain outcome. Failure can occur at any time during the clinical trial process, even with active ingredients that have been previously approved by the FDA as safe and effective. Favorable results in nonclinical 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 nonclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed nonclinical studies and clinical trials for our product candidates may not be predictive of the results we may obtain in later stage trials for such product candidates. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Clinical trial results may be inconclusive, or contradicted by other clinical trials, particularly larger clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have

nonetheless failed to obtain FDA, or other applicable regulatory agency, approval for their products. Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- 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 could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

We may 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:

- obtaining regulatory approval 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;
- obtaining institutional review board, or IRB, 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 trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of a product candidate for use in clinical trials.

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

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 the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of any clinical trial for our product candidates or if any clinical trials are terminated, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed.

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

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

Identifying and qualifying patients to participate in clinical trials for our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can

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

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

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

If we have difficulty enrolling a sufficient number of patients to conduct our trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials. We face intense competition with regards to patient enrollment in clinical trials from other dermatological companies which also seek to enroll subjects from the same patient populations. In addition, patients enrolled in our clinical trials may discontinue their participation at any time during the trial as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged related to our product candidates under evaluation. The discontinuation of patients in any one of our trials may cause us to delay or abandon our clinical trial, or cause the results from that trial not to be positive or sufficient to support a filing for regulatory approval of the applicable product candidate.

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

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of our product candidates. Product liability claims could delay or prevent completion of our development programs. If we succeed in commercializing our product candidates, such claims could result in a recall of our product candidates or a change in the approved indications for which they may be used. While we intend to maintain product liability insurance that we believe is adequate for our operations upon commercialization of our product candidates, we cannot be sure that such coverage will 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 intend to seek approval under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfy the requirements of the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

We are developing product candidates for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to 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 would likely 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, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

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

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

Even if we complete clinical testing and receive approval of any of our branded or other product candidates, the FDA may grant approval contingent on the performance of additional costly post-approval clinical trials, risk mitigation requirements such as the implementation of Risk Evaluation and Mitigation Strategy, or REMS, and/or surveillance requirements to monitor the

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

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

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

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

In addition, if our branded product candidates or any of our other product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, a practice known as off-label promotion. If we receive marketing approval for any of our branded product candidates or any of our other product candidates, physicians may nevertheless prescribe the products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied

large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

Moreover, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, and the sale and promotion of our branded product candidates or any of our other product candidates, if approved. For example, in December 2016, the 21st century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. 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 lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. In addition, costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business operations and financial performance.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. Although certain positions at the FDA may be exempt from the freeze, an understaffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

Even if we obtain FDA approvals for our branded product candidates or any of our other product candidates, the commercial success of such products will depend significantly on their

broad adoption and use by dermatologists, pediatricians and other physicians for approved indications and other therapeutic or aesthetic indications that we may seek to pursue.

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

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

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

We conduct research and development primarily to enable us to manufacture and market pharmaceuticals in accordance with FDA regulations as well as other regulatory authorities. We spent approximately \$7.2 million and \$17.0 million on research and development activities during the years ended December 31, 2015 and 2016, respectively. We are required to obtain FDA approval before marketing our product candidates in the United States. The FDA approval process is costly, time consuming and inherently risky.

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

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

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

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

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

Certain of our product candidates may be manufactured at facilities located in Canada, in addition to our facility in Israel, and therefore our operations are subject to risk inherent in doing business internationally. Such risks include the adverse effects on operations from corruption, war, international terrorism, civil disturbances, political instability, governmental activities, deprivation of contract and property rights and currency valuation changes.

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

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

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

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

## Risks Related to Regulatory Matters

***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. Insurance may not provide adequate coverage against these potential liabilities and 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.

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

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

- revisions to the Medicaid rebate program by: (a) increasing the rebate percentage for branded drugs to 23.1% of the average manufacturer price, or AMP, with limited exceptions, (b) increasing the rebate for outpatient generic, multiple source drugs dispensed to 13% of AMP; (c) changing the definition of AMP; and (d) extending the Medicaid rebate program to Medicaid managed care plans, with limited exceptions;
- the imposition of annual fees upon manufacturers or importers of branded prescription drugs, which fees will be in amounts determined by the Secretary of Treasury based upon market share and other data;
- providing a 50% discount on brand-name prescriptions filled in the Medicare Part D coverage gap beginning in 2011;
- imposing increased penalties for the violation of fraud and abuse laws and funding for anti-fraud activities;
- creating a new pathway for approval of biosimilar biological products and granting an exclusivity period of 12 years for branded drug manufacturers of biological products before biosimilar products can be approved for marketing in the United States; and
- expanding the definition of “covered entities” that purchase certain outpatient drugs in the 340B Drug Pricing Program of Section 340B of the Public Health Service Act.

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

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. The new Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition.

Moreover, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included 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 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressure.

#### **Risks Related to Commercialization of Our Product Candidates**

***Our continued growth is dependent on our ability to continue 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 continued growth is therefore dependent upon our ability to continue to successfully introduce and commercialize new product candidates.

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



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

The facial aesthetic market in general, and the market for rosacea and acne 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 VERED, TWIN and SIRS-T, if approved, will face significant competition from other approved products, including topical drugs for the treatment of rosacea such as Metrogel, Finacea and Soolantra, oral drugs such as Solodyn, Doryx, Dynacin and Minocin, and topical anti-acne drugs such as Acanya, Ziana, Epiduo, Epiduo Forte, Benzacclin, Aczone, Onexton and Differin. If approved, VERED, TWIN and SIRS-T may also compete with non-prescription anti-acne products, as well as unapproved and off-label treatments. To compete successfully in the facial aesthetic market, we will have to demonstrate that our product is safe and effective for the respective treatment, has advantages over existing therapies, and that it does not infringe the intellectual property rights of any third parties. 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 outside the United States, there are many more acne products and procedures available for use in 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 would face more competition in markets outside of the United States.

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

We believe that our principal competitors are Valeant Pharmaceuticals International, Inc. (VRX), Galderma S.A., Allergan plc (AGN), Bayer HealthCare AG (BAYRY), Mylan N.V. (MYL) and GlaxoSmithKline LLC (GSK).

In addition to the above listed competitors, some of our product candidates might be facing internal competition with other product candidates of ours, for the same markets and patient populations, due to overlap in the required treatment and/or symptoms. For example, TWIN may compete with SIRS-T for treatment of acne and VERED may compete with ivermectin cream, 1%, for treatment of rosacea.

With respect to generic pharmaceutical products, the FDA approval process often results in the FDA granting final approval to a number of ANDAs for a given product at the time a relevant patent for a corresponding brand product or other regulatory and/or market exclusivity expires. For example, on December 30, 2016, Actavis Ltd. submitted an ANDA for ivermectin, 1%, cream, and therefore we will only be able to commercialize this product after Actavis Ltd.'s six month exclusivity period expires. Thus, we expect, in accordance with the standard practices in the industry, to face immediate competition when we introduce a generic product into the market. As competition from other manufacturers intensifies, selling prices and gross profit margins often decline. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product that we develop is generally related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. Additionally, ANDA approvals often continue to be granted for a given



product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices and reduced margins for generic products compared to brand products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

In addition to the competition we face from other generic manufacturers, we face competition from brand-name manufacturers related to our generic products. Branded pharmaceutical companies may sell their branded products as “authorized generics” (an industry term that describes instances when 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 cost than the brand name drug). Further, branded pharmaceutical companies may seek to delay FDA approval of our ANDAs or reduce generic competition by, for example, obtaining new patents on drugs whose original patent protection is about to expire, filing patent infringement suits that could delay FDA approval of generics, developing new versions of their products to obtain FDA market exclusivity, filing “citizen petitions” contesting FDA approvals of generics such as on alleged health and safety grounds, developing “next generation” versions of products that reduce demand for generic versions we are developing, changing product claims and labeling, and seeking approval to market as OTC branded products.

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

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

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

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

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

***We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize VERED, TWIN or any other of our other product candidates, if approved, or generate product revenues.***

We currently have limited marketing capabilities and no sales organization. To commercialize VERED, TWIN or any other of our other product candidates, if approved, in the United States and other jurisdictions we may seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. For instance, if VERED and TWIN receive regulatory approval from the FDA, we intend to market them in the United States through a specialized internal sales force or a combination of our internal sales force and distributors, which will be expensive and time-consuming. Alternatively, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize VERED, TWIN or any of our other product candidates.

There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

If we are not successful in commercializing VERED, TWIN or any of our other product candidates, either on our own or through collaborations with one or more third parties, our revenues will suffer and we will incur significant additional losses.

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

Sales of our product candidates, if approved, will depend, in part, on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health programs, private health insurers and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Sales of our product candidates, and any future product candidates, will therefore depend substantially on the extent to which the costs of our product candidates, and any future product candidates, will be paid by third-party payors. Additionally, the market for our product candidates, and any future product candidates, will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic products can differ significantly from

payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our product candidates to each payor separately and will be a time-consuming process.

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation; in addition, the government may assert that 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 civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to certain payments or other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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 90<sup>th</sup> day of each calendar year; and
- analogous state and foreign 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 marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

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

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

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

### **Risks Related to Dependence on Third Parties**

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

We are currently party to certain collaborative arrangements with respect to the development, manufacture, study and commercialization of our product candidates, including one such agreement with Perrigo Israel Pharmaceuticals Ltd., or Perrigo Israel, relating to our E-06 product candidate. Any current or future potential collaborative arrangements may require us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory and intellectual property. For example, pursuant to our arrangements with Perrigo Israel relating to E-06, Perrigo Israel will conduct all regulatory, scientific, clinical and technical activities necessary to develop E-06. We cannot and will not control these third parties, but we may rely on them to achieve results, which may be significant to us. Relying upon collaborative arrangements to develop and commercialize our product candidates subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our product candidates;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our current or future collaborators may experience financial difficulties or changes in business focus;
- our current or future collaborators' partners may fail to secure adequate commercial supplies of our product candidates upon marketing approval, if at all;
- our current or future collaborators' partners may have a shortage of qualified personnel;

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

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

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

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

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

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practices, or cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory

approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

We do not have the ability to independently perform all aspects of our anticipated nonclinical studies and clinical trials. We will 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 intend to contract for execution of our clinical trials will play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties will not be our employees, and except for contractual duties and obligations, we will have limited ability to control the amount or timing of resources that they devote to our programs.

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

Although we will rely on these third parties to conduct certain aspects of our clinical trials and other studies and clinical trials, we will remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. Moreover, the FDA and foreign regulatory authorities will 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 will also rely on our consultants to assist us in the execution,



including data collection and analysis of our clinical trials. If we or any of our third party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

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



## Risks Related to Our Intellectual Property

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

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

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

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

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and the European Union. Therefore we cannot assure you that the patents issuing 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 profits.

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

We have granted, and may in the future grant, to third parties licenses to use our intellectual property. Generally, these licenses have granted rights to commercialize products outside the pharmaceutical field or to technology we no longer use or to otherwise use our intellectual property for a limited purpose outside the scope of our business interests. For example, in October 2011 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 TWIN for the treatment of acne. As part of this assignment agreement, we granted to Medicis a non-exclusive, transferable, sub-licensable, royalty-free, perpetual, license to practice the inventions claimed under the patent.

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

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

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

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

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

The development, manufacture, use, offer for sale, sale or importation of our product candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Therefore, there is a risk that we

could adopt a technology without knowledge of a pending patent application, which technology would infringe a third party patent once that patent is issued. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Any claims of patent infringement, even those without merit, could: be expensive and time consuming to defend; cause us to cease making, licensing or using products that incorporate the challenged intellectual property; require us to redesign, reengineer or rebrand our product candidates, if feasible; cause us to stop from engaging in normal operations and activities, including developing and marketing product candidates; and divert management's attention and resources. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our product candidates in the event of an infringement action.

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

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

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

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

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

costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

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

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

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

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

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

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references 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) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical trials or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our

achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

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

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

#### **Risks Related to Our Operations in Israel**

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

Our business and operations will be directly influenced by the political, economic and military conditions affecting Israel at any given time. A change in the security and political situation in Israel and in the economy could impede the raising of the funds required to finance our research and development plans and to create joint ventures with third parties and could otherwise have a material adverse effect on our business, operating results and financial condition. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there have been times since October 2000 when Israel has experienced an increase in unrest and terrorist activity. The establishment in 2006 of a government in the Palestinian Authority by representatives of the Hamas militant group has created additional unrest and uncertainty in the region.

During the Second Lebanon War of 2006, between Israel and Hezbollah, a militant Islamic movement, thousands of rockets were fired from Lebanon up to 50 miles into Israel. In January 2009, Israel attacked, during three weeks, Hamas strongholds in the Gaza strip, in reaction to rockets that were fired from Gaza up to 25 miles into Israel. In November 2012, Israel launched a seven-day operation against Hamas operatives in the Gaza strip in response to Palestinian groups launching over 100 rockets at Israel over a 24-hour period. In July 2014, Israel launched an

additional operation against Hamas operatives in the Gaza strip in response to Palestinian groups launching rockets at Israel. Major 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.

Popular uprisings in various countries in the Middle East and North Africa are affecting the political stability of those countries. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and these countries. Furthermore, 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.

***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.***

All of our executive officers and key employees of our business reside in Israel and although most of our management team is 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 ability of any Israeli company to pay dividends is subject to Israeli law and the amount of cash dividends payable may be subject to devaluation in the Israeli currency.***

The ability of an Israeli company to pay dividends is governed by Israeli law, which provides that cash dividends may be paid only out of retained earnings as determined for statutory purposes in Israeli currency. In the event of a devaluation of the Israeli currency against the U.S. dollar, the amount in U.S. dollars available for payment of cash dividends out of prior years' earnings will decrease.

***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 major 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 restrict our ability to manufacture product candidates and transfer know-how outside of Israel and require us to satisfy specified conditions, which are at present uncertain due to the enactment of a new regulatory framework.***

We have received royalty-bearing grants from the government of Israel through the National Authority for Technological Innovation, or the Innovation Authority (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 Innovation Authority grants relate to our product candidates that are associated with the research and development of our microencapsulation delivery system, namely VERED, TWIN and SIRS-T. When know-how is developed using Innovation Authority grants, the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984, or the Innovation Law, the Innovation Authority's rules and guidelines as well as the terms of these grants restrict our ability to manufacture product candidates and transfer know-how, developed as a result of the Innovation Authority's funded R&D, outside of Israel. Transfer of the Innovation Authority funded know-how outside of Israel where the transferring company remains an operating Israeli entity or where the transferring company ceases to exist as an Israeli entity, requires pre-approval by the Innovation Authority, which may at its sole discretion grant such approval and impose certain conditions, including requirement of payment of a redemption fee calculated according to the formulas provided in the Innovation Authority's rules and guidelines, or Redemption Fee which takes into account the consideration for such know-how paid to us in the transaction in which the know-how is transferred. The Innovation Authority's rules and guidelines establish a maximum payment of the redemption fee paid to the Innovation Authority under the formulas provided in the Innovation Authority's rules and guidelines and differentiates between certain situations, as further detailed in such rules and guidelines. In addition, the product candidates may be manufactured outside of Israel by us or by another entity only if prior approval is received from the Innovation Authority (such approval is not required for the transfer of less than 10% of the manufacturing capacity in the aggregate). In addition to the obligation to receive prior approval to manufacture outside Israel, we will be required to pay increased royalties, as defined under the Innovation Authority's rules and guidelines. The total amount of the increased royalties to be repaid to the Innovation Authority shall not exceed, in the aggregate, 300% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR, depending on the manufacturing volume that is performed outside Israel less royalties already paid to the Innovation Authority.

A company also has the option of declaring in its Innovation Authority 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.

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

The restrictions under the Innovation Authority's rules and guidelines will continue to apply even after we will repay the full amount of royalties payable pursuant to the grants. In addition,



the government of State of Israel may from time to time audit sales of product candidates which it claims incorporate technology funded via Innovation Authority programs and this may lead to additional royalties being payable on additional product candidates.

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

In August 2015, a new amendment to the Innovation Law was enacted, or Amendment No. 7, which came into effect on January 1, 2016. Since Amendment No. 7 has entered into force, the Innovation Authority was appointed to act as the entity which is responsible for the activity which was previously under the OCS' responsibility. The Innovation Authority was granted wide freedom of action, and among other things, the authority to amend the requirements and restrictions which were specified in the Innovation Law before Amendment No. 7 became effective with respect to the ownership of Funded Know-How (including with respect to the restrictions on transfer of the Funded Know-How and manufacturing activities outside of Israel) as well as with respect to royalty payment obligations which apply to companies that receive grants from the Innovation Authority. Although the Innovation Authority recently published rules which for the most part adopted the principal provisions and restrictions specified in the Innovation Law prior to the effectiveness of Amendment No. 7, as of the date of this prospectus, we are unable to assess the effect on our business of any future rules which may be published by the Innovation Authority. See "Business — Governmental Regulation — *Israeli Regulations — Office of the Chief Scientist.*"

***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 (although one of our nominees to serve as an external director, Jerrold S. Gattegno, resides 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. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce civil claim against us and our executive officers and directors.

***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 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 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 Patent Law, 5727-1967, or the Patent 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 Patent 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 Patent Law, shall determine whether the employee is entitled to remuneration for his or her service inventions and the scope and conditions for such remuneration. Recent case law clarifies that the right to receive consideration for “service inventions” can be waived by the employee and that in certain circumstances, such waiver does not necessarily have to be explicit. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of the general Israeli contract laws. Further, the Committee has not yet determined one specific formula for calculating this remuneration (but rather uses the criteria specified in the Patent Law). Although our employees have agreed to assign to us 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 25% for 2016 and is expected to be reduced to 24% in 2017 and 23% in 2018 and thereafter. 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 “Material Tax Considerations — 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.-based 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 this duty 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 or consultants and our competitiveness may be diminished.

## Risks Primarily Related to the Offering and Our Ordinary Shares

### ***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 or 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 securities 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.

### ***You will experience immediate and substantial dilution in the net tangible book value of the ordinary shares you purchase in this offering.***

The initial public offering price of our ordinary shares will substantially exceed the net tangible book value per share of our ordinary shares immediately after this offering. Therefore, based on the anticipated public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, if you purchase our ordinary shares in this offering, you will suffer, as of December 31, 2016, immediate dilution of \$      per share, or \$      if the underwriters exercise their option to purchase additional ordinary shares, in net tangible book value after giving effect to the sale of      ordinary shares in this offering at the assumed initial public offering price of \$      per share (which is the midpoint of the price range set forth on the cover page of this prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and the application of the net proceeds as described in “Use of Proceeds.” As a result of this dilution, as of December 31, 2016, investors purchasing ordinary shares from us in this offering will have contributed      % of

the total amount of our total gross funding to date but will own only      % of our equity. In addition, if outstanding options to purchase our ordinary shares are exercised in the future, you will experience additional dilution. See “Dilution.”

***There has been no prior public market for our ordinary shares, and an active trading market may not develop.***

Prior to this offering, there has been no public market for our ordinary shares. We cannot predict the extent to which an active market for our ordinary shares will develop or be sustained after this offering, or how the development of such a market might affect the market price for our ordinary shares. The initial public offering price of our ordinary shares in this offering will be agreed upon between us and the underwriters based on a number of factors, including market conditions in effect at the time of the offering, which may not be indicative of the price at which our shares will trade following completion of the offering. Investors may not be able to sell their shares at or above the initial public offering price.

***The controlling share ownership position of Arkin Dermatology will limit our 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 sole shareholder, and after this offering is completed, we will continue to be controlled by Arkin Dermatology. Upon the closing of this offering, Arkin Dermatology will beneficially own approximately      % of the voting power of our outstanding ordinary shares, or approximately      % if the underwriters exercise their option to purchase additional ordinary shares in full. Therefore, even after this offering, Arkin Dermatology will have the ability to substantially influence us and exert significant control through this ownership position. For example, Arkin Dermatology will be able to control elections of directors, amendments of our organizational documents, or 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 will be 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, after the completion of this offering, we will be 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 will not comply, with the requirements that: (1) a majority of our board of directors consist of independent directors, and (2) we have a nominating committee composed entirely of independent directors with a written charter addressing such committee’s purpose and responsibilities. See “Management — Foreign Private Issuer and Controlled Company Status — Controlled Company.” Accordingly, you will 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.***

After this offering, there will be      ordinary shares outstanding. Sales by us or our shareholders of a substantial number of our ordinary shares in the public market following this offering, 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 sold in this offering will be 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.

Upon the closing of this offering, approximately \_\_\_\_\_ of our outstanding ordinary shares will be beneficially owned by shareholders that have agreed with the underwriters that, subject to limited exceptions, for a period of 180 days after the date of this prospectus, they will not directly or indirectly offer, pledge, sell, contract to sell, sell any option or contract to purchase or otherwise dispose of any ordinary shares or any securities convertible into or exercisable or exchangeable for ordinary shares, or in any manner transfer all or a portion of the economic consequences associated with the ownership of ordinary shares, or cause a registration statement covering any ordinary shares to be filed, without the prior written consent of \_\_\_\_\_, which may, at any time without notice, release all or any portion of the shares subject to the corresponding lock-up agreements. After the expiration of the lock-up period, these shares can be resold into the public markets in accordance with the requirements of Rule 144, subject to certain volume limitations. In addition, based on a registration rights agreement we intend to enter into, following 180 days after the closing of this offering and until the fifth anniversary thereafter, Arkin Dermatology will be entitled to require us to register its shares under the Securities Act for resale into the public markets. All shares sold pursuant to an offering covered by such registration statement will be freely tradable without restriction.

In addition, we intend to file one or more registration statements on Form S-8 with the Securities and Exchange Commission, or the SEC, covering all of the ordinary shares issuable under our 2014 Share Incentive Plan or 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 the company 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.

***We have broad discretion as to the use of the net proceeds from this offering and may not use them effectively.***

We currently intend to use the net proceeds from this offering to expand our clinical development program, finance, continue the development and commercialization plan of our product candidates and for general corporate purposes, including working capital requirements. For more information, see “Use of Proceeds.” However, our management will have 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 this 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 this offering in a manner that does not produce income.

***We cannot provide assurances regarding the amount or timing of dividend payments and may decide not to pay dividends in the future.***

We do not anticipate paying any cash dividends on our ordinary shares for at least the next several years following this offering. 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 the next several years. In addition, Israeli law limits our ability to declare and pay dividends, and may subject us to certain Israeli taxes.

***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 will rely 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.

***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 intend to establish a quorum requirement such that the quorum for any meeting of shareholders is 33⅓% of the issued share capital, as required under NASDAQ requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of record shareholders, instead of 33⅓% of the issued share capital.
- we also intend to adopt and approve material changes to equity incentive plans in accordance 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 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 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 “Management — Foreign Private Issuer and Controlled Company Status.”

In addition, as a foreign private issuer, we will be exempt 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, 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. In addition, we will not be 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 lost 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 will 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 will 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 anticipate that we will incur costs associated with corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002 (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. We expect that these rules and regulations will increase our legal and financial compliance costs, introduce new costs such as investor relations and stock exchange listing fees, and will make some activities more time-consuming and costly. Our board and other personnel will 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 second annual report that we file with the SEC after the closing of this offering, our management will be 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. We have not yet commenced 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. This process will require 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, we cannot predict the outcome of this determination 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. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. 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.

***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 this 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) the last day of our fiscal year following the fifth anniversary of the closing of this



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.

***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 controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. 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. In addition, 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, 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.

***There is a significant risk that we will be a passive foreign investment company for U.S. federal income tax purposes, which could result in materially adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.***

Based on our anticipated income and the composition of our income and assets, there is a significant risk that we will be a passive foreign investment company (“PFIC”) for U.S. federal income tax purposes at least until we start generating a substantial amount of active revenue. A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will be a 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. 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 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 the section headed Material Tax Considerations — U.S. Federal Income Tax Consequences”) of our ordinary shares with respect to any “excess distribution” received from us and any gain from a sale or other disposition of our ordinary shares. Please see “Material Tax Considerations — U.S. Federal Income Tax Consequences.”

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this prospectus that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- the adequacy of our financial and other resources, particularly in light of our history of recurring losses and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- our ability to complete the development of our product candidates;
- our ability to find suitable co-development partners;
- our ability to obtain and maintain regulatory approvals for our product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained;
- our ability to commercialize our pharmaceutical product candidates;
- our ability to obtain and maintain adequate protection of our intellectual property;
- our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost;
- our ability to establish adequate sales, marketing and distribution channels;
- acceptance of our product candidates by healthcare professionals and patients;
- the possibility that we may face third party claims of intellectual property infringement;
- the 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; 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 prospectus 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 prospectus 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 prospectus to conform these statements to actual results or to changes in our expectations.

