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As filed with the Securities and Exchange Commission on February 18, 2014

Registration No. 333-193856

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 1

# FORM F-1

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

# **MEDIWOUND LTD.**

(Exact Name of Registrant as Specified in its Charter)

State of Israel (State or Other Jurisdiction of Incorporation or Organization) 2833 (Primary Standard Industrial Classification Code Number) Not Applicable (I.R.S. Employer Identification No.)

MediWound Ltd. 42 Hayarkon Street Yavne 8122745, Israel Tel: +972-8-932-4010

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

> Puglisi & Associates 850 Library Avenue, Suite 204 Newark, Delaware 19711 +1 (302) 738-6680

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

### Copies of all correspondence to:

Joshua G. Kiernan, Esq. Colin J. Diamond, Esq. White & Case LLP 1155 Avenue of the Americas New York, NY 10036 Tel: +1 (212) 854-8113 Dan Shamgar, Adv. David S. Glatt, Adv. Haim Gueta, Adv. Meitar Liquornik Geva Leshem Tal 16 Abba Hillel Silver Rd. Ramat Gan 5250608, Israel Tel: +972-3-610-3100 Fax: +972-3-610-3111 Phyllis G. Korff, Esq. Yossi Vebman, Esq. Skadden, Arps, Slate, Meagher & Flom LLP 4 Times Square New York, New York 10036 Tel: +1 (212) 735-3000 Fax: +1 (212) 735-2000 Chaim Friedland, Adv. Ari Fried, Adv. Gornitzky & Co. Zion House 45 Rothschild Blvd. Tel Aviv 6578403, Israel Tel: +972-3-710-9191 Fax: +972-3-560-6555

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 registrational 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.

#### CALCULATION OF REGISTRATION FEE

	Proposed maximum	
Title of each class of securities to be registered	aggregate offering price(1)(2)	Amount of registration fee
Ordinary shares, par value NIS 0.01 per share	\$86,250,000	\$11,109

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) of the Securities Act.

(2) Includes ordinary shares that the underwriters may purchase pursuant to their option to purchase additional ordinary shares, if any.

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 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this 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 prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion Preliminary Prospectus dated February 18, 2014

## PRELIMINARY PROSPECTUS

Shares



MediWound Ltd.

Ordinary Shares

This is MediWound Ltd.'s initial public offering. We are selling

of our ordinary shares.

We expect the public offering price to be between \$ and \$ per share. Prior to this offering, there has been no public market for our ordinary shares. We have applied to have the ordinary shares listed on the NASDAQ Global Market under the symbol "MDWD."

	Per Share	Total
Public offering price	\$	\$
Underwriting discount(1)	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional ordinary shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and will therefore be subject to reduced reporting requirements. Investing in our ordinary shares involves risks that are described in the "Risk Factors" section beginning on page 11 of this prospectus.

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.

The ordinary shares will be ready for delivery on or about , 2014.

**Credit Suisse** 

**Jefferies** 

**BMO** Capital Markets

# **Oppenheimer & Co.**

The date of this prospectus is

,2014.



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Neither we nor 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. Neither we nor the underwriters take any responsibility for, and can provide no assurance as to the reliability of, any information other than the information in this prospectus, any amendment or supplement to 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 the solicitation of an offer to buy our ordinary shares in any circumstances under which such offer or solicitation is unlawful.

This prospectus includes statistical data, market data and other industry data and forecasts, which we obtained from market research, publicly available information and independent industry publications and reports that we believe to be reliable sources.

#### i

### 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 Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and our consolidated financial statements and the related notes included at the end of this prospectus, before making an investment in our ordinary shares. Unless the context otherwise requires, all references to "MediWound," "we," "us," "our," the "Company" and similar designations refer to MediWound Ltd. and its wholly-owned subsidiaries.

# **Our Company**

We are a fully integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel products to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds and connective tissue disorders. Our innovative biopharmaceutical product, NexoBrid, received marketing authorization from the European Medicines Agency, or the EMA, in December 2012 for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns, also referred to as severe burns. NexoBrid, which is based on our patented proteolytic enzyme technology, represents a new paradigm in burn care management, and our clinical trials have demonstrated, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier upon patient admission, without harming viable tissues. Our proteolytic enzyme technology involves proteolysis, which is the breakdown of proteins into smaller building blocks, polypeptides or amino acids. We launched NexoBrid in December 2013 in the European Union through our wholly-owned German subsidiary, targeting a focused audience of burn specialists treating patients in burn centers and hospital burn units. We also plan to initiate a Phase 3 pivotal study in the United States in the first half of 2014 to support a Biologics License Application, or BLA, submission to the United States Food and Drug Administration, or FDA. We manufacture NexoBrid in our state-of-the-art, EMA-certified, cGMP-compliant, sterile pharmaceutical products manufacturing facility at our headquarters in Yavne, Israel.

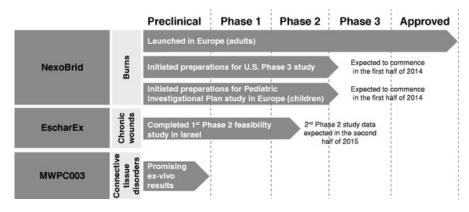
NexoBrid is an easy to use, topically-applied product that removes eschar in four hours without harming the surrounding healthy tissues. The removal of eschar is a procedure also known as debridement. Debridement is a critical first step in the successful healing of severe burns and chronic and other hard-to-heal wounds. Under existing standard of care, or SOC, burn eschar may be removed either by employing certain existing topical agents that have been found to be minimally effective or that take a significantly longer period of time to work, or by resorting to non-selective surgery, which is traumatic and may result in loss of blood and viable tissue. NexoBrid's rapid and selective debridement alleviates the known risks associated with eschar, such as infection, eventual sepsis (a systemic inflammatory response caused by severe infection), wound deterioration and consequential scarring, and it allows physicians to reach an informed decision on further treatment at an earlier stage by direct visual assessment of the actual burn depth. Furthermore, NexoBrid minimizes the burden associated with invasive surgical procedures, reduces the need for skin grafting and sacrifice of healthy tissue from donor sites on a patient's body and generally results in a more favorable overall long-term patient outcome. NexoBrid has been investigated in more than 550 patients across 15 countries and four continents in six Phase 2 and Phase 3 clinical studies. There have been over 100 presentations of NexoBrid in international scientific conferences, and in addition, NexoBrid has been presented in 11 peer-reviewed papers as well as in a chapter in Total Burn Care, a leading medical textbook, resulting in support from more than 100 burn specialists and key opinion leaders, or KOLs. Awareness of NexoBrid continues to grow through our marketing efforts and continued multinational clinical development.

The market opportunities for our patented proteolytic enzyme technology include both eschar removal of severe burns, for which NexoBrid received marketing authorization in the European Union

and designation as an orphan drug in both the European Union and the United States, and debridement of chronic and other hard-to-heal wounds for which EscharEx, our second product candidate, is being investigated in clinical trials. Approximately 100,000 patients with severe burns are hospitalized every year in the United States, and we believe there is a similar number of such patients in Europe. Severe burn patients are predominantly treated by specialists in approximately 250 burn centers and at burn units of large hospitals in the European G5 countries, which include France, Germany, Italy, Spain and the United Kingdom, and the United States, which we intend to cover with a focused and targeted sales force. Our lead product candidate, EscharEx, is being studied for the debridement of chronic and other hard-to-heal wounds. This indication represents a significant opportunity, having a total addressable patient base of more than 14 million patients in the United States and Europe alone, suffering from disorders such as diabetic foot ulcers, or DFUs, venous leg ulcers, or VLUs, pressure ulcers and surgical/traumatic hard-to-heal wounds.

We launched NexoBrid in Europe in December 2013, beginning with Germany, and intend to initiate an FDA, Phase 3 pivotal study in the United States in the first half of 2014 to support a BLA in order to enter the U.S. market, as well as a pediatric study in Europe to broaden the approved indication. We plan to target other international markets, such as Latin America and certain Asian countries, by leveraging our approved registration file for additional regional marketing authorizations. In addition, we are using our patented proteolytic enzyme technology, which underlies NexoBrid, and our wealth of data and experience for use in other indications such as debridement of chronic and other hard-to-heal wounds. We believe that such indication represents a significant additional market opportunity with a lower development risk. A Phase 2 proof-of-concept study demonstrated the efficacy of our patented proteolytic enzyme technology in various chronic and other hard-to-heal wounds. We plan to initiate a second Phase 2 study by the first half of 2014. Additionally, our technology has demonstrated promising results in the treatment of connective tissue disorders, such as Dupuytren's and Peyronie's diseases, in ex-vivo model studies, which are laboratory studies conducted on tissues or cells extracted from a living organism.

The following table sets forth our product pipeline for the development of NexoBrid for burn wounds and additional product candidates for chronic and other hard-to-heal wounds and connective tissue disorders based on our proprietary technology.



#### **Our Solutions**

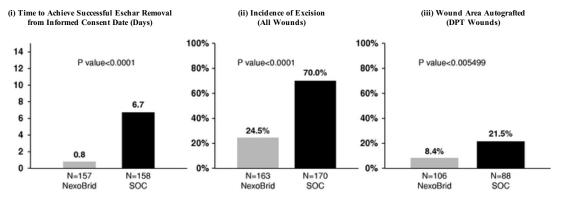
NexoBrid is a new paradigm in debridement that has been shown in clinical trials to provide fast and effective non-surgical eschar removal while not harming viable tissues. Because of the many drawbacks of current conventional debridement modalities, we believe that the clinically differentiated



profile of our patented technology that underlies NexoBrid and our pipeline products, such as EscharEx, will provide attractive solutions to address the significant unmet medical needs.

In the case of severe burns, upon admission to a burn center or unit, after routine burn patient cleansing, resuscitation and initial diagnosis, NexoBrid can be topically applied in a single application at the patient's bedside without the necessity of utilizing operating room resources. NexoBrid is prepared by simply mixing the proteolytic enzymes powder and sterile gel and applying it on the burn. The product is left on the burn for four hours, during which time the proteolytic enzymes remove the eschar without harming the surrounding healthy tissue. At the end of the four hours, NexoBrid is removed from the burn, leaving a clean wound bed.

Our clinical trials have consistently demonstrated the clinical benefits of NexoBrid compared to the current SOC. In our pivotal European Phase 3 clinical trial in severe burns, NexoBrid achieved statistically significant clinical outcomes in numerous endpoints relative to the SOC. The charts below highlight three such endpoints and NexoBrid's ability to: (i) effectively remove the eschar significantly earlier, allowing earlier direct visualization and assessment of the wound bed and burn depth, (ii) significantly reduce the need for excisional surgery in all wounds, and (iii) significantly reduce the wound area autografted in deep partial-thickness, or DPT, wounds. The clinical results confirm NexoBrid's ability to successfully remove the eschar, reduce the surgical burden and result in overall favorable long-term results.



## **Our Competitive Strengths**

*NexoBrid, a new paradigm in eschar removal, approved and launched in Europe.* Our innovative product, NexoBrid, provides an easy to use, non-surgical, topical application for effective removal of eschar from severe burns in four hours without harming surrounding viable tissues. NexoBrid provides significant advantages over existing surgical and non-surgical SOC and is an innovative solution for an unmet medical need.

Attractive markets for debridement in burn and wound care. Approximately 200,000 patients with severe burns are hospitalized every year in Europe and the United States alone. Severe burn patients are treated by burn specialists at approximately 250 burn centers and at burn units throughout the European G5 countries and the United States. We believe we can effectively target these burn centers and units with a focused marketing effort. We believe the prevalence of these patients is even higher in emerging economies. In addition to burn wounds, the debridement of chronic and other hard-to-heal wounds, such as DFUs, VLUs and pressure ulcers, represents a significantly large market of more than 14 million patients in Europe and the United States alone, which is expected to continue growing due to aging and increasing rates of diabetes and obesity.

*Extensive clinical differentiation and experience and support from key opinion leaders and physicians worldwide.* NexoBrid's extensive clinical experience consistently demonstrated, in more than 550 patients, in six Phase 2 and Phase 3 clinical studies across 15 countries, the following important advantages when compared to current standard of care:

- significantly earlier successful eschar removal in 0.8 days, versus 6.7 days when treated by SOC, as measured from the time of signing informed consent;
- significantly reducing both the incidence and the extent of wounds requiring surgical excision;
- significantly reducing both the incidence and the extent of wounds requiring autografting; and
- significantly less quantity of long-term scars and comparable quality of scars.

NexoBrid has gained awareness and support from more than 100 burn specialists and KOLs through presentations at more than 100 international scientific conferences and publication of 11 peer-reviewed papers and a chapter in Total Burn Care, a leading medical textbook on burns.

*Lower development risk for our pipeline products.* We believe we will be able to leverage the experience gained in the development and approval of NexoBrid, as well as the wealth of preclinical, clinical and manufacturing and control data, to decrease the developmental risk of our pipeline products. Our technology has demonstrated clinical efficacy in the debridement of chronic and other hard-to-heal wounds as well as promising results in ex-vivo model studies for the treatment of connective tissue disorders, such as Dupuytren's and Peyronie's diseases.

*Fully integrated platform.* We have built a fully integrated organization that allows us to maintain control over all critical aspects of our business. Our team has managed all of our clinical studies and regulatory interactions leading to EMA approval. We have a state-of-the-art, EMA-certified, cGMP-compliant manufacturing facility. Our targeted sales and marketing organization launched NexoBrid in Europe in December 2013. Over time, we believe that the combination of these capabilities will allow us to drive growth and profitability.

*High barriers to entry.* We enjoy significant barriers to entry due to our intellectual property, know-how, orphan drug status and other regulatory exclusivities. We believe that NexoBrid will have market exclusivity through patent protection at least until 2025 in Europe and 2029 in the United States.

*Experienced management team.* Our management team, led by our President and Chief Executive Officer, Gal Cohen, has decades of cumulative industry specific experience. Mr. Cohen, Professor Lior Rosenberg, our Co-founder and Chief Medical Officer, and Carsten Henke, the Managing Director of MediWound Germany GmbH have significant pharmaceutical, medical, marketing and product launch experience.

## **Our Growth Strategy**

Our goal is to become a leading biopharmaceutical company developing, manufacturing and commercializing novel products to address unmet medical needs in the fields of severe burns, chronic and other hard-to-heal wounds and connective tissue disorders. The key components of our growth strategy include:

*Maximize value of NexoBrid for debridement in severe burns in Europe.* We launched NexoBrid in Europe, starting with Germany in December 2013. We are executing our strategic plan, which includes further building our commercial organization to address the hospital call point of burn specialists, establishing pricing and reimbursement and implementing a comprehensive marketing campaign and branding and training programs, to launch NexoBrid in other European countries.

- Expand the commercialization opportunities for NexoBrid into the United States and other international markets. We intend to apply our clinical and regulatory experience and commercialization strategy in Europe to maximize the global value of NexoBrid. We plan to initiate a Phase 3 pivotal study in the United States in the first half of 2014. Additionally, through collaboration with local distributors, we plan to capitalize on our approved registration file in Europe as well as NexoBrid's ease of use and proven clinical efficacy, and the limited availability of surgical capacity in emerging markets, to commercialize NexoBrid in such markets.
- Utilize our technology to develop and commercialize products for chronic and other hard-to-heal wounds and connective tissue disorders. We are adapting the proteolytic enzymes that underlie NexoBrid for use in additional indications in order to maximize our commercial potential. EscharEx has demonstrated clinical efficacy in eschar removal of chronic and other hard-to-heal wounds. Additionally, our proteolytic enzymes have demonstrated promising results in ex-vivo model studies of connective tissue disorders.
- Selectively explore additional business development opportunities to further drive growth. We will seek to engage in targeted business development activities, such as licensing, strategic partnerships and acquisitions, that are synergistic to our business in order to expand the market potential of our products, and leverage our niche specialty commercial infrastructure with externally-sourced products that are complementary to our hospital call point.

### **Risk Factors**

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. If any of these risks actually occurs, our business, financial condition or results of operations would likely be materially adversely affected. In such case, the trading price of our ordinary shares would likely decline, and you may lose all or part of your investment. The following is a summary of some of the principal risks we face:

- Our success depends initially on our ability to commercialize NexoBrid in Europe.
- The commercial success of NexoBrid and our pipeline products will depend upon their degree of market acceptance.
- We may be unable to successfully obtain approval of NexoBrid for treatment of severe burns in the United States and other markets.
- We may be unsuccessful in commercializing our products due to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives.
- Clinical drug development is a lengthy and expensive process, with an uncertain outcome.
- Development and commercialization of NexoBrid in the United States and our pipeline products worldwide requires successful completion of the regulatory approval process, and may suffer delays or fail.
- We depend on a sole supplier to obtain our intermediate drug substance, bromelain SP, which is necessary for the production of our products.
- We have a history of net losses. We expect to continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.
- If our manufacturing facility in Yavne, Israel were to suffer a serious accident, or if a force majeure event materially affected our ability to operate and produce NexoBrid and our pipeline products, all of our manufacturing capacity could be shut down for an extended period.

### **Our Principal Shareholder**

Following the closing of this offering, entities affiliated with Clal Biotechnology Industries Ltd. will beneficially own % of our outstanding shares in the aggregate (or % if the underwriters exercise in full their option to purchase additional shares). Following the closing of this offering, we will not be a party to and are not otherwise aware of any voting agreement among our shareholders. For further information about the ownership of our ordinary shares following this offering, see "Principal Shareholders."

## Implications of Being an Emerging Growth Company

As a company with less than \$1.0 billion in revenue for our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. For example, the JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. However, we have elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Pursuant to the JOBS Act, we will remain an emerging growth company until the earliest of:

- the last day of our fiscal year following the fifth anniversary of the date of our initial public offering of common equity securities;
- the last day of our fiscal year in which we have annual gross revenue of \$1.0 billion or more;
- the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; and
- the date on which we are deemed to be a "large accelerated filer," which will occur at such time as we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months and (c) have filed at least one annual report pursuant to the Exchange Act.

### **Our Corporate Information**

We were incorporated under the laws of the State of Israel on January 27, 2000. Our principal executive offices are located at 42 Hayarkon Street, Yavne 8122745, Israel, and our telephone number is +972-8-932-4010. Our website is www.MediWound.com. The information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. Our agent for service of process in the United States is Puglisi & Associates, located at 850 Library Avenue, Suite 204, Newark, Delaware 19711, and its telephone number is +1 (302) 738-6680.

Throughout this prospectus, we refer to various trademarks, service marks and trade names that we use in our business. The "MediWound" design logo, "MediWound", "NexoBrid", "EscharEx" and other trademarks or service marks of MediWound Ltd. appearing in this prospectus are the property of MediWound Ltd. We have several other registered trademarks, service marks and pending applications relating to our products. Although we have omitted the "®" and "TM" trademark designations for such marks in this prospectus, all rights to such trademarks are nevertheless reserved. Other trademarks and service marks appearing in this prospectus are the property of their respective holders.

	THE OFFERING	
Ordinary shares we are offering	ordinary shares (or additional ordinary shares)	if the underwriters exercise in full their option to purchase
Ordinary shares to be outstanding immediately after this offering	ordinary shares (or additional ordinary shares)	if the underwriters exercise in full their option to purchase
Use of proceeds	\$ million, or \$ mi additional ordinary shares, midpoint of the price range	ceive net proceeds from this offering of approximately llion if the underwriters exercise in full their option to purchase based on an assumed initial public offering price of \$ , the set forth on the cover page of this prospectus, after deducting commissions and estimated offering expenses.
	We currently intend to use t	the net proceeds we receive from this offering as follows:
	• approximately \$25-\$30 n	nillion to expand our sales and marketing infrastructure;
	• approximately \$25-\$30 n	nillion on research and development;
	• approximately \$10 millio	on to expand our manufacturing capabilities; and
	• the balance, if any, for oth	her general corporate purposes.
	See "Use of Proceeds" on pa	age 42 for additional information.
Risk Factors	shares may lose part or all o	ares involves a high degree of risk and purchasers of our ordinary f their investment. See "Risk Factors" for a discussion of factors der before deciding to invest in our ordinary shares.
Proposed NASDAQ Global Market symbol:	We have applied to have ou symbol "MDWD."	ir ordinary shares listed on the NASDAQ Global Market under the
	reserved for issuance under our	ring is based on 3,951,051 ordinary shares outstanding as of share option plan as of December 31, 2013, of which options to of \$25.49 per share.
Unless otherwise indicated, all information in this pros	pectus:	

- assumes the issuance of ordinary shares upon the closing of this offering pursuant to the cashless exercise of 280,720 warrants held by certain of our shareholders at a weighted average exercise price of \$36.42 per share; and
- assumes an initial public offering price of \$ per ordinary share, the midpoint of the range set forth on the cover page of this prospectus;

- assumes no exercise by the underwriters of their option to purchase up to an additional ordinary shares from us;
- reflects a -for- share split effected on , 2014 by means of a share dividend of ordinary shares for each ordinary share then outstanding;
- gives effect to the adoption of our amended and restated articles of association prior to the closing of this offering, which will replace our articles of association currently in effect.

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 United States dollars, the lawful currency of the United States, and the terms "Euros" or " $\mathcal{C}$ " refer to Euros, the lawful currency of the Eurozone.

# SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data. You should read the following summary consolidated 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 "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

The summary consolidated statements of operations data for the years ended December 31, 2011, 2012 and 2013, and the consolidated balance sheet data as of December 31, 2013 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The historical results set forth below are not necessarily indicative of the results to be expected in future periods. Our financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board.