**TRADEMARKS, SERVICE MARKS AND TRADE NAMES**

Solely for convenience, the trademarks, service marks, and trade names referred to in this prospectus 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 prospectus 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 prospectus 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.

**MARKET AND INDUSTRY DATA**

This prospectus 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 prospectus should be viewed with caution. We believe that information from these industry publications included in this prospectus is reliable.

Unless otherwise noted in this prospectus, IMS Health Incorporated, or IMS, is the data source for third-party industry data and forecasts. The information we obtained from IMS databases is dated as of June 30, 2015.

## USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$      million, or approximately \$      million if the underwriters exercise in full their option to purchase additional ordinary shares, based upon an assumed initial public offering price of \$      per share (which is the midpoint of the price range set forth on the cover page of this prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share would increase (decrease) the net proceeds we receive from this offering by \$      million, assuming that the number of ordinary shares offered, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of ordinary shares we are offering. Each increase or decrease of 1.0 million in the number of ordinary shares we are offering would increase or decrease the net proceeds we receive from this offering by \$      million, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions.

We intend to use the net proceeds from this offering as follows:

- approximately \$      million to fund our planned clinical trials of VERED for the treatment of rosacea;
- approximately \$      million to fund our planned clinical trials for TWIN for the treatment of acne;
- approximately \$      million to fund our planned clinical trials for SIRS-T for the treatment of acne;
- approximately \$      million to fund our planned clinical trials for E-06 for the treatment of symptomatic interdigital tinea pedis; and
- the remainder to fund other research and development activities, including the development of ivermectin cream, 1% and      other early stage pipeline products, as well as for working capital and other general corporate purposes.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty any or all of the particular uses for the net proceeds to be received upon the closing of this offering, or the amounts, if any, that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, if needed, the progress, cost and results of our nonclinical and clinical development programs, and whether we are able to enter into future product development partnerships and technology license arrangements. As a result, our management will have broad discretion in the application of the net proceeds, which may include uses not set forth above, and investors will be relying on our judgment regarding the application of the net proceeds from this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. We do not plan to use any proceeds from this offering for the repayment of any indebtedness.

Pending their use, we plan to invest the net proceeds from this offering in short and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government or to hold such proceeds as cash.

We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next . We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

**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 provision of the Companies Law.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2016, on:

- an actual basis;
- on as adjusted basis, to give effect to (1) the issuance and sale of ordinary shares in this offering at the assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (2) the effectiveness of our amended and restated articles of association upon the closing of this offering.

You should read this table in conjunction with our audited financial statements and related notes as of December 31, 2016, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus.

	As of December 31, 2016	
	Actual	As Adjusted
	(in thousands, except share and per share data)	
Cash and cash equivalents	\$ 7,001	\$
Loans from the controlling shareholder	\$ 37,338	\$
Shareholders’ equity (capital deficiency):		
Ordinary shares of NIS 0.1 par value per share; 8,775,783 shares authorized and 3,494,579 shares issued and outstanding, actual;      shares authorized and      issued and outstanding, as adjusted	82	
Additional paid-in capital	32,274	
Accumulated deficit	(63,693)	
Total capital deficiency	(31,337)	
Total capitalization	\$ 6,001	\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$      per share (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase or decrease the as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total shareholders’ equity and total capitalization by approximately \$      million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. Each increase or decrease of 1.0 million in the number of ordinary shares we are offering would increase or decrease the as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total shareholders’ equity and total capitalization by approximately \$      million, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions.

The preceding table excludes (i) 223,862 ordinary shares issuable upon the exercise of options to purchase ordinary shares outstanding under our 2014 Share Incentive Plan as of December 31, 2016, at a weighted average exercise price of \$2.86 per share; and (ii) an additional 125,596 ordinary shares reserved for future issuance under our 2014 Share Incentive Plan.



## DILUTION

If you invest in our ordinary shares in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the net tangible book value per ordinary share after this offering. Our net tangible book value (deficit) as of December 31, 2016, was \$(31.3) million, or \$(8.97) per ordinary share. Net tangible book value per ordinary share was calculated by:

- subtracting our liabilities from our tangible assets; and
- dividing the difference by the number of ordinary shares outstanding.

After giving effect to the issuance and sale of        ordinary shares in this offering at an assumed initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value on December 31, 2016 would have been approximately \$        million, or \$        per ordinary share. This represents an immediate dilution in the as adjusted net tangible book value of \$        per ordinary share to investors purchasing our ordinary shares in this offering.

The following table illustrates the immediate dilution to new investors:

Assumed initial public offering price per ordinary share	\$
Net tangible book value (deficit) per ordinary share as of December 31, 2016	\$ (8.97)
Increase in net tangible book value per ordinary share attributable to the offering	<u>\$</u>
As adjusted net tangible book value per share after this offering	<u>\$</u>
Dilution per ordinary share to new investors	<u><u>\$</u></u>
Percentage of dilution per ordinary share to new investors	<u><u>          </u></u> %

Each \$1.00 increase or decrease in the assumed initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the as adjusted net tangible book value as of December 31, 2016 by \$        per ordinary share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

Similarly, each increase or decrease of 1.0 million shares in the number of ordinary shares we are offering would increase or decrease the as adjusted net tangible book value as of December 31, 2016 by \$       , or \$(       ) per ordinary share, respectively, and would decrease or increase dilution to investors in this offering by \$(       ) and \$        per ordinary share, respectively, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions. The as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters' over-allotment option to purchase additional shares from us is exercised in full, and based on the assumed initial public offering price of \$        per ordinary share (which is the midpoint of the price range set forth on the cover page of this prospectus), the as adjusted net tangible book value would be \$        per ordinary share and the dilution per ordinary share to new investors in this offering would be \$       , after deducting the estimated underwriting discounts and commissions.

The table below summarizes, as of December 31, 2016, on the as adjusted basis described above, the differences for our existing shareholders and new investors in this offering, with respect to the number of ordinary shares purchased from us, the total consideration paid and the average per ordinary share price paid before deducting fees and offering expenses.

	Shares purchased		Total consideration		Average price per share
	Number	%	Amount	%	
Existing shareholder			\$		\$
New investors					
Total		100	\$	100	\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ million, and increase or decrease the percent of total consideration paid by new investors by less than a quarter of a percentage point, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table and discussion above excludes (i) 223,862 ordinary shares issuable upon the exercise of options to purchase ordinary shares outstanding under our 2014 Share Incentive Plan as of December 31, 2016, at a weighted average exercise price of \$2.86 per share; and (ii) an additional 125,596 ordinary shares reserved for future issuance under our 2014 Share Incentive Plan.

To the extent any options are issued under our equity incentive plans, or we issue additional ordinary shares in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

## SELECTED FINANCIAL DATA

The following table sets forth our selected historical financial data, which is derived from our financial statements, which have been prepared in accordance with U.S. GAAP. The selected balance sheet data as of December 31, 2015 and 2016 and our selected statement of operations data for the years ended December 31, 2015 and 2016 is derived from our audited financial statements included elsewhere in this prospectus. You should read this selected financial data in conjunction with, and it is qualified in its entirety by, reference to our historical financial information and other information provided in this prospectus including “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and related notes included elsewhere in this prospectus. The historical results set forth below are not necessarily indicative of the results to be expected in future periods.

	Year Ended December 31,	
	2015	2016
	(in thousands, except share and per share data)	
Statement of Operations Data:		
Research and development expenses	\$ 7,184	\$ 17,023
General and administrative expenses	2,463	3,733
Total operating loss	9,647	20,756
Financial expenses, net	13	15
Loss for the year	\$ 9,660	\$ 20,771
Basic and diluted loss per ordinary share (1)	\$ 2.76	\$ 5.94
Weighted average number of ordinary shares outstanding – basic and diluted	3,494,579	3,494,579

(1) Basic loss per ordinary share and diluted loss per ordinary share are the same because outstanding options would be anti-dilutive due to our net losses in these periods.

	As of December 31,	
	2015	2016
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 5,895	\$ 7,001
Total assets	8,244	10,985
Total liabilities	19,762	42,322
Accumulated deficit	(42,922)	(63,693)
Total capital deficiency	(11,518)	(31,337)

## MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of the prospectus contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under “Risk Factors” and elsewhere in this prospectus. See “Special Note Regarding Forward-Looking Statements.”*

### Overview

We are a clinical stage specialty pharmaceutical company developing both branded and generic topical dermatological drug products. Our strategy is to establish ourselves as a pure-play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases, including products utilizing our proprietary microencapsulation delivery system. Our management team has extensive experience in product development and commercialization, having served in prominent roles at several leading pharmaceutical and medical dermatology companies.

Our four branded product candidates are VERED, for the treatment of rosacea, TWIN and SIRS-T, for the treatment of acne, and E-06 for the treatment of symptomatic interdigital tinea pedis. VERED, TWIN and SIRS-T are based upon our proprietary microencapsulation delivery system. We plan to develop our current branded product candidates under the FDA’s 505(b)(2) regulatory pathway.

In addition to these branded drug product candidates, our product pipeline also includes the generic product candidate ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which is being developed in collaboration with Perrigo UK. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016.

Since our inception, we have incurred significant operating losses. We incurred net losses of \$9.7 million and \$20.8 million for the years ended December 31, 2015 and 2016, respectively. As of December 31, 2016, we had an accumulated deficit of \$63.7 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates from formulation development through nonclinical development and clinical trials, and seek regulatory approval and pursue commercialization of any approved product candidate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates. Furthermore, upon closing of this offering, we expect to incur additional expenses associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

On August 4, 2014, our former shareholders entered into a securities purchase agreement with our controlling shareholder, Arkin Dermatology, or the Purchase Agreement. The Purchase Agreement detailed the terms and conditions for the sale of the company to Arkin Dermatology in exchange for a cash payment in the amount of approximately \$10.5 million in addition to an earn out payment of up to \$17.0 million based on the achievement of certain development and revenue-related milestones. In connection with the Purchase Agreement, our executive officers and certain employees are entitled, subject to certain research and development milestones and other conditions, to a special bonus in an aggregate amount of up to \$3.0 million, of which \$0.9 and \$0.1 million were paid in each of the years 2014 and 2016 to our executive officers and certain employees, respectively. As of February 28, 2017 the remaining milestones were not yet achieved, and we have not recorded a liability regarding this special bonus.

## Collaboration Agreements

On April 27, 2015, we entered into a development, manufacturing and commercialization agreement, as amended on October 26, 2015, with Perrigo UK to work towards the objective of obtaining all FDA approvals necessary for the commercialization of ivermectin cream, 1%, in the United States. Under the terms of the agreement, Perrigo UK will conduct all regulatory, scientific, clinical and technical activities necessary to develop ivermectin cream, 1%, prepare and file an ANDA with the FDA, and gain regulatory approval to market ivermectin cream, 1%, in the United States. We granted Perrigo UK the right, title and interest in and to ivermectin cream, 1%, and agreed on each party's portion of the costs, including the allocation of costs related to development and litigation expenses associated with performance under the agreement. As soon as reasonably practical after final approval by the FDA of the ANDA, if approval is granted, Perrigo UK is required to use diligent efforts to commercialize ivermectin cream, 1%, in the United States. Perrigo UK has the sole and exclusive right to establish and control the prices and all other terms and conditions for the sales of ivermectin cream, 1%, in the United States and is required to do so in good faith without derogating from our right to benefit from the commercialization of ivermectin cream, 1%. We will be entitled to 50% of Perrigo UK's gross profits related to the sale of ivermectin cream, 1%, on a quarterly basis, for a period of 20 years following the first commercial sale of ivermectin cream, 1%, in the United States. The agreement may be terminated in the event of a material breach by one of the parties, certain potential infringement claims by third parties or an uncured insolvency or bankruptcy procedure of one of the parties. In addition, the agreement may be terminated if the gross profits relating to the sale of the product do not exceed a certain threshold or if the potential market for the product has been significantly reduced due to regulatory changes.

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

We will finance all out-of-pocket trial expenses (including materials), and the third party will reimburse us for 40% of the out-of-pocket clinical trial expenses as follows (a) in case of a success of obtaining FDA approval, by financing our share of the out-of-pocket litigation expenses, or (b) in case of failure to obtain the required FDA approval for the commercialization of the product candidate, by paying us back an amount equal to 40% of its out-of-pocket expenses.

On December 31, 2015, following entering into a transfer agreement with M. Arkin (1999) Ltd., an affiliate of our controlling shareholder, we entered into an agreement with Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel"), or the E-06 Perrigo Agreement, for the development, manufacturing and commercialization of E-06. According to the E-06 Perrigo Agreement, Perrigo Israel will conduct all regulatory, scientific, clinical and technical activities necessary to develop E-06. We will finance all out-of-pocket expenses incurred by Perrigo Israel in its performance under the E-06 Perrigo Agreement. We will pay Perrigo Israel approximately \$2.0 million upon NDA submission of E-06, and approximately \$3.0 million upon the approval by the FDA of such NDA. In addition, we will be required to pay royalties to Perrigo Israel on the percentage of net sales of the product (as defined in the agreement) ranging in the mid-single digits depending on the net sale volume of the product. The E-06 Perrigo Agreement includes termination clauses based on certain commercial events. In addition, the agreement includes mutual rights to terminate the agreement for cause (as further detailed in the agreement). We also have the right to terminate the agreement in the event that we determine that the product developed under this agreement does not satisfy the criteria established by us at our sole discretion.

## Financial Operations Overview

### *Revenues*

Since 2013, we have not recognized any revenue in our statements of operations and we do not expect to generate revenue from the sale of products in the near future.

### *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 laboratories 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 nonclinical 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 nonclinical studies;
- expenses incurred to acquire, develop and manufacture materials for use in nonclinical and other studies;
- expenses incurred from the purchase and transfer of E-06, one of our branded product candidates, from an affiliated company wholly owned by our controlling shareholder; 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 our research and development expenses to increase significantly over the next several years as we increase personnel expenses, including share-based compensation, commence Phase III clinical trials for VERED in the first half of 2018, complete the ongoing Phase II clinical trial for TWIN and SIRS-T, complete the ongoing Phase II clinical trials for E-06, complete the ongoing bioequivalence study for ivermectin cream, 1% and conduct other nonclinical studies and clinical trials and prepare regulatory filings for our product candidates.

Due to the inherently unpredictable and highly uncertain nature of clinical development processes, we cannot reasonably estimate the nature, timing and expenses of the efforts that will be necessary to complete the remainder of the development of our product candidates, or when, if

ever, material net cash inflows may commence from any of our product candidates. Clinical development timelines, the probability of success and development expenses can differ materially from expectations. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

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

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

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

#### *General and administrative expenses*

Our general and administrative expenses consist primarily of salaries and related expenses, including employee benefits and share based compensation expenses, legal and professional fees for auditors and other consulting expenses not related to research and development activities. Such expenses include the process of becoming a public company, patent registration expenses, depreciation of fixed assets related to general and administrative activities and other expenses, including rent, maintenance of facilities, insurance and office expenses.

We expect that our general and administrative expenses will increase as a result of increased personnel expenses, including share-based compensation, expanded infrastructure and higher consulting, legal and tax-related service fees associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and audit fees, investor relations expenses and director and officer insurance premiums associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

#### *Financial expenses, net*

Our financial expenses consist primarily 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:

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2016</b>
	<b>(in thousands)</b>	
Research and development expenses	\$ 7,184	\$ 17,023
General and administrative expenses	2,463	3,733
Total operating loss	9,647	20,756
Financial expenses, net	13	15
Loss for the year	<u>\$ 9,660</u>	<u>\$ 20,771</u>

**Year ended December 31, 2015 compared to year ended December 31, 2016****Research and development expenses**

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

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2016</b>
	<b>(in thousands)</b>	
Payroll and related expenses	\$ 2,647	\$ 3,629
Clinical trials expenses	517	9,686
Professional consulting and subcontracted work	2,001	1,830
In-process research and development acquired	431	—
Other	1,588	1,878
Total research and development expenses	<u>\$ 7,184</u>	<u>\$ 17,023</u>

Our research and development expenses were \$7.2 million for the year ended December 31, 2015, compared to \$17.0 million for the year ended December 31, 2016. The increase of \$9.8 million is mainly attributed to an increase of \$9.2 million in clinical trial expenses due to the Phase II clinical trials of TWIN and E-06 and bioequivalence study of ivermectin cream, 1%, and to an increase of \$1.0 million in payroll and related expenses due to an increase in the number of our employees, to bonuses granted and paid during 2016 and to salary increases. These increases in clinical trial expenses were partially offset by a decrease in share based compensation expenses and a decrease of \$0.4 million as a result of the transfer of E-06 to us from an affiliated company in 2015.

**General and administrative expenses**

Our general and administrative expenses were \$2.5 million for the year ended December 31, 2015, compared to \$3.7 million for the year ended December 31, 2016. The increase of \$1.2 million is mainly attributed to an increase of \$0.7 million in professional fees due to the initial public offering process and to an increase of \$0.4 million in payroll and related expenses due to bonuses that were recognized and paid during 2016 and salary raises that were partially offset by decrease in share based compensation expenses.

**Financial expenses, net**

Our financial expenses, net, were immaterial for the years ended December 31, 2015 and 2016.



## 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. We do not currently have any approved product candidates.

Since our inception through December 31, 2016, we have funded our operations primarily through the issuance of equity securities and loans from our shareholders in the aggregate amount of \$64.2 million, funding received from the Innovation Authority in the aggregate amount of approximately \$1.4 million and from amounts received pursuant to past collaboration agreements in the aggregate amount of \$28.5 million. As of December 31, 2016, our cash and cash equivalents was \$7.0 million.

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

	Year Ended December 31,	
	2015	2016
	(in thousands)	
Net cash used in operating activities	\$ (8,044)	\$ (18,495)
Net cash used in investing activities	(210)	(391)
Net cash from financing activities	13,572	20,000
Increase in cash and cash equivalents	<u>\$ 5,301</u>	<u>\$ 1,106</u>

### Operating Activities

Net cash used in operating activities was \$8.0 million during the year ended December 31, 2015, compared to \$18.5 million during the year ended December 31, 2016.

Net cash used in operating activities in the year ended December 31, 2015 primarily resulted from our loss for the period of \$9.7 million and \$0.6 million used as an advanced payment to our CRO in connection with the ongoing Phase II clinical trial for TWIN, partially offset by \$1.1 million of share-based compensation expenses, a net reduction of \$0.4 million in working capital, \$0.4 million in-process research and development acquired due to the transfer of E-06 and \$0.3 million of depreciation of property and equipment.

Net cash used in operating activities in the year ended December 31, 2016 primarily resulted from our loss of \$20.8 million during the period, and from \$1.4 million used as advance payments for long term receivables in connection with the ongoing Phase II clinical trial for TWIN and the collaboration agreement for ivermectin cream, 1%. This amount was partially offset by \$1.0 million of share-based compensation expenses, a net reduction of \$2.3 million in working capital and \$0.4 million depreciation of property and equipment.

### Investing Activities

Net cash used in investing activities was \$0.2 million during the year ended December 31, 2015, compared to net cash used in investing activities of \$0.4 million during the year ended December 31, 2016. Net cash used for investing activities during the years ended December 31, 2015 and 2016 was primarily related to purchase of property, plant and equipment.

### Financing Activities

Net cash from financing activities was \$13.6 million during the year ended December 31, 2015, compared to \$20.0 million during the year ended December 31, 2016. Financing activities in these years consisted of loans received from our controlling shareholder.

### ***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 and commercialization of our product candidates. We believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least . 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.

In its report accompanying our audited financial statements for the year ended December 31, 2016, included elsewhere in this prospectus, our independent registered accounting firm included an explanatory paragraph stating that our recurring losses from operations and lack of sufficient working capital raise substantial doubt as to our ability to continue as a going concern. In general, a “going concern” opinion means that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without an additional infusion of capital from external sources, such as the proceeds from this offering. In addition, having a going concern qualification may make it less likely that investors or commercial banks will be willing to finance our operations. If we are unable to achieve these goals, our business will be in jeopardy and we may not be able to continue operations and may have to liquidate our assets. In such case, investors might receive less than the value at which those assets are carried on our financial statements, and it is likely that investors in this offering would lose all or a part of their investment.

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 nonclinical 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 for our product candidates;
- the expenses of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the expenses of, and timing for, strengthening our manufacturing agreements for production of sufficient clinical and commercial quantities of our product candidate; and
- the potential expenses of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through the net proceeds from this offering, 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.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2016:

	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
	(in thousands)				
Operating leases obligations (1)	\$1,705	\$419	\$1,286	\$—	\$—
Total	\$1,705	\$419	\$1,286	\$—	\$—

- (1) Operating lease obligations consist of payments pursuant to several lease agreements that were scheduled to expire on December 31, 2020. On January 13, 2016 (and for a term ending on February 28, 2017), we entered into a short term sub-lease agreement with one of the tenants in the facility in which our offices are located. Starting from March 1, 2017 our total lease payments on all of our facilities will increase to approximately \$36,000 per month.

Under the specific terms of the funding arrangement between the Company and the Innovation Authority, royalties of 3.5% to 25% are payable on the sale of products developed from product candidates funded by the Innovation Authority, 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. As of December 31, 2016 the Company does not have any royalty liability to Innovation Authority.

In addition, we will finance all out-of-pocket expenses incurred by Perrigo Israel in performing its services under the E-06 Perrigo Agreement. We will pay Perrigo Israel approximately \$2.0 million upon NDA submission of E-06, and approximately \$3.0 million upon the approval by the FDA of such NDA. In addition, we will be required to pay royalties to Perrigo Israel on the net sales of the product (as defined in the E-06 Perrigo Agreement) ranging in the mid-single digits, depending on the net sales volume of the product.

### Off-Balance Sheet Arrangements

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

### Quantitative and Qualitative Disclosure 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 in the following paragraph.

#### Interest Rate Risk

We do not anticipate undertaking any significant long-term borrowings. At present, our investments consist primarily of cash and cash equivalents. We may invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments may 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, 2016, all of our financing has been in U.S. dollars and the vast majority of our liquid assets are held in U.S. dollars. Furthermore, while we anticipate that a portion of our expenses, principally salaries and related personnel expenses in Israel, will continue to be denominated in NIS, we expect to incur an increasing amount of expenses in U.S. dollars as we progress in the development and the regulatory processes of our product candidates. Changes of 5% in the U.S. dollar/NIS exchange rate would have increased/decreased operating expenses by approximately 2% during the fiscal year ended on December 31, 2016. 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 “Risk Factors — Exchange rate fluctuations between the U.S. dollar, the NIS 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 prospectus and for the periods under review, fluctuations in the currencies exchange rates have not materially affected our results of operations or financial condition.

We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

### ***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.

### ***Significant Accounting Policies and Estimates***

We prepare our financial statements in conformity with U.S. GAAP. We describe our significant accounting policies and estimates more fully in Note 2 to our financial statements as of and for the year ended December 31, 2015, contained elsewhere in this prospectus. 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 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 financial statements included in this prospectus, 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 share-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 as well as our results and the number of options that will vest. These parameters include the expected volatility of our share price over the expected term of the options, the risk-free interest rate assumption, the share option exercise and forfeitures behaviors and expected dividends.

*Fair value of ordinary shares.* Our shares are not publicly traded, thus, the fair value of the ordinary shares, for purpose of determining the exercise price for share-based payment awards, was determined in good faith by our management and approved by our board of directors. Our management considered the fair value of our ordinary shares based on a number of objective and subjective variables, consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Private-Held-Company Equity Securities issued as Compensation, referred to as the AICPA Practice Aid.

*Volatility.* The expected share price volatility is based on the historical volatility of comparable companies.

*Risk-free interest rate.* The risk-free interest rate is based on observed interest rates appropriate for the expected term of the options granted in dollar terms.

*Expected term.* The expected term of options granted represents the period of time that the options are expected to be outstanding. Since adequate historical experience is not available to provide a reasonable estimate, the expected term was computed by averaging the vesting schedule of the options and the last available exercise date (the contracted expiry date).

*Expected dividend yield.* We have never declared or paid any cash dividends and we do not plan to pay cash dividends in the foreseeable future.

The underlying data used for computing the fair value of the options are as follows:

	2015	2016
Value of one ordinary share	<u>\$11.35</u>	<u>\$21.59</u>
Dividend yield	<u>0%</u>	<u>0%</u>
Expected volatility	<u>62.46% – 66.22%</u>	<u>68.45% – 79.1%</u>
Risk-free interest rate	<u>1.61% – 1.81%</u>	<u>0.95% – 1.34%</u>
Expected term	<u>5.5 – 7.5 years</u>	<u>5 – 6.71 years</u>

These assumptions represent our best estimates and involve inherent uncertainties and the application of our judgment. As a result, if we use significantly different assumptions or estimates, our share-based compensation expense could be materially different.

The following table presents the grant dates, number of underlying shares and related exercise prices of options granted to employees, as well as the estimated fair value of the underlying ordinary shares on the grant date.

Date of grant	Number of shares subject to awards granted	Class of shares subject to the awards granted	Type of equity instrument awarded	Exercise price per share	Estimated fair value per ordinary share at grant date
March 29, 2015	151,299	ordinary	options	\$ 2.86	\$ 11.35
April 12, 2015	22,141	ordinary	options	\$ 2.86	\$ 11.35
August 2, 2016	50,422	ordinary	options	\$ 2.86	\$ 21.59
February 12, 2017	29,906	ordinary	options	\$ 2.86	

Based on the assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, the intrinsic value of the awards outstanding as of      , 2017 was \$      million, of which \$      million related to vested options and \$      million related to unvested options.

*2015 awards.* In March and April 2015, we granted 173,440 options to our executive officers to purchase ordinary shares. Our board of directors set an exercise price of \$2.86 per share for these options. Twenty-five percent of the options vest on the first anniversary of the vesting commencement date (August 4, 2014) and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of the grant date.

In preparation for our initial public offering, we performed in April 2016 a retrospective valuation, with the assistance of a third party valuation firm, of our ordinary shares as of March and April 2015, which determined that their fair value at that time was \$11.35 per share. For the purpose of determining our enterprise value, we used the discounted cash flow, or DCF, method. Under the DCF method, our projected after-tax cash flows available to return to holders of invested capital were discounted back to present value, using the discount rate. Since it is not possible to project our after-tax cash flows beyond a limited number of years, the DCF method relies on determining a “terminal value” representing the aggregate value of the future after-tax cash flows after the end of the period for which annual projections are possible. The discount rate, known as the weighted average cost of capital, or WACC, accounts for the time value of money and the appropriate degree of risk inherent in a business. The DCF method requires significant assumptions, in particular, regarding our projected cash flows and the discount rate applicable to our business. For the purpose of that valuation we applied a discount rate of 18%, and projected after-tax cash flows based on the probabilities of the realization of the scenario in which we receive FDA approval.

Having determined our enterprise value, we allocated it among the different elements of our share capital using the option pricing method, or OPM. Under the OPM, each security — ordinary shares and options — is treated as a call option having an exercise price based on the amount and optimal conversion price. The value of the call option is determined using the Black-Scholes option pricing model. The Black-Scholes model requires significant assumptions, in particular, the time until investors in our company would experience an exit event and the volatility of our ordinary shares.

*2016 awards.* In August 2016, we granted 50,422 options to our executive officers to purchase ordinary shares. Our board of directors set an exercise price of \$2.86 per share for these options. Twenty-five percent of the options vest on the first anniversary of the vesting commencement date and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of the grant date.

In September 2016 we performed a retrospective valuation, with the assistance of a third party valuation firm, of our ordinary shares as of August 2016, which determined that their fair value at that time was \$21.59 per share. For the purpose of determining our enterprise value, we used the discounted cash flow, or DCF, method. Under the DCF method, our projected after-tax cash flows available to return to holders of invested capital were discounted back to present value, using the discount rate. Since it is not possible to project our after-tax cash flows beyond a limited number

of years, the DCF method relies on determining a “terminal value” representing the aggregate value of the future after-tax cash flows after the end of the period for which annual projections are possible. The discount rate, known as the weighted average cost of capital, or WACC, accounts for the time value of money and the appropriate degree of risk inherent in a business. The DCF method requires significant assumptions, in particular, regarding our projected cash flows and the discount rate applicable to our business. For the purpose of that valuation we applied a discount rate of 20%, and projected after-tax cash flows based on the probabilities of the realization of the scenario in which we receive FDA approval.

Having determined our enterprise value, we allocated it among the different elements of our share capital using the option pricing method, or OPM. Under the OPM, each security — ordinary shares and options — is treated as a call option having an exercise price based on the amount and optimal conversion price. The value of the call option is determined using the Black-Scholes option pricing model. The Black-Scholes model requires significant assumptions, in particular, the time until investors in our company would experience an exit event and the volatility of our ordinary shares.

*2017 awards.* In February 2017, we granted 29,906 options to one of our executive officers to purchase ordinary shares. Our board of directors set an exercise price of \$2.86 per share for these options. Twenty-five percent of the options vest on the first anniversary of the vesting commencement date and the rest vest quarterly over the following three years. Upon the occurrence of a merger or sale (as such term is defined in the agreement), 100% of the then unvested options shall become fully vested, provided, that the grantee is an employee at such time. The options expire on the tenth anniversary of the grant date.

*Future option awards.* Following the completion of our initial public offering and the listing of our shares on the NASDAQ Global Market, the determination of the fair market value of our ordinary shares for purposes of setting the exercise price of future option awards or other share-based compensation to employees and other grantees will no longer require good faith estimates by our board of directors based on various comparisons or benchmarks

### **Recent Accounting Pronouncements**

We are currently evaluating the impact of the U.S. GAAP standards as issued by the FASB that are effective for the first time for the financial year beginning on or after January 1, 2016 on our financial statements. See Note 2 to our annual financial statements included elsewhere in this prospectus.

### **JOBS Act**

On April 5, 2012, the JOBS Act was signed into law. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This means that an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to utilize this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. In addition, as a result of this election, our future financial statements may not be comparable to those of public companies that are not emerging growth companies and are required to comply with public company effective dates for new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we also elected or may elect to rely on other 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) the last day of our fiscal year following the fifth anniversary of the closing of this 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.



## BUSINESS

### Overview

We are a clinical stage specialty pharmaceutical company developing both branded and generic topical dermatological drug products. Our strategy is to establish ourselves as a pure-play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases, including products utilizing our proprietary microencapsulation delivery system. Our management team has extensive experience in product development and commercialization, having served in prominent roles at several leading pharmaceutical and medical dermatology companies.

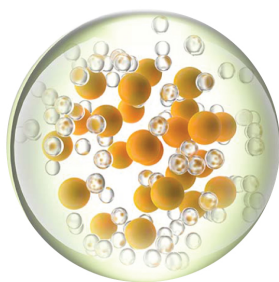
Our four branded product candidates are: VERED, for the treatment of rosacea, TWIN and SIRS-T, for the treatment of acne, and E-06 for the treatment of symptomatic interdigital tinea pedis. VERED, TWIN and SIRS-T are based upon our proprietary microencapsulation delivery system. Subject to an End of Phase II meeting to be scheduled with the FDA, we expect to commence two pivotal Phase III clinical trials for VERED in the United States in the first half of 2018 and expect to report top-line data in the first half of 2019. In May 2016, we initiated a Phase II clinical trial for TWIN in the United States, and we expect to report top-line data in mid-2017. We intend to use the data from this trial to support the commencement of pivotal Phase III trials for both TWIN and SIRS-T. In September 2016, we commenced a Phase II clinical trial for E-06 for the treatment of symptomatic interdigital tinea pedis, a fungal infection between the toes accompanied by stinging and burning and expect to report top-line data from this trial in the second half of 2017. We plan to develop our current branded product candidates under the 505(b)(2) regulatory pathway of the FDA.

In addition to these branded drug product candidates, our product pipeline also includes the generic product candidate ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which is being developed in collaboration with Perrigo UK Finco Limited Partnership, or Perrigo UK. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016.

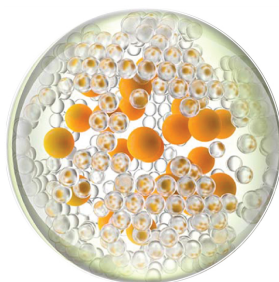
Our microencapsulation delivery system is based on silica and is formed around the active substances using our proprietary ‘sol-gel’ processes. Each ‘sol-gel’ process starts from silica precursor(s). These precursor(s) polymerize under controlled conditions to form colloidal silica particles, which constitutes the “sol” that continue interacting until a silica shell, which constitutes the “gel,” is constructed around the active substances.

As the reaction conditions are controlled, the silica shell can be shaped to form microcapsules of varied particle size distribution and diverse release rate profiles. We believe our silica-based delivery system improves the tolerability of topical dermatological drug products by creating a protective silica barrier between the drug substance and the skin and by controlling the release rate of the drug substance. Our delivery system also has the potential to enable production of novel fixed-dose combinations that otherwise would not be stable by encasing drug substances within the protective silica shell based on stability data. Silica is an inorganic inert excipient, which the FDA has already approved as a safe excipient for topical drug products. We believe the use of silica as a delivery system will allow for shorter regulatory approval process for our branded product candidates compared with delivery systems based on novel excipients.

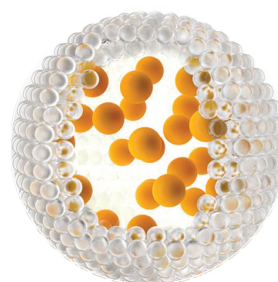
The images below illustrate our proprietary ‘sol-gel’ process:



Silica monomers and drug substances are emulsified together



Silica monomers migrate to the oil/water interface in a well-controlled process



A silica shell is formed

### Overview of Our Product Candidates

VERED is an innovative topical formulation containing 5% encapsulated benzoyl peroxide, or E-BPO, that we are developing for the treatment of rosacea. If approved, we expect VERED to be the first product containing encapsulated benzoyl peroxide for the treatment of rosacea. We believe VERED, if approved, has the potential to redefine the standard of care for the treatment of rosacea, a chronic skin disorder characterized by facial redness and inflammatory lesions. According to the U.S. National Rosacea Society, approximately 16 million people in the United States are affected by rosacea. According to a study we commissioned, approximately 4.8 million people in the United States experience subtype II symptoms and physicians estimate that they treat only 20% of the U.S. rosacea population. The topical drugs approved by the FDA to treat subtype II rosacea generated aggregate revenues of approximately \$420 million in the United States for the 12 months ended June 30, 2015. We evaluated VERED in a double blind, randomized, dose-ranging Phase II clinical trial involving 92 adult patients at ten centers in the United States. Based on the results of this trial, VERED has demonstrated statistically significant improvements compared to the control vehicle group in achieving the IGA success co-primary endpoint ( $p=0.0013$ ) and in reducing papulopustular-lesions based on the percentage change in the inflammatory lesion count from baseline at week 12 ( $p=0.02$ ). VERED has also shown to be well tolerated and its safety profile is similar to that of vehicle. Subject to an End of Phase II meeting to be scheduled with the FDA, we expect to commence two pivotal Phase III clinical trials for VERED in the United States in the first half of 2018 and expect to report top-line data in the first half of 2019.

TWIN is a novel, non-antibiotic topical cream formulation that we are developing for the treatment of acne. Acne is one of the three most prevalent skin conditions in the world and is the most commonly treated skin disorder in the United States. According to the American Academy of Dermatology, acne affects approximately 40 to 50 million people in the United States alone, of which approximately 10% are treated with prescription medications. The North American market for topical prescription drugs for acne was estimated to be approximately \$1.7 billion for the 12 months ended June 30, 2015. The leading topical drug product for 2015 was Epiduo, a fixed-dose combination of benzoyl peroxide and adapalene. TWIN is under development as a fixed-dose combination of benzoyl peroxide and tretinoin. These active substances have been separately encapsulated in silica using our proprietary technology. In nonclinical stability tests, encapsulation stabilized tretinoin in the presence of benzoyl peroxide, and in nonclinical skin irritation studies conducted in minipigs, it reduced irritation and improved the tolerability for TWIN. We believe that reduced irritation will enhance patient compliance. We initiated a Phase II clinical trial for TWIN in the United States in May 2016, and we expect to report top-line data in mid-2017.

We are also developing SIRS-T, a topical cream containing encapsulated tretinoin for the treatment of acne. The topical tretinoin drugs most commonly used to treat acne generated aggregate revenues of approximately \$529 million in the United States for the 12 months ended

June 30, 2015. While fixed-dose combination drugs like Onexton, Ziana and Epiduo are most commonly used as first-line treatments in cases of moderate and severe acne and as second-line treatments in cases of mild acne, antiseptics, such as benzoyl peroxide, or retinoids, such as tretinoin or adapalene, are used as first-line treatment in cases of mild acne. We believe that a more tolerable tretinoin drug product will improve patient compliance. We intend to leverage data from the ongoing TWIN Phase II clinical trial, which is evaluating two different concentrations of encapsulated tretinoin. We plan to request an End of Phase II meeting with the FDA for both TWIN and SIRS-T following the completion of the ongoing Phase II trial for TWIN.

E-06 is a fixed-dose combination of an antifungal drug substance and a mid-potency steroid that is being developed for the treatment of symptomatic interdigital tinea pedis. The incidence rate of interdigital tinea pedis in the U.S. population is estimated to be approximately 3% to 10%, and we believe approximately 20% of that population seeks treatment. The ultimate goal of treatment is to eradicate the infection, which is generally accomplished through use of a topical antifungal agent. Until the infection is eradicated, the involved cutaneous tissues can remain inflamed and painful. Most forms of inflammation can be reduced or eliminated by the use of steroids. E-06 is designed to treat the underlying fungal infection as well as to rapidly relieve inflammation, which we believe will improve patient comfort and compliance. In September 2016, we commenced a Phase II clinical trial for E-06, with top-line data expected in the second half of 2017.

As of the date of this prospectus, no deaths or other serious adverse events have been reported in any of our ongoing clinical trials.

In addition to these branded drug product candidates, our product pipeline also includes the generic product candidate including ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea, which is being developed in collaboration with Perrigo UK. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016.

The following table summarizes the development pipeline for our branded and generic product candidates:

Product Candidate	Indication	Status	Upcoming Milestone
VERED	Papulopustular (subtype II) rosacea	Preparing for Phase III clinical trial	Initiate pivotal Phase III clinical trials first half of 2018
TWIN	Acne vulgaris	Phase II clinical trial ongoing	Top-line Phase II clinical trial results mid-2017
SIRS-T	Acne vulgaris	Preparing for Phase III clinical trial	Initiate Phase III clinical trials second half of 2018
E-06	Symptomatic interdigital tinea pedis	Phase II clinical trial ongoing	Top-line Phase II clinical trial results second half of 2017
Ivermectin cream, 1%	Papulopustular (subtype II) rosacea	Bioequivalence study ongoing	ANDA submission upon study completion

### Corporate and Management Experience

Since 2007, we have been focused on the development of dermatological drug products. In 2014, we were acquired by Arkin Dermatology Ltd., or Arkin Dermatology. Mr. Moshe Arkin, our chairman of the board of directors, owns 100% of the share capital of Arkin Dermatology. Mr. Moshe Arkin has vast experience in the development and commercialization of dermatology drug products, having held leadership roles in several dermatology companies, and has extensive

ties to leading innovative and generic drug companies. Among other positions, Mr. Moshe Arkin headed Agis, growing it into a leading U.S. dermatological company until its acquisition by Perrigo Company in March 2005 for \$850 million. Our chief executive officer, Alon Seri-Levy, has considerable experience in the field of drug development and computer-aided drug design.

### Our Strengths

We believe we are well positioned to develop and commercialize treatments for skin diseases based on the following.

- *Diversified clinical stage product pipeline.* We are currently conducting a Phase II clinical trial for TWIN in acne, for which we expect to report top-line data in mid-2017, and a Phase II trial for E-06 in tinea pedis, for which we expect to report top-line data in the second half of 2017. We are also scheduled to commence two pivotal Phase III trials for VERED in rosacea in the first half of 2018. We intend to commence pivotal Phase III clinical trials for SIRS-T in the second half of 2018 based on the results of our ongoing TWIN Phase II clinical trial. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016 and we expect to submit an ANDA to the FDA after completion of this study.
- *Expertise in generic drug development and commercialization.* We have an established collaboration with Perigo UK to develop ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea. Our intellectual property and formulation teams also have considerable expertise in the identification and development of generic dermatological products and continue to identify new opportunities to expand our pipeline of generic product candidates. Furthermore, Mr. Moshe (Mori) Arkin, who serves as the chairman of our board of directors, has substantial experience leading companies focused on the development and commercialization of generic drugs.
- *Proprietary microencapsulation drug delivery system.* Our silica-based delivery system is designed to improve the tolerability of topical dermatological drug products by entrapping drug substances in porous silica microcapsules, thereby creating a protective barrier between the drug substance and the skin and controlling the release rate of the entrapped substance. This delivery system is designed to substantially improve the stability of topical fixed-dose combinations of non-compatible drug substances, allowing us to produce stable fixed-dose combinations of active ingredients that have been well tolerated in the clinical trials we have conducted to date.
- *Experienced management team.* Our executive management team has extensive experience in the development and commercialization of dermatology drug products. Mr. Moshe (Mori) Arkin, who serves as the chairman of our board of directors, has held leadership roles in several innovative and generic drug companies. Mr. Arkin was the chairman of Agis Industries Ltd., expanding it into becoming a leading pharmaceutical company in the United States until its acquisition by Perrigo Company where he served as vice chairman. Our chief executive officer, Alon Seri-Levy, has considerable experience in the field of drug development and computer-aided drug design.
- *Efficient FDA regulatory pathway.* We expect the review process for our branded product candidates to be conducted according to the FDA's 505(b)(2) regulatory pathway, which permits us to rely upon the FDA's previous findings of safety and efficacy of an approved product. Silica, which forms the basis of our proprietary microencapsulation delivery system, is an inorganic inert excipient already approved by the FDA as a safe excipient in other topical drug products.
- *Barriers to entry for competing products.* We have developed an in-depth understanding of the critical chemical and physical parameters affecting the release rate of active pharmaceutical ingredients from microcapsules made of silica. This complex

understanding is essential to obtain a desired, well-defined, controlled-release profile for each drug candidate and in order to maintain it to support commercial scale production. In addition to our patent portfolio, we have considerable proprietary know-how that permits us to employ our proprietary process to produce a silica-based delivery system with a well-defined, controlled-release profile of the drug candidate. If any of VERED, TWIN or SIRS-T are approved for marketing, we believe that our patent portfolio, combined with our know-how, will create a barrier to entry for generic drugs with comparable and bioequivalent release profiles.

### **Our Strategy**

Our strategy is to establish ourselves as a pure-play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases, including products utilizing our proprietary microencapsulation delivery system. To achieve this objective, the key elements of our strategy are:

- *Complete development of our branded and generic product candidates.* We intend to advance our branded and generic product candidates through clinical development and obtain regulatory approvals. In certain cases, we will collaborate with pharmaceutical partners in order to expedite this process.
- *Expand our diversified pipeline.* We intend to expand our portfolio of branded product candidates to also include new chemical entities that may address additional skin conditions. We will focus on skin conditions where we believe there is a need for improved drug therapies.
- *Improve efficacy and tolerability of existing drugs.* We intend to continue to identify new opportunities to apply our proprietary delivery system to other drug substances in order to improve efficacy and tolerability of additional approved topical drug products, with a goal of improving patient comfort, compliance and quality of life.
- *Maximize commercial potential of our product candidates.* We intend to independently commercialize our product candidates in the United States, if approved. In other markets, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.
- *Expand and protect our intellectual property.* We intend to expand and protect our intellectual property in the areas of silica-based delivery systems, encapsulation processes and drug formulations in order to maintain a defensible and valuable intellectual property portfolio.

### **Dermatology Market Overview**

Medical dermatology focuses on therapeutic solutions to treat skin conditions such as psoriasis, atopic dermatitis, acne, rosacea, and tinea pedis. These diseases affect millions of people worldwide and can have significant, multidimensional effects on patients' quality of life, including their physical, functional and emotional well-being. The symptoms of medical dermatology diseases are often visible, and as a result, patients can be motivated to seek treatment and to pay out-of-pocket for this treatment.

We believe that an overall lack of innovation in research and development of new dermatology products has resulted in limited number of effective treatment options. For example, the mechanisms of action most commonly used to treat acne have been available for over 30 years. Consequently, the few truly innovative therapies launched over the past few decades have resulted in significant sales. Furthermore, because dermatology medications have relatively short clinical trials compared to other pharmaceuticals, development costs are contained.

We also believe that the field of dermatology offers an exceptional opportunity to build relationships with opinion leaders, advocacy groups and medical practitioners. We believe that the consolidation in the dermatology industry has resulted in an enhanced opportunity for a medical dermatology-focused company such as ours to build relationships with these stakeholders and has contributed to the availability of a large and growing talent pool of experienced employees who can make significant contributions to us.

In addition, the fact that the U.S. market is served by a relatively small, easily targeted number of practicing dermatologists, could allow a small and dedicated sales force to efficiently cover the customer base.

## **Branded Product Candidates**

### ***VERED for Papulopustular (Subtype II) Rosacea***

*VERED product candidate.* VERED is an innovative 5% encapsulated benzoyl peroxide topical formulation, or E-BPO 5%, under development for the treatment of rosacea. To our knowledge, VERED is the first product candidate to contain encapsulated benzoyl peroxide, and we believe VERED, if approved, has the potential to redefine the standard of care for the treatment of rosacea. In 2012, we completed a Phase II trial for VERED in the United States that demonstrated statistically significant improvements compared to the control vehicle in achieving the IGA success co-primary endpoint ( $p=0.0013$ ) and in reducing papulopustular-lesions based on the percentage change in the inflammatory lesion count from baseline at week 12 ( $p=0.02$ ). Moreover, the safety of VERED was similar to that of the vehicle. We expect to utilize the FDA's 505(b)(2) regulatory pathway in seeking approval of VERED and therefore intend to rely in part on data from studies that we have not conducted or sponsored and for which we have not obtained a right of reference in support of an NDA.

*Market opportunity.* Rosacea is a chronic skin disorder characterized by persistent facial erythema and temporary inflammatory lesions (papules, pustules or both). Rosacea generally affects adults aged 30 and above and is more prevalent in women and adults with fair-skin. The papulopustular subtype resembles acne, except that comedones are absent, and patients may report associated burning and stinging sensations. According to the U.S. National Rosacea Society, approximately 16 million people in the United States alone are affected, of which 4.8 million experience subtype II symptoms. The topical drugs most commonly used to treat rosacea generated aggregate revenues of approximately \$420 million in the United States for the 12 months ended June 30, 2015.

*Needs addressed.* Benzoyl peroxide is approved by the FDA for the treatment of acne and is widely considered to be safe and effective. According to a 1983 study by Montes et al., it was also found to be an effective treatment for rosacea but caused irritation. Our encapsulation delivery system creates a silica-based barrier between each benzoyl peroxide crystal and the skin and as a result is designed to reduce irritation typically associated with topical application of benzoyl peroxide, possibly making it tolerable to rosacea-affected skin. The release profiles of the drug substance were designed to reduce irritation while maintaining efficacy. In our Phase II clinical trial, our encapsulated benzoyl peroxide product candidate was tolerable and effective. Silica is chemically inert, photochemically and physically stable, and has been shown to be safe in products approved for topical use.

*Nonclinical results.* We completed a Good Laboratory Practices, or GLP, 13-week repeat-dose toxicity trial in Göttingen minipigs, including toxicokinetics. No systemic effects or adverse local effects were noted, which suggests that VERED may be safe for topical use.

*Phase II trial design.* In August 2012, we completed a double blind, randomized, dose-ranging Phase II trial for VERED involving 92 adult patients at ten centers in the United States. The VERED Phase II trial had two co-primary endpoints: Success in Investigator Global Assessment, or IGA, namely, a two-grade reduction in IGA on a scale of 0 to 4 ("clear", "almost clear", "mild",

“moderate”, “severe”) with “clear” or “almost clear” at week 12; and a reduction in the mean inflammatory lesion count at week 12 (end of trial). In this trial, we defined “clear” as no inflammatory lesions present with no or very mild erythema immediately localized to and around where inflammatory lesions were present, and “almost clear” as very mild erythema immediately localized to and around inflammatory lesions with very few small papules/pustules. The FDA asked us to modify our definition of “clear” on the IGA scale so that the category of “clear” represents the absence of the disease. The second co-primary endpoint was the change from baseline in inflammatory lesions (papules and pustules) count at end of trial. All patients were 18 years of age or older, with 12 or more inflammatory lesions at enrollment. Patients were randomly divided into three groups of 30 to 32 patients each and received a once daily dose, with one group receiving VERED (E-BPO 5%), a second group receiving a 1% concentration of encapsulated benzoyl peroxide, or E-BPO 1%, and a third control group receiving the vehicle (placebo) alone. The evaluator rated the following signs and symptoms of local skin irritation on a scale of 0 to 3 (“none”, “mild”, “moderate”, “severe”): dryness, scaling, pruritus, stinging and burning. Information on adverse events was also collected.