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	(4,819)		11,985		(8,501
	(1,350)		(1,045)		(6,850)
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_	_	_	_		(32
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	\$	(in thousand \$ 6,149 3,128 3,021 	$\begin{array}{c} \hline (\text{in thousands, e} \\ \hline (\text{in thousands, e} \\ 3,128 \\ \hline 3,021 \\ \hline - \\ 1,266 \\ \hline (4,287) \\ \hline 96 \\ \hline (628) \\ \hline (4,287) \\ \hline 96 \\ \hline (628) \\ \hline (4,819) \\ \hline (1,350) \\ \hline (1,350) \\ \hline \hline (1,350) \\ \hline \hline (1,350) \\ \hline (1,350) \\ \hline (1,350) \\ \hline (1,350) \\ \hline \hline (1,350) \\ \hline (1,350) \\ \hline (1,350) \\ \hline \hline (1,350) \\ \hline (1,350) \hline \hline (1,350) \\ \hline (1,350) \hline \hline \hline (1,350) \hline \hline (1,350) \hline \hline \hline \hline \hline \hline \hline \hline (1,350) \hline \hline$	$\begin{array}{c cccc} \hline (in thousands, except share data) \\ \hline (in thousands, exc$	(in thousands, except share and data)         (in thousands, except share and data) $3,128$ $2,247$ $3,021$ $1,557$ $  1,266$ $1,173$ $(4,287)$ $(2,730)$ $96$ $15,406$ $(628)$ $(691)$ $(4,819)$ $11,985$ $(1,350)$ $(1,045)$ $\$$ $(6,169)$ $\$$ $\$$ $(6,169)$ $\$$ $\$$ $(1.49)$ $\$$ $\$$ $(1.49)$ $\$$ $\$$ $(1.49)$ $\$$ $\$$ $(1.49)$ $\$$

	As of December 31, 2013
	Pro forma a Actual adjusted(5)
	(in thousands)
Consolidated balance sheet data:	
Cash and cash equivalents and short-term bank deposits	\$ 9,553
Working capital(6)	10,042
Total assets	14,826
Total non-current liabilities	32,607
Total shareholders' equity (deficit)	(19,804)

### (1) Includes equity-based compensation expenses as follows:

Year Ended December 31,			
2011	2012	2013	
(i	n thousands	5)	
\$ 182	\$ 124	\$ 315	
_		24	
373	210	192	
\$ 555	\$ 334	\$ 531	
109	30	76	
\$ 664	\$ 364	\$ 607	
	2011 \$ 182 373 \$ 555 109	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	

- (2) Research and development expenses, net is presented net of participation by others and net of the change in the fair value of the liability associated with government grants from the Office of the Chief Scientist. Participation by others totaled \$2.7 million, \$2.2 million and zero for the years ended December 31, 2011, 2012 and 2013, respectively. The effect of the participation by the Office of the Chief Scientist totaled \$0.5 million, \$0.1 million and \$0.9 million for the years ended December 31, 2011, 2012 and 2013, respectively. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Operating expenses—Research and development" for more information.
- (3) Discontinued operation consists of revenues and expenses related to our exclusive, worldwide license for the development, manufacturing and commercialization of the PolyHeal Product, which expired following the termination of our collaboration with Teva. We account for our discontinued operation in accordance with IFRS accounting standard 5, "Non-current Assets Held for Sale and Discontinued Operations." See "Management's Discussion and Analysis of Financial Condition and Results of Operations— Financial Operations Overview—Discontinued operation" for more information.
- (4) Basic and diluted earnings (loss) per ordinary share is computed based on the basic and diluted weighted average number of ordinary shares outstanding during each period. For additional information, see Note 20 to our consolidated financial statements included elsewhere in this prospectus.
- (5) Pro forma as adjusted gives effect to (a) the issuance of ordinary shares upon the closing of this offering, pursuant to a cashless exercise of 280,720 warrants held by certain of our shareholders, at a weighted average exercise price of \$36.42 per share, and (b) the issuance and sale of ordinary shares by us in this offering at an assumed initial public offering price of \$ per ordinary share, the midpoint of the range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(6) Working capital is defined as total current assets minus total current liabilities.

# **RISK FACTORS**

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks and uncertainties described below, in addition to the other information set forth in this prospectus, including the consolidated financial statements and the related notes included elsewhere in this prospectus, before purchasing our ordinary shares. If any of the following risks actually occurs, our business, financial condition, cash flows, and results of operations could be materially adversely affected. In that case, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business operations.

#### **Risks Relating to Our Business and Industry**

### Our success will depend initially on our ability to commercialize NexoBrid in Europe.

We are currently marketing a single product, NexoBrid, based on our patented proteolytic enzyme technology, which has already been approved by the European Medicines Agency, or the EMA, for marketing in the European Union for the treatment of adults with deep partial- and full-thickness burns, which we refer to as severe burns. NexoBrid is not currently approved for marketing in any other jurisdiction, including the United States, and has not been approved for any other indication or for use in children. We launched NexoBrid in Europe, starting with Germany in December 2013, and we anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend on the commercial success of NexoBrid in Europe.

We intend to market, sell and distribute NexoBrid in Europe through our own sales force. We have only recently established a commercial organization for the marketing, sales and distribution of NexoBrid, including an office in Germany. In order to successfully commercialize NexoBrid, we must continue to build our marketing, sales, distribution, managerial and other non-technical capabilities, which includes many challenges, such as recruiting and retaining talented personnel; training employees; setting the appropriate system of incentives; managing additional headcount; and integrating a new business unit into an existing corporate infrastructure. The continued development of our own sales infrastructure will be expensive and time-consuming. Moreover, we do not have substantial experience as a company in establishing a significant sales infrastructure and we cannot be certain that we will successfully develop this capability. We will have to compete with other pharmaceutical, biotechnology and wound care companies to recruit, hire, train and retain personnel for medical affairs, marketing and sales. If we are unable to successfully commercialize NexoBrid in Europe, sales of NexoBrid will be severely affected, which will have a material adverse effect on our business, financial condition and results of operations.

### The commercial success of NexoBrid and our pipeline products will depend upon their degree of market acceptance.

NexoBrid and our pipeline products may not gain market acceptance by physicians and their teams, healthcare payors and others in the medical community. Although many physicians in burn centers throughout Europe, the United States and other international markets have used NexoBrid for severe burns as part of our clinical trials, we cannot guarantee that use of NexoBrid will be accepted in the market. If NexoBrid and our pipeline products do not achieve an adequate level of acceptance, we may not generate revenue and we may not achieve or sustain profitability. The degree of market acceptance of NexoBrid in Europe and, if we receive marketing approval, in other countries and for

our pipeline products, will depend on a number of factors, some of which are beyond our control, including:

- the willingness of physicians to administer our products and their acceptance as part of the medical department routine;
- obtaining third-party coverage or reimbursement for our products;
- the ability to offer NexoBrid and our pipeline products for sale at an attractive value;
- the efficacy and potential advantages of NexoBrid and our pipeline products relative to current standard of care;
- the prevalence and severity of any side effects; and
- the efficacy, potential advantages and timing of introduction to the market of alternative treatments.

Failure to achieve market acceptance for NexoBrid or any of our pipeline products, if and when they are approved for commercial sale, will have a material adverse effect on our business, financial condition and results of operations.

# We may be unable to successfully obtain approval of NexoBrid for treatment of severe burns in the United States and other markets.

We initially plan to rely on sales of NexoBrid in Europe for the treatment of severe burns for a significant portion of our total revenues. However, our continued growth depends, in large part, on our ability to develop and obtain marketing authorization for NexoBrid for treatment of severe burns in additional markets, and most importantly, in the United States from the United States Food and Drug Administration, or the FDA. Although we plan to initiate a Phase 3 pivotal study in the first half of 2014 to support a Biologics License Application, or BLA, submission to the FDA, we will not be able to submit a BLA until that study is complete. We cannot predict whether such clinical study will be successful and, even if it is successful, how long the FDA will take to review and approve NexoBrid following our BLA submission or whether any such approval in the United States will ultimately be granted. Similarly, we cannot predict how long regulatory authorizations will be granted at all. A number of companies in the pharmaceutical and biotechnology industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. See "—Clinical drug development is a lengthy and expensive process, with an uncertain outcome" and "—Development and commercialization of NexoBrid in the United States and our pipeline products worldwide requires successful completion of the regulatory approval process, and may suffer delays or fail." The failure to receive such marketing authorization, especially in the United States, would have a materially adverse impact on our business prospects.

# We may be unsuccessful in commercializing our products due to unfavorable pricing regulations, third-party coverage and reimbursement policies or healthcare reform initiatives.

While we are working closely with IMS Health, a leading information, services and technology company, to design and execute a country-specific market access strategy, which includes pricing and reimbursement targets for NexoBrid in most of Europe, we cannot guarantee that we will receive favorable pricing and reimbursement. Additionally, we cannot predict the pricing and reimbursement of NexoBrid or our pipeline products in any other jurisdiction. The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. In some foreign jurisdictions, including the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these jurisdictions, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate.



As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in NexoBrid or our pipeline products, even after obtaining regulatory approval.

Additionally, we cannot be sure that reimbursement will be available for NexoBrid or any pipeline product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may affect the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize NexoBrid or any pipeline product that we successfully develop. Eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in certain other countries, such as the United States. In the United States, third-party payors often rely upon other payors, such as a Medicare coverage policy and payment-funded and private payors for NexoBrid or any pipeline product could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that may affect our ability to sell NexoBrid or any of our pipeline products profitably, if approved. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the market acceptance or demand for NexoBrid or any of our pipeline products, if approved;
- the ability to set a price that we believe is fair for NexoBrid or any of our pipeline products, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

### Clinical drug development is a lengthy and expensive process, with an uncertain outcome.

We intend to develop and commercialize pipeline products based on patented proteolytic enzyme technology for new indications, such as for debridement of chronic and other hard-to-heal wounds and treatment of connective tissue disorders. However, before obtaining regulatory approval for the sale of our pipeline products in any jurisdiction, we must conduct, at our own expense, clinical studies to demonstrate that the products are safe and effective.

Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can

occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process. For example, on August 3, 2004, the FDA put one of our Phase 2 studies of NexoBrid on a clinical hold due to safety concerns in the study group, including four deaths and a higher incidence of pain and pyrexia compared to the SOC group. Although the Data Safety Monitoring Board unanimously concluded that no causal relationship between these deaths and the NexoBrid treatment was established and provided a reasoning for the higher incidence of such adverse events, the FDA delayed the continuation of the development plan until we proposed to initiate an additional smaller Phase 2 study to demonstrate the effectiveness of our proposed corrective measures. We successfully completed this smaller Phase 2 study, allowing us to continue the development plan, but experienced a significant delay and higher costs as a result. Even if preclinical or clinical trials are successful, we still may be unable to commercialize the product, as success in preclinical trials, early clinical trials, including Phase 2 trials, or previous clinical trials, does not ensure that later clinical trials will be successful.

Similar or other events could delay or prevent our ability to complete necessary clinical trials for our pipeline products, including:

- regulators may not authorize us to conduct a clinical trial within a country or at a prospective trial site or may change the design of a study;
- delays may occur in reaching agreement on acceptable clinical trial terms with regulatory authorities or prospective sites, or obtaining institutional review board approval;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional trials or to abandon strategic projects;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we expect, or patients may not participate in necessary follow-up visits to obtain required data, any of which would result in significant delays in our clinical testing process;
- our third-party contractors, such as a research institute, may fail to comply with regulatory requirements or meet their contractual obligations to us;
- we may be forced to suspend or terminate our clinical trials if the participants are being exposed, or are thought to be exposed, to unacceptable health risks or if any participant experiences an unexpected serious adverse event;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;
- the cost of our clinical trials may be greater than we anticipate;
- an audit of preclinical or clinical studies by regulatory authorities may reveal noncompliance with applicable protocols or regulations, which could lead to disqualification of the results and the need to perform additional studies; and
- delays may occur in obtaining our clinical materials.

Moreover, we do not know whether preclinical tests or clinical trials will begin or be completed as planned or will need to be restructured. Significant delays could also shorten the patent protection period during which we may have the exclusive right to commercialize our pipeline products or could

allow our competitors to bring products to the market before we do, impairing our ability to commercialize our pipeline products.

# Development and commercialization of NexoBrid in the United States and our pipeline products worldwide requires successful completion of the regulatory approval process, and may suffer delays or fail.

In the United States and Europe, as well as other jurisdictions, we are required to apply for and receive marketing authorization before we can market our products, as we have already completed for NexoBrid in the European Union. This process can be time consuming and complicated and may result in unanticipated delays. To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting preclinical and clinical safety and efficacy as well as detailed information on the manufacturing and control of the product, proposed labeling and other additional information. Before marketing authorization is granted, regulatory authorities generally require the inspection of the manufacturing facility or facilities and quality systems (including those of third parties) at which the product candidate is manufactured and tested, to assess compliance with strictly enforced cGMP, as well as potential audits of the non-clinical and clinical trial sites that generated the data cited in the marketing authorization application.

We cannot predict how long the applicable regulatory authority or agency will take to grant marketing authorization or whether any such authorizations will ultimately be granted. Regulatory agencies, including the FDA and the EMA, have substantial discretion in the approval process, and the approval process and the requirements governing clinical trials vary from country to country. The policies of the FDA, EMA or other regulatory authorities may change or may not be explicit, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of NexoBrid or our pipeline products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, Europe or elsewhere. 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 and we may not achieve or sustain profitability.

In addition, any regulatory approval that we receive may also contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing information and reports, registration and continued compliance with good manufacturing practices, or cGMP, for any clinical trials that we conduct post-approval. Although our manufacturing facility is cGMP-certified, we may face difficulties in obtaining regulatory approval for the manufacturing and quality control process of our pipeline products.

Any delays or failures in obtaining regulatory and marketing approval for NexoBrid in the United States, or for our pipeline products worldwide, would adversely affect our business, prospects, financial condition and results of operations.

# We depend on a sole supplier to obtain our intermediate drug substance, bromelain SP, which is necessary for the production of our products.

We currently procure bromelain SP, an intermediate drug substance in the manufacturing of NexoBrid and our pipeline products, from a single supplier, Challenge Bioproducts Corporation Ltd., or CBC. CBC's manufacturing facilities are located in the Republic of China and it uses proprietary methods to manufacture bromelain SP. Our supply agreement with CBC has no fixed expiration date and can be voluntarily terminated by us, with at least six months advance written notice, or by CBC, with at least twenty-four-months advance written notice. Although we have a contractual right to procure this material from other suppliers, subject to payment of a one-time, non-material licensing fee to CBC, procuring this material from any other source would require time and effort which may interrupt our supply of bromelain SP and may cause an interruption of the supply of NexoBrid and our pipeline products to the marketplace and for future clinical trials or other development purposes. Regulatory authorities could require that we conduct additional studies in support of a new supplier, which could result in significant additional costs or delays. Furthermore, there can be no assurance that we would be able to procure alternative supplies of bromelain SP at all or at comparable quality or competitive prices or upon fair and reasonable contractual terms and conditions. Although we believe that we currently store sufficient inventory of bromelain SP in our warehouse to continue normal operations for approximately two years, this inventory may prove insufficient, and any interruption or failure to source additional bromelain SP from CBC or other third parties in a timely manner, or at all, would adversely affect our business, prospects, financial condition and results of operations.

# We have a history of net losses. We expect to continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

We are not profitable and have incurred significant net losses, including net losses of \$6.2 million and \$15.3 million for the years ended December 31, 2011 and 2013, respectively. We had net income of \$10.9 million for the year ended December 31, 2012, which resulted from non-recurring financial income attributed to the revaluation of an option to repurchase our own shares from a third party. As of December 31, 2013, we had an accumulated deficit of \$47.4 million and a shareholders' deficit of \$19.8 million. We expect to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. To date, we have not generated any product revenue from NexoBrid. We have financed our operations primarily through the sale of equity securities, debt financing, licensing agreements and government grants. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. If we are unable to successfully commercialize NexoBrid or one or more of our pipeline products or if revenue from NexoBrid or any pipeline product that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses and future capital requirements may increase substantially if and as we:

- accelerate our clinical development activities, particularly with respect to our U.S. Phase 3 clinical trial of NexoBrid for the treatment of severe burns, our NexoBrid pediatric clinical trial in severe burns in Europe, our Phase 2 trial for EscharEx for the debridement of chronic and other hard-to-heal wounds and our clinical trials for our product candidate for the treatment of connective tissue disorders;
- continue to build our sales, marketing and distribution infrastructure in Europe and thereafter in the United States to commercialize NexoBrid
  and any other pipeline products for which we obtain marketing approval;
- further scale-up the manufacturing process for NexoBrid;
- seek regulatory and marketing approvals for NexoBrid and any other pipeline product that successfully completes clinical trials;



- initiate additional preclinical, clinical or other studies for NexoBrid and our pipeline products and seek to identify and validate new products;
- acquire rights to other product candidates and technologies;
- change or add suppliers;
- maintain, expand and protect our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company; and
- experience any delays or encounter issues with any of the above.

# If our manufacturing facility in Yavne, Israel were to suffer a serious accident, or if a force majeure event materially affected our ability to operate and produce NexoBrid and our pipeline products, all of our manufacturing capacity could be shut down for an extended period.

We currently rely on a single manufacturing facility in Yavne, Israel, and we expect that all of our revenues in the near future will be derived from products manufactured at this facility. If this facility were to suffer an accident or a force majeure event such as war, missile or terrorist attack, earthquake, major fire or explosion, major equipment failure or power failure lasting beyond the capabilities of our backup generators or similar event, our revenues would be materially adversely affected and any of our clinical trials could be materially delayed. In this situation, our manufacturing capacity could be shut down for an extended period, we could experience a loss of raw materials, work in process or finished goods inventory and our ability to operate our business would be harmed. In addition, in any such event, the reconstruction of our manufacturing facility and storage facilities, and obtaining regulatory approval for the new facilities could be time-consuming. During this period, we would be unable to manufacture NexoBrid or our pipeline products. In addition, we currently have limited inventory of NexoBrid that we can supply to our customers in the event that we are unable to further manufacture NexoBrid.

Moreover, our business insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

### We may not be able to expand our production or processing capabilities or satisfy growing demand.

We are currently seeking to expand our manufacturing capabilities in order to increase our capacity to manufacture NexoBrid and future products. We cannot guarantee that we will be able to obtain the requisite approvals, including meeting regulatory and quality requirements, or the necessary capital resources for procuring this facility, or if we do, that the facility will satisfy additional growing demand. Conversely, there can be no assurance, even if we obtain a new facility, that demand for our products will increase proportionately to the increased production capability. Furthermore, we cannot assure that this or similar projects will be implemented in a timely and cost efficient manner, and that our current production will not be adversely affected by the operational challenges of implementing the expansion project.

# We are subject to a number of other manufacturing risks, any of which could substantially increase our costs and limit supply of NexoBrid and our pipeline products.

The process of manufacturing NexoBrid and our pipeline products is complex, highly regulated and subject to the risk of product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal

manufacturing processes or quality requirements for our products could result in reduced production yields, product defects and other supply disruptions. If microbial, viral, or other contaminations are discovered in NexoBrid or our pipeline products or in the manufacturing facilities in which NexoBrid or our pipeline products are or will be made, such manufacturing facilities may need to be closed to investigate and remedy the contamination.

Although we have not experienced any contaminations, major equipment failures, or other similar manufacturing problems of such magnitude, any adverse developments affecting manufacturing operations for NexoBrid or our pipeline products may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of NexoBrid or our pipeline products. We may also have to take inventory write-offs and incur other charges and expenses for our products that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

# Our ability to continue manufacturing and distributing our products depends on our continued adherence to current good manufacturing practices regulations.

The manufacturing processes for our products are governed by detailed regulations that are set forth in current cGMP. Failure by our manufacturing and quality operations unit to adhere to established regulations or to meet a specification or procedure set forth in cGMP requirements could require that a product or material be rejected and destroyed. Our adherence to cGMP regulations and the effectiveness of our quality control systems are periodically assessed through inspections of our manufacturing facility by regulatory authorities. Such inspections could result in deficiency citations, which would require us to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If critical deficiencies are noted or if we are unable to prevent recurrences, we may have to recall products or suspend operations until appropriate measures can be implemented. Since cGMP reflects ever-evolving standards, we regularly need to update our manufacturing processes and procedures to comply with cGMP. These changes may cause us to incur additional costs and may adversely impact our profitability. For example, more sensitive testing assays (if and when they become available) may be required or existing processes may require revalidation, all of which may be costly and time-consuming and could delay or prevent the manufacturing of NexoBrid or launch of a new product.

# Our agreements with Teva Pharmaceutical Industries Ltd., PolyHeal Ltd. and Pliva Croatia Ltd. have been terminated, expired or are otherwise not being performed and it is uncertain whether we will have continuing obligations or liabilities under these agreements.

In 2007, we entered into a series of agreements with Teva Pharmaceutical Industries Ltd., or Teva, to collaborate in the development, manufacturing and commercialization of NexoBrid, and in 2010 we entered into a series of agreements with Teva and PolyHeal Ltd., or PolyHeal, to collaborate in the development, manufacturing and commercialization of PolyHeal's wound product, or the PolyHeal Product. We refer to these agreements as the 2007 Teva Agreement and the 2010 PolyHeal Agreement, respectively. Under the 2007 Teva Agreement, we granted Teva an exclusive right to market and distribute NexoBrid in specific countries; and under the 2010 PolyHeal Agreement, PolyHeal granted us an exclusive global license to develop, manufacture and commercialize the PolyHeal Product, and we granted an exclusive sub-license to Teva to commercialize the PolyHeal Product worldwide. In addition, in accordance with these agreements, Teva made investments in our ordinary shares and agreed to fund our research and development expenses and certain manufacturing costs and perform all marketing activities for both NexoBrid, under the 2007 Teva Agreement, and the PolyHeal Product, under the 2010 PolyHeal Agreement. In November 2012, we informed Teva of the first administration of the next generation of the PolyHeal Product, under the 2010 PolyHeal Agreement to 2010 PolyHeal Agreement. Upon achievement of this milestone, Teva was to invest an additional \$6.8 million in exchange for our ordinary shares of

PolyHeal from its existing shareholders. The PolyHeal shareholders include our own parent company, Clal Biotechnology Industries Ltd., which holds approximately 38% of PolyHeal's outstanding shares. Teva has indicated that it disputes its obligation to make the milestone investment. We have commenced discussions regarding this matter with Teva, however, as of the date of this prospectus, we have not received the milestone investment from Teva and we cannot assure you that Teva will invest this amount. Accordingly, we have not purchased any of the additional shares of PolyHeal from its shareholders, since we believe that Teva's failure to invest suspends our obligation to purchase such shares pursuant to the 2010 PolyHeal Agreement. However, in the event it is successfully and conclusively determined that our obligation to purchase such shares is independent of Teva's fulfillment of its investment obligation, we could be required to purchase \$6.8 million of additional ordinary shares of PolyHeal from its existing shareholders even if we do not receive such investment from Teva, which could have an adverse effect on our financial condition.

In addition, we believe that Teva is obligated to us for payments totaling an aggregate of \$4.7 million pursuant to the 2007 Teva Agreement and the 2010 PolyHeal Agreement. We have commenced discussions with Teva regarding these payments, which are primarily reimbursement for development and manufacturing costs that we believe were to be borne by Teva pursuant to the 2007 Teva Agreement and the 2010 PolyHeal Agreement through the effective date of termination of such agreements, which took place in December 2012.

In December 2012, based on the 2010 PolyHeal Agreement, we entered into a distribution agreement with a wholly-owned subsidiary of Teva, or the Teva Subsidiary, pursuant to which the Teva Subsidiary would have the right to distribute the PolyHeal Product in the Russian Federation and the Ukraine. We refer to this agreement as the Pliva Agreement. In 2013, as a result of the termination of our collaboration with Teva under the 2010 PolyHeal Agreement, our license agreement with PolyHeal expired as well. See "Management's Discussion and Analysis of Financial Condition and Results of Operations— Financial Operations—Operating Expenses—Research and development expenses". As a result, we no longer hold the rights to commercialize the PolyHeal Product, and, consequently, in order not to be in a position that we cannot maintain our obligations under the Pliva Agreement, we have begun discussions with Teva regarding a termination of the Pliva Agreement. There is no certainty that we will reach an agreement on the terms for such termination, or that such termination and its terms will be determined independently and not as part of a settlement of our payment demands to Teva relating to the 2007 Teva Agreement and the 2010 PolyHeal Agreement, as described above. Therefore, we cannot preclude the possibility of an adverse settlement relating to such termination, including a payment from us to the Teva Subsidiary, which could have an adverse effect on our financial condition and results of operation.

Furthermore, if we are unable to reach a negotiated settlement with Teva and the Teva Subsidiary relating to our disputes under the 2007 Teva Agreement, the 2010 PolyHeal Agreement or the Pliva Agreement, these matters may result in costly litigation or arbitration proceedings that would increase our expenses and may disrupt our management's focus on our business.

# NexoBrid, our current pipeline products or future product candidates may cause unanticipated and undesirable side effects or have other properties, which are currently unknown to us.

NexoBrid and all of our current pipeline products rely on our patented proteolytic enzyme technology, although they may vary on their specific formulations or mode of applications. Like most pharmaceutical products, our approval label in Europe for NexoBrid lists certain side effects. If we or others identify previously unknown problems with NexoBrid or its underlying proteolytic enzymes, including adverse events of unanticipated severity or frequency, problems with our manufacturers or

manufacturing processes, or failure to comply with regulatory requirements, the following consequences, among others may occur:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- harm to our reputation, reduced demand for our products and loss of market acceptance;
- refusal by the regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Any of these events could prevent us from achieving or maintaining market acceptance of NexoBrid, our pipeline products or future product candidates, which would adversely affect our business, prospects, financial condition and results of operations.

# We face competition from the existing standard of care and potential changes in medical practice and technology and the possibility that our competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours.

The medical, biotechnology and pharmaceutical industries are intensely competitive and subject to significant technological and practice changes. We may face competition from many difference sources with respect to NexoBrid and our pipeline products or any product candidates that we may seek to develop or commercialize in the future. Possible competitors may be medical practitioners, pharmaceutical and wound care companies, academic and medical institutions, governmental agencies and public and private research institutions, among others. Should any competitor's product candidates receive regulatory or marketing approval prior to ours, they may establish a strong market position and be difficult to displace, or will diminish the need for our products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products, treatments or procedures that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product that we may develop. In addition, we face competition from the current standard of care for eschar removal in severe burns, which is surgery, where debridement can occur by tangential excision, dermabrasion or hydro jet, or non-surgical alternatives, such as topical medications applied to the eschar to facilitate the natural healing process. We face competition in the removal of eschar in severe burns from Smith & Nephew Plc's Santyl, a collagenase-based product indicated for debriding chronic dermal ulcers and severely burned areas. In chronic and other hard-to-heal wounds, we expect to face competition from other debriding agents and wound bed preparation techniques, such as topical medication, mechanical debridement and surgery. With respect to the treatment of connective tissue disorders, our primary competitor, if and when we enter this market, will likely be Auxulium Pharmaceuticals, Inc., which produces Xiaflex, a collagenase-based drug for the treatment of Dupuytren's and Peyronie's diseases. Xiaflex has received marketing approval in the United States for such indications and in the European Union, under the name Xiapex, for Dupuytren's disease. Additionally, in the United States, Xiaflex has orphan drug designation for treatment of both Dupuytren's diseases. Accordingly, we may not be permitted to market a product that competes with Xiaflex in the United States for such indications of its orphan market exclusivity period, which we believe occurs in 2017 and 2023 for Dupuytren's and Peyronie's diseases, respectively. We also cannot confirm at this stage of development that our pipeline products, if approved, will be superior or comparable to Xiaflex.

Many of our current or future competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we may have. Mergers and

acquisitions in the pharmaceutical and biotechnology industries or wound care markets may result in even more resources being concentrated among a smaller number of our competitors. For example, Healthpoint Biotherapeutics, which markets Santyl, was acquired by Smith & Nephew Plc in 2012. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

# While NexoBrid has been granted orphan drug designation for treatment of severe burns in the United States and the European Union, we may lose orphan drug designation.

NexoBrid has been designated an orphan drug in the United States and European Union. One of the incentives provided by an orphan drug designation is market exclusivity for seven and ten years in the United States and the European Union, respectively. While the marketing exclusivity of an orphan drug prevents other sponsors from obtaining approval of a similar medicinal product for the same indication (unless the sponsor demonstrates clinical superiority or a market shortage occurs), it would not prevent other sponsors from obtaining approval of the same compound for other indications. In addition, the FDA or the EMA may revisit any orphan drug designation and retains the ability to withdraw the designation at any time. The U.S. Congress has considered, and may consider in the future, legislation that would restrict the duration or scope of the market exclusivity of an orphan drug and, thus, we cannot be sure that the benefits to us of the existing statute will remain in effect.

# Regulatory approval for NexoBrid and our pipeline products is and may be limited to specific indications and conditions for which clinical safety and efficacy have been demonstrated, and the prescription or promotion of off-label uses could adversely affect our business.

The marketing approval for NexoBrid in the European Union is limited to the treatment of deep partial- and full-thickness burns in adults. In addition, any additional regulatory approval of NexoBrid for severe burns and any regulatory approval we may receive for any of our pipeline products in the future, if any, would be limited to those specific indications for which such pipeline product had been deemed safe and effective by the EMA, the FDA or other regulatory authority. Additionally, labeling restrictions may also limit the manner in which a product may be used. For example, NexoBrid's label provides that it should only be used in specialized burns centers or by burn specialists and should not be applied to more than 15% of the patient's total body surface area. It is not, however, unusual for physicians to prescribe medication for unapproved, or "off-label," uses or in a manner that is inconsistent with the manufacturer's labeling. To the extent such off-label uses are pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, should any of our future products have a significant price difference and if they are used interchangeably, off-label uses may cause a decline in our revenues.

Furthermore, while physicians may choose to prescribe treatments for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the EMA, the FDA or other regulatory authorities. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In the United States, "off-label promotion" by pharmaceutical companies has resulted in significant litigation under the Federal False Claims Act, violations of which may result in substantial civil penalties and fines. More generally, failure to follow the rules and guidelines of regulatory agencies relating to promotion and advertising, such as that promotional materials not be false or misleading, can result in refusal to

approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution.

### If we fail to manage our growth effectively, our business could be disrupted.

Our future financial performance and ability to successfully commercialize our products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We have made and expect to continue to make significant investments to enable our future growth through, among other things, new product development, clinical trials for new indications and expansion of our marketing and sales infrastructure. We are also in the process of planning a larger manufacturing facility in order to increase production capacity. We must also be prepared to further increase production capabilities, expand our work force and train, motivate and manage additional employees as the need for additional personnel arises. Even following expansion, our facilities, personnel, systems, procedures and controls may not be adequate to support our future operations, or we may expand, but then fail to grow our sales of NexoBrid or other pipeline products sufficiently to support such operational growth. Any failure to manage future growth effectively could have a material adverse effect on our business and results of operations.

# We depend on key persons on our senior management team to operate our business effectively, and we may be unable to retain existing, or hire additional, skilled personnel.

Our success depends upon the continued service and performance of key persons on our senior management team. Our President and Chief Executive Officer has been with our company since 2006, our Chief Financial and Operation Officer has been with our company since 2007 and our Chief Medical Officer founded our company in 2000. We have also recently retained the managing director for our German subsidiary to lead the commercialization of NexoBrid in Europe. The loss of the services of any of these key personnel could delay or prevent the continued successful implementation of our growth strategy, or could otherwise affect our ability to manage our company effectively and to carry out our business plan. Members of our senior management team may resign at any time and there can be no assurance that we will be able to continue to retain such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified and skilled sales and marketing, research and development, operational, managerial and finance personnel. Competition for skilled personnel is intense and the unexpected loss of an employee with a particular skill could materially adversely affect our operations until a replacement can be found and trained. While we have not previously had difficulties retaining or attracting senior management or skilled personnel, if we cannot retain our existing skilled scientific and operational personnel and attract and retain sufficiently-skilled additional scientific and operational personnel, as required, for our research and development and manufacturing operations on acceptable terms, we may not be able to continue to develop and commercialize our existing products or new products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

# We may need substantial additional capital in the future, which may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our pipeline products or intellectual property. If additional capital is not available, we may have to delay, reduce or cease operations.

Although we believe our existing cash, cash equivalents, short-term investment balances and the net proceeds from this offering will be sufficient to meet our currently anticipated cash requirements through the next 12 months, we may seek additional funding in the future. This funding may consist of equity offerings, debt financings, collaborations, licensing arrangements or any other means to expand our sales and marketing capabilities, develop our pipeline products and increase our commercial manufacturing capabilities or other general corporate purposes. Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop



and commercialize NexoBrid and our pipeline products. Additional funding may not be available to us on acceptable terms, or at all.

To the extent that we raise additional capital through, for example, the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt or to issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves or reserve for future potential arrangements when we might be able to achieve more favorable terms.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- delay, scale back or discontinue the development, manufacturing scale-up or commercialization of NexoBrid or our pipeline products;
- seek corporate partners for NexoBrid or one or more of our pipeline products on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to NexoBrid or our pipeline products that we otherwise would seek to develop or commercialize ourselves.

Any such consequence will have a material adverse effect on our business, operating results and prospects and on our ability to develop our pipeline products.

### Exchange rate fluctuations between the U.S. dollar and the Israeli shekel, the Euro and other non-U.S. currencies may negatively affect our earnings.

The dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in Israeli shekels. As a result, we are exposed to the risks that the shekel may appreciate relative to the dollar, or, if the shekel instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the shekel, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the shekel against the dollar. For example, although the dollar appreciated against the shekel in 2011, the rate of devaluation of the dollar against the shekel was 2.3% and 7.0% in 2012 and 2013, respectively, which was compounded by inflation in Israel at a rate of 1.6% and 1.9%, respectively. This had the effect of increasing the dollar cost of our operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

In addition, we expect that our revenues initially will be denominated in currencies other than the dollar and the shekel, such as the Euro. Therefore, our operating results and cash flows are also subject to fluctuations due to changes in the relative values of the dollar and these foreign currencies. These fluctuations could negatively affect our operating results and could cause them to vary from quarter to quarter. Furthermore, to the extent that we receive revenues from sales in certain countries,

such as certain countries in the Asia Pacific region, where our sales are expected to be denominated in dollars, a strengthening of the dollar versus other currencies could make our products less competitive in those foreign markets and collection of receivables more difficult.

# Certain of our business practices could become subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug and Cosmetic Act, or the FDCA, the Public Health Service Act, the Federal False Claims Act, provisions of the U.S. Social Security Act, including the provision known as the "Anti-Kickback Law," or any regulations promulgated under their authority, may result in various administrative, civil and criminal sanctions, jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid, other regulatory authorities and the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Law, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs and devices for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs. As a result, arrangements with potential referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or of rewarding past prescribing.

In addition, significant enforcement activity has taken place under federal and state false claims act statutes and violations of the federal False Claims Act can result in treble damages, and penalty of up to \$11,000 for each false claim submitted for payment. The federal False Claims Act, as well as certain state false claims acts, permit relators to file complaints in the name of the United States (and if applicable, particular states). These relators may be entitled to receive up to 30% of total recoveries and have been active in pursuing cases against pharmaceutical companies. Where practices have been found to involve improper incentives to use products, the submission of false claims, or other improper conduct, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. In addition, to avoid exclusion from participation in federal healthcare programs, many manufacturers have been required to enter into Corporate Integrity Agreements that prescribe allowable corporate conduct. Failure to satisfy requirements under the FDCA can also result in a variety of administrative, civil and criminal penalties, including injunctions or consent decrees that prescribe allowable corporate conduct.

To enhance compliance with applicable healthcare laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. As NexoBrid is not yet approved for marketing in the United States, we have not adopted U.S. healthcare compliance and ethics programs that generally incorporate the OIG's recommendations, but even if we do, having such a program can be no assurance that we will avoid any compliance issues.

In addition, we are subject to analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign 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; state and foreign 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 certain circumstances. Many of these laws differ from each other in significant ways and often are not preempted by the U.S. Health Insurance Portability and Accountability Act of 1996 thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

As a public company with securities registered under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, we will be subject to the U.S. Foreign Corrupt Practices Act, or FCPA. The FCPA and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. We intend to implement policies mandating compliance with these anti-bribery laws, however, we may operate in parts of the world that have experienced governmental corruption to some degree and in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different than in the United States. Our internal control policies and procedures may not be sufficient to effectively protect us against reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our financial condition, results of operations and cash flows.

# We could be subject to product liability lawsuits, which could result in costly and time-consuming litigation and significant liabilities.

The development of biopharmaceutical products involves an inherent risk of product liability claims and associated adverse publicity. Our products may be found to be harmful or to contain harmful substances. This exposes us to substantial risk of litigation and liability or may force us to discontinue production of certain products. Although we have product liability insurance covering up to \$5.0 million in claims in the E.U., the coverage may not insure us against all claims made. Product liability insurance is costly and often limited in scope. There can be no assurance that we will be able to obtain or maintain insurance on reasonable terms or to otherwise protect ourselves against potential product liability claims that could impede or prevent commercialization of NexoBrid or our pipeline products. Furthermore, a product liability claim could damage our reputation, whether or not such

claims are covered by insurance or are with or without merit. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our business or financial condition. Furthermore, product liability lawsuits, regardless of their success, would likely be time consuming and expensive to resolve and would divert management's time and attention, which could seriously harm our business.

# Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our technology and products.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our intellectual property and proprietary technologies, our products and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely on a combination of patent, trademark and trade secret laws, non-disclosure and confidentiality agreements, licenses, assignments of invention agreements and other restrictions on disclosure and use to protect our intellectual property rights.

As of January 27, 2014, we had been granted a total of 57 patents and have 17 pending national phase applications. The family of patents that covers NexoBrid specifically includes 31 granted patents worldwide and five pending applications. However, there can be no assurance that patent applications relating to our products, processes or technologies will result in patents being issued, or that any patents that have been issued will be adequate to protect our intellectual property or that we will enjoy patent protection for any significant period of time. Additionally, any issued patents may be challenged by third parties, and patents that we hold may be found by a judicial authority to be invalid or unenforceable. Other parties may independently develop similar or competing technology or design around any patents that may be issued to or held by us. Our current patents will expire or they may otherwise cease to provide meaningful competitive advantage, and we may be unable to adequately develop new technologies and obtain future patent protection to preserve our competitive advantage or avoid adverse effects on our business.

At present, we consider our patents relating to our proteolytic enzyme technology, which underlies NexoBrid and our current pipeline products, to be material to the operation of our business as a whole. Our patents which cover NexoBrid claim specific mixtures of proteolytic enzymes, methods of producing such mixtures and methods of treatment using such mixtures. Although the protection achieved is significant for NexoBrid and our pipeline products, when looking at our patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents which claim chemical structures which were previously unknown. If our patents covering NexoBrid in various jurisdictions were subject to a successful challenge or if a competitor were able to successfully design around them, our business and competitive advantage could be significantly affected.

In addition, the patent landscape in the biotechnology field is highly uncertain and involves complex legal, factual and scientific questions, and changes in either patent laws or in the interpretation of patent laws in the United States and other countries may diminish the value and strength of our intellectual property or narrow the scope of our patent protection. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products or enforce our patents due to lack of information about the exact use of our process by third parties. Even if patents are issued to us, they may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to prevent competitors from using similar technology or marketing similar products, or limit the length of time our technologies and products have patent protection. In addition, we are a party to license agreements with each of Mark Klein and L.R. R&D Ltd., an entity which is wholly-owned by Prof. Lior Rosenberg, that impose various obligations upon us as a licensee, including, with respect to the agreement with Mark Klein, the obligation to make milestone and royalty payments contingent on the sales of NexoBrid. If we fail to comply with these obligations, the licensor may

terminate the license, in which event we might not be able to market any product that is covered by the licensed intellectual property, including NexoBrid.

Our material patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after their filing, if at all, and because publications of discoveries in scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in such patent applications. As a result, the patents we own and license may be invalidated in the future, and the patent applications we own and license may not be granted. For example, if a third party has also filed a patent application covering an invention similar to one covered in one of our patent applications, we may be required to participate in an adversarial proceeding known as an "interference proceeding," declared by the U.S. Patent and Trademark Office or its foreign counterparts, to determine priority of invention. The costs of these proceedings could be substantial and our efforts in them could be unsuccessful, resulting in a loss of our anticipated patent products covered by that patent. Additionally, patents and patent applications owned by third parties may prevent us from pursuing technology or marketing products covered by that patent. Additionally, patents and patent applications owned by third parties may prevent us from pursuing certain opportunities such as entering into specific markets or developing certain products. Finally, we may choose to enter into markets where certain competitors have patents or patent protection over technology that may impede our ability to compete effectively.

Our currently issued patents are nominally due to expire at various dates between 2025 and 2029. However, because of the extensive time required for development, testing and regulatory review of a potential product, and although such delays may entitle us to patent term extensions, it is possible that, before NexoBrid can be commercialized in additional jurisdictions and/or before any of our future products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Our pending and future patent applications may not lead to the issuance of patents or, if issued, the patents may not be issued in a form that will provide us with any competitive advantage. We also cannot guarantee that:

- any of our present or future patents or patent claims or other intellectual property rights will not lapse or be invalidated, circumvented, challenged or abandoned;
- our intellectual property rights will provide competitive advantages or prevent competitors from making or selling competing products;
- our ability to assert our intellectual property rights against potential competitors or to settle current or future disputes will not be limited by our agreements with third parties;
- any of our pending or future patent applications will be issued or have the coverage originally sought;
- our intellectual property rights will be enforced in jurisdictions where competition may be intense or where legal protection may be weak; or
- we will not lose the ability to assert our intellectual property rights against, or to license our technology to, others and collect royalties or other payments.

In addition, our competitors or others may design around our patents or protected technologies. Effective protection of our intellectual property rights may also be unavailable or limited in some countries, and even if available, we may fail to pursue or obtain necessary intellectual property protection in such countries, including because filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents and

other intellectual property rights, and the laws of certain foreign countries do not protect our rights to the same extent as the laws of the United States. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and we may be unable to prevent such competitors from importing those infringing products into territories where we have patent protection but enforcement is not as strong as in the United States or into jurisdictions in which we do not have patent protection. These products may compete with our product candidates and our patents and other intellectual property rights may not be effective or sufficient to prevent them from competing in those jurisdictions.

In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. Such lawsuits could entail significant costs to us and divert our management's attention from developing and commercializing our products. Lawsuits may ultimately be unsuccessful and may also subject us to counterclaims and cause our intellectual property rights to be challenged, narrowed, invalidated or held to be unenforceable.

Additionally, unauthorized use of our intellectual property may have occurred or may occur in the future. Any failure to identify unauthorized use of, and otherwise adequately protect, our intellectual property could adversely affect our business, including by reducing the demand for our products. Any reported adverse events involving counterfeit products that purport to be our products could harm our reputation and the sale of our products. Moreover, if we are required to commence litigation related to unauthorized use, whether as a plaintiff or defendant, such litigation would be time-consuming, force us to incur significant costs and divert our attention and the efforts of our management and other employees, which could, in turn, result in lower revenue and higher expenses.

### In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how.

We rely on proprietary information (such as trade secrets, know-how and confidential information) to protect intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. We generally seek to protect this proprietary information by entering into confidentiality agreements, or consulting, services or employment agreements that contain non-disclosure and non-use provisions with our employees, consultants, contractors, scientific advisors and third parties. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. We have limited control over the protection of trade secrets used by our suppliers and service providers and could lose future trade secret protection if any unauthorized disclosure of such information occurs. In addition, our proprietary information may otherwise become known or be independently developed by our competitors or other third parties. To the extent that our employees, consultants, contractors, scientific advisors and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our and relevant third parties are able to establish that we are using their proprietary information without their permission, we may be required to obtain a license to that information, or if such a license is not available, re-design our products to avoid any such unauthorized use or temporarily delay or permanently stop manufacturing or sales of the affected products. Furthermore, laws regarding trade secret rights in certain

We also rely on physical and electronic security measures to protect our proprietary information, but we cannot provide assurance that these security measures will not be breached or provide adequate protection for our property. There is a risk that third parties may obtain and improperly utilize our proprietary information to our competitive disadvantage. We may not be able to detect or prevent the unauthorized use of such information or take appropriate and timely steps to enforce our intellectual property rights.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including potential competitors. While we take steps to prevent our employees from using the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims successfully, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

### If we are unable to protect our trademarks from infringement, our business prospects may be harmed.

We own trademarks that identify "MediWound", "NexoBrid" and "EscharEx", among others, and have registered these trademarks in certain key markets. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

### We may be subject to claims that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties.

Our development, marketing or sale of NexoBrid or our pipeline products may infringe or be accused of infringing one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. We may also be subject to claims that we are infringing, misappropriating or otherwise violating other intellectual property rights, such as trademarks, copyrights or trade secrets. Third parties could therefore bring claims against us or our strategic partners that would cause us to incur substantial expenses, including litigation costs or costs associated with settlement, and, if successful against us, could cause us to pay substantial damages. Further, if such a claim were brought against us, we could be forced to temporarily delay or permanently stop manufacturing or sales of NexoBrid or our pipeline products that is the subject of the suit.

If we are found to be infringing, misappropriating or otherwise violating the patent or other intellectual property rights of a third party, or in order to avoid or settle claims, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. 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 nonexclusive, which could result in our competitors gaining access to the same intellectual property. 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 claims, we or our strategic partners are unable to enter into licenses on acceptable terms.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition, to the extent that we gain greater visibility and market exposure as a public company in the United States, we

face a greater risk of being involved in such litigation. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, opposition, re-examination and similar proceedings before the U.S. Patent and Trademark Office and its foreign counterparts, regarding intellectual property rights with respect to NexoBrid or our pipeline products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. A negative outcome could result in liability for monetary damages, including treble damages and attorneys' fees if, for example, we are found to have willfully infringed a patent. A finding of infringement could prevent us from developing, marketing or selling a product or force us to cease some or all of our business operations. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, and patent litigation and other proceedings may also absorb significant management time.

# We are subject to extensive environmental, health and safety, and other laws and regulations.

Our business involves the controlled use of chemicals. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any such chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents.

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

We generally enter into non-competition agreements with our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli labor courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the protection of a company's trade secrets or other intellectual property.

# 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.

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 term and as part of the scope of his or her



employment with a company 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 such agreement between an employer and an employee, 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 inventions. Recent decisions by the Committee (which have been upheld by the Israeli Supreme Court on appeal) have created uncertainty in this area, as it held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. Further, the Committee has not yet determined the method for calculating this remuneration nor the criteria or circumstances under which an employee's waiver of his right to remuneration will be disregarded. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, 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 or former employees, or be forced to litigate such claims, which could negatively affect our business.

## Potential future acquisitions of companies or technologies may distract our management, may disrupt our business and may not yield the returns expected.

We may acquire or make investments in businesses, technologies or products, whether complementary or otherwise, as a means to expand our business, if appropriate opportunities arise. We cannot give assurances that we will be able to identify future suitable acquisition or investment candidates, or, if we do identify suitable candidates, that we will be able to make the acquisitions or investments on reasonable terms or at all. In addition, we have no prior experience in integrating acquisitions and we could experience difficulties incorporating an acquired company's personnel, operations, technology or product offerings into our own or in retaining and motivating key personnel from these businesses. We may also incur unanticipated liabilities. The financing of any such acquisition or investment, or of a significant general expansion of our business, may not be readily available on favorable terms. Any significant acquisition or investment, or major expansion of our business, may require us to explore external financing sources, such as an offering of our equity or debt securities. We cannot be certain that these financing sources will be available to us or that we will be able to made terms for an acquisition, any indebtedness that we may incur in such a financing may inhibit our operational freedom, while any equity securities that we may issue in connection with such a financing would dilute our shareholders. Any such difficulties could disrupt our ongoing business, distract our management and employees, increase our expenses and adversely affect our results of operations. Furthermore, we cannot provide any assurance that we will realize the anticipated benefits or synergies of any such acquisition or investment.