**VERED Phase II trial results.** The table below summarizes the P-values obtained in the Phase II clinical trial. Both E-BPO 1% and VERED demonstrated statistically significant improvement in comparison to the vehicle in reducing papulopustular-lesions based on the percentage change in the inflammatory lesion count from baseline at week 12,  $p=0.014$  and  $p=0.02$ , respectively, and VERED also demonstrated statistically significant improvement in comparison to the vehicle in achieving the IGA success co-primary endpoint ( $p=0.0013$ ). The FDA requirement to modify our definition of “clear” on the IGA scale so that the category of “clear” represents the absence of the disease affects the categorization of results only for those patients that were defined as “mild” at baseline and were defined as “clear” at the end of the trial. Out of the 11 patients that were defined as “mild” at baseline, there was only one patient that was treated with VERED and reached “clear” at the end of the trial. All three formulations were well tolerated. A few patients had moderate local application site irritation (dryness, scaling, pruritus, stinging and burning) during treatment. Out of a total of 92 patients that were randomized, 28 patients in each treatment group completed the study. Two patients in the vehicle group discontinued the study early: one subject withdrew consent and one subject was lost to follow-up. Four subjects in the E-BPO 1% group discontinued the study early: two patients withdrew consent and two patients discontinued the study due to “application site dermatitis” and “cyst” (not an application site reaction). Two patients in the VERED group discontinued the study early: one subject was lost to follow-up, and one subject was discontinued due to an “application site reaction”.

VERED Phase II P-Values			
Variable at Week 12	Covariate	P-value 1% E-BPO vs. Vehicle	P-value 5% E-BPO vs. Vehicle
Dichotomized IGA (a)	Baseline IGA	0.0836(b)	0.0013(b)
Change in inflammatory lesion count	Baseline IGA	0.0049(c)	0.1874(c)
	Baseline inflammatory lesion count	0.0153(d)	0.1792(d)
Percent change in inflammatory lesion count	Baseline IGA	0.0123(c)	0.0202(c)
	Baseline inflammatory lesion count	0.0140(d)	0.0200(d)

(a) Primary Success: 2-grade improvement from Baseline in the IGA, with visit IGA of clear or almost clear

(b) P-value from model with factors of treatment, analysis center, and baseline IGA using PROC GENMOD with binomial distribution, logit link, and likelihood ratio test.

(c) P-value from ANCOVA with factors of treatment, analysis center, and baseline IGA using PROC GLM.

(d) P-value from ANCOVA with factors of treatment, analysis center, and baseline inflammatory lesion count using PROC GLM.

Last observation carried forward used to impute missing observations.



The following photographs, taken over 12 weeks of treatment, show the effect of VERED on a rosacea patient participating in our Phase II clinical trial who responded positively to treatment. The papules and pustules that are clearly seen at baseline are almost cleared at week 8 and are entirely cleared at week 12.

Subject treated with VERED:



The table below summarizes the two primary efficacy endpoints. A clear trend of dose response with IGA success of 20.0% for the vehicle, 37.5% for the E-BPO 1% and 53.3% for VERED was observed. Both VERED and E-BPO 1% significantly reduced the number of inflammatory lesions with a trend towards dose response indicated by median reduction of 10 lesions in the vehicle group compared to 12.5 and 15 in the E-BPO 1% and VERED groups, respectively.

#### Summary of Primary Efficacy Endpoints (ITT Subjects)

	Vehicle (N=30)	1% E-BPO (N=32)	VERED (N=30)
<b>Week 12</b>			
<b>Dichotomized IGA – Primary Success</b>			
Failure	24 (80.0%)	20 (62.5%)	14 (46.7%)
Success	6 (20.0%)	12 (37.5%)	16 (53.3%)
<b>Inflammatory Lesion Count – Change from Baseline</b>			
Mean	-7.4	-21.6	-14.1
SD	17.24	23.31	8.78
Median	-10.0	-12.5	-15.0
Min. to Max.	-45 to 67	-94 to -5	-34 to 5
LS Mean (a)	-8.8	-21.5	-14.7
LS SE (a)	3.16	3.04	3.15
95% CI for LS Mean (a)	[-15.1, -2.5]	[-27.5, -15.4]	[-21.0, -8.4]

(a) Obtained from an ANCOVA (analysis of covariance) with factors of treatment, analysis center, and baseline IGA.

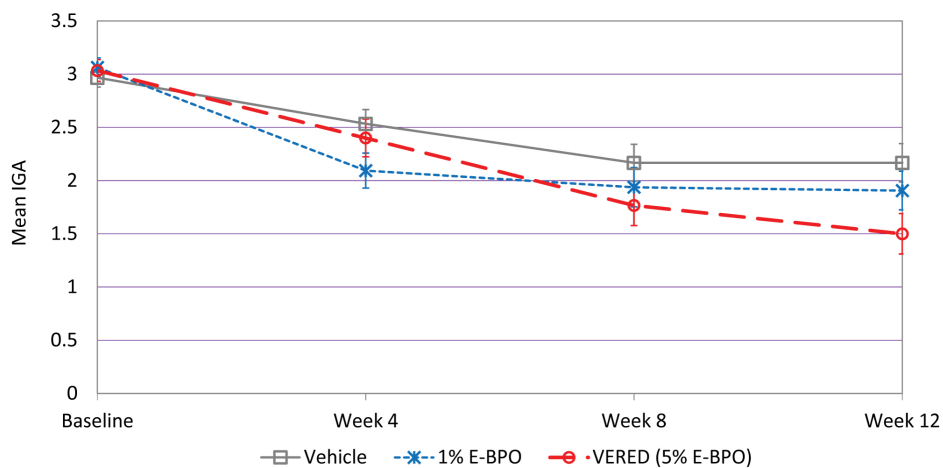
Primary success: 2-grade improvement from baseline in the IGA, with visit IGA of clear or almost clear.

LOCF (last observation carried forward) used to impute missing observations.



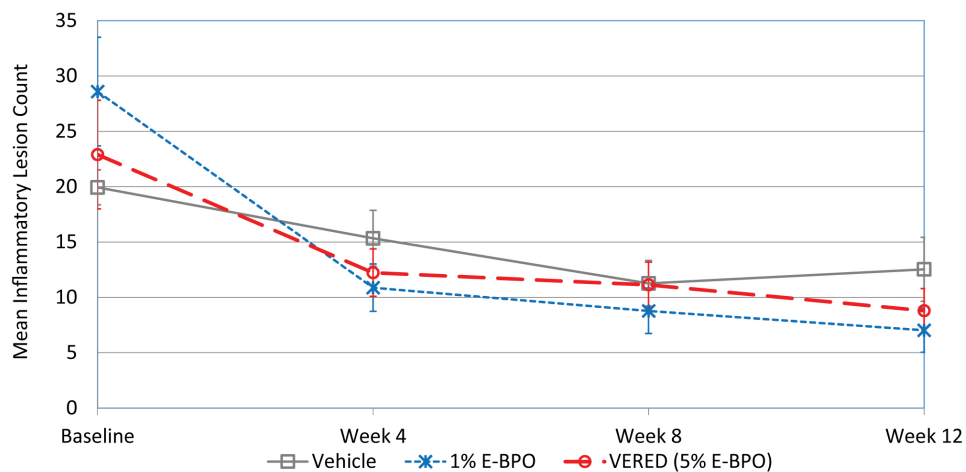
The reduction in mean IGA over time and the reduction in mean inflammatory lesion count over time in the vehicle, E-BPO 1% and VERED in each visit are shown in the following two figures.

VERED Phase II Mean IGA Primary Endpoint (ITT Population):



Mean +/- standard error is presented in the figure  
Last observation carried forward used to impute missing observations

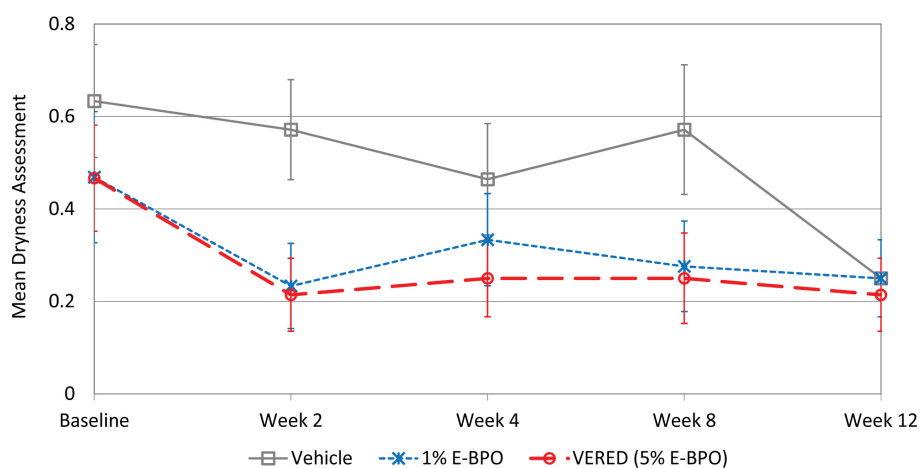
VERED Phase II Mean Inflammatory Lesion Count Primary Endpoint (ITT Population):



Mean +/- standard error is presented in the figure  
Last observation carried forward used to impute missing observations

Dryness: For VERED, the majority ( $\geq 75.0\%$ ) of subjects had no dryness post-baseline. Only one subject had moderate dryness (at week 8) and no subjects had severe dryness post-baseline.

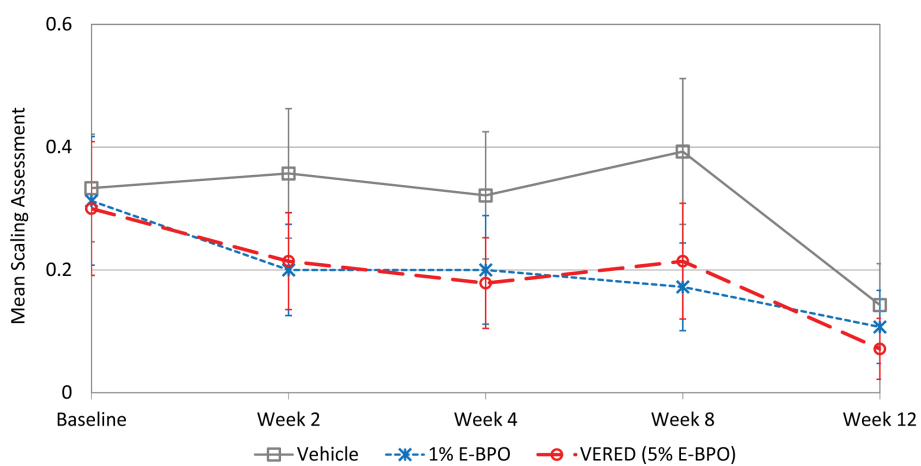
## VERED Phase II Mean Dryness Assessment (Safety Population):



Mean +/- standard error is presented in the figure

Scaling: For VERED, most subjects ( $\geq 78.6\%$ ) had no scaling post-baseline. Only one subject had moderate scaling (at week 8) and no subjects had severe scaling post-baseline.

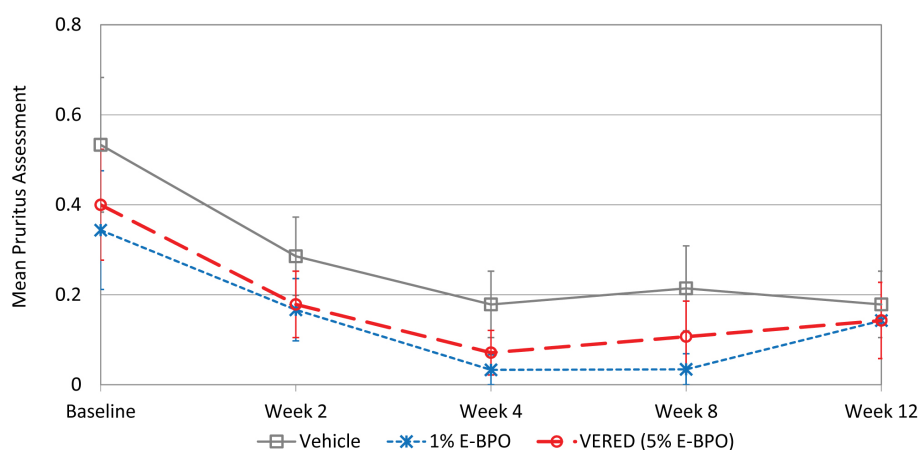
## VERED Phase II Mean Scaling Assessment (Safety Population):



Mean +/- standard error is presented in the figure

Pruritus: For VERED, most subjects ( $\geq 82.1\%$ ) had no pruritus post-baseline. Only one subject had moderate pruritus (at weeks 8 and 12) and no subjects had severe pruritus post-baseline.

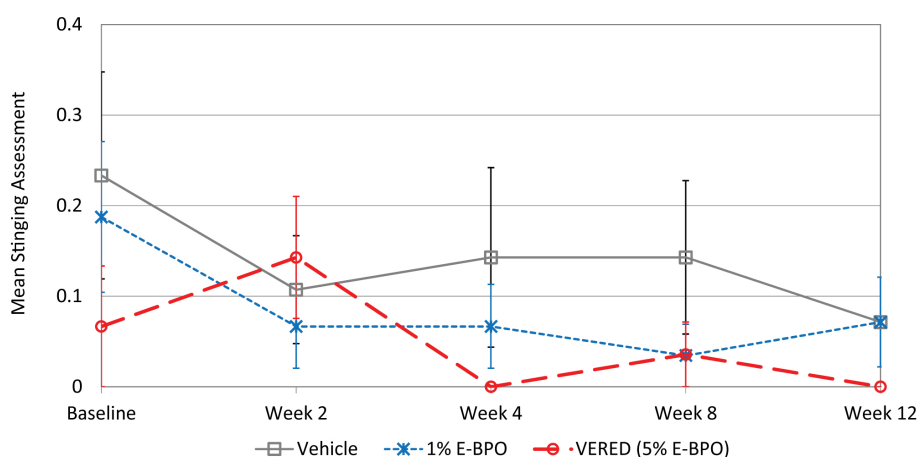
## VERED Phase II Mean Pruritus Assessment (Safety Population):



Mean +/- standard error is presented in the figure

**Stinging:** For VERED, most patients ( $\geq 85.7$ ) had no stinging post-baseline. No patients had moderate stinging post-baseline. One subject had severe stinging (and burning) on day 3 and it was reported as an application site reaction and deemed related to study medication. Subject was discontinued from the study due to the application site reaction.

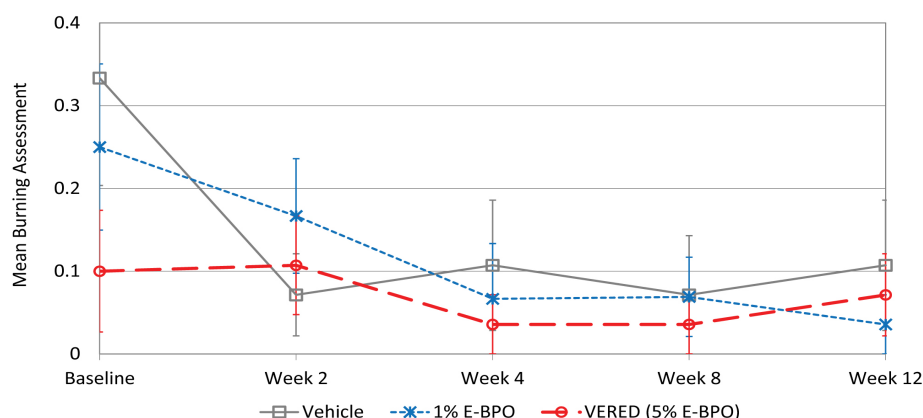
## VERED Phase II Mean Stinging Assessment (Safety Population):



Mean +/- standard error is presented in the figure

**Burning:** For VERED, most patients ( $\geq 89.3\%$ ) had no burning post-baseline. No patients had moderate burning post-baseline. One subject had severe burning (and stinging) on day 3 and it was reported as an application site reaction and deemed related to study medication. Subject was discontinued from the study due to the application site reaction.

## Mean Burning Assessment (Safety Population):



Mean +/- standard error is presented in the figure

In sum, the Phase II trial found that both E-BPO 1% and VERED had a favorable effect on rosacea. As a result of these findings, we selected E-BPO 5% (VERED) for further development.

**Phase III Clinical Development Plan.** Subject to an End of Phase II meeting we expect to schedule with the FDA, we expect to commence two pivotal double blind, placebo-controlled multi-center Phase III clinical trials in the United States in the first half of 2018. These clinical trials will each evaluate 275 patients and will be followed by a single open label long-term safety study for six months.

### **TWIN for Acne**

**TWIN product candidate.** TWIN is a once daily topical cream containing a fixed-dose combination of encapsulated benzoyl peroxide and the encapsulated retinoid tretinoin that we are developing for acne. Studies have shown that benzoyl peroxide and tretinoin are effective in treating acne as monotherapies, 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, TWIN can be kept refrigerated throughout the supply chain and then stored in ambient conditions upon its distribution to a patient. Nonclinical data suggest that TWIN may be more tolerable than generic tretinoin gel 0.1% and Epiduo, a branded fixed-dose combination of benzoyl peroxide and adapalene, without any 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 to utilize the FDA's 505(b)(2) regulatory pathway in seeking approval of TWIN and therefore intend to rely in part on data from studies that we have not conducted or sponsored and for which we have not obtained a right of reference in support of an NDA.

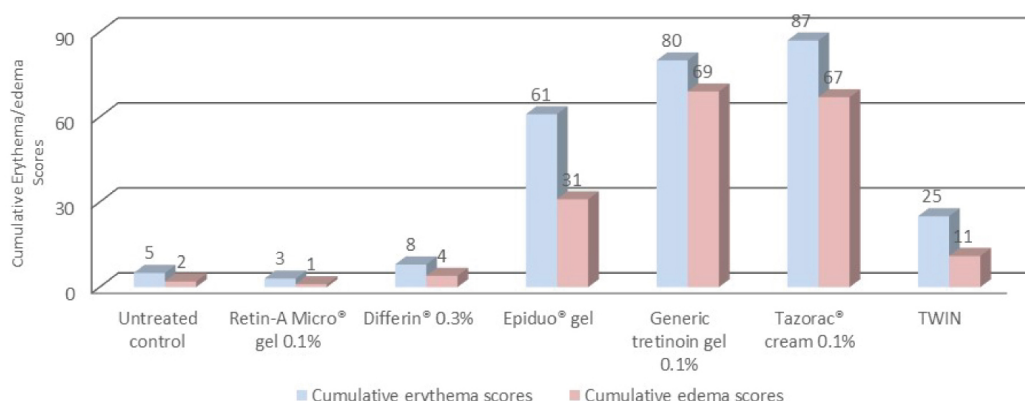
**Market opportunity.** Acne is one of the top three most prevalent skin conditions in the world and is the most commonly treated skin disorder in the United States. Acne is characterized by areas of scaly red skin, non-inflammatory blackheads and whiteheads, inflammatory lesions, papules and pustules and occasionally boils and scarring that occur on the face, neck, chest, back, shoulders and upper arms. It is one of the most common reasons for visiting a dermatologist. According to the American Academy of Dermatology, acne affects approximately 40 to 50 million people in the United States alone. The most prominent age group is adolescents, in which approximately 81% to 95% of boys and 79% to 82% of girls are affected. For most people, acne diminishes over time and tends to disappear, or at the very least to decrease, by the age of 25. There is, however, no way to predict how long it will take for acne symptoms to disappear

entirely, and some individuals continue to suffer from acne well into their 30s, 40s and beyond. Though not life threatening, acne can have a significant adverse effect on those suffering from it. In addition to carrying a risk of permanent facial scarring, it causes psychological strain, social withdrawal and lowered self-esteem, sometimes to the point of failure in school and work. Early effective treatment is therefore advocated to lessen the overall long-term impact. The U.S. market for topical branded prescription drugs for acne was estimated to be approximately \$1.7 billion for the 12 months ended June 30, 2015, of which \$600 million was attributed to fixed-dose combinations.

**Needs addressed.** According to the international consensus conference known as the Global Alliance to Improve Outcomes in Acne the combination of a topical retinoid and antimicrobial agent remains the preferred approach for almost all patients with acne. However, clinicians have been reluctant to prescribe benzoyl peroxide together with tretinoin because benzoyl peroxide causes degradation of the tretinoin molecules. Such a combination may also cause skin reactions such as erythema and dryness when applied to the skin and, therefore, patients may fail to comply with their suggested treatment regimens. Using our proprietary microencapsulation delivery system, we believe we successfully solved the industry-wide challenge of stabilizing tretinoin in the presence of benzoyl peroxide. The silica microcapsule is designed to protect tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability and enabling a suitable clinical and commercial shelf life. The silica shell also creates a barrier between the drug substances and the skin and as a result is expected to reduce irritation typically associated with topical application of benzoyl peroxide and tretinoin, which would potentially result in greater tolerability to acne-affected skin. The release profiles of both drug substances were designed to reduce irritation while maintaining stability and efficacy. Our nonclinical studies results support this solution.

**Nonclinical results.** We completed an *in vivo* non-occlusive cumulative 14-day skin irritation trial with 14-day recovery in five Göttingen minipigs, comparing TWIN with the following commercially available acne treatments: generic tretinoin gel 0.1%, Retin-A Micro gel 0.1%, Differin gel 0.3%, Tazorac cream 0.1% and Epiduo, a fixed-dose combination gel of 2.5% benzoyl peroxide and 0.1% adapalene. Erythema and edema were scored 0 to 4 (none, very slight, well-defined, moderate or severe), and were monitored over a 28-day period (14-day application period and the additional 14-day recovery period). TWIN exhibited less cumulative erythema and edema than Epiduo, generic tretinoin gel 0.1% and Tazorac cream 0.1% as shown in the figure below.

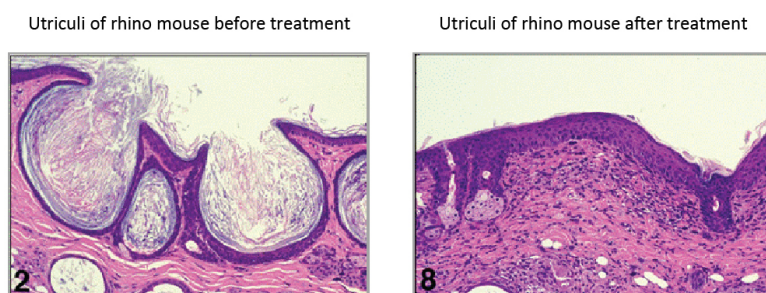
Cumulative erythema and edema scores in five minipigs:



In a 21-day rhino mouse model, we also evaluated the efficacy of encapsulated tretinoin in TWIN as compared with an untreated control group and a positive control, generic tretinoin cream 0.05%. The rhino mouse model is widely used for assessing chemicals that affect epithelial

differentiation such as retinoids. The model includes a histological evaluation of epidermal thickness coupled with the number of horn-filled utriculi. Retinoids cause an increase in epidermal thickness and reduction in number of horn-filled utriculi. In our study, both TWIN and generic tretinoin demonstrated the retinoids' effect and were each well tolerated.

The following histological images show the increase of epidermal thickness and reduction in number of utriculi in the rhino mouse as a result of TWIN treatment:



We completed a GLP 13-week repeat-dose toxicity trial in Göttingen minipigs. No systemic effects or adverse local effects were noted in TWIN, demonstrating that TWIN is safe for topical use. In addition, we completed a GLP sensitization trial in guinea pigs and concluded that TWIN is expected to be classified as a non-sensitizer.

**Planned activities.** In the first half of 2016, we initiated a double blind, dose-ranging placebo-controlled, six-arm, multi-center Phase II trial in the United States in 660 patients. Upon the completion of the Phase II trial, for which we expect to report top-line data in mid-2017, we plan to initiate two pivotal double blind, placebo-controlled, two-arm, multi-center Phase III clinical trials in patients to be followed by a single open label long-term safety trial.