#### **Risks Related to an Investment in Our Ordinary Shares**

# An active, liquid and orderly trading market for our ordinary shares may not develop, which may inhibit the ability of our shareholders to sell ordinary shares following this offering.

Prior to this offering there has been no public market for our ordinary shares. An active, liquid or orderly trading market in our ordinary shares may not develop upon completion of this offering, or if it does develop, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair

our ability to raise capital by selling shares and may impair our ability to acquire other companies by using our shares as consideration.

# The market price of our ordinary shares may be subject to fluctuation and you could lose all or part of your investment.

The initial public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. The price of our ordinary shares may decline following this offering. The stock market in general has been, and the market price of our ordinary shares in particular will likely be, subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our ordinary shares on the NASDAQ Global Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our products;
- the mix of products that we sell and related services that we provide;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for NexoBrid or any of our pipeline products;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant shareholders, of our ordinary shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our ordinary shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our ordinary shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company shareholders have often instituted

securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

# 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, if at all. We do not have control over these analysts and we do not have commitments from them to write research reports about us. The price of our ordinary shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

# Future sales of our ordinary shares could reduce the market price of our ordinary shares.

If our existing shareholders, particularly our directors, their affiliates, or our executive officers, sell a substantial number of our ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. The perception in the public market that our shareholders might sell our ordinary shares could also depress the market price of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities. Substantially all of our shares outstanding prior to this offering and our shares issuable upon the exercise of warrants and vested options are subject to lock-up agreements with the underwriters that restrict the ability of their holders to transfer such shares for 180 days after the date of this prospectus. Consequently, upon expiration of the lock-up agreements, an additional approximately of our ordinary shares and ordinary shares warrants to purchase ordinary shares and the exercise of issuable upon the exercise of outstanding options will be eligible for sale in the public market of which approximately will be subject to restrictions on volume and manner of sale pursuant to Rule 144 under the Securities Act of 1933, as amended. However, we intend to file one or more registration statements on Form S-8 with the U.S. Securities and Exchange Commission, or the Commission, covering all of the ordinary shares issuable under our share option plans and such shares will be available for resale following the expiration of the restrictions on transfer. After this offering, the holders of approximately ordinary shares will be entitled to registration rights. 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. 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.

## Investors in this offering will experience immediate substantial dilution in net tangible book value.

The initial public offering price of our ordinary shares in this offering is considerably greater than the net tangible book value per share of our outstanding ordinary shares immediately after this offering. Accordingly, investors in this offering will incur immediate dilution of \$ per share, based on an assumed initial public offering price of \$ per share, the midpoint of the estimated initial public offering price range shown on the cover of this prospectus. In addition, if outstanding options to purchase our ordinary shares are exercised in the future, you will experience additional dilution. See "Dilution."

#### The significant share ownership position of Clal Biotechnology Industries Ltd. may limit your ability to influence corporate matters.

After giving effect to this offering, Clal Biotechnology Industries Ltd., or CBI, will own or control, directly and indirectly, % of our outstanding ordinary shares (or % if the underwriters fully exercise their option to purchase additional ordinary shares). Accordingly, CBI will be able to significantly influence the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. CBI's interests may not be consistent with those of our other shareholders. In addition, CBI's significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of 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 further build our sales and marketing infrastructure, fund research and development projects and scale up manufacturing and for other general corporate purposes. 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 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, 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 U.S. Securities Exchange Act of 1934, as amended, or 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, or the Sarbanes-Oxley Act, as well as rules implemented by the Commission and the NASDAQ Stock Market, and provisions of Israeli corporate and securities laws 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. 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.

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 have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our share capital, nor do we anticipate paying any cash dividends on our share capital in the foreseeable future. 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 investors' sole source of gain for the foreseeable future. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes.

# We are a "controlled company" within the meaning of NASDAQ Stock Market rules and, as a result, will qualify for, and intend to rely on, certain exemptions from certain corporate governance requirements.

As a result of the number of shares beneficially owned by Clal Biotechnology Industries Ltd., after the completion of this offering, we will be a "controlled company" under the NASDAQ Stock Market 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 comply with the requirements that: (a) a majority of our board of directors consist of independent directors, and (b) we have a compensation committee and a nominating committee composed entirely of independent directors with a written charter addressing each committee's purpose and responsibilities. Upon the closing of this offering, a majority of our board of directors. Under Israeli law, we are nevertheless required to have a compensation committee. See "Management—Corporate Governance Practices." 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 Stock Market.

# As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable Commission and NASDAQ requirements.

As a foreign private issuer, we will be permitted, and intend, to follow certain home country corporate governance practices instead of those otherwise required under the NASDAQ Stock Market for domestic U.S. issuers. This will be the case even if we cease to be a "controlled company" within the meaning of the NASDAQ Stock Market rules. For instance, we intend to follow home country practice in Israel with regard to the quorum requirement for shareholder meetings. As permitted under the Israeli Companies Law, 5759-1999, or the Israeli Companies Law, our articles of association to be effective upon the closing of this offering will provide that the quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares instead of the 33<sup>1</sup>/3% of the issued share capital requirement. We may in the future elect to follow home country practices in Israel (and consequently avoid the requirements that would otherwise apply to a U.S. company listed on the NASDAQ Global Market) with regard to other matters, as well, such as the formation of compensation, nominating and governance committees, separate executive sessions of independent directors and non-management directors and the requirement to obtain shareholder approval for certain dilutive events (such as for the establishment or amendment of certain equity-based compensation plans, issuances that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company). 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 to you than what is accorded to investors under the NASDAQ Stock Market rules applicable to domestic U.S. issuers.

# As a foreign private issuer, we will not be subject to U.S. proxy rules and will be exempt from filing certain Exchange Act reports.

As a foreign private issuer, we will be exempt from the rules and regulations 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. In addition, we will not be required under the Exchange Act to file annual and current reports and financial statements with the Commission as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act, we will be permitted to disclose compensation information for our executive officers on an aggregate, rather than an individual, basis and we will generally be exempt from filing quarterly reports with the Commission under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our directors or executive officers are U.S. citizens or residents and we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the Commission, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

# 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 Jumpstart Our Business Startups Act, or 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 cease to be a foreign private issuer in the future. Nevertheless, as a foreign private issuer that is an emerging growth company, we will not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act for 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 \$1.0 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. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions under the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

# We have not yet determined whether our existing internal control over financial reporting systems are compliant with Section 404 of the Sarbanes-Oxley Act, and we cannot provide any assurance that there are no material weaknesses or significant deficiencies in our existing internal controls.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the Commission and the Public Company Accounting Oversight Board, starting with the second annual report that we file with the Commission 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 applicable to emerging growth companies discussed above, our independent registered public accounting firm will also need to attest to management's assessment of 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 or results of operations and could result in an adverse opinion on int

#### Our U.S. shareholders may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if for any taxable year 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Our status as a PFIC may also depend on how quickly we use the cash proceeds from this offering in our business. Based on certain estimates of our gross income and gross assets, our intended use of proceeds of this offering, and the nature of our business, we do not expect that we will be classified as a PFIC for the taxable year ending December 31, 2014. There can be no assurance that we will not be considered a PFIC for any taxable year. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than as capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders (as defined in "Taxation—U.S. Federal Income Tax Consequences"), and having interest charges apply to distributions by us and the proceeds of share sales. Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares; however, we do not intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we are classified as a PFIC.

## **Risks Primarily Related to our Operations in Israel**

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

Our headquarters, manufacturing and research and development facilities are located in Yavne, Israel. In addition, the majority of our key employees, officers and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since

the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Further, our operations could be disrupted by the obligations of personnel to perform military service. As of December 31, 2013, we had 40 employees based in Israel. Some of these employees, including a number of our executive officers, are military reservists, and may be called upon to perform military reserved duty of up to 54 days in each three year period until they reach the age of 40. In the case of officers and certain reservists with specific military professions, the duty may extend up to 84 days in each three year period and continue until the age of 45 or even 49. In certain emergency circumstances, these employees and executives may be called periods of time. In response to increased tension and hostilities, there have been occasional call-ups of military reservists, as was the case in connection with Israel's military campaigns in Gaza in December 2008 and November 2012, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of one or more of our executive officers or other key employees for military service. Such disruption could materially adversely affect our business and operating results.

During the Second Lebanon War of 2006, between Israel and Hezbollah, a militant Islamic movement, rockets were fired from Lebanon into Israel causing casualties and major disruption of economic activities in northern Israel. An escalation in tension and violence between Israel and the militant Hamas movement (which controls the Gaza Strip) and other Palestinian Arab groups, culminated with Israel's military campaign in Gaza in December 2008 and again in November 2012 in an endeavor to prevent continued rocket attacks against Israel's southern towns. While there are occasional negotiations between Israel and the Palestinian Authority with the ultimate aim of reaching an official "final status agreement," there can be no guarantee that an agreement can be reached by the parties. In addition, Israel faces threats from more distant neighbors, in particular, Iran, an ally of Hezbollah and Hamas.

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, and additional countries may impose restrictions on doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business or customers in those countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downtums in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our revenues to decrease and adversely affect our share price. Similarly, Israeli companies are limited in conducting business with entities from several countries. For example, in 2008, the Israeli legislature passed a law forbidding any investments in entities that transact business with Iran.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts, terrorist activities or political instability in the region would likely negatively affect business conditions generally and could harm our results of operations.

# We received Israeli government grants for certain research and development activities. The terms of those grants require us to satisfy specified conditions and to pay penalties in addition to repayment of the grants upon certain events.

Our research and development efforts were and are financed in part through grants from the Israeli Office of the Chief Scientist, or OCS. The total gross amount of grants actually received by us from the OCS, including accrued LIBOR interest as of December 31, 2013, totaled approximately \$9.9 million and the amortized cost (using the interest method) of the liability as of that date totaled approximately \$6.6 million. As of December 31, 2013, we had not paid any royalties to the OCS. We expect to receive additional grants from the OCS through March 2014, and we intend to apply for further grants for 2014-2015. However, as the funds available for OCS grants out of the annual budget of the State of Israel have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

Even following full repayment of any OCS grants, we must nevertheless continue to comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 5744-1984, and related regulations, or collectively, the R&D Law. When a company develops know-how, technology or products using OCS grants, the terms of these grants and the R&D Law restrict the transfer outside of Israel of such know-how, and the manufacturing or manufacturing rights of such products, technologies or know-how, without the prior approval of the OCS. Therefore, if aspects of our technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties outside of Israel of know-how or manufacturing or manufacturing rights related to those aspects of such technologies. We may not receive those approvals. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel.

The transfer of OCS-supported technology or know-how or manufacturing or manufacturing rights related to aspects of such technologies outside of Israel may involve the payment of significant penalties and other amounts, depending upon the value of the transferred technology or know-how, the amount of OCS support, the time of completion of the OCS-supported research project and other factors. These restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with OCS funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the OCS.

# Provisions of Israeli law and our amended and restated articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, us, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting 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.

# It may be difficult to enforce a judgment of a U.S. court against us, our officers and directors or the Israeli experts named in this prospectus in Israel or the United States, to assert U.S. securities laws claims in Israel or to serve process on our officers and directors and these experts.

We are incorporated in Israel. All of our executive officers and the Israeli experts and all of our directors listed in this prospectus reside outside of the United States, and most of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, including a judgment 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 also may be difficult for you 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. 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 in which to bring 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 proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this prospectus.

# 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 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 companies. In particular, 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, in 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 vote at a meeting of the shareholders or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company with regard to such vote or appointment. 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. companies.

# FORWARD-LOOKING STATEMENTS; CAUTIONARY INFORMATION

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business", contains forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "projects," "should," will," "would," and similar expressions intended to identify forward-looking statements. The statements we make regarding the following matters are forward-looking by their nature:

- the timing and conduct of our trials of NexoBrid and our other pipeline product candidates, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of NexoBrid and our pipeline products;
- our expectations regarding future growth, including our ability to develop new products;
- our commercialization, marketing and manufacturing capabilities and strategy and the ability of our marketing team to cover regional burn centers and units;
- our ability to maintain adequate protection of our intellectual property;
- our plans to develop and commercialize our pipeline products;
- our estimates regarding expenses, future revenues, capital requirements and the need for additional financing;
- our estimates regarding the market opportunity for NexoBrid and our pipeline products;
- our expectation regarding the duration of our inventory of intermediate drug substance and products;
- the impact of our research and development expenses as we continue developing product candidates.
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- the impact of government laws and regulations; and
- our expectations regarding the use of proceeds from this offering;

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those described in "Risk factors." In addition, the sections of this prospectus entitled "Prospectus Summary" and "Business" contain information obtained from independent industry sources that we have not independently verified.

You should not unduly rely on any forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus, to conform these statements to actual results or to changes in our expectations.

# **USE OF PROCEEDS**

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

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ would increase (decrease) the net proceeds that we receive from the 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 underwriting discounts and commissions and estimated offering expenses. Similarly, each increase (decrease) of 100,000 shares in the number of ordinary shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses.

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

- approximately \$25-\$30 million to expand our sales and marketing infrastructure;
- approximately \$25-\$30 million on research and development;
- approximately \$10 million to expand our manufacturing capabilities; and
- the balance, if any, for other general corporate purposes.

Our management estimates that the majority of the net proceeds from this offering allocated to the expansion of our sales and marketing infrastructure will be spent on the ongoing expansion of NexoBrid, starting in Europe. Additionally, our management estimates that the majority of the net proceeds from this offering allocated to research and development will be spent on the ongoing development of NexoBrid, both in the Phase III trial in the United States and the pediatric trial in the European Union. The balance of such research and development funding is expected to be allocated to the continued development of EscharEx for debridement of chronic and other hard-to-heal wounds and of our proteolytic enzyme technology for the treatment of connective tissue disorders. Although the costs associated with such research and development plans are uncertain, see "Risk Factors—Clinical drug development is a lengthy and expensive process, with an uncertain outcome," our management currently believes that the use of approximately \$25-\$30 million on research and development will be sufficient to fund our Phase III trial for NexoBrid in the United States and our pediatric trial in the European Union until completion.

Our management will have significant flexibility in applying the net proceeds. Pending the uses described above, we intend to invest the net proceeds in interest-bearing investment-grade securities or deposits.

# DIVIDEND POLICY

We have never declared or paid cash dividends to our shareholders and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

See "Risk Factors—Risks Related to an Investment in Our Ordinary Shares—We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future" and "Description of Share Capital—Dividend and Liquidation Rights" for an explanation concerning the payment of dividends under Israeli law."

# CAPITALIZATION

The following table presents our cash and cash equivalents and capitalization as of December 31, 2013:

- on an actual basis; and
- on a pro forma as adjusted basis, (i) to give effect to the issuance of ordinary shares upon the closing of this offering, pursuant to the cashless exercise of 280,720 warrants held by certain of our shareholders at a weighted average exercise price of \$36.42 per share, and (ii) to give further effect to the issuance and sale of ordinary shares in this offering, at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses.

This table should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

		Pro forma
	Actual	as adjusted
		ands, except
\$	9,553	\$
_		
	9.200	
	.,	
	11	
	62,229	
	(34,600)	
	(32)	
	(47,412)	
	(19,804)	
\$	(10,604)	\$
	<u>\$</u>	share and p \$ 9,553 9,200 11 62,229 (34,600) (32) (47,412)

(1) On , 2014, we effected a -for- share split by means of a share dividend of ordinary shares for ordinary share then outstanding. The number of outstanding shares has been adjusted to reflect this share split.

The preceding table excludes 850,000 ordinary shares reserved for issuance under our share option plan as of December 31, 2013, of which options to purchase 625,280 ordinary shares have been granted at a weighted average exercise price of \$25.49 per share.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ would increase (decrease) the pro forma as adjusted amount of each of share premium, total shareholders' equity and total capitalization 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 underwriting discounts and commissions and estimated offering expenses.

# 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. On a pro forma as-adjusted basis, after giving effect to the exercise of warrants to purchase of our ordinary shares and to adjustments relating to this offering, our consolidated net tangible book value as of December 31, 2013 was \$ million, or \$ per ordinary share. Pro forma as-adjusted consolidated net tangible book value per ordinary share was calculated by:

- subtracting our consolidated liabilities from our consolidated tangible assets;
- dividing the difference by the number of ordinary shares outstanding on a pro forma as-adjusted basis;
- increasing the consolidated tangible assets to reflect the net proceeds of this offering received by us as described under "Use of proceeds;" and
- adding ordinary shares offered in this prospectus to the number of ordinary shares outstanding.

The following table illustrates the immediate increase in our pro forma as-adjusted consolidated net tangible book value of \$ per ordinary share and the immediate pro forma as-adjusted dilution to new investors:

Assumed initial public offering price per ordinary share Actual net tangible book value per ordinary share as of December 31, 2013	¢	\$
Decrease per share attributable to the exercise of warrants	\$	
Increase in net tangible book value per ordinary share attributable to the offering		
Pro forma as-adjusted net tangible book value per ordinary share as of December 31, 2013 after giving effect to the offering		
Dilution per ordinary share to new investors		\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per ordinary share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the consolidated net tangible book value attributable to this offering by \$ per ordinary share, the pro forma as-adjusted consolidated net tangible book value after giving effect to this offering by \$ per ordinary share and the dilution per ordinary share to new investors in this offering by \$ , assuming that the number of ordinary shares offered remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

The table below summarizes, as of December 31, 2013, on the pro forma as-adjusted basis described above, the differences between the number of ordinary shares purchased from us, the total consideration paid and the weighted average price per share paid by existing shareholders and by investors purchasing our ordinary shares in this offering at an assumed initial public offering price of

\$ per ordinary share (the midpoint of the price range set forth on the cover page of this prospectus) before deducting underwriting discounts and commissions and estimated offering expenses.

		ares hased	Total Consideration		Average Price
	Number	%	Amount	%	per Share
Existing shareholders		(	%\$		%\$
New investors					
Total		1009	%\$	100	)%

The above discussion and tables are based on ordinary shares issued and outstanding as of December 31, 2013, on a pro forma as-adjusted basis as described above.

The discussion and table above assume no exercise of the underwriters' option to purchase additional ordinary shares. If the underwriters exercise their option to purchase additional ordinary shares in full, the proforma as-adjusted number of our ordinary shares held by new investors will increase to , or approximately %, of the total proforma as-adjusted number of our ordinary shares outstanding after this offering.

The preceding table excludes 850,000 ordinary shares reserved for issuance under our share option plan as of December 31, 2013, of which options to purchase 625,280 ordinary shares have been granted at a weighted average exercise price of \$25.49 per share.

If all of such outstanding options were exercised, pro forma as-adjusted consolidated net tangible book value per share would be \$\$, dilution per ordinary share to new investors would be \$\$, the number of shares held by our existing shareholders would increase to \$\$, constituting % of our total issued shares (while new shareholders in this offering would only hold % of our issued shares), the total consideration amount paid by existing shareholders would increase to \$\$, or % of total consideration received by us for our shares (while the percentage of consideration paid by new shareholders in this offering would decrease to %) and the average price per share paid by our existing shareholders would instead be \$\$.

# SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data. You should read the following selected consolidated 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 consolidated financial statements and the related notes appearing elsewhere in this prospectus.

The selected consolidated statements of operations data for the years ended December 31, 2011, 2012 and 2013 and the consolidated balance sheets data as of December 31, 2012 and 2013 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The historical results set forth below are not necessarily indicative of the results to be expected in future periods. Our financial statements have been prepared in accordance with IFRS, as issued by the International Accounting Standards Board, or IASB.

				ear ended cember 31,		
	2	2011	_	2012		2013
				ls, except s share data		and
Consolidated statements of operations data:			per	share uata	,	
Operating expenses:						
Research and development, gross	\$	6,149	\$	3,804	\$	4,513
Participation by OCS and others		3,128		2,247		878
Research and development, net of participations(1)(2)		3,021		1,557		3,635
Selling and marketing		—		—		2,259
General and administrative(1)		1,266		1,173		1,687
Operating loss	(	(4,287)	(	(2,730)		(7,581)
Financial income		96		15,406		2,401
Financial expense		(628)		(691)		(3,321)
Income (loss) from continuing operations	(	(4,819)		11,985		(8,501)
Loss from discontinued operation(1)(3)	(	(1,350)	(	(1,045)		(6,850)
Net income(loss)	\$ (	(6,169)	\$	10,940	\$	(15,351)
Foreign currency translation adjustments		_		_		(32)
Total comprehensive income (loss)	\$ (	(6,169)	\$	10,940	\$	(15,383)
Basic net income (loss) per share(4)	\$	(1.49)	\$	2.65	\$	(3.72)
Diluted net income (loss) per share(4)	\$	(1.49)	\$	2.42	\$	(3.72)
Weighted average number of ordinary shares used in computing income (loss) per ordinary share:						
Basic		4,127		4,127		4,124
Diluted		4,127	_	4,526	_	4,124

	As of December 31			er 31,
	2012		2013	
		(in tho	usan	ids)
Consolidated balance sheet data:				
Cash and cash equivalents and short-term bank deposits	\$	337	\$	9,553
Working capital(5)		(112)		10,042
Total assets	2	25,438		14,826
Total non-current liabilities		6,440		32,607
Total shareholders' equity (deficit)	1	15,634		(19,804)

(1) Includes equity-based compensation expenses as follows:

	Year Ended December 31,
	2011 2012 2013 (in thousands)
Research and development	\$ 182 \$ 124 \$ 315
Selling and marketing	— — 24
General and administrative	373 210 192
Equity-based compensation expenses from continuing operations	\$ 555 \$ 334 \$ 531
Discontinued operation	109 30 76
Total equity-based compensation expenses	\$ 664 \$ 364 \$ 607

- (2) Research and development expenses, net is presented net of participation by others and net of the change in the fair value of the liability associated with government grants from the Office of the Chief Scientist. Participation by others totaled \$2.7 million, \$2.2 million and zero for the years ended December 31, 2011, 2012 and 2013, respectively. The effect of the participation by the Office of the Chief Scientist totaled \$0.5 million, \$0.1 million and \$0.9 million for the years ended December 31, 2011, 2012 and 2013, respectively. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Operating expenses—Research and development" for more information.
- (3) Discontinued operation consists of revenues and expenses related to our exclusive, worldwide license for the development, production and commercialization of the PolyHeal Product, which expired following the termination of our collaboration with Teva. We account for our discontinued operation in accordance with IFRS accounting standard 5, "Non-current Assets Held for Sale and Discontinued Operations." See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Discontinued operation" for more information.
- (4) Basic and diluted earnings (loss) per ordinary share is computed based on the basic and diluted weighted average number of ordinary shares outstanding during each period. For additional information, see Note 20 to our consolidated annual financial statements included elsewhere in this prospectus.

(5) Working capital is defined as total current assets minus total current liabilities.