### ***SIRS-T for Acne***

***SIRS-T product candidate.*** SIRS-T is a topical cream formulation containing encapsulated tretinoin that is under development for the treatment of acne. We expect that this product candidate, if approved, will compete directly with Retin-A Micro, Atralin and Retin-A, which contain tretinoin as well as with generic tretinoin. Topical tretinoin products are currently available in strengths ranging from 0.025% to 0.1% where the majority of sales for these products are for the 0.05% strength. Since encapsulation has the potential to provide decreased skin irritation and better tolerability, we believe that SIRS-T will have better tolerability than Retin-A without affecting efficacy. We expect to utilize the FDA's 505(b)(2) regulatory pathway in seeking approval of SIRS-T and therefore intend to rely in part on data from studies that we have not conducted or sponsored and for which we have not obtained a right of reference in support of an NDA.

***Needs addressed.*** SIRS-T is being developed for dermatologists and patients that prefer a more tolerable tretinoin, primarily as first-line treatment for patients with mild acne that can be treated by a single active pharmaceutical ingredient. The silica shell in SIRS-T is designed to create a barrier between the drug substances and the skin and as a result is expected to reduce irritation typically associated with topical application of tretinoin, which would make SIRS-T more tolerable to acne-affected skin. We believe that a more tolerable tretinoin drug product would improve patients' compliance with treatment regimens and therefore may become the leading tretinoin drug product.

***Nonclinical results.*** In a 21-day rhino mouse model, we evaluated the efficacy of encapsulated tretinoin in TWIN along with an untreated control group and a generic tretinoin cream 0.05%. In our study, both TWIN and generic tretinoin demonstrated the retinoid's effect. This finding was confirmed by a non-occlusive cumulative 14-day skin irritation trial with 14-day recovery in five Göttingen minipigs, comparing SIRS-T 0.1% with generic tretinoin gel 0.1%. Erythema and edema

were scored as very slight, well-defined, moderate or severe, and were monitored over a 28-day period (14-day application period and the additional 14-day recovery period). SIRS-T 0.1% was found to be only mildly irritating, similar to the untreated group, while generic tretinoin gel 0.1% was shown to be more irritating than SIRS-T 0.1%.

*Planned activities.* We intend to use TWIN's Phase II trial results in order to select the preferred dose for SIRS-T. Subject to an End of Phase II meeting we expect to schedule with the FDA, we plan to commence pivotal Phase III clinical trials for SIRS-T in the second half of 2018, with results anticipated during the second half of 2019.

#### ***E-06 for Symptomatic Interdigital Tinea Pedis***

*E-06 branded product candidate.* E-06 is a fixed-dose combination of an antifungal drug substance and a mid-potency steroid under development for the treatment of symptomatic inflammatory interdigital tinea pedis caused by dermatophytes (especially *Trichophyton rubrum* and *Trichophyton mentagrophytes* which are easily transmitted through human contact in warm humid environments, including gyms, pools and changing rooms). The condition usually manifests in the interspace of the fourth and fifth digits and may spread to areas between the other toes. The goal of treatment is to eradicate the infection and to decrease the inflammation present in the skin and relief signs and symptoms of the disease. E-06 contains an antifungal drug substance and a mid-potency steroid, both of which have been used for many decades in approved innovative and generic drug products and which have histories of safe use under prescribed conditions. In addition, the E-06 formulation contains established excipients at levels at or below the limits listed in the FDA's Inactive Ingredient Database. We expect to utilize the FDA's 505(b)(2) regulatory pathway in seeking approval of E-06 and therefore intend to rely in part on data from studies that we have not conducted or sponsored and for which we have not obtained a right of reference in support of an NDA.

*Market opportunity.* Seventy percent of the U.S. population is estimated to be infected by tinea pedis at some point in life and approximately 15% to 20% of the population suffers from tinea pedis at any given time. Common symptoms include maceration, scaling and itching of the skin. Only two topical fixed-dose combinations of an antifungal and a steroid are approved by the FDA: clotrimazole/betamethasone and nystatin/triamcinolone. They are both generic with 9.1 million cumulative prescriptions resulting in ex-factory sales of \$324M in the 12-month period ending in June 2015. The combination of clotrimazole/betamethasone has the disadvantage of a high potency betamethasone steroid and the nystatin/triamcinolone has the disadvantage of a weak nystatin antifungal. We believe that a combination of a new antifungal agent and a mid-potency steroid, if approved, will be able to capture a significant market share from the existing combinations and may further expand the overall market.

*Needs addressed.* Until the fungal infection is eradicated, the involved cutaneous tissues can remain inflamed and painful. Therefore, a product that can also decrease the inflammation present in the skin while the infection is being eradicated is desirable. Most forms of inflammation can be reduced or eliminated by the use of corticosteroids, but high potency corticosteroids can suppress the immune system and thereby make it difficult to eradicate infections. Our drug product candidate is being developed to provide a fixed-dose combination drug capable of eradicating the infection while reducing cutaneous inflammation, thereby improving patient comfort and compliance.

*Planned activities.* In September 2016, we initiated a double blind, placebo-controlled, four-arm, multi-center Phase II trial in the United States in 280 patients. Upon completion of the Phase II trial, which is expected in the second half of 2017, we plan to initiate two parallel pivotal double blind, placebo-controlled, two-arm, multi-center Phase III clinical trials in patients to be followed by a single open label long-term safety trial.

#### **Generic Drug Product Candidates**

In addition to our branded product candidates, we are focused on introducing generic product candidates to the dermatological drug market. In order to identify and exploit opportunities for

generic drugs, we take advantage of the extensive experience of our executive management team in the development and commercialization of dermatology drug product candidates. Our generic pipeline includes a generic dermatological product candidate that is being developed in collaboration with Perrigo UK: ivermectin cream, 1%, for the treatment of inflammatory lesions associated with rosacea. A bioequivalence study for ivermectin cream, 1%, was initiated in June 2016.

### **Our Topical Drug Delivery Technology Platform**

Innovative drug delivery systems are often used to enhance therapeutic effects of existing drugs, giving pharmaceutical companies competitive and financial advantages and providing patients with improved medication. Yet, only one microsphere delivery system, Microsponge, has ever been approved by the FDA for topical prescription drug products. The dearth of topical drug microsphere delivery systems might be attributed to the nature of the dermatology market, which has not justified the extensive investments required to obtain FDA approval for a novel delivery system. However, our product candidates take advantage of the fact that silica has already been approved by the FDA as a safe excipient for topical drug products (it is used as a thickener and filler in numerous products) and utilize our expertise in sol-gel encapsulation processes to potentially expedite the approval process of drugs that are based on our delivery systems.

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 rate 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, in 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 in the range of 1-40 mm. This process results in an aqueous suspension in which the drug substances are entrapped in silica particles.

Our silica-based delivery system is designed to improve the tolerability of topical dermatological drug products by entrapping drug substances in porous silica microcapsules. We believe that this entrapment creates a protective barrier between the drug substance and the skin and controls the release rate of the drug substance. We believe that our delivery system may also enable highly effective novel fixed-dose combinations of two or more otherwise unstable drug substances by creating a silica protective layer around labile drug substances.

### **Collaboration Agreements**

On April 27, 2015, we entered into a development, manufacturing and commercialization agreement, as amended on October 26, 2015, with Perrigo UK to work towards the objective of obtaining all FDA approvals necessary for the commercialization of ivermectin cream, 1%, in the United States. Perrigo UK will conduct all regulatory, scientific, clinical and technical activities necessary to develop ivermectin cream, 1%, prepare and file an ANDA with the FDA, and gain regulatory approval to market ivermectin cream, 1%, in the United States. We granted Perrigo UK the right, title and interest in and to ivermectin cream, 1%, and agreed on each party’s portion of the costs associated with performance under the agreement. As soon as reasonably practical after final approval by the FDA of the ANDA, if approval is granted, Perrigo UK is required to use diligent efforts to commercialize ivermectin cream, 1%, in the United States. Perrigo UK drug company has the sole and exclusive right to establish and control the prices and all other terms



and conditions for the sales of ivermectin cream, 1%, in the United States and is required to do so in good faith without derogating from our right to benefit from the commercialization of ivermectin cream, 1%. We will be entitled to 50% of Perrigo UK's gross profits related to the sale of ivermectin cream, 1%, on a quarterly basis, for a period of 20 years following the first commercial sale of the ivermectin cream, 1%, in the United States. The agreement may be terminated in the event of a material breach by one of the parties, certain potential infringement claims by third parties or an uncured insolvency or bankruptcy proceeding of one of the parties. In addition, the agreement may be terminated if the gross profits relating to the sale of the product do not exceed a certain threshold or if the potential market for the product has been significantly reduced due to regulatory changes.

On December 31, 2015, following entering into a transfer agreement with M. Arkin (1999) Ltd., an affiliate of our controlling shareholder, we entered into an agreement with Perrigo Israel for the development, manufacturing and commercialization of E-06. According to this agreement, Perrigo Israel will conduct regulatory, scientific, clinical and technical activities necessary to develop E-06. We will be responsible for all out-of-pocket expenses incurred by Perrigo Israel in its performance under the development plan. We will pay Perrigo Israel approximately \$2 million upon NDA submission of E-06, and approximately \$3 million upon the approval by the FDA of such NDA. In addition, we will be required to pay royalties to Perrigo Israel on the percentage of net sales of the product (as defined in the agreement) ranging in the mid-single digits depending on the net sales volume of the product.

### **Intellectual Property**

Our intellectual property and proprietary technology are essential to the development, manufacture and sale of VERED, TWIN, SIRS-T and E-06. 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, licenses, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others.

We have established a patent portfolio describing and claiming our proprietary processes, formulations, composition of matter, and methods of use for our proprietary silica microencapsulation platform and other technologies that, as of March 14, 2017, includes nine granted U.S. patents and 16 pending U.S. patent applications (which includes five provisional applications and two PCT applications that have not entered National Phase), 28 granted foreign patents and 27 patent applications pending in certain countries worldwide (including two PCT applications that have not entered National Phase). Our product candidates VERED, TWIN, SIRS-T and E-06 are covered by one of our granted U.S. patents (US 8,617,580), six of our pending U.S. patent applications and one published PCT application, 22 of our granted foreign patents (in Canada, Mexico, India, Japan, Europe, Israel and China) and 21 of our foreign patent applications (in Canada, Mexico, India, China, Japan, Korea and Europe), which claim protection for our product candidates. Our remaining patents and patent applications relate to processes, methods of use and formulations which are not part of our product candidates or are unpublished applications protecting early stage developments.

We believe only one of our U.S. patents (which expires in 2028 and which relates to TWIN's process, formulation and composition of matter and has counterparts in Canada, Mexico, Japan, and Europe (in Europe it is still an application) and one of our pending patent applications in the United States (which if issued would expire in 2030 and relates to TWIN's tretinoin encapsulation process and product and has counterparts in Canada, Mexico, China, India, Japan and Europe) are material to our business and operations. If this application is not approved, or any of these patents are invalidated, deemed unenforceable or otherwise successfully challenged, such loss would have a material adverse effect on the commercialization of TWIN and our future prospects.

More specifically, our intellectual property and proprietary technology is protected through a series of 21 patent families. The patents and patent applications that protect specific products include dermatological formulations comprising benzoyl peroxide, retinoids like tazarotene,

tretinoin and adapalene, and combinations of benzoyl peroxide and retinoids. Our patent portfolio includes claims protecting three types of proprietary aspects of our technologies: microcapsules encapsulating active agents, compositions comprising microcapsules, formulations comprising microcapsules, process for preparing microcapsules, product (microcapsules)-by-process (encapsulation), and method of using microcapsules, compositions comprising them and formulations comprising them and method of treatment.

We have four accepted trademark applications in Israel, one registered trademark in the United States and four trademark applications pending in the United States and Canada. These registrations and pending applications, if approved, will cover potential brand names for our VERED product candidate in Israel, Canada and the United States.

## **Competition**

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

There are numerous companies that have product candidates in the dermatology market. Among them are Allergan, Inc., Bayer HealthCare AG, Dr. Reddy's Laboratories Ltd., Galderma S.A., GlaxoSmithKline LLC, Merz Pharmaceuticals, Mylan N.V., Novan Inc., Dermira Inc., Foamix Pharmaceuticals Ltd., Perrigo Company plc., Spear Pharmaceuticals and Spear Dermatology Products Inc., Sun Pharmaceutical Industries, Ltd., Teligent, Inc. and Valeant Pharmaceuticals International.

In order for our approved drug 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.

VERED, TWIN, SIRS-T and E-06 are aimed at the well-established rosacea, acne, and tinea pedis markets. If approved, we expect them to compete with current standard-of-care treatments, whether branded, generic or over-the-counter, as well as with new treatments to be approved in the future. The current standard-of-care for rosacea includes Metrogel, Finacea and the recently launched Soolantra as well as oral Oracea (doxycycline embedded in a delivery system). 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 such as Differin, Atralin, Retin-A, Retin-A Micro and Tazorac that are based on single retinoid drug products, and fixed-dose combinations of benzoyl peroxide such as Epiduo, Epiduo Forte, Duac, Benzaclin, Onexton and Acanya, that are fixed-dose combinations of tretinoin and clindamycin such as Ziana and Veltin, and topical antibiotics such as Aczone. The standard-of-care for symptomatic inflamed tinea pedis is a combination of clotrimazole and betamethasone, such as Lotrisone, and a combination of nystatin and triamcinolone, such as Mycolog II. Our fixed-dose combination product candidates TWIN, and E-06 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, including ivermectin cream, 1%, is expected to face direct competition from branded drugs and authorized generics which are prescription drugs produced by the branded pharmaceutical companies and marketed under a private label, at generic prices. On December 30, 2016, Actavis Ltd. submitted an ANDA for ivermectin, 1%, cream, and therefore we will only be able to commercialize this product after Actavis Ltd.'s six month exclusivity period expires.

### **Marketing, Sales and Distribution**

We currently do not have any sales, marketing or distribution capabilities. In order to commercialize our product candidates, if approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience. We plan to build a focused, specialized sales force to target key dermatologists in the United States. This market is characterized by a large patient population that is served to a large extent by a relatively small, and therefore accessible, number of treating physicians, principally dermatologists and pediatricians. We believe that the dermatology market can be accessed by a small specialty sales force. In addition, dermatological treatments in the United States have a strong track record of achieving eligibility for insurance reimbursement. In other markets, we may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates.

### **Manufacturing**

We rely on and expect to continue to rely on third party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our product candidates and products, if approved. We currently do not have any agreements for the commercial production of raw materials. We believe that the manufacturing process can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our product candidates in the ordinary course of business.

### **Government Regulation**

Our business is subject to extensive government regulation. We have been voluntarily certified by the Israel notified body, the Standards Institution of Israel for the design, development and production of pharmaceutical products, a partner of IQNet. Regulation by governmental authorities in the United States and other jurisdictions is a significant factor in the development, manufacture and commercialization of our product candidates and in our ongoing research and development activities.

### ***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 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. We believe that the applications for our branded product candidates will be section 505(b)(2) NDAs and that those for our generic product candidates will be section 505(j) 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 laboratory tests, animal studies and formulation studies in compliance with the FDA's 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 IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with 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 cGMPs and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- payment of user fees and FDA review and approval of the NDA.

#### *Nonclinical studies*

Nonclinical 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. Nonclinical safety tests must be conducted in compliance with the FDA regulations. The results of the nonclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND which must become effective before clinical trials may commence. Long-term nonclinical 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 FDA as part of the IND.

An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In addition, information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on the NIH-maintained website, [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on the NIH-maintained website, [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov).

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

- *Phase I:* 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 II:* 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 III:* 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; and

In most cases of an ANDA, the proposed generic drug must be shown to be bioequivalent to the reference listed drug (RLD, or reference product) and in other cases, the bioequivalent study is being conducted in in-vitro and not in clinical trials. The FDCA provides that a generic drug is bioequivalent to the listed drug if: the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. During bioequivalence studies, an applicant compares the systemic exposure profile of a test drug product to that of the RLD on the target population at the same regimen and exposure period as the RLD were the resulted efficacy outcomes are being compared to demonstrate being equivalent.

#### *Submission of an NDA to the FDA*

The results of the nonclinical 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 user fees, as well as the annual fees required for commercial manufacturing establishments and for approved products, can be substantial. The NDA review fee alone can exceed \$2.3 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 Prescription Drug User Fee Act, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity. The FDA, however, may not approve a drug within these established goals, and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but rather a Complete Response Letter that describes additional work that must be completed before the application can be approved.

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.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate 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. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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 us to develop additional data or conduct additional nonclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

### ***Post-Approval Requirements***

Any drug products for which we receive 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. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies.

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 of our product candidates will be required to 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. 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.



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

#### *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. With the enactment of the Food and Drug Administration Safety and Innovation Act, or the FDASIA, in 2012, sponsors must also submit pediatric trial 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 regulation. 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, 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. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the FDASIA.

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

#### ***The Hatch-Waxman Amendments***

##### *ANDA Approval Process*

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as 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 its NDA process. Approval to market and distribute these drugs is obtained by submitting an ANDA with 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 nonclinical 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. We are developing certain of our product candidates as generic drugs, for which we intend to submit ANDAs to the FDA.

##### *505(b)(2) NDAs*

Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendment, and permits the filing of an NDA where at least some of the information required for approval comes from studies



or trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendment, and permits the filing of an NDA where at least some of the information required for approval comes from studies or trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. 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 nonclinical 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. We are developing our branded product candidates with the expectation that we will submit 505(b)(2) NDAs to FDA for these products.

#### *Orange Book Listing*

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. 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 that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) 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 the 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 exclusivity period and the patent holder brings suit within 45 days of notice of 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. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation.

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

#### *Non-Patent Exclusivity*

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

Another form of non-patent exclusivity is clinical investigation exclusivity. A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/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.

#### *Patent Term Restoration and Extension*

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, or PTE, which permits an extended patent term of up to five years for the developed pharmaceutical to compensate for patent term lost during product development and the FDA regulatory review. The PTE period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of a NDA and the ultimate approval date. However, the PTE cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the PTE application in consultation with the FDA.

#### *Review and Approval of Drug Products Outside the United States*

In addition to regulations in the United States, if we target non-U.S. markets, we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries.

The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

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

### ***Pharmaceutical Coverage, Pricing and Reimbursement***

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

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of VERED and TWIN, in addition to the costs required to obtain the FDA approvals. For example, VERED and TWIN 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 March 2010, the President of the United States signed the Affordable Care Act, one of the most significant healthcare reform measures in decades. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The comprehensive \$940 billion dollar overhaul is expected to extend coverage to approximately 32 million previously uninsured Americans. The Affordable Care Act contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which impacted existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additionally, the Affordable Care Act:

- increased the minimum level of rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. The new Presidential Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. These included 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 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. We expect that additional state and federal healthcare initiatives will be adopted in the future, any of which could impact the coverage and reimbursement for drugs, including our product candidates, if approved.

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 Laws and Regulations***

Although we currently do not have any product candidates on the market, our current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine 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. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, civil money penalties and exclusion from participation in federal healthcare programs. 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.

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. 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. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

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.

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.

HIPAA, as amended by HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of

uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

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 and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Because we intend to commercialize products that could be covered by a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal controls and facilitate compliance can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

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 and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

### ***Israeli Regulations***

Our clinical operations in Israel also are subject to approval by Israel's Ministry of Health and the Helsinki Committee of each medical institution in which a clinical trial is conducted. All phases of clinical trials conducted in Israel must be conducted in accordance with the Public Health Regulations (Medical Studies Involving Human Subjects, 1980), including amendments and addenda thereto, the Guidelines for Clinical Trials in Human Subjects issued by the Israel Ministry of Health, or the Guidelines, and the International Conference for Harmonized Tripartite Guideline for Good Clinical Practice. The regulations and the Guidelines stipulate that a medical study on humans will only be approved after the Helsinki Committee at the hospital intending to perform the study has approved the medical study and notified the relevant hospital director in writing. In addition, certain clinical trials require the approval of the Ministry of Health. The Helsinki Committee will not approve the performance of the medical study unless it is satisfied that it has advantages to the study participants and society at large that justify the risk and inconvenience for the participants and that the medical and scientific information justifies the performance of the

requested medical study. The relevant hospital director, and the Ministry of Health, if applicable, also must be satisfied that the study is not contrary to the Helsinki Declaration or to other regulations. The Ministry of Health also licenses and regulates the marketing of pharmaceuticals in Israel, requiring the relevant pharmaceutical to meet internationally recognized cGMP standards.

### ***Office of the Chief Scientist***

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

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

- In general, the Recipient Company is obligated to pay the Innovation Authority royalties from the revenues generated from the sale of products (and related services) developed (in all or in part) as a result of, a research and development program funded by the Innovation Authority at rates which are determined under the Innovation Authority's rules and guidelines (currently a yearly rate of 1.3% to 5% on sales of products or services developed under the approved programs, depending on the type of the Recipient Company — i.e., whether it is a "Small Company", a "Large Company" or a "Traditional Industrial Company" as such terms are defined in the Innovation Authority's rules and guidelines), up to the aggregate amount of the total grants received by the Innovation Authority, plus annual interest (as determined in the Innovation Authority's rules and guidelines);
- products developed as a result of the Innovation Authority funded R&D must, as a general matter, be manufactured in Israel. The Recipient Company is prohibited from manufacturing products developed using these Innovation Authority grants outside of the State of Israel without receiving prior approval from the Innovation Authority (except for the transfer of less than 10% of the manufacturing capacity in the aggregate which requires only a notice). If the Recipient Company receives approval to manufacture products developed with government grants outside of Israel, it will be required to pay increased royalties to the Innovation Authority, up to 300% of the grant amount plus interest, depending on the manufacturing volume that is performed outside of Israel. The Company may also be subject to an accelerated royalty repayment rates. A Recipient Company also has the option of declaring in its Innovation Authority grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval following the receipt of the grant; and
- under the Innovation Authority's rules and guidelines, a Recipient Company is prohibited from transferring the Innovation Authority-financed know-how and related intellectual property rights outside of Israel except under limited circumstances, and only with the approval of the Research Committee and subject to certain payments to the Innovation Authority calculated according to formulas provided under the Innovation Authority's rules and guidelines (which are capped to amounts specified under such rules and guidelines).

We have received grants from the Innovation Authority in connection with our research and development of our microencapsulation delivery system and therefore, we are subject to the aforementioned restrictions with respect to product candidates incorporating such, namely, VERED, TWIN and SIRS-T. Such restrictions will continue to apply even after we pay the full amount of royalties payable pursuant to the grants. For additional information on our royalty obligations related to Innovation Authority grants, see Note 5 to our financial statements as of and for the year ended December 31, 2016, contained elsewhere in this prospectus.

Even if our Innovation Authority funded know-how is transferred to another Israeli entity, the transfer would require the Innovation Authority'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 Innovation Authority 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 Innovation Authority as a condition to the Innovation Authority's approval.

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

Pursuant to Amendment No. 7 of the Innovation Law, the Innovation Authority is authorized to change the restrictions imposed on the recipients of grants that were stipulated under the Innovation Law prior to the effectiveness of Amendment No. 7 with a new set of arrangements in connection with ownership obligations of know-how (including with respect to restrictions on transfer of know-how and manufacturing activities outside of Israel), as well as royalties obligations associated with approved programs. Amendment No. 7 also includes new provisions with respect to sanctions imposed for violations of the Innovation Law. Although the Innovation Authority recently published rules which for the most part adopted the principal provisions and restrictions specified in the Innovation Law prior to the effectiveness of Amendment No. 7, as of the date of this prospectus, we are unable to assess the effect on our business of any future rules which may be published by the Innovation Authority.

We may not receive the required approvals for any actual proposed transfer and, if received, we may be required to pay the Innovation Authority a portion of the consideration that we receive upon any sale of the Innovation Authority funded know-how to a non-Israeli entity. The scope of the support received, the royalties that we have already paid to the Innovation Authority, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which the Innovation Authority 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 Innovation Authority.

## Employees

As of February 28, 2017, we had 43 employees, all based in Israel. We have never experienced any employment-related work stoppages and believe our relationships with our employees are good.

Area of Activity	As of February 28, 2017
Administrative	6
Research, development and quality assurance	37
Total	<u>43</u>

## Facilities

Our principal executive offices are located in a leased facility in Weizmann Science Park, Ness Ziona 7403650, Israel. The facility houses our offices, warehouse, laboratories and production area. Our lease will expire on December 31, 2020.



We intend to add new facilities or expand our existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

### **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. As of the date of this prospectus, we hold a valid poison permit for our activity in Ness Ziona (in effect until April 13, 2018), and a valid business license in effect until December 31, 2019.

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. For instance, new Israeli regulations were promulgated in 2011 relating to the discharge of industrial sewage into the sewer system. These regulations establish new and potentially significant fines for discharging forbidden or irregular sewage into the sewage system.

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.

### **Legal Proceedings**

We are not subject to any material legal proceedings.

## MANAGEMENT

**Executive officers, directors and director nominees**

The following table sets forth information concerning our executive officers, directors and director nominees, including their ages as of February 28, 2017:

Name	Age	Position
Moshe Arkin	64	Chairman of the Board of Directors
Alon Seri-Levy	56	Chief Executive Officer
Gilad Mamlok	49	Chief Financial Officer
Haim Barsimantov	42	Chief Technology Officer
Ofer Toledano	52	Vice President Research and Development
Ofra Levy-Hacham	50	Vice President Quality and Regulatory Affairs
Karine Neimann	45	Vice President Projects and Planning, Chief Chemist
Itzik Yosef	40	Vice President Operations
Dov Zamir	63	Vice President Special Projects
Itai Arkin	28	Director Nominee
Ran Gottfried (1)	72	External Director Nominee
Jerrold S. Gattegno (1)	64	External Director Nominee

(1) Proposed to serve as an external director under the Companies Law subject to ratification of their election as external directors under the Companies Law by our shareholders within three months following this offering.

**Mr. Moshe Arkin** has served as chairman of our board of directors since 2014. Mr. Moshe Arkin currently sits on the board of directors of several health care companies including Exalenz Bioscience Ltd. (TASE:EXEN), a developer of advanced systems for gastrointestinal and liver disorders since 2006, Quiet Therapeutics Ltd., a cancer drug discovery and development and SoniVie Ltd., a private company developing systems for the treatment of pulmonary arterial hypertension. From 2005 to 2008, Mr. Arkin served as the head of generics at Perrigo Company (NYSE:PRGO; TASE:PRGO) and from 2005 until 2011 as the vice chairman of its board of directors. Prior to joining us, Mr. 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. (NYSE:MRK). 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.

**Mr. 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, Mr. Seri-Levy established the computer-aided drug design department at Peptor Ltd., an Israeli research and development company specialized in the development of peptide-based drug products. Mr. 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.

**Mr. Gilad Mamlok** has served as our chief financial officer since March 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 ("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.

**Mr. Haim Barsimantov** has served as our chief technology officer since September 2016. From 2000 until 2007, Mr. Barsimantov served as our plant manager. Since 2007 and until August 2016, Mr. Barsimantov served as our chief operating officer.

**Mr. 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.

**Ms. Ofra Levy-Hacham** has served as our vice president of quality and regulatory affairs since 2011. Prior to joining Sol-Gel, Dr. Levy-Hacham served as a scientific specialist and project manager at Biotechnology General Ltd., a fully integrated biopharmaceutical services private company from 2010 until 2011. From 2008 until 2010, Dr. Levy-Hacham served as the vice president chemistry, manufacturing and controls at HealOr Ltd., a private company engaging in the development of therapeutics for the treatment of various skin lesions and conditions. Dr. Levy-Hacham holds a Ph.D. in chemistry from The Technion - Israel Institute of Technology, Haifa, Israel.

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

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

**Mr. Dov Zamir** has served as our vice president special projects since August 2016. Prior to joining us, Mr. 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, Mr. Zamir was VP of Pharma and Analytical R&D at Taro Pharmaceutical in Haifa, and for three years prior to that he managed its Analytical R&D lab. Mr. Zamir holds a Ph.D. in organic chemistry from Tel-Aviv University, Israel.

**Mr. Itai Arkin** will become a member of our board of directors immediately following the pricing of this offering. Mr. Itai Arkin currently serves as Investment Manager at Arkin Holdings Ltd. and on the board of directors of Exalenz Bioscience Ltd. (TASE:EXEN). Mr. Itai Arkin is an investment committee member of both Accelmed, a leading Israeli MedTech investment firm since March 2014, and of Sphera Global Healthcare, a leading healthcare hedge fund. Mr. Itai Arkin holds a B.A. in business administration (cum laude) from Interdisciplinary Center, Herzliya, Israel. 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.

**Mr. Ran Gottfried** will become a member of our board of directors immediately following the pricing of this offering and will serve as an external director under the Companies Law subject to the ratification of his appointment at a general meeting of our shareholders to be held following the completion of this offering. 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 2005 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 2011, Mr. Gottfried served as a director of Bezeq (TASE:BEZQ), 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.

**Mr. Jerrold S. Gattegno** will become a member of our board of directors immediately following the pricing of this offering and will serve as an external director under the Companies Law subject to the ratification of his appointment at a general meeting of our shareholders to be held following the completion of this offering. Mr. Gattegno worked in the New York, Washington D.C. and London offices of Deloitte Touche Tohmatsu Limited, a public accounting firm, from 1973 until 2015, where he served in various senior positions, including as the founding partner of Deloitte's multistate tax practice and as a managing partner in Deloitte's Washington National Tax Office. Mr. Gattegno has served as a member of the Hispanic Association of Colleges and Universities 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.

### **Compensation of Executive Officers and Directors**

The aggregate compensation paid by us to our executive officers and directors for the year ended December 31, 2016 was approximately \$3.0 million. This amount includes approximately \$0.1 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.

### **Foreign Private Issuer and Controlled Company Status**

#### ***Foreign Private Issuer***

After the consummation of this offering, we will be a "foreign private issuer" under the U.S. securities laws and the NASDAQ corporate governance rules. As a foreign private issuer, we will be 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 will 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 will 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":

- we intend to establish a quorum requirement such that the quorum for any meeting of shareholders is 33⅓% of the issued share capital, as required under NASDAQ requirements, however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of record shareholders, instead of 33⅓% of the issued share capital;
- we intend to 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 will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules; 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).

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. Following the closing of this offering, 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, after the completion of this offering, we will be 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 will not comply, with the requirements that: (1) a majority of our board of directors consist of independent directors; and (2) we have a nominating committee composed entirely of independent directors with a written charter addressing such committee's purpose and responsibilities. See "Management — Board of Directors and Officers." Accordingly, you will 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.

### **Board of Directors and Officers**

Upon the closing of this offering, our board of directors will consist of        directors, including two directors, who are intended to qualify as external directors and whose appointment fulfills the requirements of the Companies Law for the company to have two external directors (see "Management — External Directors"). These two directors, as well as one additional director, will 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 seven (7) and must include at least two external directors. The minimum and maximum number of directors may be changed, at any time and from time to time, by vote of our shareholders.

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 2017 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").

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

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

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

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

### **Alternate Directors**

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

### **External Directors**

#### ***Qualifications of External Directors***

Under the Companies Law, companies incorporated under the laws of the State of Israel that are “public companies,” including companies with shares listed on The NASDAQ Global Market, are required to appoint at least two external directors who meet the qualification requirements set forth in the Companies Law. Following a recent amendment to the Companies Law enacted on February 17, 2016, or Amendment 27, such external directors are no longer required to be Israeli residents in case of a company listed on a foreign stock exchange (such as NASDAQ). Appointment of external directors must be made by a general meeting of our shareholders no later than three months following the closing of this offering, and therefore we intend to hold a shareholders’ meeting within three months of the closing of this offering for the appointment of two external directors.

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 transactions with controlling shareholders, 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 will consist of , and . 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 is an audit committee financial expert as defined by the 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 required to be “independent” as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, which is different from the general test for independence of board and committee members.

### ***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 “Management — Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli law.” 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 plans to adopt an audit committee charter 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;

- 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 above, 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 entitled to demand from us any document, file, report or any other information that is required for the fulfillment of its roles and duties and to interview any of our employees or any employees of our subsidiaries in order to receive more details about his or her line of work or other issues that are connected to the roles and duties of the audit committee. Following Amendment 27, a company whose audit committee's composition 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 and companies that have publicly issued debentures 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).

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 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 participate 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.

However, following a recent amendment to the Companies Regulations (Reliefs from Requirement to Establish a Compensation Policy) 5773-2013, or the Compensation Policy Relief Regulations, as of April 2016, if a company initially offer its securities to the public, like us, 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, notwithstanding the Companies Law, 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 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 exercise value of cashless variable equity-based components which are not exercised in cash; 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 the office 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 which 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 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 than re-presented 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.

Our compensation policy, which will become effective immediately prior to the closing of this 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 the Company in the long-term, such as caps 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 relocation, signing and special bonuses) as well as change of control related bonuses, equity-based compensation, benefits and retirement and termination of employment arrangements. All cash bonuses are limited to a maximum amount linked to the executive officer's base salary (or to the total annual compensation in the case of the special bonus for special achievements).

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. Furthermore, the performance objectives will be recommended by our chief executive officer and 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 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 entitles our executive officer to compensation in the form of share options or other equity-based awards, such as restricted share units, in accordance with our share incentive plan then in place (subject to the compensation committee and Board resolutions). 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 governs the compensation of the members of our board of directors and determines that the compensation of the directors shall be in accordance with the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director), 5760-2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel), 5760-2000, or the compensation of directors regulations, as such regulations may be amended from time to time; provided, however, that under special circumstances such as in the case of a professional director, an expert director or a director who makes a unique contribution to the Company, such director's compensation may be different than the compensation of all other directors and maybe greater than the maximal amount allowed, in our case, by the compensation of directors regulations. Our directors may also be entitled to receive equity-based compensation in the form of share options subject to an annual maximum and to a vesting period in order to promote long-term retention of the awarded director as well as to the approval of our shareholders as required under the Companies Law. Furthermore, the chairman of our board of directors may be entitled to a higher base compensation or equity-based compensation.

Our compensation policy was approved by our board of directors and our controlling shareholder in and is filed as an exhibit to the registration statement of which this prospectus forms a part.

### **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 prospectus, we have not yet appointed our internal auditor.

## **Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli 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 parties 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 entity (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 "Management — Disclosure of Compensation of Directors and Executive Officers."

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 the discretion of how to vote lies with the person voting or not.

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 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, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires the abovementioned approval every three years, however, such 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.

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, a recent amendment to regulations promulgated under the Companies Law will require us, after we become 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, as was previously permitted for Israeli public companies listed overseas. This disclosure will not be as extensive as that required of a U.S. domestic issuer. We intend to commence providing such disclosure, at the latest, in the annual proxy statement for our first annual general meeting of shareholders following this offering, which will be furnished under cover of a Form 6-K and we may elect to provide such information at an earlier date.

### ***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 the 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, provided that those provisions that must be included in the compensation policy according to the Companies Law have been considered by the compensation committee and board of directors, 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 are 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 completed in lieu of a special tender offer (See "Description of Share Capital — Acquisitions under Israeli law") or a private placement which qualifies as a related party transaction (See "Management — Fiduciary Duties and Approval of Specified Related Party Transactions and Compensation under Israeli law"), 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 a 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 out of a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738-1968 (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 a 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 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 such 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 prospectus, 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.

### **Employment and Consulting Agreements with Executive Officers**

We have entered into written employment or service agreements with each of our executive officers. See "Certain Relationships and Related Party Transactions — Employment Agreements" for additional information.

### **Directors' Service Contracts**

There are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their employment or service as directors of our company.

### **Share Incentive Plan**

On December 2, 2014, we adopted the 2014 Share Incentive Plan, or the Plan. 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.

We may issue under the Plan up to 349,458 of our ordinary shares, 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, and such number is approved by our shareholders. 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.

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 option granted under the Plan will be determined in accordance with the limitation 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 (the "Israeli Tax Ordinance"). Section 102 of the Israeli Tax Ordinance allows employees, directors and officers who are not controlling shareholders 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. 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 Internal Revenue Code of 1986, or options other than incentive stock options (referred to as “nonqualified stock options”), as determined by our compensation committee or our board of directors and stated in the 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 options and restricted shares at such time and under such circumstances as it, in its sole discretion, deems appropriate. In the event of a merger or sale, 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.

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 February 28, 2017, options to purchase 253,768 ordinary shares, under our Plan, at an exercise price of \$2.86 per share were outstanding.

## PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 28, 2017 by:

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

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days as of February 28, 2017, 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 prior to the offering is based on 3,494,579 ordinary shares outstanding as of February 28, 2017. The percentage of ordinary shares beneficially owned after the offering is based on the number of shares outstanding prior to the offering plus the ordinary shares that we are selling in this offering.

The percentages of ordinary shares beneficially owned after the offering assume that the underwriters will not exercise their over-allotment option to purchase additional ordinary shares in the offering. 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.

Upon the closing of this offering, none of our shareholders will have different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

As of February 28, 2017, there were no U.S. persons that were holders of record of our ordinary shares.

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, 7403648 Israel.

Name of Beneficial Owner	Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering	
	Number	Percentage	Number	Percentage
<b>5% or greater shareholders</b>				
M.Arkin Dermatology Ltd. (1)	3,494,579	100%		%
<b>Directors and executive officers</b>				
Moshe Arkin (1)	3,494,579	100%		
Alon Seri-Levy (2)	50,749	1.5%		
Gilad Mamlok	*	*	*	*
Haim Barsimantov	*	*	*	*
Ofer Toledano	*	*	*	*
Ofra Levy-Hacham	*	*	*	*
Karine Neimann	*	*	*	*
Itzik Yosef	*	*	*	*
Dov Zamir	—	—	—	—
Gilad Mamlok	—	—	—	—
Itai Arkin	—	—	—	—
Ran Gottfried	—	—	—	—
Jerrold S. Gattegno	—	—	—	—
<b>All directors and executive officers as a group (9 persons)</b>				
(3)	<u>3,621,834</u>	<u>100%</u>	<u></u>	<u>%</u>

\* Less than 1%.

- (1) Consists of 3,494,579 ordinary shares directly owned by Arkin Dermatology. Mr. Moshe Arkin, the chairman of our board of directors, owns 100% of the outstanding share capital of Arkin Dermatology. As a result, Mr. Arkin has sole power to vote or to direct the vote and sole power to dispose or to direct the disposition of, all shares owned by Arkin Dermatology. Mr. Arkin disclaims beneficial ownership in the ordinary shares except to the extent of his pecuniary interest therein.
- (2) Consists of options to purchase 50,749 ordinary shares currently exercisable or exercisable within 60 days of February 28, 2017.
- (3) Consists of options to purchase 127,255 ordinary shares currently exercisable or exercisable within 60 days of February 28, 2017.



## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

### 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 “Risk Factors — Risks Relating 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.

### Securities Purchase Agreement

On August 4, 2014, our former shareholders entered into a securities purchase agreement with our controlling shareholder, Arkin Dermatology, or the Purchase Agreement. The Purchase Agreement detailed the terms and conditions for the sale of the company to Arkin Dermatology in exchange for a cash payment in the amount of approximately \$10.5 million in addition to an earn out payment of up to \$17.0 million based on the achievement of certain development and revenue-related milestones. In connection with the Purchase Agreement, certain of our employees, including our chief executive officer, are entitled, subject to the achievement of certain research and development milestones and other conditions, to a special bonus in an aggregate amount of up to \$3.0 million.

### Project Transfer Agreement with Our Controlling Shareholder

On December 31, 2015, we assumed, following entering into a transfer agreement with M. Arkin (1999) Ltd., an affiliate of our controlling shareholder, an agreement with Perrigo Israel for the development, manufacturing and commercialization of E-06. The consideration for the transfer of the project, in the amount of \$431,000, was paid to the related company during 2015 by utilizing a loan from our controlling shareholder.

### Loan Agreements with Our Controlling Shareholder

Since January 1, 2014, we have received several loans in an aggregate principal amount of approximately \$37.3 million from Arkin Dermatology, our controlling shareholder. These loans are denominated in U.S. dollars, bear no interest and are backed by a promissory note, or the Promissory Note. The Promissory Note is an unsecured note, has no repayment date and is subject to acceleration in certain events of default.

### 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 “Management — Exculpation, Insurance and Indemnification of Directors and Officers.”

We have entered into agreements with each of our current director 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 this 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) % 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) \$ 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**

Upon the closing of this offering, we will enter into a registration rights agreement, pursuant to which we will grant 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.

## DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our amended and restated articles of association are summaries and do not purport to be complete.

### General

Upon the closing of this offering, our authorized share capital will consist of        ordinary shares, par value NIS        per share, of which, effective upon closing of this offering,        shares will be issued and outstanding (assuming that the underwriters do not exercise their over-allotment option to purchase additional ordinary shares).

All of our outstanding ordinary shares will be validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

### 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 seven (7) directors, including two external directors as required 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 falls below the minimum number provided in our amended and restated articles so the number of directors in office shall be at least the minimum number. In such case, a shareholders meeting shall be held within six months of such appointment in order to elect directors. 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 “Management — Corporate Government Practices — Board of directors and 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 “Management — 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.

### **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.

### **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 as opposed to the Israeli law.

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. In any meeting of shareholders, we will follow the quorum requirements for general meetings under the NASDAQ Marketplace Rules, pursuant to which the quorum required for our general meetings of shareholders will consist of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 33⅓% of the issued share capital. 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 33⅓% 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 (66 $\frac{2}{3}$ %). 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, as set forth in our amended and restated articles of association.

### **Registration Rights**

For a discussion of registration rights we have granted to our controlling shareholder prior to this offering, please see "Certain Relationships and 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 closing of this offering, no preferred shares will be 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.

### **Establishment**

We were incorporated under the laws of the State of Israel on October 28, 1997. We are registered with the Israeli Registrar of Companies in Jerusalem.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our ordinary shares is .

### **Listing**

We intend to apply to list our ordinary shares on The NASDAQ Global Market under the symbol “SLGL.”

### **Home Country Practices**

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 intend to establish a quorum requirement such that the quorum for any meeting of shareholders is 33 and 1/3% of the issued share capital, as required under NASDAQ requirements; however, if the meeting is adjourned for lack of quorum, the quorum for such adjourned meeting will be any number of record shareholders, instead of 33 and 1/3% of the issued share capital;
- we intend to adopt and approve material changes to equity incentive plans in accordance with the Israeli Companies Law, 5759-1999, or 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 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.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our ordinary shares. Sales of substantial amounts of our ordinary shares following this offering, or the perception that these sales could occur, could adversely affect prevailing market prices of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities. Assuming that the underwriters do not exercise their over-allotment option to purchase additional ordinary shares in this offering and assuming no exercise of options outstanding following this offering, we will have an aggregate of            ordinary shares outstanding upon the closing of this offering. Of these shares, the            ordinary shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless purchased by “affiliates” (as that term is defined under Rule 144 of the Securities Act), who may sell only the volume of shares described below and whose sales would be subject to additional restrictions described below.

The remaining            ordinary shares will be held by our existing shareholders and will be deemed to be “restricted securities” under Rule 144. Restricted securities may only be sold in the public market pursuant to an effective registration statement under the Securities Act or pursuant to an exemption from registration such as under Rule 144 under the Securities Act. These rules are summarized below.

### Eligibility of Restricted Shares for Sale in the Public Market

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the ordinary shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

- all the ordinary shares sold in this offering will be eligible for immediate sale upon the closing of this offering; and
- ordinary shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

### Lock-up Agreements

All of our directors, executive officers and shareholders have signed lock-up agreements pursuant to which, subject to certain exceptions, such persons have agreed not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of 180 days after the date of this prospectus without the prior written consent of            .            may, at any time without prior notice, release all or any portion of the ordinary shares from the restrictions in any such agreement.

### Rule 144

#### *Shares Held For Six Months*

In general, under Rule 144 as currently in effect, and subject to the terms of any lock-up agreement, commencing 90 days following the closing of this offering, a person, including an affiliate, who has beneficially owned our ordinary shares for six months or more, including the holding period of any prior owner other than one of our affiliates (i.e., commencing when the shares were acquired from us or from an affiliate of us as restricted securities), is entitled to sell our shares, subject to the availability of current public information about us (which information will be deemed to be available as long as we continue to file required reports with the SEC). In the case of an affiliate shareholder, the right to sell is also subject to the fulfillment of certain additional conditions, including manner of sale provisions, notice requirements, and a volume limitation that limits the number of shares that may be sold thereby, within any three-month period, to the greater of:

- 1% of the number of ordinary shares then outstanding; or
- the average weekly trading volume of our ordinary shares on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Rule 144 also provides that affiliates that sell our ordinary shares that are not restricted securities must nonetheless comply with the same restrictions applicable to restricted securities, other than the holding period requirement.

#### ***Shares Held by Non-Affiliates for One Year***

Under Rule 144 as currently in effect, a person who is not considered to have been one of our affiliates at any time during the three months preceding a sale and who has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than one of our affiliates, is entitled to sell his, her or its shares under Rule 144 without complying with the provisions relating to the availability of current public information or with any other conditions under Rule 144. Therefore, unless subject to a lock-up agreement or otherwise restricted, such shares may be sold immediately upon the closing of this offering.

#### **Rule 701**

In general, under Rule 701 as currently in effect, each of our employees, consultants or advisors who purchases our ordinary shares from us in connection with a compensatory stock plan or other written agreement executed prior to the closing of this offering is eligible to resell such ordinary shares in reliance on Rule 144, but without compliance with some of the restrictions, as described below.

Rule 701 will apply to the options granted under our 2014 Share Incentive Plan prior to the closing of this offering, along with the shares acquired upon exercise of these options, including exercises following the closing of this offering. Securities issued in reliance on Rule 701 are restricted securities and may be sold beginning 90 days following the closing of this offering in reliance on Rule 144 by:

- persons other than affiliates, without restriction; and
- affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144,

in each case, without compliance with the six-month holding period requirement of Rule 144.

#### **Form S-8 Registration Statements**

Following the closing of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register, in the aggregate, ordinary shares, issued or reserved for issuance under our 2014 Share Incentive Plan. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a share option or other award and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180-day lock-up or, if subject to the lock-up, immediately after the 180-day lock-up period expires.

#### **Registration Rights**

Upon the closing of this offering, we will enter into a registration rights agreement, pursuant to which we will grant demand registration rights, short-form registration rights and piggyback registration rights to Arkin Dermatology, our controlling shareholder. For more information on these registration rights, see “Certain Relationships and Related Party Transactions — Registration Rights Agreement.”

## **MATERIAL TAX CONSIDERATIONS**

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

### **Israeli Tax Considerations and Government Programs**

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 a 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 25% of a company's taxable income of 24% in 2017 and is expected to decrease to 23% in 2018. 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, 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. 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 at the date of this prospectus, we still have no 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 is 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 finance 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 income Tax Ordinance, 1961. Expenditures not so approved are deductible in equal amounts over three years.

From time to time we may apply the Office of the Chief Scientist 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 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, 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 ten 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 15% 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 (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 Investments 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:

<b>Tax Year</b>	<b>Development Region “A”</b>	<b>Other Areas within Israel</b>
2011 – 2012	10%	15%
2013	7%	12.5%
2014	9%	16%
2017 onwards (1)	7.5%	16%

(1) In December 2016, the Israeli Parliament (the Knesset) approved an amendment to the Investment Law pursuant to which the tax rate applicable to Preferred Enterprises in Development Region “A” would be reduced to 7.5% as of 2017.

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 2016 (iii) non-Israeli residents — 20% in 2016, subject 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 with 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 Preferred Enterprise.

### **Taxation of Our Shareholders**

#### ***Capital Gains***

Capital gain tax is imposed on the disposition of capital assets by an Israeli resident, and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Israeli Income Tax Ordinance of 1961 (New Version) (the “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 CPI between the date of purchase and the date of disposition. Inflationary Surplus is not 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 months period, such gain will be taxed at the rate of 30%.

Real Gain derived by corporations will be generally subject to a corporate tax rate of 25% in 2016, which is expected to be reduced to 24% in 2017 and 23% in 2018 and thereafter.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income — 25% for corporations in 2016, which is expected to be reduced to 24% in 2017 and 23% in 2018 and thereafter, and a marginal tax rate of up to 50% in 2016 for individuals, including an excess tax which is levied on individuals whose taxable income in Israel exceeds certain thresholds (NIS 810,720 in 2016 and NIS 640,000 in 2017 and thereafter, as discussed below).

Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares by a non-Israeli shareholder may be exempt under the Ordinance from Israeli taxation provided that the following cumulative conditions are met: (i) the shares were purchased upon or after the registration of the securities on the stock exchange prior to January 1, 2009, (ii) the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed, (iii) if the seller is a corporation, no more than 25% of its means of control are held, directly and indirectly, by an Israeli resident shareholders, and (iv) if the seller is a corporation, there is no Israeli Resident that is 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. resident 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 at 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.

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities from the Real Gain at the rate of 25%.

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 June 30 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 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 dividend by our company from income attributed to a Benefited Enterprise will generally be subject to withholding tax in Israel at a rate of 15% unless a reduced tax rate is provided under an applicable tax treaty. A distribution of 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% with respect to dividends to be distributed as of 2016; Israeli resident companies — 0% for a Preferred Enterprise; Non-Israeli residents — 20% with respect to dividends to be distributed as of 2016, 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 income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a “Controlling Shareholder” (as defined above) at the time of distribution or at any time during the preceding 12 months period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel.