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

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

#### Overview

We are a fully integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel products to address unmet needs in the fields of severe burns, chronic and hard-to-heal wounds and connective tissue disorders. Our innovative biopharmaceutical product, NexoBrid, received marketing authorization from the European Medicines Agency, or EMA, in December 2012 for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns, also referred to as severe burns. NexoBrid represents a new paradigm in burn care management and has clinically demonstrated, with statistical significance, the ability to non-surgically and rapidly remove the eschar, without harming viable tissue.

We have devoted significant efforts to the research and development of our patented proteolytic enzyme technology upon which NexoBrid is based. We launched NexoBrid in December 2013 in the European Union through our wholly-owned German subsidiary, targeting a focused audience of burn specialists treating patients with severe burns in burn centers and hospital burn units. We also plan to initiate a Phase 3 pivotal study in the United States in the first half of 2014 to support a Biologics License Application, or BLA, submission to the U.S. Food and Drug Administration, or FDA. However, we expect that it will be several years, if ever, before we have approval to commercialize NexoBrid for the treatment of burn wounds in the United States and other international markets.

We were founded in 2000 and have achieved a number of significant milestones since then:

- From 2003 to 2007, we conducted preclinical studies of NexoBrid and completed three Phase 2 studies on NexoBrid in the United States, Israel, and internationally.
- In August 2007, we entered into an agreement, which was terminated in 2012, with Teva Pharmaceutical Industries Ltd., or Teva, to commercialize NexoBrid.
- In 2009, we completed our European Phase 3 study of NexoBrid confirming that NexoBrid effectively and safely removes eschar.
- In 2011, we received European Union cGMP certification for our manufacturing facility in Yavne, Israel.
- In December 2012, we received EMA marketing authorization for NexoBrid in the European Union.
- In December 2013, we launched NexoBrid in Europe, beginning in Germany.

To date, we have financed our operations primarily with the net proceeds from private placements of our ordinary shares, convertible loans, participation by others and government grants from the Israeli Office of the Chief Scientist, or OCS.

Since inception, we have incurred significant operating losses. Our net operating losses were \$4.3 million, \$2.7 million and \$7.6 million for the years ended December 31, 2011, 2012 and 2013, respectively. As of December 31, 2013, we had an accumulated deficit of \$47.4 million. We have not generated any revenue to date from sales of NexoBrid.



We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- initiate a Phase 3 pivotal study of NexoBrid in the United States to support a BLA submission to the FDA and initiate a pediatric study in Europe to further extend NexoBrid's approved indication;
- establish and expand our sales, marketing and distribution infrastructure to commercialize NexoBrid and any other products for which we may obtain marketing approval;
- continue our research and preclinical and clinical development of our pipeline products, including EscharEx;
- seek marketing approvals for NexoBrid and any other products in new territories;
- maintain, expand and protect our intellectual property portfolio;
- hire additional operational, clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development, any future commercialization efforts and our transition to a public company;
- acquire or in-license other products and technologies; and
- identify additional product candidates.

In August 2007, we entered into a series of agreements with Teva to collaborate in the development, manufacturing and commercialization of NexoBrid, and in 2010 we entered into additional agreements with Teva, and PolyHeal Ltd., or PolyHeal, to collaborate in the development, manufacturing and commercialization of PolyHeal's wound product, or the PolyHeal Product. We refer to these agreements as the 2007 Teva Agreement and the 2010 PolyHeal Agreement, respectively. In consideration for these agreements, Teva made investments in our ordinary shares and agreed to fund certain of our research and development expenses and manufacturing costs and perform all marketing activities for both NexoBrid, under the 2007 Teva Agreement, and the PolyHeal Product, under the 2010 PolyHeal Agreement.

Effective as of December 31, 2012, our collaboration under both the 2007 Teva Agreement and the 2010 PolyHeal Agreement had terminated. As a result of such terminations, Teva no longer holds any rights to the development, manufacturing or commercialization of either NexoBrid or the PolyHeal Product, no longer funds any of our research and development expenses, and we repurchased all our ordinary shares held by Teva in consideration for future sales-based royalty payments, having an estimated amortized cost of \$16.8 million as of December 31, 2013. The obligation to pay Teva future royalty payments no longer includes amounts from the sale or license of the PolyHeal Product since the license to the PolyHeal Product has expired. Consequently, we have classified our prior operations in connection with PolyHeal as a discontinued operation. For more information see "—Financial Operations Overview—Operating Expenses—Research and development expenses—Participation by others" and "—Financial Operations Overview—Discontinued operation."

#### **Financial Operations Overview**

#### Revenue

To date, we have not generated any revenue from sales of NexoBrid. We expect to generate initial revenue from sales of NexoBrid in the first half of 2014, after launching NexoBrid in December 2013 and following preliminary onsite training and hands-on demonstrations in selected hospitals and burn centers throughout Germany. Our ability to generate revenue will depend on the successful commercialization of NexoBrid.

## **Operating Expenses**

# Research and development expenses

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our pipeline products progress in clinical trials. However, we do not believe that it is possible at this time to accurately project total program-specific expenses to reach commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will affect our clinical development programs and plans.

Since 2011, we cumulatively spent approximately \$14.5 million on research and development of NexoBrid of which \$6.3 million was funded by participation by others and government grants. Our total research and development expenses, net of participations in 2013 were approximately \$3.6 million. Our research and development expenses relate primarily to the development of NexoBrid. We charge all research and development expenses to operations as they are incurred. We expect research and development expenses to increase in absolute terms in the near term.

The successful development of our patented proteolytic enzyme technology used in NexoBrid for additional pipeline products is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of our technology for additional indications. This uncertainty is due to numerous risks and uncertainties associated with developing products, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- preclinical results;
- clinical trial results;
- the terms and timing of regulatory 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 for NexoBrid or any other product candidate that we may develop in the future.

A change in the outcome of any of these variables with respect to the development of other products that we may develop could result in a significant change in the costs and timing associated with their development. For example, if the EMA, FDA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate for the completion of clinical development of our product candidates or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

Research and development expenses consist primarily of costs incurred for our research activities, including:

- employee-related expenses, including salaries, benefits and related expenses, including equity-based compensation expenses;
- expenses incurred under agreements with third parties, including contract research organizations, contract manufacturing organizations and consultants that conduct regulatory activities, clinical trials and preclinical studies;

- expenses incurred to acquire, develop and manufacture clinical trial materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other operating costs;
- costs associated with preclinical activities and regulatory operations;
- costs associated with obtaining and maintaining patents and other intellectual property; and
- depreciation of tangible and intangible fixed assets used to develop our product candidates.

#### Participation by others

Our research and development expenses are net of the following participations by third parties.

Participation by Teva. Starting in 2007, we entered into a number of agreements with Teva related to collaboration in the development, manufacturing and commercialization of solutions for the burn and chronic wound care markets. As of December 31, 2012, all of these agreements terminated.

Under the 2007 Teva Agreement, we granted Teva an exclusive right to market and distribute NexoBrid in specific countries. Pursuant to the 2010 PolyHeal Agreement, PolyHeal granted us an exclusive global license to develop, manufacture and commercialize the PolyHeal Product, and we granted an exclusive sub-license to Teva to commercialize the PolyHeal Product worldwide. In consideration for these agreements, Teva made investments in our ordinary shares and agreed to fund certain of our research and development expenses and manufacturing costs and perform all marketing activities for both NexoBrid, under the 2007 Teva Agreement, and the PolyHeal Product, under the 2010 PolyHeal Agreement. Additionally, we entered into a shareholders' rights agreement with Teva and certain of our existing shareholders, which we refer to as the Teva Shareholders' Rights Agreement, which included our right to repurchase our ordinary shares from Teva.

On November 15, 2012, we informed Teva of the administration of the next generation of the PolyHeal Product in humans, which constituted a milestone under the 2010 PolyHeal Agreement. Upon achievement of this milestone, Teva was to invest an additional \$6.8 million in exchange for our ordinary shares and we were to purchase, for an identical amount, ordinary shares of PolyHeal from its existing shareholders. Teva has indicated that it disputes its obligation to make the milestone investment. We have commenced discussions regarding this matter with Teva, however, as of the date of this prospectus we had not received the milestone investment from Teva and we cannot assure you that Teva will invest this amount. Accordingly, we have not purchased any of the additional shares of PolyHeal from its shareholders, since we believe that Teva's failure to invest suspends our obligation to purchase such shares pursuant to the 2010 PolyHeal Agreement. In December 2012, our collaboration under both the 2007 Teva Agreement and the 2010 PolyHeal Agreement terminated. As a result, Teva no longer holds any rights to independently commercialize either NexoBrid or the PolyHeal Product, and as of January 2013 no longer participated in funding the development of either product. See "Risk Factors—Risks Relating to our Business and Industry—Obligations" under our prior collaborations with Teva Pharmaceutical Industries Ltd.

On September 2, 2013, in accordance with the terms of the Teva Shareholders' Rights Agreement, we repurchased all of our ordinary shares held by Teva, in consideration for an obligation to pay Teva future royalty payments of 20% of our revenues from the sale or license of NexoBrid resulting in royalty payments up to a total amount of \$30.6 million and from the sale or license of the PolyHeal Product resulting in royalty payments up to a total amount of \$10.8 million. The obligation to pay Teva future royalty payments no longer includes amounts from the sale or license of the PolyHeal Product since the license to the PolyHeal Product has expired. We initially account for these future royalty payments at their estimated fair value, calculated using a discounted cash flow model based on sales projections at \$19.2 million as of the repurchase date. The liability was revalued as of December 31, 2013, and the amortized cost was approximately \$16.8. As a result of the revaluation, we recorded a



financial income of \$2.4 million. Additionally, in connection with the revaluation of our option to repurchase our shares from Teva, which was presented as a derivative instrument in our balance sheet, we recorded nonrecurring financial income of approximately \$15.4 million for the year ended December 31, 2012. The total repurchased shares, valued at \$34.6 million, appear in our consolidated statements of changes in equity as treasury shares.

Following our termination of the 2010 PolyHeal Agreement, our collaboration agreement with PolyHeal had expired and we no longer had the rights to the PolyHeal Product. We have classified our prior PolyHeal operations as a discontinued operation. See "-Discontinued operation" for more information.

Participation by the Chief Scientist. We receive grants (subject to repayment through future royalty payments) as part of the NexoBrid research and development programs approved by the OCS. The requirements and restrictions for such grants are found in the R&D Law. Under the R&D Law, royalties of 3% - 3.5% on the revenues derived from sales of products or services developed in whole or in part using these OCS grants are payable to the Israeli government. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest generally equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. The total gross amount of grants actually received by us from the OCS, including accrued LIBOR interest as of December 31, 2013, totaled approximately \$9.9 million and the amortized cost (using the interest method) of the liability as of that date totaled approximately \$6.6 million. As of December 31, 2013, we had not paid any royalties to the OCS.

In addition to paying any royalty due, we must abide by other restrictions associated with receiving such grants under the R&D Law that continue to apply following repayment to the OCS. These restrictions may impair our ability to outsource manufacturing, engage in change of control transactions or otherwise transfer our know-how outside of Israel and may require us to obtain the approval of the OCS for certain actions and transactions and pay additional royalties and other amounts to the OCS. In addition, any change of control and any change of ownership of our ordinary shares that would make a non-Israeli citizen or resident an "interested party," as defined in the R&D Law, requires prior written notice to the OCS. If we fail to comply with the R&D Law, we may be subject to criminal charges.

Research and development grants received from the OCS are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales. The amount of the liability for the loan is first measured at fair value using a discount rate that reflects a market rate of interest that reflects the appropriate degree of risks inherent in our business. The change in the fair value of the liability associated with grants from the Office of the Chief Scientist is reflected as an increase or decrease in our research and development expenses for the relevant quarter.

#### Selling and marketing expenses

Selling and marketing expenses consist primarily of employee-related expenses, including salaries, benefits and related expenses, including equitybased compensation expenses for personnel engaged in marketing, as well as promotion, advertising, market access and sales activities. These expenses also include costs related to the maintenance of our offices in Germany which is focused primarily on marketing NexoBrid. As part of our growth strategy, we intend to increase our dedicated European sales and marketing infrastructure, as well as expand our marketing effort to new markets. We therefore expect selling and marketing expenses to increase in absolute terms and as a percentage of our consolidated revenues.

#### General and administrative expenses

Our general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits and related expenses, including equity-based compensation expenses;
- legal and professional fees for auditors and other consulting expenses not related to research and development activities or to sales and marketing activities;
- cost of offices, communication and office expenses;
- information technology expenses; and
- depreciation of tangible fixed assets related to our general and administrative activities or to sales and marketing activities.

We expect that our general and administrative expenses will increase in the future as our business expands and we incur additional general and administrative costs associated with being a public company in the United States, including compliance under the Sarbanes-Oxley Act of 2002 and rules promulgated by the U.S. Securities and Exchange Commission. These public company-related increases will likely include costs of additional personnel, additional legal fees, accounting and audit fees, directors' liability insurance premiums and costs related to investor relations. In addition, upon the completion of this offering, and subject to certain conditions, we have agreed to pay a bonus of approximately \$0.4 million in the aggregate to certain of our executive officers for their contribution to completing this offering.

#### Financial Income/Financial Expense

Financial income includes interest income, revaluation of financial instruments, revaluation of derivative instruments and exchange rate differences. Financial expense consists primarily of revaluation of liabilities in respect of government grants, revaluation of contingent consideration related to the purchase of treasury shares, revaluation of derivative instruments, exchange rate differences and expenses related to convertible loans. The interest due on government grants received from the OCS is also considered a financial expense, and is recognized beginning on the date we receive the grant until the date on which the grant is expected to be repaid as part of the revaluation to fair value of liabilities in respect of government grants.

In the year ended December 31, 2012, we recorded nonrecurring financial income of \$15.4 million, resulting from the revaluation of our option to repurchase our shares from Teva, which was presented as a derivative instrument in our balance sheet. In the year ended December 31, 2013, we recorded nonrecurring financial income of \$2.4 million, resulting from the revaluation of the contingent consideration for the purchase of treasury shares.

# **Discontinued** Operation

The 2010 PolyHeal Agreement provided that in the event that the collaboration with Teva was terminated, we would have nine months to find a successor to take over the sub-license for commercializing PolyHeal. As no such successor was found, our exclusive global license from PolyHeal expired. Following the expiration of our PolyHeal license, we accounted for our operation related to PolyHeal as a discontinued operation in accordance with IFRS accounting standard 5, "Non-current Assets Held for Sale and Discontinued Operations." Accordingly, the results of operations of the development, manufacturing and sales of PolyHeal, including impairments of inventories and our exclusive global license of the PolyHeal Product are reported separately as a discontinued operation in our statement of operations for the periods presented below, as well as for all historical periods to be presented in future quarterly and annual releases of our results of operations. Additionally, PolyHeal has a right to repurchase all of its ordinary shares held by us.



### Taxes on income

The standard corporate tax rate in Israel for the 2014 tax year and thereafter is 26.5% and was 24%, 25% and 25% for the 2011, 2012 and 2013 tax years, respectively.

We do not generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$52.0 million as of December 31, 2013. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses.

Under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investment Law, and other Israeli legislation, we may be entitled to certain additional tax benefits, including reduced tax rates, accelerated depreciation and amortization rates for tax purposes on certain assets, deduction of public offering expenses in three equal annual installments and amortization of other intangible property rights for tax purposes.

## **Results of Operations**

#### Comparison of the years ended December 31, 2012 and 2013

The following table summarizes our results of operations for the years ended December 31, 2012 and 2013:

	Year o Decemi	
	2012	2013
	(thous	ands)
Operating expenses:		
Research and development, gross	\$ 3,804	\$ 4,513
Participation by OCS and others	2,247	878
Research and development, net of participations	1,557	3,635
Selling and marketing	—	2,259
General and administrative	1,173	1,687
Operating loss	(2,730)	(7,581)
Financial income	15,406	2,401
Financial expense	(691)	(3,321)
Income (loss) from continuing operations, net	11,985	(8,501)
Loss from discontinued operation	(1,045)	(6,850)
Net income (loss)	\$ 10,940	\$ (15,351)

### Research and development expenses

Research and development expenses, gross, increased 19% from \$3.8 million in the year ended December 31, 2012 to \$4.5 million in the year ended December 31, 2013. The expenses primarily related to development of NexoBrid and the increase resulted primarily from employee-related expenses. In the year ended December 31, 2012 we received \$2.2 million in participation by others from Teva for research and development expenses related to NexoBrid. As a result of the termination of our agreements with Teva on December 31, 2012, during the year ended December 31, 2013, we bore all expenses related to the research and development of NexoBrid and did not receive any participation from Teva. Such expenses primarily included salary and related expenses for research and development employees totaling \$2.1 million and subcontracting costs related to non-clinical development activity of \$1.4 million for the year ended December 31, 2013. Salary and related expenses

increased \$0.7 million in the year ended December 31, 2013 due to an increased headcount of employees focused on research and development. Subcontracting costs related to non-clinical development activity decreased by \$0.3 million in the year ended December 31, 2013 due to completion of our Phase 3b clinical trial for NexoBrid.

#### Selling and marketing expenses

Selling and marketing expenses were zero in the year ended December 31, 2012 compared to \$2.3 million in the year ended December 31, 2013. The increase was primarily due to the ramp up of selling and marketing activities for NexoBrid as part of the preparation for NexoBrid's launch in Europe in December 2013. The increase in selling and marketing expenses included an increase of \$0.9 million in salary and related expenses, primarily due to increased headcount from zero to eight employees and an increase of \$1.2 million related to increased promotional efforts related to pre-launch activities for NexoBrid.

# General and administrative expenses

General and administrative expenses increased from \$1.2 million in the year ended December 31, 2012 to \$1.7 million in the year ended December 31, 2013. The increase in general and administrative expenses primarily included an increase of \$0.2 million in professional fees and an increase of \$0.1 million in salary and related expenses.

# Financial income

Financial income decreased from \$15.4 million in the year ended December 31, 2012 to \$2.4 million in the year ended December 31, 2013. For the year ended December 31, 2012, financial income included \$15.4 million related to the revaluation to fair value of our option to repurchase our ordinary shares from Teva in connection with the termination of our agreements with Teva. For the year ended December 31, 2013, financial income included \$2.4 million related to the revaluation of the contingent consideration for the purchase of treasury shares from Teva.

#### Financial expense

Financial expense increased from \$0.7 million in the year ended December 31, 2012 to \$3.3 million in the year ended December 31, 2013. The increase was primarily due to a financial expense of \$0.8 million related to the revaluation of the derivative liability related to the warrants issued to our shareholders, as well as \$1.7 million in interest payments on our convertible loans, during the year ended December 31, 2013.

# Comparison of years ended December 31, 2011 and 2012

The following table summarizes our results of operations for the years ended December 31, 2011 and 2012, in dollars:

	Year ended December 31,
	2011 2012
	(thousands)
Operating expenses:	
Research and development, gross	\$ 6,149 \$ 3,804
Participation by OCS and others	3,128 2,24
Research and development, net of participations	3,021 1,55
Selling and marketing	
General and administrative	1,266 1,177
Operating loss	(4,287) (2,73)
Financial income	96 15,40
Financial expense	(628) (69
Income (loss) from continuing operations, net	(4,819) 11,98
Loss from discontinued operation	(1,350) (1,04
Net income (loss)	\$ (6,169) \$ 10,94

# Research and development expenses

Research and development expenses, gross, decreased 38% from \$6.1 million in the year ended December 31, 2011 to \$3.8 million in the year ended December 31, 2012. Our research and development expenses are highly dependent on the development phases of our projects and therefore fluctuate significantly from year to year. The decrease was primarily the result of lower clinical trial costs for the development of NexoBrid, which decreased from \$3.5 million in the year ended December 31, 2011 to \$1.1 million in the year ended December 31, 2012 as we completed our Phase 3b study of NexoBrid and additional development and regulatory activities relating to the review of our EMA marketing file.

## Selling and marketing expenses

For both the years ended December 31, 2011 and 2012, we had no selling and marketing expenses for NexoBrid. During this time Teva was responsible for all marketing activities relating to NexoBrid.

#### General and administrative expenses

General and administrative expenses remained stable at \$1.3 million in the year ended December 31, 2011 and \$1.2 million in the year ended December 31, 2012.

## Financial income

Financial income increased from \$0.1 million in the year ended December 31, 2011 to \$15.4 million in the year ended December 31, 2012. The increase was primarily due to \$15.4 million in financial income related to the revaluation to fair value of our option to repurchase our ordinary shares from Teva in connection with the termination of our agreements with Teva.

### Financial expense

Financial expense remained stable at \$0.6 million in the year ended December 31, 2011 and \$0.7 million in the year ended December 31, 2012.

# Liquidity and Capital Resources

To date, we have financed our operations through private placements of equity securities, loans, convertible loans, participation by others and government grants.

We believe that based on our current business plan, our existing cash, cash equivalents, short-term investment balances and the net proceeds from this offering will be sufficient to meet our currently anticipated cash requirements through the next 12 months.

#### Cash flows

The following table summarizes our consolidated statement of cash flows for the years ended December 31, 2011, 2012 and 2013.

	Year e	Year ended December 31,		
	2011	2012	2013	
	(in thousands)			
Net cash provided by (used in):				
Continuing operating activities	\$ (3,557)	\$ (4,199)	\$ (8,075)	
Continuing investing activities	3,377	(407)	(2,855)	
Continuing financing activities	7,268	1,768	19,241	
Discontinued operation	(6,153)	(529)	(1,665)	

# Net cash provided by (used in) continuing operating activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net income for non-cash items include depreciation and amortization and equity-based compensation.

Net cash used in continuing operating activities was \$4.2 million in the year ended December 31, 2012 compared to \$8.1 million in the year ended December 31, 2013. The increase was attributable primarily to the ramp up of our sales and marketing efforts to commercialize NexoBrid in Europe and the decrease in participation by Teva following the termination of our collaborations with Teva.

Net cash used in continuing operating activities was \$3.6 million for the year ended December 31, 2011 compared to \$4.2 million for the year ended December 31, 2012. The increase was attributable primarily to lower reimbursement from Teva of our research and development expenses.

### Net cash provided by (used in) continuing investing activities

The use of cash in continuing investing activities has historically been primarily related to the purchases of property and equipment. Net cash used in investing activities was \$0.4 million during the year ended December 31, 2012 compared to \$2.9 million during the year ended December 31, 2013. The increase was attributable primarily to investments in short-term bank deposits.

Net cash provided by continuing investing activities was \$3.4 million during the year ended December 31, 2011 compared to net cash used in investing activities of \$0.4 million during the year ended December 31, 2012. Net cash provided by investing activities during the year ended December 31, 2011 included proceeds from short term bank deposits of approximately \$4.2 million.



#### Net cash provided by (used in) continuing financing activities

Net cash provided by continuing financing activities was \$1.8 million during the year ended December 31, 2012 compared to \$19.2 million during the year ended December 31, 2013. The increase was attributable primarily to receipt of proceeds from convertible and non-convertible loans and the issuance of ordinary shares and warrants to certain of our existing shareholders during the year ended December 31, 2013. See "—Cash and funding sources."

Net cash provided by continuing financing activities was \$7.3 million during the year ended December 31, 2011 compared to \$1.8 million during the year ended December 31, 2012. Net cash provided by financing activities during the year ended December 31, 2011 included proceeds from the issuance of ordinary shares to Teva under the 2010 PolyHeal Agreement. See "—Cash and funding sources."

### Net cash provided by (used in) discontinued operation

Net cash used in our discontinued operation was \$0.5 million in the year ended December 31, 2012 compared to \$1.7 million in the year ended December 31, 2013. The increase in cash used in our discontinued operation was attributable primarily to increased operating expenses relating to the development and commercialization of the PolyHeal Product after Teva discontinued its participation under the 2010 PolyHeal Agreement and prior to the expiration of our license with PolyHeal.

Net cash used in our discontinued operation was \$6.2 million in the year ended December 31, 2011 compared to net cash used in our discontinued operation of \$0.5 million in the year ended December 31, 2012. Net cash used by our discontinued operation during the year ended December 31, 2011 included the purchase of PolyHeal's exclusive global license for \$6.75 million.

# Cash and funding sources

The table below summarizes our sources of financing for the years ended December 31, 2011, 2012 and 2013.

	O Sh	suance of Ordinary ares and Varrants	Net Loans from hareholders		/ern men t Grants	 Total
			(in thousa	inds)		
Year ended December 31, 2013	\$	16,079	\$ 3,015	\$	276	\$ 19,370
Year ended December 31, 2012		_	1,555		213	1,768
Year ended December 31, 2011		6,727	—		541	7,268

Our sources of financing in the year ended December 31, 2013 totaled \$19.4 million and consisted of loans, convertible bridge loans, issuance of ordinary shares and warrants and government grants. For the year ended December 31, 2013, issuance of ordinary shares included \$15.8 million in net proceeds from the issuance and sale of ordinary shares to certain existing investors pursuant to a share purchase agreement entered into in June 2013 and closed on August 19, 2013, and also includes proceeds from the exercise of options, totaling \$0.3 million. Loans from shareholders for the year ended December 31, 2013 included the proceeds from convertible loans totaling \$3.0 million which were converted into our ordinary shares and warrants on August 19, 2013. During the year ended December 31, 2013, loans from shareholders also included proceeds from, and repayment of loans in the amount of \$0.9 million.

Our sources of financing in the year ended December 31, 2012 totaled \$1.8 million and consisted primarily of loans from certain of our existing shareholders totaling \$1.6 million and government grants totaling \$0.2 million.

Our sources of financing in the year ended December 31, 2011 totaled \$7.3 million and consisted primarily of issuance of ordinary shares and warrants and government grants. For the year ended December 31, 2011, issuance of ordinary shares included \$6.7 million in net proceeds from the issuance and sale of ordinary shares to Teva in connection with the 2010 PolyHeal Agreement. For the year ended December 31, 2011, government grants totaled \$0.5 million.

We have no ongoing material financial commitments (such as lines of credit), other than leases, that we expect will affect our liquidity over the next five years.

# Funding requirements

We believe that our existing cash and cash equivalents, together with the net proceeds of this offering will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. 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 present and future funding requirements will depend on many factors, including, among other things:

- the progress, timing and completion of preclinical testing and clinical trials for NexoBrid or any future pipeline product;
- selling and marketing activities undertaken in connection with the anticipated commercialization of NexoBrid and any other product candidates and costs involved in the development of an effective sales and marketing organization;
- the time and costs involved in obtaining regulatory approval for NexoBrid and our pipeline products and any delays we may encounter as a
  result of evolving regulatory requirements or adverse results with respect to any of these products;
- the number of potential new products we identify and decide to develop;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of NexoBrid and any other pipeline product.

For more information as to the risks associated with our future funding needs, see "Risk factors—We may need substantial additional capital in the future which may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our pipeline products or intellectual property. If additional capital is not available, we may have to delay, reduce or cease operations."

#### Contractual obligations and commitments

Our significant contractual obligations as of December 31, 2013 are summarized in the following table.

			Payr	nents	due by perio	d	
	Le	ess than 1 year	tween 1 I 2 years	an	etween 2 d 5 years lousands)	More than 5 years	Total
Operating lease obligations(1)	\$	655	\$ 651	\$	1,104	—	\$ 2,410

(1) Operating lease obligations consist of payments pursuant to lease agreements for office and laboratory facilities, as well as lease agreements for 15 vehicles, which generally run for a period of three years.

The obligation amounts in the above table do not include royalties that we are obligated to pay to the OCS and others based upon future sales of our products. As of December 31, 2013, the maximum royalties payable to the OCS were approximately \$9.9 million, contingent upon sales of NexoBrid. Other royalties are payable, contingent on sales of NexoBrid and our pipeline products, including: a) approximately \$30.6 million in future royalty payments to Teva contingent on sales of NexoBrid related to the repurchase of our ordinary shares from Teva, as of December 31, 2013, and b) royalty and milestone payments payable to Mark Klein upon reaching certain aggregate sales of NexoBrid and our pipeline products, including a one-time lump-sum of \$1.5 million upon reaching aggregate revenues of \$100 million from the sales of NexoBrid and our pipeline products. See Note 14 to our consolidated financial statements included elsewhere in this prospectus. The obligation to pay Teva future royalty payments no longer includes amounts from the sale or license of the PolyHeal Product since the license to the PolyHeal Product has expired.

#### **Off-balance Sheet Arrangements**

As of the date of this prospectus, we do not have any, and during the periods presented we did not have any, off-balance sheet arrangements.

#### Quantitative and Qualitative Disclosure about Market Risk

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our consolidated financial position, results of operations or cash flows.

#### Foreign currency exchange risk

The U.S. dollar is our functional and reporting currency. A portion of our expenses are denominated in shekels, accounting for 24%, 27% and 42% of our expenses in the years ended December 31, 2011, 2012 and 2013, respectively. We also have expenses, although to a much lesser extent, in other non-dollar currencies, in particular the Euro, and for the next few years, we expect that the substantial majority of our revenue, if any, will be denominated in Euros from the sale of NexoBrid in the European Union. This exposes us to risk, associated with exchange rate fluctuations vis-à-vis the U.S. dollar. See "Risk Factors— Exchange rate fluctuations between the U.S. dollar and the Israeli shekel, the Euro and other non-U.S. currencies may negatively affect our earnings." Furthermore, we anticipate that a portion of our expenses, principally of salaries and related personnel expenses, will continue to be denominated in shekels.

To the extent the U.S. dollar weakens against the shekel, we will experience a negative impact on our profit margins. A devaluation of the shekel in relation to the U.S. dollar has the effect of reducing



the U.S. dollar amount of our expenses or payables that are payable in shekels, unless those expenses or payables are linked to the U.S. dollar. Conversely, any increase in the value of the shekel in relation to the U.S. dollar has the effect of increasing the U.S. dollar value of our unlinked shekel expenses, which would have a negative impact on our profit margins. In 2013, the value of the shekel appreciated in relation to the U.S. dollar by 7.0%, the effect of which was compounded by inflation in Israel, at a rate of 1.9% rate. In 2012, the value of the shekel appreciated in relation to the U.S. dollar by 2.3%, the effect of which was compounded by inflation in Israel, at the rate of 1.6%. In 2011, the value of the shekel declined in relation to the U.S. dollar by 7.7%, which was partly offset by a 2.2% rate of inflation in Israel.

Because exchange rates between the U.S. dollar and the shekel (as well as between the U.S. dollar and other currencies) fluctuate continuously, such fluctuations have an impact on our results and period-to-period comparisons of our results. The effects of foreign currency re-measurements are reported in our consolidated financial statements of operations.

The following table presents information about the changes in the exchange rates of the shekel against the U.S. dollar and changes in the exchange rates of the Euro against the U.S. dollar:

	Change in Average	Exchange Rate
Period	Shekel against the U.S. dollar (%)	Euro against the U.S. dollar (%)
Period 2011	(7.7)	(3.2)
2012	2.3	2.0
2013	7.0	4.5

As we begin marketing and sales of NexoBrid in Europe and clinical trials of NexoBrid in the United States, we will continue to monitor exposure to currency fluctuations. We do not currently engage in currency hedging activities in order to reduce this currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency 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 inflation in Israel exceeds the devaluation of the shekel against the U.S. dollar or if the timing of such devaluation lags behind inflation in Israel.

# **Application of Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the accounting policies discussed below are critical to our financial results and to the understanding of our past and future performance, as these policies relate to the more significant areas involving management's estimates and assumptions. We consider an accounting estimate to be critical if: (a) it requires us to make assumptions because information was not available at the time or it included matters that were highly

uncertain at the time we were making our estimate; and (b) changes in the estimate could have a material impact on our financial condition or results of operations.

# **Research and development expenses**

Research expenses are recognized as expenses when incurred. Costs incurred on development projects are recognized as intangible assets as of the date as of which it can be established that it is probable that future economic benefits attributable to the asset will flow to us considering its commercial feasibility. This is generally the case when regulatory approval for commercialization is achieved and costs can be measured reliably. Given the current stage of the development of our products, no development expenditures have yet been capitalized. Intellectual property-related costs for patents are part of the expenditure for the research and development projects. Therefore, registration costs for patents are expensed when incurred as long as the research and development project concerned does not meet the criteria for capitalization.

# Equity-based compensation

We account for our equity-based compensation for employees in accordance with the provisions of IFRS 2 "Share-based Payment," which requires us to measure the cost of equity-based compensation based on the fair value of the award on the grant date.

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value of our equity-based awards. The resulting cost of an equity incentive award is recognized as an expense over the requisite service period of the award, which is usually the vesting period. We recognize compensation expense over the vesting period using the accelerated method pursuant to which each vesting tranche is treated as a separate amortization period from grant date to vest date, and classify these amounts in the consolidated financial statements based on the department to which the related employee reports.

### **Option Valuations**

The determination of the grant date fair value of options using an option pricing model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, risk-free interest rates and expected dividends, which are estimated as follows:

- *Volatility*. The expected share price volatility was based on the historical equity volatility of the ordinary shares of comparable companies that are publicly traded.
- *Expected Term.* The expected term of options granted represents the period of time that options granted are expected to be outstanding. Since adequate historical experience is not available to provide a reasonable estimate, the expected term is determined based on the midpoint between the available exercise dates (the end of the vesting periods) and the last available exercise date (the contracted expiry date).
- *Risk-Free Rate.* The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with a term equivalent to the contractual life of the options.
- *Expected Dividend Yield*. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

If any of the assumptions used in the Black-Scholes model change significantly, equity-based compensation for future awards may differ materially compared with the awards granted previously.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted to employees on the dates indicated. No option grants were made in the year ended December 31, 2012.

	January 6, 2013	December 24, 2013
Expected volatility (%)	85	84
Expected term (years)	5.50-7.00	5.50-7.00
Risk-free rate (%)	2.09	1.03-1.73
Expected dividend yield (%)	0	0

The following table presents the grant dates, number of underlying shares and related exercise prices of awards granted to employees and non-employees since January 1, 2013 as well as the estimated fair value of the underlying ordinary shares on the grant date.

	Number of shares		Estimated fair value		
Date of grant	subject to awards granted		xercise price per share	р	er ordinary share at grant date
January 6, 2013	16,500	\$	52.28	\$	58.08
December 24, 2013	238,000	\$	49.00	\$	54.52

Based on the assumed initial public offering price of \$ per share, the midpoint of the range set forth on the cover page of this prospectus, the intrinsic value of the awards outstanding as of December 31, 2013 was \$ million, of which \$ million related to vested options and \$ million related to unvested options.

## Valuation of our ordinary shares

Due to the absence of an active market for our ordinary shares, the fair value of our ordinary shares for purposes of determining the exercise price for award grants was determined in good faith by our management and approved by our board of directors. In connection with preparing our financial statements, our management considered the fair value of our ordinary shares based on a number of objective and subjective factors consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, referred to as the AICPA Practice Aid.

We have set out below the application of the above methodologies to the valuation of our ordinary shares with respect to the grants on January 6, 2013 and December 24, 2013.

January 6, 2013. We determined that the fair value of our ordinary shares was \$58.08 per share as of January 6, 2013. This determination was based on our agreement with Teva, dated November 8, 2010, pursuant to which Teva had an option to purchase our ordinary shares at a price per share of \$58.08 upon receipt of EMA marketing approval for NexoBrid, which we achieved on December 18, 2012. We believe that this determination of fair value is generally supported by the third-party valuation prepared in February 2013 with respect to the value of our ordinary shares as of December 31, 2013. For the purpose of that valuation, we used the discounted cash flow, or DCF, method to determine our enterprise value. Using this method, our projected after-tax cash flows available to return to holders of invested capital are discounted back to present value, using a discount rate. The discount rate, known as the weighted cost of capital, accounts for the time value of money and the appropriate degree of risks inherent in the business. We applied a discount rate of 15.77%. Our projected after-tax cash flows were based on the weighted average of two scenarios: in the first scenario we received FDA approval for NexoBrid (80% probability) and in the second scenario we did not receive FDA approval (20%

probability). The resulting enterprise value was divided by the number of outstanding shares and resulted in a price per share of \$45.30. We used the \$58.08 per share amount payable by Teva since it reflected the value attributed to our ordinary shares by a well-known and experienced biopharmaceutical market participant on an arms' length basis.

December 24, 2013. We determined that the fair value of our ordinary shares was \$54.52 per share as of December 24, 2013. This determination was based on a third-party valuation prepared in January 2014 with respect to the value of our ordinary shares as of December 31, 2013. Our price per share was based on the weighted average of two scenarios: in the first scenario, we assumed completion of the public offering and used underwriter value indications for equity value (60% probability); and in the second, we implied a going concern scenario being a private company (40% probability). Our underwriter's enterprise value indication was divided by the number of outstanding shares and resulted in a price per share of \$56.20. For the purpose of the going concern scenario valuation, we used the DCF method to determine our equity value. Using this method, our projected after-tax cash flows available to return to holders of invested capital are discounted back to present value, using a discount rate. The discount rate, known as the weighted cost of capital, accounts for the time value of money and the appropriate degree of risks inherent in the business. We applied a discount rate of 17%. Our projected after-tax cash flows were based on the weighted average of two scenarios: in the first scenario, we received FDA approval for NexoBrid (80% probability); and in the second, we did not receive FDA approval (20% probability). The resulting enterprise value was divided by the number of outstanding shares and resulted in a price per share of s52.00. Applying the 60% and 40% probabilities described above on a weighted basis resulted in a fair value of \$54.52 per share.

# Government grants from the Office of the Chief Scientist

Research and development grants received from the OCS are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales. The amount of the liability for the loan is first measured at fair value using a discount rate that reflects a market rate of interest that reflects the appropriate degree of risks inherent in our business. We used a discount rate of 12% based in part on our cost of capital determined by an independent valuation analysis conducted at the time of our initial recognition of OCS grants as a liability on our balance sheets. The difference between the amount of the grant received and the fair value of the liability is accounted for as a government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability. If no economic benefits are expected from the research activity, the grant receipts are recognized as a reduction of the related research and development expenses. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37, "Provisions, Contingent Liabilities and Contingent Assets."

At the end of each reporting period, we evaluate whether there is reasonable assurance that the liability recognized will be repaid based on our best estimate of future sales and, if not, the appropriate amount of the liability is derecognized against a corresponding reduction in research and development expenses.

#### Fair value of financial instruments

The right to repurchase our shares from Teva and the related contingent consideration paid upon its exercise. The right to repurchase our shares from Teva, which was presented on our balance sheets as of December 31, 2012 as a derivative instrument, was measured at fair value. The fair value of this derivative instrument as of that date, which was estimated to be approximately \$15.4 million, was determined using an option pricing model similar to those used for our equity awards to employees. On September 2, 2013, we exercised our rights to repurchase all our shares held by Teva in consideration for an obligation to pay Teva future royalty payments of 20% of our revenues from the sale or license

of NexoBrid resulting in royalty payments up to a total amount of \$30.6 million and from the sale or license of the PolyHeal Products resulting in royalty payments up to a total amount of \$10.8 million. We account for this obligation as a liability on our balance sheet in an amount equal to the fair value of the future royalty payments. In order to determine the fair value, we estimated the amount and timing of the future payments to Teva based on our projected results of operations. The obligation to pay Teva future royalty payments no longer includes amounts from the sale or license of the PolyHeal Product since the license to the PolyHeal Product has expired. For this purpose, we used the same projections as we had used in connection with the valuation of our ordinary shares as of September 30, 2013. Similar to that valuation, we used the weighted average valuation of two scenarios to determine the projected amount and timing of royalty payments: in the first scenario we received FDA approval for NexoBrid (80% probability) and in the scond scenario we did not receive FDA approval (20% probability). The resulting liability as of the exercise date was estimated at approximately \$19.2 million. The contingent consideration was revalued as of December 31, 2013 to be approximately \$16.8 million and we recorded a financial income of \$2.4 million.

#### Impairment of non-financial assets

The intangible assets are reviewed for impairment at each reporting date until they begin generating net cash inflows and subsequently whenever there is an indication that the asset may be impaired. We evaluate the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs and is calculated based on the projected cash flows that will be generated by the cash generating unit.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, may not increase the value above the lower of (i) the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years, and (ii) its recoverable amount.

# **Recent Accounting Pronouncements**

There are no IFRS standards as issued by the IASB or interpretations issued by the IFRS interpretations committee (e.g., IFRS 10, 11, 12, 13 and IAS 19R) that are effective for the first time for the financial year beginning on or after January 1, 2013 that would be expected to have a material impact on our financial position.

## **JOBS Act Exemptions**

The JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

# BUSINESS

# **Our Company**

We are a fully integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel products to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds and connective tissue disorders. Our innovative biopharmaceutical product, NexoBrid, received marketing authorization from the European Medicines Agency, or the EMA, in December 2012 for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns, also referred to as severe burns. NexoBrid, which is based on our patented proteolytic enzyme technology, represents a new paradigm in burn care management, and our clinical trials have demonstrated, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier upon patient admission, without harming viable tissues. We launched NexoBrid in December 2013 in the European Union through our wholly-owned German subsidiary, targeting a focused audience of burn specialists treating patients in burn centers and hospital burn units. We also plan to initiate a Phase 3 pivotal study in the United States in the first half of 2014 to support a Biologics License Application, or BLA, submission to the United States Food and Drug Administration, or FDA. We manufacture NexoBrid in our state-of-the-art, EMA-certified, cGMP-compliant, sterile pharmaceutical products manufacturing facility at our headquarters in Yavne, Israel.

NexoBrid is an easy to use, topically-applied product that removes eschar in four hours without harming the surrounding healthy tissues. The removal of eschar is a procedure also known as debridement. Debridement is a critical first step in the successful healing of severe burns and chronic and other hard-to-heal wounds. Under existing standard of care, or SOC, burn eschar may be removed either by employing certain existing topical agents that have been found to be minimally effective or that take a significantly longer period of time to work, or by resorting to non-selective surgery, which is traumatic and may result in loss of blood and viable tissue. NexoBrid's rapid and selective debridement alleviates the known risks associated with eschar, such as infection, eventual sepsis, wound deterioration and consequential scarring, and it allows physicians to reach an informed decision on further treatment at an earlier stage by direct visual assessment of the actual burn depth. Furthermore, NexoBrid minimizes the burden associated with invasive surgical procedures, reduces the need for skin grafting and sacrifice of healthy tissue from donor sites on a patient's body and generally results in a more favorable overall long-term patient outcome. NexoBrid has been investigated in more than 550 patients across 15 countries and four continents in six Phase 2 and Phase 3 clinical studies. There have been over 100 presentations of NexoBrid in international scientific conferences, and in addition, NexoBrid has been presented in 11 peer-reviewed papers as well as in a chapter in Total Burn Care, a leading medical textbook, resulting in support from more than 100 burn specialists and key opinion leaders, or KOLs. Awareness of NexoBrid continues to grow through our marketing efforts and continued multinational clinical development.

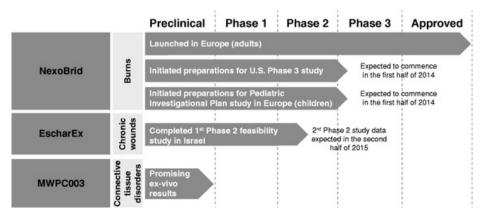
The market opportunities for our patented proteolytic enzyme technology include both eschar removal of severe burns, for which NexoBrid received marketing authorization in the European Union and designation as an orphan drug in both the European Union and the United States, and debridement of chronic and other hard-to-heal wounds for which EscharEx, our second product candidate, is being investigated in clinical trials. Approximately 100,000 patients with severe burns are hospitalized every year in the United States, and we believe there is a similar number of such patients in Europe. Severe burn patients are predominantly treated by specialists in approximately 250 burn centers and at burn units of large hospitals in the European G5 countries, which include France, Germany, Italy, Spain and the United Kingdom, and the United States, which we intend to cover with a focused and targeted sales force. Our lead product candidate, EscharEx, is being studied for the debridement of chronic and other hard-to-heal wounds. This indication represents a significant opportunity, having a total addressable patient base of more than 14 million patients in the United

States and Europe alone, suffering from disorders such as diabetic foot ulcers, or DFUs, venous leg ulcers, or VLUs, pressure ulcers and surgical/traumatic hard-to-heal wounds.

We launched NexoBrid for severe burns in Europe in December 2013, beginning with Germany, and intend to initiate an FDA, Phase 3 pivotal study in the United States in the first half of 2014 to support a BLA in order to enter the U.S. market, as well as a pediatric study in Europe to broaden the approved indication. We plan to target other international markets, such as Latin America and certain Asian countries, by leveraging our approved registration file for additional regional marketing authorizations. In addition, we are using our patented proteolytic enzyme technology, which underlies NexoBrid, and our wealth of data and experience for use in other indications such as debridement of chronic and other hard-to-heal wounds. We believe that such indication represents a significant additional market opportunity with a lower development risk. A Phase 2 proof-of-concept study demonstrated the efficacy of our patented proteolytic enzyme technology in various chronic and other hard-to-heal wounds. We plan to initiate a second Phase 2 study by the first half of 2014. Additionally, our technology has demonstrated promising results in the treatment of connective tissue disorders, such as Dupuytren's and Peyronie's diseases, in ex-vivo model studies, which are laboratory studies conducted on tissues or cells extracted from a living organism, which in our case were conducted on diseased contracted cords that had been surgically removed from patients with a Depuytren contracture.

### Summary of our Products and Development Programs

The following table sets forth our product pipeline for the development of NexoBrid for burn wounds and additional product candidates for chronic and other hard-to-heal wounds and connective tissue disorders based on our proprietary technology.



### **Our Market Opportunity**

### **Burn Wounds**

Severe burns require specialized care in hospitals or burn centers. Approximately 100,000 patients with severe burns are hospitalized every year in the United States, and we believe there is a similar number of such patients in Europe. The prevalence of patients with severe burns is even higher in emerging economies. For example, according to an IMS study, approximately 400,000 patients are hospitalized every year with burns in India. We believe these patients can benefit from NexoBrid's effective and selective, non-surgical eschar removal.