The Ordinance provides that a non-Israeli resident (either individual or corporation) is generally subject to an Israeli income 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 months period); those rates are subject to a reduced tax rate under the provisions of an applicable double tax treaty. Thus, under the U.S.-Israel Double Tax Treaty the following 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 tax rate is 12.5%, (ii) if both the conditions mentioned in section (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 tax rate is 15% and (iii) in all other cases, the tax 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 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.

Payers of dividends on our ordinary shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder regarding his, her or its foreign residency, to withhold tax upon the distribution of dividend at the rate of 25%, so long as the shares are registered with a nominee company.

#### **Excess Tax**

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 2% in 2016 (to be increased to 3% in 2017 and thereafter) on annual income exceeding a certain threshold (NIS 810,720 for 2016 and NIS 640,000 for 2017 and thereafter, 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 Consequences

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. This discussion applies only to U.S. Holders that hold our ordinary shares as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the “Code”), that have acquired their ordinary shares in this offering 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 as part of a straddle, hedging, constructive sale, conversion or integrated transaction;
- persons that actually or constructively own 10% or more of the total combined voting power of all classes of our voting share capital;
- 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 pursuant to the exercise of any employee share option or otherwise as compensation; or
- pass-through entities, or persons holding our ordinary shares 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 THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES.

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 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 (1) 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 (2) 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, 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 directly and that is a partner of a partnership holding our ordinary shares is urged to consult its own tax advisor.

### **Passive Foreign Investment Company**

Based on our anticipated income and the composition of our income and assets, there is a significant risk that we will be a passive foreign investment company (“PFIC”) for U.S. federal income tax purposes at least until we start generating a substantial amount of active revenue. However, because PFIC status is a factual determination based on actual results for the entire taxable year, our U.S. counsel expresses no opinion with respect to our PFIC status. A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will generally be a PFIC for U.S. federal income tax purposes for any taxable year if either:

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

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 ambiguities in applying the PFIC test to us. No rulings from the U.S. Internal Revenue Service (the “IRS”), however, have been or will be sought with respect to our status as a PFIC.

If we are a PFIC for any taxable year during which you hold our ordinary shares, we generally will continue to be treated as a PFIC with respect to your investment in our ordinary shares for all succeeding years during which you hold our ordinary shares, unless we cease to be a PFIC and you make a “deemed sale” election with respect to our ordinary shares. If such election is made, you will be deemed to have sold our ordinary shares you hold at their fair market value on the last day of the last taxable year in which we were a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, your ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

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, unless you make a valid “mark-to-market” election as discussed below. 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 for our ordinary shares 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 for our ordinary shares;
- 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 cannot be treated as capital gains, even if you hold our ordinary shares 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 shares in such lower-tier PFICs that are directly or indirectly owned by us in that proportion which the value of our ordinary shares you own bears to the value of all of our ordinary shares, 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. We expect our ordinary shares will be listed on NASDAQ. 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. NASDAQ 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 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 the acquisition, ownership and disposition of our ordinary shares.

**YOU ARE STRONGLY URGED TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR BEING A PFIC ON YOUR INVESTMENT IN OUR ORDINARY SHARES 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 (1) our ordinary shares are readily tradable on an established securities market in the United States (such as NASDAQ), (2) 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, (3) certain holding period requirements are met and (4) you are not under an obligation to make related payments with respect to positions in substantially similar or related property. As discussed above under “Passive foreign investment company,” there is a significant risk that we will be a PFIC for U.S. federal income tax purposes, and, as a result, the qualified dividend rate may be unavailable with respect to dividends we pay.

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” but could, in the case of certain U.S. Holders, constitute “general 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 (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.

### **Taxation of Disposition of Ordinary Shares**

Subject to the PFIC rules discussed above, upon a sale or other disposition of ordinary shares, 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. If the consideration you receive for our ordinary shares 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 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.

Your tax basis in our ordinary shares generally will equal the cost of such ordinary shares. Any gain or loss on the sale or other disposition of our ordinary shares 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 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.

### **Information Reporting and Backup Withholding**

Dividend payments with respect to ordinary shares and proceeds from the sale, exchange or redemption of ordinary shares 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, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain U.S. 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 THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES.



## UNDERWRITING

Under the terms of an underwriting agreement, which will be filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to purchase from us the number of ordinary shares shown opposite its name below:

Underwriters	Number of Shares
Total	

The underwriting agreement provides that the underwriters' obligation to purchase ordinary shares depends on the satisfaction of the conditions contained in the underwriting agreement including:

- the obligation to purchase all of the ordinary shares offered hereby (other than those ordinary shares covered by their option to purchase additional shares as described below), if any of the shares are purchased;
- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

The underwriting agreement also provides that if an underwriter defaults, the offering may be terminated.

### Commissions and Expenses

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. The underwriting fee is the difference between the price to the public and the amount the underwriters pay to us for the shares.

	No Exercise	Full Exercise
Per share	\$	\$
Total	\$	\$

The representative has advised us that the underwriters propose to offer the ordinary shares directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of \$      per share. After the offering, the representative may change the offering price and other selling terms.

The expenses of the offering that are payable by us are estimated to be \$      (excluding the underwriting discounts and commissions). We have also agreed to reimburse the representative for certain of its expenses, in an amount of up to \$      , incurred in connection with this offering, as set forth in the underwriting agreement.

### Option to Purchase Additional Shares

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus to purchase, from time to time, in whole or in part, up to an aggregate of      of additional shares at the public offering price less underwriting discounts and commissions. This option may be exercised solely for the purpose of covering overallocments, if any, in connection

with this offering. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in the offering as indicated in the table at the beginning of this Underwriting section.

### **Lock-Up Agreements**

We, all of our directors and executive officers and their affiliates and each holder of our ordinary shares have agreed that, for a period of 180 days after the date of this prospectus, we and they will not directly or indirectly, without the prior written consent of \_\_\_\_\_, (1) offer for sale, sell, pledge, or otherwise dispose (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) of any ordinary shares (including, without limitation, ordinary shares that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and ordinary shares that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for ordinary shares (other than the ordinary shares and shares issued pursuant to employee benefit plans, qualified share option plans, or other employee compensation plans existing on the date of this prospectus), or sell or grant options, rights or warrants with respect to any ordinary shares or securities convertible into or exchangeable for ordinary shares, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of ordinary shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ordinary shares or other securities, in cash or otherwise, (3) make any demand for or exercise any right or file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any ordinary shares or securities convertible, exercisable or exchangeable into ordinary shares or any of our other securities, or (4) publicly disclose the intention to do any of the foregoing.

\_\_\_\_\_ may release the ordinary shares and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release ordinary shares and other securities from lock-up agreements, \_\_\_\_\_ will consider, among other factors, the holder's reasons for requesting the release, the number of ordinary shares and other securities for which the release is being requested and market conditions at the time. At least three business days before the effectiveness of any release or waiver of any of the restrictions described above with respect to an officer or director of the Company, \_\_\_\_\_ will notify us of the impending release or waiver and we have agreed to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver, except where the release or waiver is effected solely to permit a transfer of ordinary shares that is not for consideration and where the transferee has agreed in writing to be bound by the same terms as the lock-up agreements described above to the extent and for the duration that such terms remain in effect at the time of transfer.

### **Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

### Stabilization, Short Positions and Penalty Bids

The representative may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the ordinary shares, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the ordinary shares while the offering is in progress.
- A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriter in excess of the number of shares it is obligated to purchase is not greater than the number of shares that it may purchase by exercising its option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in its option to purchase additional shares. The underwriter may close out any short position by either exercising its option to purchase additional shares, purchasing shares in the open market, or both. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through its option to purchase additional shares. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Syndicate covering transactions involve purchases of the ordinary shares in the open market after the distribution has been completed in order to cover syndicate short positions.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the ordinary shares originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.
- Passive market making transactions in the ordinary shares on the NASDAQ Global Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of ordinary shares and extending through the completion of distribution.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a decline in the market price of the ordinary shares. As a result, the price of the ordinary shares may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ Global Market, in the over the counter market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the ordinary shares. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

## **Electronic Distribution**

A prospectus in electronic format may be made available on Internet sites or through other online services maintained by one or more of the underwriters or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representative on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

## **Listing on The NASDAQ Global Market**

We intend to apply to list our ordinary shares on The NASDAQ Global Market under the symbol "SLGL."

## **Stamp Taxes**

If you purchase ordinary shares offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

## **Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses.

## **Selling Restrictions**

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the shares of ordinary shares or possession or distribution of this prospectus or any other offering or publicity material relating to the ordinary shares in any country or jurisdiction (other than the U.S.) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any ordinary shares or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of ordinary shares by it will be made on the same terms.

### **Determination of Offering Price**

Prior to the offering, there has not been a public market for our ordinary shares. Consequently, the public offering price for our ordinary shares will be determined by negotiations between us and the representative for this offering. Among the factors to be considered in these negotiations are:

- the prevailing market conditions;
- our financial information and past and present operations;
- market valuations of other companies that we and the representative believe to be comparable to us;
- estimates of our business potential and the present state of our development;
- an assessment of our management;
- the present state of our development and other factors deemed relevant.

We offer no assurances that the public offering price will correspond to the price at which the ordinary shares will trade in the public market subsequent to the offering or that an active trading market for the ordinary shares will develop and continue after the offering.

### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any ordinary shares which are the subject of the offering contemplated herein may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any ordinary shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of ordinary shares result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any ordinary shares under, the offers contemplated here in this prospectus will be deemed to have represented, warranted and agreed to and with each underwriter and us that:

- it is a qualified investor as defined under the Prospectus Directive; and

- in the case of any ordinary shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the ordinary shares acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in the circumstances in which the prior consent of the representative has been given to the offer or resale or (ii) where ordinary shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of such ordinary shares to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation and the provision above, the expression an “offer of ordinary shares to the public” in relation to any ordinary shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any ordinary shares to be offered so as to enable an investor to decide to purchase or subscribe for the ordinary shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

### **United Kingdom**

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the “FSMA”)) as received in connection with the issue or sale of the ordinary shares in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the ordinary shares in, from or otherwise involving the United Kingdom.

### **Notice to Residents of Canada**

The ordinary shares may be sold only to purchasers purchasing as principal that are both “accredited investors” as defined in National Instrument 45-106 Prospectus and Registration Exemptions and “permitted clients” as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ordinary shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

### **Switzerland**

This document, as well as any other material relating to the shares which are the subject of the offering contemplated by this prospectus, do not constitute an issue prospectus pursuant to Article 652a and/or 1156 of the Swiss Code of Obligations. The shares will not be listed on the SIX Swiss Exchange and, therefore, the documents relating to the shares, including, but not limited to, this document, do not claim to comply with the disclosure standards of the listing rules of SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange. The shares are being offered in Switzerland by way of a private placement, i.e., to a small number of selected investors only, without any public offer and only to investors who do not purchase the shares with the intention to distribute them to the public. The investors will be individually approached by the issuer from time to time. This document, as well as any other material relating to the shares, is personal and confidential and does not constitute an offer to any other person. This document may only be used by those investors to whom it has been handed out in connection with the offering described herein and may neither directly nor indirectly be distributed or made available to other persons without express consent of the issuer. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in (or from) Switzerland.

## **Hong Kong**

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

## **Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries’ rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

## **Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any shares, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

**Israel**

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Israeli Securities Law and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and any offer of the ordinary shares is directed only at investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange Ltd., underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum.



**EXPENSES RELATED TO OFFERING**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the offer and sale of ordinary shares in this offering. The underwriting discounts and commissions to be paid to the underwriters represent of the total amount of the offering. All amounts listed below are estimates except the SEC registration fee, NASDAQ listing fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

<b>Itemized expense</b>	<b>Amount</b>
SEC registration fee	\$
FINRA filing fee	
NASDAQ Global Market listing fee	
Printing and engraving expenses	
Legal fees and expenses	
Transfer agent and registrar fees	
Accounting fees and expenses	
Miscellaneous	
<b>Total</b>	<b>\$</b>

## LEGAL MATTERS

The validity of the ordinary shares being offered by this prospectus and other legal matters concerning this offering relating to Israeli law will be passed upon for us by Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Tel-Aviv, Israel. Certain legal matters in connection with this offering relating to U.S. federal law will be passed upon for us by Latham & Watkins LLP. Certain legal matters concerning this offering relating to U.S. federal law will be passed upon for the underwriters by .

## EXPERTS

The financial statements as of December 31, 2016 and 2015 and for each of the two years in the period ended December 31, 2016 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of Kesselman and Kesselman, an independent registered public accounting firm and member firm of PricewaterhouseCoopers International Limited, given on the authority of said firm as experts in auditing and accounting. The offices of Kesselman and Kesselman are located at Trade Tower, 25 Hamered Street, Tel Aviv 68125, Israel.

## ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this prospectus, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States

We have irrevocably appointed as our agent to receive service of process in any action against us in any U.S. federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. The address of our agent is .

We have been informed by our legal counsel in Israel, Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., that it may be difficult to initiate an action with respect to U.S. securities law in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum to hear such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact by expert witnesses which can be a time-consuming and costly process. Certain matters of procedure may also be governed by Israeli law.

Subject to certain time limitations and legal procedures, Israeli courts may enforce a U.S. judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that:

- the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment;
- the judgment may no longer be appealed;
- the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy; and
- the judgment is executory in the state in which it was given.

Even if these conditions are met, an Israeli court will not declare a foreign civil judgment enforceable if:

- the judgment was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases);
- the enforcement of the judgment is likely to prejudice the sovereignty or security of the State of Israel;
- the judgment was obtained by fraud;
- the opportunity given to the defendant to bring its arguments and evidence before the court was not reasonable in the opinion of the Israeli court;
- the judgment was rendered by a court not competent to render it according to the laws of private international law as they apply in Israel;
- the judgment is contradictory to another judgment that was given in the same matter between the same parties and that is still valid; or
- at the time the action was brought in the foreign court, a lawsuit in the same matter and between the same parties was pending before a court or tribunal in Israel.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet site that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through this web site at <http://www.sec.gov>.

We are not currently subject to the informational requirements of the Exchange Act. As a result of this offering, we will become subject to the informational requirements of the Exchange Act applicable to foreign private issuers and will fulfill the obligations of these requirements by filing reports with the SEC. As a foreign private issuer, we will be exempt from the rules under the Exchange Act relating 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. In addition, we will not be required under the Exchange Act to file periodic 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 intend to file with the SEC, within 120 days after the end of our fiscal year ended December 31, 2016, and each subsequent fiscal year, an annual report on Form 20-F containing financial statements which will be examined and reported on, with an opinion expressed, by an independent registered public accounting firm. We also intend to file with the SEC reports on Form 6-K containing unaudited financial information for the first three quarters of each fiscal year.

We maintain a corporate website at [www.sol-gel.com](http://www.sol-gel.com). Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

**SOL-GEL TECHNOLOGIES LTD.**  
**FINANCIAL STATEMENTS**  
**AS OF DECEMBER 31, 2016**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

### SOL-GEL TECHNOLOGIES LTD.

In our opinion, the accompanying balance sheets and the related statements of operations, changes in capital deficiency and cash flows present fairly, in all material respects, the financial position of Sol-Gel Technologies Ltd. As of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by the Board of Directors and management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, in recent years the Company has not generated any revenues and is therefore dependent on the continuing support of its controlling shareholder. The Company has an accumulated deficit of approximately \$63.7 million as of December 31, 2016 and does not have sufficient cash to meet its liquidity requirements for the following twelve months. Consequently, there is substantial doubt about the Company's ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Tel-Aviv, Israel  
March 30, 2017

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

*Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,  
P.O. Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax: +972 -3- 7954556, [www.pwc.com/il](http://www.pwc.com/il)*

## SOL-GEL TECHNOLOGIES LTD.

## BALANCE SHEETS

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

	December 31	
	2015	2016
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,895	\$ 7,001
Prepaid expenses and other current assets	244	472
Advance payment	—	823
<b>TOTAL CURRENT ASSETS</b>	<b>6,139</b>	<b>8,296</b>
<b>NON-CURRENT ASSETS:</b>		
Advance payment	625	—
Long term receivables	—	1,190
Restricted long term deposits	92	107
Property and equipment, net	785	798
Funds in respect of employee rights upon retirement	603	594
<b>TOTAL NON-CURRENT ASSETS</b>	<b>2,105</b>	<b>2,689</b>
<b>TOTAL ASSETS</b>	<b>\$ 8,244</b>	<b>\$ 10,985</b>
<b>Liabilities net of capital deficiency</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 311	\$ 667
Accrued expenses and other	1,487	3,623
Loans from the controlling shareholder	17,338	37,338
<b>TOTAL CURRENT LIABILITIES</b>	<b>19,136</b>	<b>41,628</b>
<b>LONG-TERM LIABILITIES –</b>		
Liability for employee rights upon retirement	626	694
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>626</b>	<b>694</b>
<b>COMMITMENTS</b>		
<b>TOTAL LIABILITIES</b>	<b>\$ 19,762</b>	<b>\$ 42,322</b>
<b>CAPITAL DEFICIENCY:</b>		
Ordinary shares, NIS 0.1 par value – authorized: 8,775,783 as of December 31, 2015 and 2016; issued and outstanding: 3,494,579 as of December 31, 2015 and 2016	82	82
Additional paid-in capital	31,322	32,274
Accumulated deficit	(42,922)	(63,693)
<b>TOTAL CAPITAL DEFICIENCY</b>	<b>(11,518)</b>	<b>(31,337)</b>
<b>TOTAL LIABILITIES NET OF CAPITAL DEFICIENCY</b>	<b>\$ 8,244</b>	<b>\$ 10,985</b>

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

**SOL-GEL TECHNOLOGIES LTD.****STATEMENTS OF OPERATIONS**

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

	Year ended December 31,	
	2015	2016
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	\$ 7,184	\$ 17,023
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	2,463	3,733
<b>TOTAL OPERATING LOSS</b>	9,647	20,756
<b>FINANCIAL EXPENSES, NET</b>	13	15
<b>LOSS FOR THE YEAR</b>	<u>\$ 9,660</u>	<u>\$ 20,771</u>
<b>BASIC AND DILUTED LOSS PER ORDINARY SHARE</b>	<u>\$ 2.76</u>	<u>\$ 5.94</u>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE</b>	<u>3,494,579</u>	<u>3,494,579</u>

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



## SOL-GEL TECHNOLOGIES LTD.

## STATEMENTS OF CHANGES IN CAPITAL DEFICIENCY

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

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total
	Number of shares	Amounts		Amounts	
<b>BALANCE AS OF JANUARY 1, 2015</b>	3,494,579	\$82	\$ 30,193	\$ (33,262)	\$ (2,987)
<b>CHANGES DURING 2015:</b>					
Loss for the year				(9,660)	(9,660)
Share-based compensation			1,129		1,129
<b>BALANCE AS OF DECEMBER 31, 2015</b>	3,494,579	82	31,322	(42,922)	(11,518)
<b>CHANGES DURING 2016:</b>					
Loss for the year				(20,771)	(20,771)
Share-based compensation			952		952
<b>BALANCE AS OF DECEMBER 31, 2016</b>	<u>3,494,579</u>	<u>\$82</u>	<u>32,274</u>	<u>\$ (63,693)</u>	<u>\$ (31,337)</u>

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

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

	Year ended December 31	
	2015	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Loss	\$ (9,660)	\$ (20,771)
Adjustments required to reconcile loss to net cash used in operating activities:		
Depreciation	300	359
Changes in accrued liability for employee rights upon retirement	(86)	68
Share-based compensation	1,129	952
In-process research and development acquired	431	—
Finance expenses, net	17	8
Changes in operating asset and liabilities:		
Prepaid expenses and other current assets	1	(228)
Accounts payable, accrued expenses and other	449	2,505
Advance payment	(625)	(198)
Long term receivables	—	(1,190)
Net cash used in operating activities	(8,044)	(18,495)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(291)	(385)
Long term deposits	(8)	(15)
Amounts funded in respect of employee rights upon retirement, net	89	9
Net cash used in investing activities	(210)	(391)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Loans received from the controlling shareholder	13,572	20,000
Net cash provided by financing activities	13,572	20,000
<b>EFFECT OF EXCHANGE RATE ON CASH AND CASH EQUIVALENTS</b>	(17)	(8)
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	5,301	1,106
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR</b>	594	5,895
<b>CASH AND CASH EQUIVALENTS AT END OF THE YEAR</b>	<u>\$ 5,895</u>	<u>\$ 7,001</u>
<b>SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:</b>		
Purchase of property and equipment	<u>\$ 23</u>	<u>\$ 10</u>
Acquisition of in-process research and development product candidate	<u>\$ 431</u>	<u>\$ —</u>

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

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS**

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

**NOTE 1 — NATURE OF OPERATIONS**

Sol-Gel Technologies Ltd. (hereafter — 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. In addition to these novel product candidates, the Company's product pipeline includes generic product candidates.

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.

On August 4, 2014, 100% of the Company's shares were acquired by its current controlling shareholder (the "controlling shareholder").

The Company has an accumulated deficit of approximately \$63.7 million and its activities have been funded mainly by its shareholders.

The Company has been engaged in development activities since its incorporation.

Since its acquisition by the controlling shareholder, the Company has not generated any material revenues and is therefore dependent on the continuing support of its controlling shareholder. As a result, management cannot determine with reasonable certainty if and when the Company will obtain the required funds in order to complete the clinical development of its main product candidates and continue operations. Consequently, there is no assurance that the Company's business will generate positive cash flows and there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. If the Company is unable to obtain the appropriate funds, the Company will need to curtail or cease operations.

**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES****a. 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").

**b. 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 financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation.

**c. Functional and presentation currency**

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of the Company are conducted. The Company's financing has been provided in dollars,

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS** (continued)  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES** (continued)

revenues are expected to be 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.

**d. 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.

**e. 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.

**f. 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 two years ended December 31, 2016, the Company did not recognize an impairment loss for its long-lived assets.

**g. Share-based compensation**

The Company accounts for employees' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures.

## SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)  
(U.S. dollars in thousands, except share and per share amounts)

## NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (continued)

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.

**h. 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.

Grants received from the National Authority for Technological Innovation, (hereafter — “NATI”), formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, or 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. As of December 31, 2016, the Company does not have a royalty liability to the NATI (see note 5a).

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company out sources 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.

**i. Income taxes:**

## 1) Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. The Company has provided a full valuation allowance with respect to its deferred tax assets.

## 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.

**j. Loss per share**

Basic loss per share is computed on the basis of the net loss for the period divided by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options, which

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS (continued)**  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (continued)**

are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include 130,775 and 194,300 options for the years ended December 31, 2015 and 2016, respectively, because the effect would be anti-dilutive.

**k. Fair value measurement**

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The carrying amount of the cash and cash equivalents and accrued expenses and other liabilities approximates their fair value.

**l. Concentration of credit risks**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents and third party credit exposure as part of long-term receivables. The Company deposits cash and cash equivalents with highly rated financial institutions (Israeli banks). The Company has not experienced any credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments. The Company assesses risk associated with the quality of the third party credit by evaluating the third party's financial standing and other factors.

**m. Newly issued and recently adopted accounting pronouncements:**

1) In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Prior to this, there was no guidance under U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in this update provide that guidance. The amendments in this ASU are effective for the annual period ending after December 15, 2016. Therefore, the Company has prospectively adopted this new standard on December 15, 2016. The adoption of this standard did not have a material impact on our consolidated financial statements as of December 31, 2016.

## SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)  
(U.S. dollars in thousands, except share and per share amounts)

## NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES (continued)

In doing so, the amendments reduce diversity in the timing and content of footnote disclosures. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). For the period ended December 31, 2016, management evaluated the Company's ability to continue as a going concern and concluded that there is substantial doubt of its ability to continue as a going concern.

2) In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its financial statements.

3) In March 2016, the FASB issued ASU No. 2016-09, Compensation — Stock Compensation (Topic 718). ASU No. 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The amendments are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted but all of the guidance must be adopted in the same period. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

## NOTE 3 — PROPERTY AND EQUIPMENT

	December 31	
	2015	2016
Cost:		
Laboratory equipment	\$ 1,065	\$ 1,263
Office equipment and furniture	182	234
Computers and software	222	282
Leasehold improvements	466	528
	1,935	2,307
Less:		
Accumulated depreciation and amortization	(1,150)	(1,509)
Property and equipment, net	<u>\$ 785</u>	<u>\$ 798</u>

Depreciation and amortization expense totaled \$300 and \$359 for the years ended December 31, 2015 and 2016, respectively.

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS (continued)**  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 4 — 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 were 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, 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 \$162 and \$261 for the years ended December 31, 2015 and 2016, respectively, of which \$159 and \$185 in the years ended December, 2015 and 2016, respectively, were in respect of the Contribution Plan.

The Company expects to contribute approximately \$193 in the year ending December 31, 2017 to insurance companies in connection with its expected severance liabilities for that year.

**NOTE 5 — COMMITMENTS****a. Royalty Commitments**

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

Under the terms of the funding arrangements with the NATI, royalties of 3.5% to 25% are payable on the sale of products developed from product candidates funded by the NATI, 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.

As of December 31, 2016, the Company had recognized and received grants from the NATI in the amount of \$1,431. Through December 31, 2016, the Company recorded an accumulated royalty expense of \$1,997, of which an amount of \$492 was paid during 2016, as royalties to the NATI with respect to revenue recognized until 2013. As of December 31, 2016, the Company does not have any liabilities to the NATI.



**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS** (continued)  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 5 — COMMITMENTS** (continued)

The Company did not receive any grants from the NATI for the years ended December 31, 2015 and 2016.

1. 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:

- i. Royalties of 1.5% of net sales related to certain patents.
- ii. 1.5% – 8% of proceeds received by the Company for the sub-license or license of certain patents.

The term of the above mentioned agreements terminated on May 4, 2013. 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. As of December 31, 2016 and 2015, the Company does not have any liability regarding these patents.

**b. Lease Agreements**

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 2020.

On January 13, 2016 (and for a term ending on February 28, 2017) the Company entered into a sub-lease agreement with one of the tenants in the facility in which the offices are located for the leasing of additional office space.

The annual lease expenses for the years ended December 31, 2015 and 2016 were approximately \$256 and \$316, respectively.

As of December 31, 2016, future minimum lease commitments under these operating lease agreements are as follows:

Year	Amount
2017	\$ 419
2018	429
2019	429
2020	429
Total	\$1,706

As security for its obligation under the lease agreements the Company deposited \$99 in an amount equal to four monthly lease payments, which are classified as restricted long-term deposits.

## SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)  
(U.S. dollars in thousands, except share and per share amounts)

## NOTE 5 — COMMITMENTS (continued)

**c. Vehicle Lease Agreements**

The Company has entered into operating lease agreements for vehicles used by its employees for a period of 3 years. The annual lease expenses for the years ended December 31, 2015 and 2016 were \$163 and \$156, respectively.

The expected annual lease payments under this agreement for the next three years are \$122, \$40 and \$6 for the years ending December 31, 2017, 2018 and 2019, respectively.

As security for its obligation under the lease agreements the Company deposited \$20, \$8 of which is classified as restricted long term deposits.

**d.** In connection with the acquisition of the Company, as described in note 1, the Executive Officers and certain employees are entitled, subject to certain research and development milestones and other conditions, as set forth in the agreement, to a special bonus in an aggregate amount of up to \$3,000, of which \$873 and \$127 were paid in each of the years 2014 and 2016 to Executive Officers and certain employees, respectively. As of December 31, 2016 the remaining milestones were not yet achieved and the Company has not recorded a liability regarding this special bonus.

**e.** In June 2008, the Company entered into a Master Clinical Trial Services Agreement with a third party, which was later amended in April 2016, to retain its services as a 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 \$3,919 during the term of the engagement and based on achievement of certain milestones, \$1,730 of which were recognized as an expense through December 31, 2016.

**f.** In March 2015, the Company entered into a Clinical Development Master Services Agreement (which was amended during 2016) with a third party, to retain it as another clinical research organization, for its Phase II clinical trial for acne. As consideration for its services the Company will pay a total amount of approximately \$7,230 during the term of the engagement and based on achievement of certain milestones, \$191 and \$4,707 of which were recognized as an expense through December 31, 2015 and 2016, respectively.

In addition, as security for its obligation under this agreement, the Company made an advance payment in the amount of \$823, which is expected to be used by the end of the clinical trial (in 2017) and therefore it is classified as a current asset.

**g.** In April 2015, the Company entered into a development, manufacturing and commercialization agreement, as amended on October 26, 2015, with a third party, to work towards the objective of obtaining all FDA approvals necessary for the commercialization of one of its product candidates in the U.S. Under this agreement, the third party is obligated to conduct all regulatory, scientific, clinical and technical activities necessary to develop the product and prepare and file an abbreviated new drug application, or ANDA, with the FDA and gain regulatory approval. As soon as reasonably practical after FDA approval, the third party has exclusive rights and is required to use diligent efforts to commercialize this product in the U.S., including all required sales, marketing and distributing activities associated with the agreement. The Company is entitled to 50% of the third party's gross profits related to the sale of this product, as such term is defined in the agreement, on a quarterly basis, for a period of 20 years following the first commercial sale of this product in the U.S.

## SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)  
(U.S. dollars in thousands, except share and per share amounts)

## NOTE 5 — COMMITMENTS (continued)

Each party is responsible for its own costs in relation to performance under the agreement. The Company will finance all out-of-pocket clinical trial expenses (including materials), and the third party will reimburse the Company for 40% of the out-of-pocket clinical trial expenses as follows (a) in case of success of obtaining the FDA approval, by financing the Company's share in the out-of-pocket litigation expenses (and by a cash payment if such financing is less than the reimbursement owed to the Company), or (b) in case of failure to obtain the required FDA approval for the commercialization of the product candidate, by paying back the Company an amount equal to 40% of its out-of-pocket expenses. The Company recognized the third party's obligation in an amount of \$1,190 as long term receivables.

The total consideration for the clinical trial is approximately \$5,157 during the term of the engagement, of which the Company will recognize 60% as an expense. During the year ended December 31, 2016, the Company recognized \$1,785 as an expense.

**h.** On May 28, 2015, the Company entered into a Product Development, Manufacturing and Supply Agreement with a third party (hereafter — the CMO), a manufacturer of pharmaceutical drug products for consumer use, for the development, manufacture and supply of clinical materials for our Phase III trial of one of the products candidates.

CMO will develop an acceptable, scaled-up formulation and manufacturing process for this product. Unless earlier terminated, the initial term of the agreement is set for a period of five years which automatically renews thereafter for additional two year periods except if either party provides a notice of non-renewal not less than 12 months prior to the end of the then applicable renewal term. Until the Company determines at its sole discretion that an acceptable stable, scaled-up formulation and manufacturing process has been developed for each product, either party may terminate the agreement by providing 120 days' prior written notice to the other party. The CMO will manufacture, deliver and sell to the Company pursuant to written purchase orders at the times and quantities specified by the Company, \$797 and \$580 of which were recognized as an expense through December 31, 2015 and 2016, respectively.

**i.** On December 31, 2015, the Company assumed, following the transfer of an in-process research and development product candidate (hereafter — the product) from a related party, an agreement with a third party for the development, manufacturing and commercialization of this product. According to this agreement, the third party will conduct all regulatory, scientific, clinical and technical activities necessary to develop the product. The Company will be responsible to pay all out-of-pocket expenses incurred by the third party in performing its services under the development plan. The Company will pay the third party approximately \$2,000 upon NDA submission of the product, and approximately \$3,000 upon the approval of the FDA on the first NDA for the product. In addition, the Company will be required to pay royalties to the third party on the net sales of the product (as defined in the agreement) ranging from 5.5% to 6.5% depending on the net sale volume of the product. See also note 9d. As of the date of these financial statements, none of the agreed upon milestones have been met.

**j.** In June 2016, the Company entered into a development, manufacturing and commercialization agreement, with a third party, to work towards the objective of obtaining all FDA approvals necessary for the commercialization of one of its product candidates in the U.S. Under this agreement, the third party is obligated to conduct all regulatory, scientific, clinical and technical activities necessary to develop the product and prepare and file an abbreviated new drug application, or ANDA, with the FDA and gain regulatory approval. The Company is obligated for sourcing the active pharmaceutical ingredient (API) during the development phase. As soon as

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS (continued)**  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 5 — COMMITMENTS (continued)**

reasonably practical after FDA approval, the third party has exclusive rights and is required to use diligent efforts to commercialize this product in the U.S., including all required sales, marketing and distributing activities associated with the agreement. The Company is entitled to 50% of the third party's gross profits related to the sale of this product, as such term is defined in the agreement, on a quarterly basis, for a period of 20 years following the first commercial sale of this product in the U.S. As of the date of these financial statements, none of the agreed upon milestones have been met.

**NOTE 6 — LOANS FROM THE CONTROLLING SHAREHOLDER**

Until December 31, 2014, the Company received loans from its controlling shareholder in the amount of \$3,335.

In 2015 and 2016, the Company received additional loans from its controlling shareholder in the amounts of \$13,572 and \$20,000, respectively.

In addition, the consideration for the transfer in 2015, as detailed in note 9d, was added to the loans.

The loans are classified as a current liability and denominated in US dollars, bear no interest and are backed by a promissory note. The Promissory Note is an unsecured note, has no repayment date and is subject to acceleration in certain events of default.

**NOTE 7 — SHARE CAPITAL****a. 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.

**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 349,458 ordinary shares, par value NIS 0.1 each, or such other number as the Board may determine, subject to certain terms and conditions as defined in the Plan. According to the Plan, the Company may issue shares or restricted shares, may grant options or restricted share units and other share-based awards (hereafter — the awards) to the Company employees, consultants, directors and other service providers.

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

The awards may be exercised after vesting and in accordance with vesting schedules which will be determined by the Board of Directors for each grant. The maximum term of the awards is 10 years. The fair value of each option granted under this Plan is estimated using the Black-Scholes option pricing method. Expected volatility is based on the historical volatility of comparable peer companies.

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS (continued)**  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 7 — SHARE CAPITAL (continued)**

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 of December 31, 2016, 125,596 ordinary shares remain available for grant under the Plan.

**2) Options granted to employees:**

a. In March and April 2015, the Company granted 173,440 options to the Executive Officers of the Company to purchase ordinary shares at an exercise price of \$2.86 per share. 25% of the options vest on the first anniversary of the vesting commencement date (August 4, 2014) and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of the grant date.

b. In August 2016, the Company granted 50,422 options to the Executive Officers of the Company to purchase shares of NIS 0.1 par value ordinary shares of the Company at an exercise price of \$2.86 per share. 25% of the options vest on the first anniversary of the vesting commencement date and the rest vest quarterly over the following three years. The options expire on the tenth anniversary of the grant date.

The fair value of options granted to employees in 2015 and 2016 were \$1,618 and \$986, respectively. The underlying data used for computing the fair value of the options are as follows:

	2015	2016
Value of one ordinary share	\$11.35	\$21.59
Dividend yield	0%	0%
Expected volatility	62.46% – 66.22%	68.46% – 79.1%
Risk-free interest rate	1.61% – 1.81%	0.95% – 1.34%
Expected term	5.5 – 7.5 years	5 – 6.71 years

The total unrecognized compensation cost of employee options at December 31, 2016 is \$523, which is expected to be recognized over a period of 2.8 years.

## SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)  
(U.S. dollars in thousands, except share and per share amounts)

## NOTE 7 — SHARE CAPITAL (continued)

c. The following table summarizes the number of options outstanding under the Plan for the years ended December 31, 2015 and 2016, and related information:

	Year ended December 31					
	2015			2016		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at the beginning of the year	—	—	—	173,440	\$2.86	9.25
Granted	173,440	\$2.86	9.25	50,422	\$2.86	9.59
Options outstanding at the end of the year	173,440	\$2.86	9.25	223,862	\$2.86	8.55
Options exercisable at the end of the year	54,200	\$2.86	9.25	106,854	\$2.86	9.59

The aggregate intrinsic value of the total outstanding and of total exercisable options as of December 31, 2016 is approximately \$4,193 and \$2,001, respectively.

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

	Year ended December 31	
	2015	2016
Research and development expenses	\$ 468	\$541
General and administrative expenses	661	411
	<u>\$1,129</u>	<u>\$952</u>

## NOTE 8 — TAXES ON INCOME

The Company is taxed under Israel tax laws:

## a. Tax rates

The income of the Company and the Capital gains, other than income from Benefitted Enterprises (see b below), are subject to the normal corporate tax rates (26.5% for 2015 and 25% for 2016).

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. As a result, the regular tax rate will be 24% in 2017 and 23% in 2018 and thereafter.

## b. 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.

**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS** (continued)  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 8 — TAXES ON INCOME** (continued)

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, 2016, 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.

The Amendment sets alternative benefit tracks to the ones currently in place under the provisions of the Investment Law, including a reduced corporate tax rate. Tax rate for "Preferred Enterprise" income of companies not located in national development zone A, is 16% for fiscal year 2014 and thereafter.

The benefits are granted to companies that qualify under criteria set forth in the Investment Law; for the most part, those criteria are similar to the criteria that have existed in the Investment Law prior to its amendment and the benefit period is unlimited in time. However, in accordance with the Amendment, the classification of licensing income as Preferred income is subject to the issuance of a pre-ruling by the Israel Tax Authority.

Under the transitional provisions of the Investment Law, a company is allowed to continue to enjoy the tax benefits available under the Investment Law prior to its amendment until the end of the period of benefits, as defined in the Investment Law.

In each year during the period of benefits of its Benefitted Enterprise, the Company will be able to opt for application of the Amendment, thereby making available to itself the tax rate described above. The Company's election to apply the Amendment is irrevocable.

As of December 31, 2016, 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.

## SOL-GEL TECHNOLOGIES LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)  
(U.S. dollars in thousands, except share and per share amounts)

## NOTE 8 — TAXES ON INCOME (continued)

## c. Tax assessments

Tax assessments filed by the Company through the year 2012 are considered to be final.

## d. Losses for tax purposes carried forward to future years

As of December 31, 2016, the Company had approximately \$47.4 million of net carry forward tax losses which are available to reduce future taxable income with no limited period of use.

## e. Deferred income taxes:

	As of December 31	
	2015	2016
In respect of:		
Net operating loss carry forward	\$ 9,468	\$ 10,912
Research and development expenses	1,377	2,935
Other	43	152
Less – valuation allowance	(10,888)	(13,999)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

## f. Reconciliation of theoretical tax expenses to actual expenses

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.

## g. Provision for uncertain tax positions

As of December 31, 2015 and 2016, the Company does not have a provision for uncertain tax positions.

## NOTE 9 — 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 bonus to Executive Officers, see note 5d.

c. As to options granted to Executive Officers, see note 7b2.

d. On December 31, 2015, a related company (wholly owned by the Company's controlling shareholder) transferred an in-process research and development product candidate (hereafter — the product) to the Company, together with a collaboration agreement with third party to research, develop and manufacture the product, in consideration of \$431.

This was considered a transaction between entities under common control and thus it was recorded on historical cost basis and therefore the Company recognized the consideration of \$431 as a research and development expense in 2015. The amount was paid to the related company during 2015 by utilizing a loan from the controlling shareholder.



**SOL-GEL TECHNOLOGIES LTD.****NOTES TO THE FINANCIAL STATEMENTS** (continued)  
(U.S. dollars in thousands, except share and per share amounts)**NOTE 10 — SUBSEQUENT EVENTS**

On February 12 2017, the Company granted 29,906 options to one of its Executive Officers to purchase ordinary shares at an exercise price of \$2.86 per share. 25% of the options vest on the first anniversary of the vesting commencement date and the rest vest quarterly over the following three years. Upon the occurrence of a merger or sale (as such term is defined in the agreement), 100% of the then unvested options shall become fully vested, provided, that the grantee is an Employee of the Company at such time.

The options expire on the tenth anniversary of the grant date.



## Ordinary Shares

Until and including \_\_\_\_\_, 2017, 25 days after the date of this prospectus, all dealers that buy, sell or trade our ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as underwriters and with respect to unsold allotments or subscriptions.

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 6. Indemnification of Office Holders (including Directors).**

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of a 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 out of a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738-1968 (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 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 all the injured parties by the breach in 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; and
- 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.
- 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 duty of loyalty 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 duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty 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 in a public company 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 such 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 registration statement, 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.

We have entered into agreements with each of our current office holders 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 this 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 office holders based on such indemnification agreement is the greater of (1) % 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) \$ million (as may be increased from time to time by shareholders’ approval). Such

indemnification amounts are in addition to any insurance amounts. Each office holder 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. However, in the opinion of the SEC, indemnification of office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

#### **Item 7. Recent Sales of Unregistered Securities.**

In August 2014, we issued a total of 3,388,359 ordinary shares to Arkin Dermatology in connection with the conversion of outstanding preferred shares into ordinary shares following the execution of the Purchase Agreement. In connection with the foregoing conversion, the par value of the ordinary shares (in the amount of approximately \$80) was paid.

All of the foregoing issuances were made outside of the United States pursuant to Regulation S or to U.S. entities pursuant to Section 4(a)(2) of the Securities Act.

### **EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
1.1*	Form of Underwriting Agreement.
3.1**	Articles of Association of the Registrant (currently in effect).
3.2*	Form of Amended and Restated Articles of Association of the Registrant to become effective upon closing of this offering.
4.1*	Form of Specimen Share Certificate.
5.1*	Form of Opinion of Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Israeli counsel to the Registrant, as to the validity of the ordinary shares.
10.1**	2014 Share Incentive Plan.
10.2*	Form of Registration Rights Agreement.
10.3**∞	Project Transfer Agreement by and between the Registrant and with M. Arkin (1999) Ltd. dated as of December 31, 2015.
10.4*+	Innovative Product Development and Contract Manufacturing Agreement between M. Arkin (1999) Ltd. and Perrigo Israel Pharmaceuticals Ltd., dated as of January 23, 2012.
10.5*+	Development, Manufacturing and Commercialization Agreement between Perrigo UK Finco Limited Partnership and Sol-Gel Technologies Ltd., dated as of April 27, 2015.
10.6*+	Amendment to the Development, Manufacturing and Commercialization Agreement between the Registrant and Perrigo UK Finco Limited Partnership, dated as of October 26, 2015.
10.7*+	Development, Manufacturing and Commercialization Agreement between the Registrant and Perrigo UK Finco Limited Partnership, dated as of June 19, 2016.
10.8*	Form of Indemnification Agreement.
10.9*	Compensation Policy.
10.10∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of October 10, 2007.
10.11∞	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 29, 2014.

Exhibit No.	Description
10.12 <sup>∞</sup>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of March 30, 2016.
10.13 <sup>∞</sup>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of September 20, 2016.
10.14 <sup>∞</sup>	Lease Agreement by and between the Registrant and Rachel Zacks, dated as of January 30, 2017.
10.15**	Promissory Note by and between the Registrant and Moshe Arkin, dated as of August 2, 2016.
10.16**	Schedule A, as amended, of Promissory Note by and between the Registrant and Moshe Arkin, dated as of December 21, 2016.
10.17	Assignment Agreement between the Registrant and Medicis Pharmaceutical Corporation, dated October 9, 2011.
21.1**	List of subsidiaries of the Registrant.
23.1*	Consent of Kesselman and Kesselman, Member Firm of PricewaterhouseCoopers International Limited.
23.2*	Consent of Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co., Israeli counsel to the Registrant (included in Exhibit 5.1).
24.1**	Power of Attorney (included in the signature page of the Registration Statement).
99.1**	Consent of director nominee.
99.2**	Consent of director nominee.
99.3**	Consent of director nominee.

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\* To be filed by amendment

\*\* Previously filed

<sup>∞</sup> Informal English translation of the original Hebrew document

+ Confidential treatment to be requested

#### **Item 9. Undertakings.**

- a. The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- b. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

- c. The undersigned registrant hereby undertakes that:
  - 1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - 2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ness Ziona, State of Israel on \_\_\_\_\_, 2017.

**Sol-Gel Technologies Ltd.**

By: \_\_\_\_\_

Name: Alon Seri-Levy

Title: Chief Executive Officer

**POWER OF ATTORNEY**

Each person whose signature appears below constitutes and appoints Alon Seri-Levy and Gilad Mamlok, and each of them, as attorney-in-fact with full power of substitution, for him or her in any and all capacities, to do any and all acts and all things and to execute any and all instruments which said attorney and agent may deem necessary or desirable to enable the registrant to comply with the Securities Act, and any rules, regulations and requirements of the Securities and Exchange Commission thereunder, in connection with the registration under the Securities Act of ordinary shares of the registrant (the "Shares"), including, without limitation, the power and authority to sign the name of each of the undersigned in the capacities indicated below to the Registration Statement on Form F-1 (the "Registration Statement") to be filed with the Securities and Exchange Commission with respect to such Shares, to any and all amendments or supplements to such Registration Statement, whether such amendments or supplements are filed before or after the effective date of such Registration Statement, to any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act, and to any and all instruments or documents filed as part of or in connection with such Registration Statement or any and all amendments thereto, whether such amendments are filed before or after the effective date of such Registration Statement, and each of the undersigned hereby ratifies and confirms all that such attorney and agent shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
_____ Alon Seri-Levy	Chief Executive Officer	_____, 2017
_____ Gilad Mamlok	Chief Financial Officer	_____, 2017
_____ Moshe Arkin	Director	_____, 2017



**SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant's duly authorized representative has signed this registration statement on Form F-1 in on this       day of       , 2017.

By:

By: \_\_\_\_\_

Name:

Title:

ASSIGNMENT

**WHEREAS: MEDICIS PHARMACEUTICAL CORPORATION**, a corporation organized under the laws of Delaware (hereinafter ASSIGNOR), is an owner of certain patent rights pursuant to that certain Development and License Agreement between ASSIGNOR and ASSIGNEE (defined below), dated October 9, 2011 (hereinafter AGREEMENT); and

**WHEREAS:** ASSIGNOR desires to assign to **SOL-GEL TECHNOLOGIES LTD.**, a corporation organized under the laws of the Country of Israel (hereinafter ASSIGNEE) ASSIGNOR'S entire interest in and to a US patent application # 13/537,646, titled: "Stabilized Topical Formulations Containing Core-Shell Microcapsules" (the "**PATENT**").

**NOW, THEREFORE**, for good and valuable consideration provided by ASSIGNEE to ASSIGNOR, the receipt of which is hereby acknowledged, ASSIGNOR hereby sells, assigns and transfers to ASSIGNEE, its successors, legal representatives, or assigns, ASSIGNOR'S full and exclusive rights, titles and interests to the PATENT, and to any additional legal protections to be obtained for said PATENT or any continuations, continuations-in-part, divisions, renewals, extensions, substitutions, replacements, or reissues thereof, and every priority right that is or may be predicated upon or arise from the PATENT, or any legal equivalent of any thereof in any country for the full term or terms for which the same may be granted.

SAID ASSIGNOR hereby further covenants that ASSIGNOR has full right to convey the entire right, title, and interest herein sold, assigned, transferred, and set over herein.

AND SAID ASSIGNOR further covenants that ASSIGNOR will, at any time, when reasonably called upon to do so by the ASSIGNEE, its successors, legal representatives, or assigns, at ASSIGNEE'S cost and expense, communicate thereto any facts known to him relating to said PATENT; execute and deliver any and all lawful papers (including, but not limited to, granting powers of attorney and executing inventor declarations for continuations-in-part and reissues of patent applications hereby assigned); make all rightful oaths, affidavits, or declarations; testify in any legal proceedings, mediations, arbitrations, or other proceedings; and perform all other reasonable lawful acts that may be deemed by ASSIGNEE necessary or desirable to obtain, secure, and/or vest the benefit of the rights herein assigned, and perfect the title to said PATENT and all related rights thereto in the name of and for the benefit for the ASSIGNEE, its successors, legal representatives, or assigns, and to assist or enable the ASSIGNEE, its successors, legal representatives, or assigns to enforce, protect, or otherwise benefit from the rights in said, applications and patents hereby granted.

ASSIGNEE hereby grants to ASSIGNOR and ASSIGNOR'S affiliates a non-exclusive, transferable, sub-licensable, royalty-free, perpetual, license to practice those inventions claimed under the PATENT.

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This ASSIGNMENT shall be binding upon ASSIGNOR'S heirs, executors, administrators, successors, and/or assigns.

Date: 8/16/13

/s/  
\_\_\_\_\_  
**MEDICIS PHARMACEUTICAL CORPORATION**

I hereby accept the above assignment for and on behalf/of the ASSIGNEE

Date: August 8, 2013

/s/ Alon Seri-Levy  
\_\_\_\_\_  
**SOL-GEL TECHNOLOGIES LTD.**

\_\_\_\_\_