Burns are life threatening and debilitating traumatic injuries causing considerable morbidity and mortality. A burn may result from thermal, electrical or chemical means that destroy the skin to varying

depths. According to Critical Care, an international clinical medical journal, burns are also among the most expensive traumatic injuries because of long and costly hospitalization, rehabilitation and wound and scar treatment.

Most burn injuries involve part or the entire thickness of the skin and in some cases, the deeper subcutaneous fat tissue or underlying structures. The severity of the burn depends on three main factors:

- (i) The extent of the surface the burn occupies is usually referred to as percent of total body surface area, or TBSA. A burn on an adult's entire palm would generally amount to 1% TBSA, and the average hospitalized patient has a burn covering approximately 10% TBSA. Burns covering more than 15-20% TBSA usually require hospitalization and may result in dehydration, shock and increased risk of mortality.
- (ii) The depth of the burn, referred to in terms of "degree" is generally classified into four categories:
  - a. Superficial or first degree burns. Such burns do not penetrate the basal membrane and usually heal naturally.
  - b. Dermal/partial thickness or second degree burns. Such burns are characterized by varying amounts of damaged dermis and can be further subdivided into superficial and deep partial-thickness burns. Superficial partial-thickness burns may heal spontaneously after removal of the covering thin eschar. Conversely, deep partial-thickness burns are often difficult for physicians to accurately diagnose before eschar removal and may progress and transform into full-thickness burns if not debrided in a timely manner, depending on the magnitude of latent tissue death of the surrounding skin.
  - c. *Full thickness or third degree burns*. Such burns are characterized by death of the entire dermal tissue down to the subcutaneous fat and must be debrided and treated by autografting, which is the process of harvesting skin from healthy donor sites on a patient's body and transplanting it on the post-debridement, clean wound bed.
  - d. *Fourth degree burns.* Such burns, which are rare, extend beyond the subcutaneous fat tissue into the underlying structures, such as muscle or bone, and also require debridement and further substantial treatment.
- (iii) Other factors, which include the age of the victim, the body part where the burn occurred and any co-morbidities of the patient. For example, children or elderly burn victims, or victims with burns to the extremities, joints or head/neck area or with co-morbidities such as smoke inhalation, diabetes or obesity, may require hospitalization, regardless of the TBSA or degree of the burn.

When patients are hospitalized for a severe burn, the first step in the treatment after patient stabilization and resuscitation is usually eschar removal. The eschar is the burned tissue in the wound and is deprived of blood and isolated from all natural systemic defense mechanisms. Debridement is an essential first step in the treatment of patients with severe burns, allowing for:

- the prevention of local infection, sepsis (a systemic inflammatory response caused by severe infection) and additional damage to surrounding viable tissue; and
- the initiation of the body's healing process and scar prevention.

In addition to minimizing the possibility of additional complications, once the eschar is removed, a physician may properly diagnose the true extent of the trauma by a direct visual assessment of the clean wound bed. An informed treatment strategy can be decided upon only if the depth of the burn and extent of the tissue damage is known. Diagnosis of burn depth is difficult, especially because the

burn commonly changes its appearance during the first days after injury due to burn progression. Burns that are initially difficult to classify due to the presence of eschar are referred to as "indeterminate" burns. This ambiguity can delay the assessment of the burn depth and formulation of proper treatment. Unless the burns are life-threatening, definitive treatment is postponed for several days post injury until diagnosis is clearer, when burn progression by death of the surrounding and underlying tissue has already occurred and ended. During this delay, local and systemic effects of post-burn inflammation and bacterial contamination can occur. Therefore, earlier, selective eschar removal is essential to prevent eschar-related complications and to allow the physician to reach an informed decision on further treatment.

Currently, there are two main treatment modalities for debridement:

- Surgical Debridement
  - Surgical debridement predominantly includes tangential excision, a procedure in which a surgeon amputates the entire dead tissue
    mass, layer after layer, down to healthy, viable tissue. The excision is extended into healthy intact tissue to make sure that no trace of
    the eschar remains, resulting in up to an estimated 30-50% of healthy tissue being excised during this procedure. Other methods
    include dermabrasion, in which a mechanically powered, hand-held rotating abrading cylinder is used to slowly scrape off tissue, and
    hydro surgery, in which a high-pressure flow of water abrades the tissue. These alternative methods have attempted to limit the trauma
    associated with tangential excision, but entail spray of contaminated eschar or take a significantly longer time to complete than
    tangential excision.
  - The benefits of surgical eschar removal are that it is usually fast and effective. Disadvantages include the significant trauma of the procedure, associated blood loss, risk of surgery in delicate areas of the body such as hands, added costs, and, most importantly, the loss of viable tissue that necessitates additional surgical procedures for harvesting skin from healthy donor sites and autografting.
  - Due to the disadvantages of surgery in extensive burns some surgeons limit their debriding surgery to only a part of the affected area (15-30% TBSA in most centers) in a single session, thus delaying full debridement by days. After several days, complications related to eschar contamination begin and some of the benefits of the earlier debridement may not be realized. On the other hand, when excising burns immediately, all suspected necrotic tissue will be excised inevitably resulting in over-excision especially in "indeterminate" burns, as after surgical excision, the remaining skin often no longer has any spontaneous healing potential and will heal only by autografting.
- Non-surgical Debridement
  - Non-surgical debridement includes many different treatment options that do not require direct surgical removal of the skin to remove eschar. With non-surgical debridement, the eschar is naturally, but slowly, removed by contaminant microorganisms, tissue autolysis, or self-decomposition, and the inflammatory process that may lead to serious local and systemic complications. In seeking to facilitate such natural processes or mitigate the risks associated with the slow infectious-inflammatory processes, topical medication, antimicrobial agents, enzymes and biological/chemical applications are applied onto the eschar.
  - Benefits of this approach are that it is non-surgical, reduces trauma to the patient and is easier to apply. Disadvantages include numerous dressing changes and mechanical scraping with limited debridement efficacy. This prolongs the eschar removal process, which may lead to death of the tissue surrounding the initial burn wound, causing partial-thickness wounds

to transform into full-thickness wounds and forming granulation tissue that may develop into heavy scars.

As demonstrated in our clinical trials, NexoBrid combines the advantages of surgical and non-surgical debridement modalities by providing fast and effective eschar removal while not harming viable tissues. This allows for earlier direct visual assessment of the burn wound in order to formulate proper treatment.

## Chronic and Other Hard-to-Heal Wounds

The chronic and other hard-to-heal wound market consists of a broader addressable population of more than 14 million patients in Europe and the United States alone suffering from some form of chronic wound such as DFUs, VLUs and pressure ulcers and additional patients suffering from surgical/traumatic hard-to-heal wounds. Chronic and other hard-to-heal wounds represent a \$25 billion burden to the United States healthcare system alone. Chronic and hard-to-heal wounds are caused by an impairment in the biochemical and cellular healing processes due to local or systemic conditions and generally can take several weeks to heal, if not longer. Such wounds can lead to significant morbidity, including pain, infection, impaired mobility, hospitalization, reduced productivity, amputation and mortality. In each of the various wound types, the presence of the eschar is a frequent cause for chronification of wounds and the removal of eschar is the key step to commence healing. Eschar needs to be removed to prevent further deterioration of the wound that may result in additional negative patient outcomes. If not effectively treated, these wounds can lead to potentially severe complications including further infection, osteomyelitis, fasciatis, amputation and increased mortality. Most advanced wound care therapies, including negative pressure wound therapy, such as KCI's V.A.C. Therapy, and skin substitutes like Organogenesis' Apligraf and Shire's Dermagraft, are complementary to our lead product candidate, EscharEx, as these products require a clean wound bed to effectively heal a wound. Four common chronic and other hard-to-heal wounds are:

- *Diabetic Foot Ulcers.* Diabetes can lead to a reduction in blood flow, which can cause patients to lose sensation in their feet and may prevent them from noticing injuries, sometimes leading to the development of DFUs, which are open sores or ulcers on the feet that may take several weeks to heal, if ever. In the United States alone, over 23 million people, or approximately 8% of the population, suffer from diabetes, a chronic, life-threatening disease. Every year 5% of diabetics or approximately 1.3 million people develop DFUs.
- Venous Leg Ulcers. VLUs develop as a result of vascular insufficiency, or the inability for the vasculature of the leg to return blood back toward the heart properly, and affect approximately 600,000 people per year in the United States alone. These ulcers usually form on the sides of the lower leg, above the ankle and below the calf, and are slow to heal and often recur if preventative steps are not taken. The risk of venous ulcers can be increased as a result of a blood clot forming in the deep veins of the legs, obesity, smoking, lack of physical activity or work that requires many hours of standing.
- Pressure Ulcers. Pressure ulcers form as a result of pressure sores, or bed sores, which are injuries to the skin or the tissue beneath the skin. Constant pressure on an area of skin reduces blood supply to the area and over time can cause the skin to break down and form an open ulcer. These often occur in patients who are hospitalized or confined to a chair or bed and most often form on the skin over bony areas, where there is little cushion between the bone and the skin, such as lower parts of the body. Annually, 2.5 million pressure ulcers are treated in the United States in acute care facilities alone.
- Surgical/traumatic wounds. Surgical wounds form as a result of various types of surgical procedures such as investigative or corrective, minor or major, open (traditional) or minimal access surgery, elective or emergency, and incisions (simple cuts) or excision (removal of tissue),



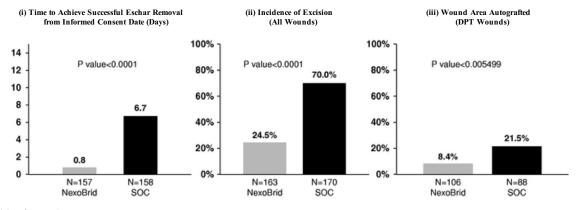
among others. Traumatic wounds form as a result of cuts, lacerations or puncture wounds, which have caused damage to the skin and underlying tissue. Severe traumatic wounds may require surgical intervention to close the wound and stabilize the patient. Surgical/traumatic hard-to-heal wounds develop for various reasons, such as local surgical complications, suboptimal closure techniques, presence of foreign materials, exposed bones or tendons and infection. In the United States, millions receive post-surgical wound care annually.

### **Our Solutions**

NexoBrid is a new paradigm in debridement that has been shown in clinical trials to provide fast and effective non-surgical eschar removal while not harming viable tissues. Because of the many drawbacks of current conventional debridement modalities, we believe that the clinically differentiated profile of our patented technology that underlies NexoBrid and our pipeline products, such as EscharEx, will provide attractive solutions to address significant unmet medical needs.

In the case of severe burns, NexoBrid is used in the following way: Upon admission to a burn center or unit, after routine burn patient cleansing, resuscitation and initial diagnosis, NexoBrid can be topically applied in a single application at the patient's bedside without the necessity of utilizing operating room resources. NexoBrid is prepared by simply mixing the proteolytic enzyme powder and sterile gel and applying it on the burn. The mixed product is left on the burn for four hours, during which time the proteolytic enzymes remove the eschar without harming the healthy tissue surrounding the burn. At the end of the four hours, NexoBrid is removed from the burn, leaving a clean wound bed.

Our clinical trials have consistently demonstrated the clinical benefits of NexoBrid compared to the current SOC. In our European pivotal Phase 3 clinical trial in severe burns, NexoBrid achieved statistically significant clinical outcomes in numerous endpoints relative to the SOC. The charts below highlight three such endpoints and NexoBrid's ability to: (i) effectively remove the eschar significantly earlier, allowing earlier direct visualization and assessment of the wound bed and burn depth, (ii) significantly reduce the need for excisional surgery in all wounds, and (iii) significantly reduce the wound area autografted in deep partial-thickness, or DPT, wounds. The clinical results confirm NexoBrid's ability to successfully remove the eschar, reduce the surgical burden and result in overall favorable long-term results.



### **Our Competitive Strengths**

*NexoBrid, a new paradigm in eschar removal, approved and launched in Europe.* Our innovative product, NexoBrid, provides an easy to use, non-surgical, topical application for removal of eschar from

patients with severe burns. When applied at the patient's bedside to the burn area, NexoBrid removes the eschar in four hours without harming surrounding viable tissues. NexoBrid provides significant advantages over existing surgical and non-surgical SOC and is an innovative solution for the unmet medical need of an effective and selective means for debridement. NexoBrid was launched in Europe, starting with Germany in December 2013, and future launches in the European Union are expected in 2014.

Attractive markets for debridement in burn and wound care. Approximately 200,000 patients with severe burns are hospitalized every year in Europe and the United States. Severe burn patients are predominantly treated by burn specialists at approximately 250 burn centers and at burn units throughout the European G5 countries and the United States. We believe we can effectively target these burn centers and units with a focused marketing effort. We believe the prevalence of patients with severe burns is even higher in emerging economies. For example, according to an IMS study, approximately 400,000 patients are hospitalized every year with burns in India. In addition to burn wounds, the debridement of chronic and other hard-to-heal wounds, such as DFUs, VLUs and pressure ulcers, represents a significantly large market of more than 14 million patients in Europe and the United States alone. Due to aging and increasing rates of diabetes and obesity, the incidence and market for advanced treatment of such wounds is estimated to grow over 8% per year.

*Extensive clinical differentiation and experience and support from key opinion leaders and physicians worldwide.* NexoBrid's approval in Europe is based on its highly robust and statistically significant efficacious clinical results. NexoBrid has extensive clinical experience and has been investigated in more than 550 patients in six Phase 2 and Phase 3 clinical studies. The studies consistently demonstrated a significant improvement over the current SOC in clinical sites across more than 15 countries covering four continents. NexoBrid demonstrated several advantages when compared to SOC including:

- significantly earlier successful eschar removal in 0.8 days, versus 6.7 days when treated by SOC, as measured from the time of signing informed consent;
- significantly reducing both the incidence and the extent of wounds requiring surgical excision;
- significantly reducing both the incidence and the extent of wounds requiring autografting; and
- significantly less quantity of long-term scars and comparable quality of scars.

Due to these clinically meaningful differentiating factors, we believe that NexoBrid has gained awareness and support from more than 100 burn specialists and KOLs through presentations at more than 100 international scientific conferences and publication of 11 peer-reviewed papers as well as a chapter in Total Burn Care, a leading medical textbook on burns.

*Lower development risk for our pipeline products.* We believe our patented proteolytic enzyme technology underlying NexoBrid can be used to bring additional products to the market. We believe we will be able to leverage the experience gained in the development and approval of NexoBrid, as well as the wealth of preclinical, clinical and manufacturing and control data, to decrease the developmental risk of our pipeline products. For example, our technology has proven effective in a Phase 2 trial for debridement in various chronic and other hard-to-heal wounds. Additionally, our technology has demonstrated promising results in ex-vivo model studies of connective tissue disorders, such as Dupuytren's and Peyronie's diseases.

*Fully integrated platform.* We have built a fully integrated organization that allows us to maintain control over all critical aspects of our business, including research and development, manufacturing and commercialization. Our research and development team has managed all of our clinical studies and regulatory interactions leading to successful marketing approval of NexoBrid in Europe. We have a state-of-the-art, EMA-certified, cGMP-compliant manufacturing facility that produces our sterile pharmaceutical products using our proprietary methods. Our targeted sales and marketing organization

launched NexoBrid in Europe, starting with Germany in December 2013. Over time, we believe that the combination of these capabilities will allow us to drive growth and profitability.

*High barriers to entry.* We enjoy significant barriers to entry due to our intellectual property, know-how, orphan drug status and other regulatory exclusivities. NexoBrid has patent protection (composition of matter) in all major global markets, including protection at least until 2025 in Europe and 2029 in the United States. Our intellectual property position is significantly reinforced by our technical know-how. NexoBrid has orphan drug status in Europe and the United States, which provides us post-approval market exclusivity of seven and ten years, respectively. Lastly, since NexoBrid is classified as a biologic in the United States, which requires us to follow a BLA submission path, we expect to enjoy twelve years of market exclusivity in the United States post FDA approval.

*Experienced management team.* Our management team, led by our President and Chief Executive Officer, Gal Cohen, has decades of cumulative industry specific experience. Specifically, Mr. Cohen was the Project Manager for the launch of Copaxone in the United States and in Europe and also served as Director of Strategic Business Planning and New Ventures for Teva Pharmaceuticals Industries Ltd., or Teva. Our Co-founder and Chief Medical Officer, Professor Lior Rosenberg, is a prominent KOL in the field of burn and wound management and has developed several approved medical devices for the wound care market. Professor Rosenberg serves as the Head of the International Society of Burn Injuries disaster committee and until very recently served as the Head of the Department of Plastic Surgery in one of the largest medical centers in Israel. Carsten Henke, the Managing Director of MediWound Germany GmbH, has over twenty years of experience in marketing and sales and was previously associated with Teva, Serono, Sanofi and Merck Group, where he led the marketing and sales efforts of significant products.

## **Our Growth Strategy**

*Maximize value of NexoBrid for debridement in severe burns in Europe.* We have developed a well-defined commercialization strategy to launch NexoBrid in Europe, starting with Germany in December 2013. We are executing our strategic plan, which includes, for example, building our commercial organization, establishing pricing and reimbursement and implementing a comprehensive marketing campaign and branding and training programs. Our sales force is targeting a focused group of specialists in burn centers and burn units of large hospitals. We believe we can comprehensively cover this specialty hospital call point with approximately 30 professionals. We are currently expanding our team in Europe who will be leading our marketing efforts and working with healthcare professionals. Additionally, we are working closely with IMS Health to design and locally execute a market access strategy for most of Europe. Our pricing strategy is underpinned by several completed and on-going market access studies throughout Europe, based on the cost-effectiveness and value proposition offered by NexoBrid.

*Expand the commercialization opportunities for NexoBrid into the United States and other international markets.* We intend to apply our clinical and regulatory experience and commercialization strategy in Europe to maximize the global value of NexoBrid. We plan to initiate a Phase 3 pivotal study in the United States in the first half of 2014 to support a BLA submission to the FDA. We anticipate that we will build a similarly-sized and focused commercial organization in the United States to cover the specialty hospital call point and maximize value of NexoBrid if we are able to obtain FDA approval. Additionally, we believe the ease of use of NexoBrid, its proven clinical efficacy and the limited surgical capacity in certain emerging economies, including Latin America, the Commonwealth of Independent States and Asia, represent a significant market opportunity, as generally, the incidence of severe burns is higher in such regions, driven by limited safety and prevention measures. We plan to enter into these emerging markets through collaboration with local distributors and to capitalize on our approved registration file in Europe to obtain regional marketing authorizations.

*Utilize our technology to develop and commercialize products for chronic and other hard-to-heal wounds and connective tissue disorders.* We are adapting the proteolytic enzymes that underlie NexoBrid for use in additional indications in order to realize the full commercial potential of such technology. EscharEx, our lead product candidate, has demonstrated clinical efficacy in eschar removal of chronic and other hard-to-heal wounds, which have an addressable patient population of over 14 million in the United States and Europe alone and present a large market opportunity for our technology. Additionally, our proteolytic enzymes have demonstrated promising results in ex-vivo model studies of connective tissue disorders by relaxing the contracted tissue associated with these disorders. We believe that our accumulated wealth of data and experience with proteolytic enzymes as well as the well-defined clinical regulatory precedent can facilitate an expedited and lower-risk development pathway for our current and future pipeline products.

Selectively explore additional business development opportunities to further drive growth. We will seek to engage in targeted business development activities, such as licensing, strategic partnerships and acquisitions, that are synergistic to our business in order to achieve two main goals: First, to expand the market potential of NexoBrid and our pipeline products. Second, to leverage our niche specialty commercial infrastructure with externally-sourced products that are complementary to our hospital call point.

## NexoBrid and Our Clinical History

NexoBrid, our innovative biopharmaceutical product, received marketing authorization from the EMA for the removal of eschar in adults with deep partial- and full-thickness thermal burns. The active ingredient in NexoBrid is a mixture of proteolytic enzymes enriched in bromelain prepared from an extract of pineapple plant stems. Proteolysis is a breakdown of proteins into smaller building blocks, polypeptides or amino acids. Our research and development team further developed and optimized this patented proteolytic enzyme technology which is the basis for NexoBrid and all of our current pipeline products. One vial of NexoBrid containing 2 grams of concentrate of proteolytic enzymes enriched in bromelain is sufficient for treating a burn wound area of 100cm<sup>2</sup>.

We developed NexoBrid to fulfill the previously unmet need for an effective and selective debriding agent that combines the efficacy and speed of surgery with the non-invasiveness of non-surgical methods. NexoBrid enhances the ability of physicians to conduct an earlier direct visual assessment of the burn depth to reach an informed decision on further treatment as well as to reduce the surgical burden and achieve a favorable long-term patient outcome.

NexoBrid has been investigated in more than 550 patients across 15 countries and four continents in six Phase 2 and Phase 3 clinical studies, and we are currently preparing an FDA pivotal Phase 3 clinical study in the United States to support a BLA submission as well as a pediatric study in Europe to broaden the approved indication. While we are marketing our product for the removal of eschar in burn wounds under the name "NexoBrid," in clinical trials the product has been referred to as "Debridase" and "Debrase."

The following table sets forth information regarding the completed clinical trials of NexoBrid:

	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Trial 6
Study Type	Retrospective Phase 2     Investigator initiated	Dose range Phase 2	Prospective Phase 2     IND/FDA	Phase 2     IND/FDA	Phase 3     EMA	Phase 3b     EMA
Design	Data collected from files of patients treated with NexoBrid	Parallel, controlled, observer-blind, randomized, single-center	Parallel, controlled, observer-blind, three- arm, randomized, multi-center	Parallel, controlled, open label, three-arm, randomized, single-center	Parallel, controlled, open label, two-arm, randomized, multi-center	Parallel, controlled, blinded, two-arm, multi-center
Main Objectives	Safety     Efficacy	Comparison of efficacy and safety	Safety     Efficacy	• Safety	Safety     Efficacy	Long term scar assessment     Quality of life
Wound Types	Deep partial/full thickness thermal burns	Deep partial/full thickness thermal burns	Deep partial/full thickness thermal burns	Deep partial/full thickness thermal burns	Deep partial/full thickness thermal burns	Scar formation
Number of Patients	• 154	• 20	• 140	• 30	• 182	• 89
Study Length	• 1985-2000	• 2002-2005	• 2003-2004	• 2006-2007	• 2006-2009	• 2011
Location	• Israel	• Israel	International	United States	International	International

## Trial 1: Retrospective Phase 2—Israel

Trial 1 evaluated the safety and efficacy of NexoBrid in hospitalized subjects between 0.5 and 82 years of age with severe burns of up to 67% TBSA. Data from 154 subjects with complete file documentation (including a signed informed consent form and pre- and post-eschar removal photographs) were analyzed. According to the trial, NexoBrid allowed early and fast debridement, reduced surgical burden and was determined to be safe locally and systemically.

# Trial 2: Dose Range Phase 2—Israel

Trial 2 evaluated the efficacy and safety of three doses of NexoBrid. Twenty hospitalized adult subjects, with severe burns of 1-15% TBSA were randomized and provided a one, two or four gram dose of NexoBrid powder per twenty grams of a sterile gel substance, or Gel Vehicle. The study confirmed that the use of two grams of NexoBrid mixed with twenty grams of Gel Vehicle per  $100 \text{ cm}^2$  was a safe and effective dose.

# Trial 3: Prospective Phase 2-International/Investigational New Drug, or IND

Trial 3 evaluated the safety and enzymatic eschar removal efficacy of NexoBrid as compared to the Gel Vehicle and SOC. A total of 140 hospitalized adult subjects, with severe burns ranging from 2-15% TBSA (but not more than 30% TBSA in total), were randomized in a 2:1:1 ratio to NexoBrid, Gel Vehicle, and SOC treatment. The trial results showed that NexoBrid was a fast and effective enzymatic debriding agent, combining the advantage of early eschar removal with reduced surgical burden.

## Trial 4: Prospective Phase 2—United States/IND

Trial 4 evaluated the safety and exploratory efficacy of NexoBrid in comparison to the Gel Vehicle and SOC in hospitalized adult subjects, with severe burns ranging from 1-5% TBSA. Thirty hospitalized subjects were randomized and provided NexoBrid, the Gel Vehicle or SOC treatment. Although this study was designed as a safety study and was conducted in a limited number of patients, the results suggest that NexoBrid provided effective debridement and may be an alternative to surgical

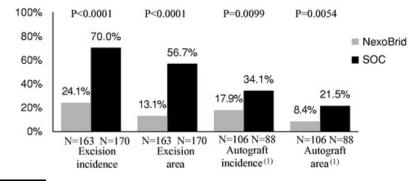
debridement. According to the trial, NexoBrid had a similar safety profile to the Gel Vehicle and SOC and the Gel Vehicle was not shown to have any deleterious effect.

## Trial 5: Phase 3—EMA

Trial 5 evaluated the safety and efficacy of NexoBrid. The study was a prospective, controlled, two-arm, parallel, open-label, randomized, multi-center design. It included 182 enrolled patients, between the ages of four and fifty-five, who were hospitalized with severe burn wounds covering from 5-30% TBSA. The two arms consisted of patients who were treated with NexoBrid and patients who were treated with SOC, which included surgical and non-surgical eschar removal. The treatment of the study arms differed only by the studied eschar removal modalities. The co-primary endpoints were the percentage of wound area that was excised and the percentage of wound area that was autografted. The secondary endpoints included need for and extent of eschar excision, time to wound closure, time to complete ( $\Box$  90%) eschar removal and blood loss. The study was successfully concluded when pre-planned interim analysis demonstrated a statistically significant difference in both primary endpoints between the groups.

The results showed that NexoBrid significantly reduced both the percentage of wounds requiring excision or autografting and the percentage of wound area requiring excision or autografting. P-value is a measure of statistical significance, with P<0.05 considered statistically significant.

In patients who received NexoBrid, 24.5% of wounds required excision, whereas, in patients who received SOC, 70.0% of wounds required excision (P<0.0001). With regard to the proportion of wound area excised when excision was required, patients who received NexoBrid had 13.1% of wound area excised, compared to 56.7% of wound area excised for patients receiving SOC (P<0.0001). The results were similar for autografting, although this endpoint could only be evaluated for DPT wounds, as full-thickness wounds always require autografting due to the lack of viable dermis, regardless of the technique used to remove the eschar. In patients receiving NexoBrid, 17.9% of DPT wounds required autografting, whereas, in patients who received SOC, 34.1% of DPT wounds required autografting (P=0.0099). With regard to the proportion of wound area autografted, patients who received NexoBrid had 8.4% of DPT wound area autografted, compared to 21.5% of DPT wound area autografted for patients receiving SOC (P<0.0054).



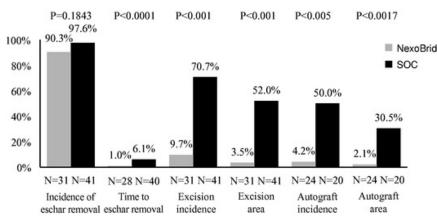
(1) Only DPT wounds are presented, as full-thickness wounds always require autografting due to the lack of viable dermis, regardless of the technique used to remove the eschar.

NexoBrid successfully removed the eschar in 96.3% of the wounds compared to 93.5% of the wounds debrided by SOC.

The results also showed that NexoBrid significantly reduced the time required to achieve successful eschar removal, allowing for early and direct assessment of the wound bed. For patients with successful

eschar removal, defined as at least 90%, those who received NexoBrid achieved successful eschar removal in 0.8 days, whereas patients who received SOC achieved successful eschar removal in 6.7 days, as measured from the time of signing informed consent (P<0.0001), which represents the time at which a patient can start being treated with an investigational product in a clinical trial setting.

With regard to hand burns, results showed that the use of NexoBrid significantly reduced surgical burden in terms of the need for excision, grafting or escharotomy. In patients who received NexoBrid, 9.7% required excision, whereas, in patients who received SOC, 70.7% required excision (P<0.0001). When excision was required, the proportion of wound area excised was 3.5% for patients receiving NexoBrid and 52.0% for patients receiving SOC (P<0.0001). As for autografting, 4.2% of patients treated with NexoBrid required autografting, whereas 50.0% of patients treated with SOC required autografting (P=0.0005). When autografting was performed, the proportion of wound area autografted was 2.1% for patients who received NexoBrid and 30.5% for patients who received SOC (P=0.0017). With respect to escharotomies, no escharotomy was needed for hand burns treated with NexoBrid, whereas 9.7% of hand burns treated with SOC required escharotomies (P=0.07).

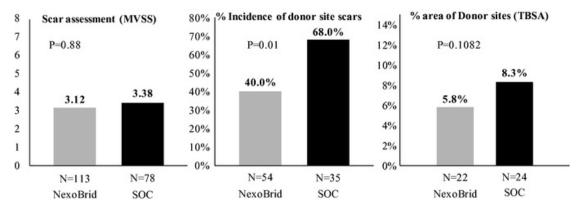


#### Trial 6: Phase 3b-EMA

Trial 6 assessed long-term scar formation and quality of life in adults and children who received NexoBrid or SOC during the Phase 3 clinical study. The follow-up was completed two to four years after injury. The study was a prospective, controlled, two-arm, parallel, blinded, multi-center design and included 89 patients. Scar quality was assessed using the Modified Vancouver Scar Scale, or MVSS. The MVSS measures pliability, height, vascularity, and pigmentation, as well as pain and pruritus. Scores range from 0 to 18, with a higher score indicating a more severe scar. To assess quality of life, the study used the Short Form-36 questionnaire, or SF-36, for adults and the Burn Outcome Questionnaire, or BOQ, for children.

The results confirmed that based on the MVSS the quality of scars was comparable between the patients who received NexoBrid and those who were treated with SOC (3.12 vs. 3.38, respectively, P=0.88). However, patients who received NexoBrid experienced a significantly reduced overall quantity of scarring as compared to those who received SOC; with NexoBrid, 40% of patients had donor site scars, as compared to 68% of patients with SOC (P=0.01). Donor site scars on those who received

NexoBrid were also 30% smaller than scars on those who received SOC (P=0.1082). It was also confirmed that quality of life using the SF-36 and BOQ was comparable in both groups.



## Clinical development overall safety assessment

The most commonly reported adverse reactions when using NexoBrid are local pain and transient pyrexia/hyperthermia. The data from its clinical development showed that through precautionary measures, including preventive analgesia as routinely practiced for extensive dressing changes in bum patients as well as antibacterial soaking of the treatment area before and after NexoBrid application, the frequency of pain and pyrexia/hyperthermia was reduced. NexoBrid was not found to be associated with a significantly increased risk of serious or severe adverse events compared to SOC. Serious infections occurred with similar frequency in the SOC and NexoBrid cohorts and the incidence was low. Adverse events occurring in □3.0% of treated subjects (e.g. pruritus, or itching, anemia, insomnia, nausea, vomiting and skin graft failure) are common in burn patients and their rate was comparable between NexoBrid and SOC treated patients and below the rates reported in the literature. NexoBrid debridement was associated with a slightly higher rate of wound complications, general infections, wound infections/wound cultures and extent in antibiotic-use. The imbalances were small, wound infections were only mild to moderate in severity and each responded well to treatment. No detrimental effect on long-term outcome has been detected for the NexoBrid treated patients.

During clinical development, there were five deaths (four reported in the Phase 2 study)(Trial 3) resulting from medical reasons in NexoBrid patients compared to one non-related death in the SOC group. Neither the analysis of the narratives contained in the death investigative report, nor the opinions of the physicians who treated the patients, nor the Data Safety monitoring Board have associated NexoBrid with the deaths in patients who received the treatment. The EMA concluded that the benefit-risk of NexoBrid for the removal of eschar in adults with deep partial, mixed and full thickness burns is positive.

#### Planned and future clinical trials

### Phase 3—United States

We have initiated preparations for a prospective, controlled, masked, randomized, multi-center Phase 3 study for approximately 200 patients, which we expect to commence in the first half of 2014 with a twenty-four-month follow-up. The study objective is to evaluate the efficacy and safety of NexoBrid in removing burn eschar earlier and reducing surgical needs in hospitalized subjects with severe burns of 4-15% TBSA. The primary endpoints are eschar removal, surgical burden, cosmesis and function. Interim results, with pre-defined stopping rules after a twelve-month follow-up, are currently expected to be available in the first half of 2017, with final results following in the first half of 2018.

### Pediatric Investigational Plan-Europe

We have also initiated preparations for a prospective, controlled, randomized, multi-center Pediatric Investigational Plan, or PIP, study, which we expect to commence in the first half of 2014, for approximately 160 patients, with a twenty-four month follow-up. The primary endpoints are eschar removal, surgical burden, cosmesis and function. We are conducting this study as part of the regulatory requirements in Europe to conduct PIPs and in order to broaden the approved indication to the treatment of severe burns in children. Interim results, with pre-defined stopping rules after a twelve-month follow-up, are currently expected to be available in the first half of 2017, with final results following in the first half of 2018.

#### Observational Survey-Europe

As part of the marketing authorization requirements in Europe, as customary for recently approved drugs, we are working with regulatory authorities to design an observational cohort survey to assess risk minimization measures in burn patients who were treated with NexoBrid. We plan to initiate the survey in 2014 and include between 100 and 200 patients.

#### Ongoing Studies—Israel/Europe

We are conducting two ongoing studies, which we expect to be completed in the first half of 2014 and include approximately 20 to 30 patients each. The first is a safety and efficacy study of NexoBrid in hospitalized patients, with severe burns ranging from 4% to 30% TBSA, which will also explore its pharmacokinetic attributes. We are conducting this study in order to collect further pharmacokinetic information to allow application of NexoBrid to more than 15% TBSA. The second study will be based on self-reported questionnaires to assess the functionality of extremities in patients treated with NexoBrid compared to SOC to further study the effect of NexoBrid on patients' overall long-term outcomes.

### **Pipeline Products and Clinical Results**

In addition to the continued development of NexoBrid, we are in various stages of development of additional product candidates, such as EscharEx, for other indications based on the same patented proteolytic enzyme technology that underlies NexoBrid. We intend to continue to develop these product candidates in order to further establish and confirm their safety and efficacy so that we can thereafter seek marketing authorization for such product candidates.

#### Chronic and other hard-to-heal wounds

We have completed a first Phase 2 feasibility study in Israel for the use of our patented proteolytic enzyme technology on chronic and other hard-to-heal wounds and have initiated preparations for a second Phase 2 study. Based on the preliminary study, we believe that our technology may be effective for debridement of chronic and other hard-to-heal wounds. Our product for debridement of chronic and other hard-to-heal wounds, EscharEx, is based on the same patented proteolytic enzyme technology as NexoBrid but differs in other aspects, such as in formulation or presentation.

## First Phase 2 feasibility study—Israel

This first Phase 2 feasibility study was conducted in Israel to study the efficacy of our technology on chronic and other hard-to-heal wounds. The study assessed twenty-four patients at two sites. The results showed that our technology was effective in debriding various chronic and other hard-to-heal wound etiologies, such as DFUs, VLUs, pressure sores and trauma on diseased skin.

## Second Phase 2 study—Israel

We have also initiated preparations for a prospective, controlled, masked, randomized, multi-center Phase 2 study of approximately 72 patients in Israel and possibly additional countries that we expect

will commence in the first half of 2014. This study will assess the safety and efficacy of EscharEx in treating chronic and other hard-to-heal wounds. The endpoints include eschar removal, surgical burden and wound healing. Results are currently expected to be available in the second half of 2015.

Although we have conducted clinical trials, including those necessary to receive marketing authorization for NexoBrid in severe burns, the development of EscharEx for chronic and other hard-to-heal wound indications is still in Phase 2 studies, and there is no certainty that EscharEx will achieve all the objectives of the trials as required or successfully complete the process for such indication. See "Risk Factors—Development and commercialization of NexoBrid in the United States and our pipeline products worldwide requires successful completion of the regulatory approval process, and may suffer delays or fail."

# Connective tissue disorders

In addition to severe burns and chronic and other hard-to-heal wound indications, we are in the preliminary stages of developing an injectable product based on our patented proteolytic enzyme technology for connective tissue pathologies and indications, including:

- *Dupuytren's disease:* a condition where one or more fingers are permanently flexed, caused by the formation of scar-like tissues below the palmar skin (Palmar Fascia), forming hard "cords" that freeze the fingers in non-functional flexion contraction. This condition affects approximately 6.2 million individuals in the United States alone.
- *Peyronie's disease:* the development of scar-like tissue, similar to Dupuytren's cords in the shaft of the penis, causing pain and distortion on erection, preventing intercourse. Peyronie's disease is typically caused by trauma and affects men over 50 years old. Surgical treatment may be an option in some cases, but can cause complications and may result in a shortening and even greater distortion of the penis. Approximately 3.7% to 7.1% of the male population above the age of 50 suffers from Peyronie's disease in the United States and approximately 3.2% of such age group suffer from the disease in Europe.
- *Frozen shoulder syndrome:* a disorder that causes the smooth tissues of the shoulder capsule to become thick, stiff and inflamed, affecting approximately 2% to 5% of the worldwide population and 10% to 20% of people with diabetes according to industry sources.

Currently, SOC for connective tissue disorders involves surgery, with a very high recurrence rate, and some non-surgical alternatives. One such alternative is Xiaflex, a collagenase-based injectable enzyme that has received orphan status in the United States for the treatment of Dupuytren's and Peyronie's diseases.

#### Clinical trials

We are performing preclinical model studies in Israel for the use of our patented proteolytic enzyme technology in treating connective tissue disorders. Our technology has shown promising results in preclinical model studies for the treatment of connective tissue pathologies.

If we are successful in developing an injectable product for connective tissue disorders based on our patented proteolytic enzyme technology, we believe that there exists a focused audience of specialists that could be reached with a targeted sales and marketing force such as plastic and orthopaedic (musculoskeletal and hand) surgeons in the case of Dupuytren's contracture.

#### Preclinical model study-Israel

In this preclinical model study, more than sixty excised Dupuytren cords were injected with either our pipeline product candidate or Saline (control) solution following Starkweather's ex-vivo validated model. Our pipeline product candidate treatment repeatedly provided enzymatic degradation of Dupuytren cords (fasciotomy) in a tearing test model.



Although we have conducted preclinical trials, the development stage of our pipeline product candidate for connective tissue disorder indications is still in its preliminary phase and there is no certainty that such product will achieve all the aims of the trials as required and/or successfully complete the process for such indication. See "Risk Factors—Development and commercialization of NexoBrid in the United States and our pipeline products worldwide requires successful completion of the regulatory approval process, and may suffer delays or fail."

## **Research and Development**

Our research and development strategy is centered on developing our patented proteolytic enzyme technology, which underlies NexoBrid, into additional products for high-value indications. For more information regarding our product pipeline, see "—Pipeline Products and Clinical Results." Our research and development team is located at our facilities in Yavne, Israel, and consists of 10 employees as of December 31, 2013 and is supported by highly experienced consultants in various research and development disciplines.

We receive government grants (subject to the payment of royalties) as part of NexoBrid's research and development programs approved by the Israeli Office of the Chief Scientist, or OCS. The total gross amount of grants actually received by us from the OCS, including accrued LIBOR interest as of December 31, 2013, totaled approximately \$9.9 million and the amortized cost (using the interest method) of the liability totaled approximately \$6.4 million and \$6.6 million as of December 31, 2012 and 2013, respectively. Because the repayment of OCS grants is in the form of future royalties, the balance of the commitments to the OCS is presented as an amortized liability on our balance sheet. As of December 31, 2013, we had not paid any royalties to the OCS.

We incurred approximately \$3.0 million, \$1.6 million and \$3.6 million in research and development expenses (after deducting participation by others and government grants) in the years ended December 31, 2011, 2012 and 2013, respectively. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Participation by others" for more information.

### **Clinical Trials**

We conduct clinical tests and preclinical studies to support the efficacy and safety of our products and their ingredients and to extend and validate their benefits for human health. Preclinical studies allow us to substantiate the safety of our products and obtain preliminarily indications of their pharmacological profile. As of December 20, 2013, we had conducted more than twenty preclinical studies, according to the principles of Good Laboratory Practices, or GLP, and more than six clinical studies, according to the principles of Good Clinical Practices, or GCP, for NexoBrid and our pipeline products. As a result, we have developed significant experience in planning, designing, executing, analyzing, and publishing clinical studies.

Our research and development team manages our clinical studies and coordinates the project planning, trial design, execution, outcome analyses and clinical study report submission. During the design, execution and analyses of our studies, our research and development team consults with key opinion leaders and top tier consultants in the relevant field of research to optimize both design and execution, as well as to strengthen the scientific, medical and regulatory compliance level of the investigational plan. Our clinical studies have been conducted in collaboration with leading medical and research centers in countries such as Australia, Brazil, France, Germany, India, Israel, the United Kingdom and the United States. For information regarding the clinical validation of NexoBrid, see "—NexoBrid and Our Clinical History."

#### Manufacturing, Supply and Production

We operate a manufacturing facility in Yavne, Israel, in a building that we sub-lease from Clal Life Sciences L.P., with 19 employees as of December 31, 2013. This facility allows us to manufacture sterile

biopharmaceutical products, such as NexoBrid. Additionally, the facility meets current cGMP requirements, as certified by each of the EMA, the Israeli Ministry of Health and an E.U. Notified Body. In 2005 and 2009, a cGMP audit was conducted by a European Qualified Person for our European Phase 3 clinical studies, following which our facility was approved and reapproved as cGMP-compliant. Since 2010, we have passed audits conducted by each of the Israeli Ministry of Health, the Dutch Ministry of Health on behalf of the EMA and a European Qualified Person. Additionally, as we seek regulatory approval in the United States and other international jurisdictions for NexoBrid, the FDA or other regional applicable agencies, may inspect our plant to confirm it meets all regulatory requirements. Any changes in our production processes for NexoBrid must be approved by the EMA and similar authorities in other jurisdictions.

While we believe that our current manufacturing capacity at the facility is sufficient to meet the expected initial demand for NexoBrid, we are considering plans to increase the capacity by constructing an additional manufacturing facility, which we estimate would be completed in the second half of 2016 and cost approximately \$10 million.

The intermediate drug substance used by us in the manufacturing of NexoBrid is bromelain SP, which is derived from pineapple plant stems. We have entered into an agreement with Challenge Bioproducts Corporation Ltd., a corporation organized and existing under the laws of the Republic of China, or CBC, dated January 11, 2001, as amended on February 28, 2010, pursuant to which CBC uses proprietary methods to manufacture bromelain SP and supplies us with this intermediate drug substance in bulk quantities. According to the terms of the agreement, CBC shall not, and shall not permit related companies or a third party to, manufacture, use, supply or sell the raw materials for the use or production of a product directly or indirectly competing with any of our products. Our supply agreement with CBC has no fixed expiration date and can be voluntarily terminated by us, with at least six-months advance written notice, or by CBC, with at least twenty-four months advance written notice.

Upon obtaining bromelain SP from CBC, we further process it into the drug substance and then into the drug product to finally create the powder form of NexoBrid. The necessary inactive ingredients contained in NexoBrid, or the excipients, are readily available and generally sold to us by multiple suppliers. In addition to this powder, we manufacture a gel substance by combining water for injections produced by us at our facility and additional excipients. The powder and gel are kept in separate containers in one package of NexoBrid and are simply mixed by a healthcare professional prior to use. NexoBrid is authorized to be sold in Europe in packages containing either a vial of two grams of powder and a bottle of 20 grams of gel or a vial of five grams of powder and a bottle of 50 grams of gel. Once the powder and gel are mixed, NexoBrid should be applied within 15 minutes at a ratio of either 2 grams of powder and 20 grams of gel to a burn wound area of 100 cm<sup>2</sup> or 5 grams of powder and 50 grams of gel to a burn wound area of 250 cm<sup>2</sup>, as applicable; however, under current usage, NexoBrid's label provides that it should not be applied to more than 15% TBSA. Prior to mixture and application, NexoBrid has a shelf life of three years when stored under refrigeration.

# Marketing, Sales and Distribution

We have developed a well-defined commercialization strategy to launch NexoBrid in Europe, which started in Germany in December 2013. We intend to market NexoBrid by targeting a focused segment of burn specialists treating patients with severe burns in the approximately 125 burn centers throughout the European Union followed by burn units of large hospitals. We believe that additional smaller hospitals will follow the treatment trends once established by the burn centers and large hospital burn units. Additionally, we believe we will not need to conduct on-going sales force visits to promote the product in these institutions, we can comprehensively cover this specialty hospital call point with approximately 30 professionals. In Europe, the marketing, sales and distribution of NexoBrid will be carried out by our wholly-owned German subsidiary, MediWound Germany GmbH, which consists of a marketing team of specialized and knowledgeable sales representatives who will also train physicians on its proper use. Additionally, we are working closely with IMS Health, a leading information, services

and technology company, to design and locally execute a market access strategy for most of Europe, and we expect to expand our network to other European countries while applying for reimbursement. See "—Government Regulation—Pharmaceutical Coverage, Pricing and Reimbursement." In addition to recently receiving marketing authorization for NexoBrid in the European Union, key opinion leaders in the burn care field worldwide are already aware of NexoBrid's efficiency in removing eschar due to over 100 scientific presentations at international conferences, 11 peer-reviewed papers as well as a chapter in Total Burn Care, the leading medical textbook on burns.

Moreover, we anticipate that we will build a similarly-sized and focused commercial organization in the United States to cover the specialty hospital call point and maximize value of NexoBrid upon FDA approval. We plan to enter into other international markets through collaboration with local distributors and leverage our approved registration file in Europe to obtain regional marketing authorizations.

We have received third-party pricing studies conducted in Germany and the United Kingdom, which suggested an approximate price of  $\notin$  350 per twogram vial of NexoBrid. Currently, we are refining the price point for NexoBrid in the European Union and expect that the price will reflect NexoBrid's benefits and potential cost savings relative to surgical treatment.

## **Intellectual Property**

Our intellectual property and proprietary technology are important to the development, manufacture, and sale of NexoBrid and our future pipeline products. We seek to protect our intellectual property, core technologies and other know-how, through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, licenses, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others. Additionally, we rely on our research and development program, clinical trials, know-how and marketing and distribution programs to advance our products. As of January 27, 2014, we had been granted a total of 57 patents and have 17 pending national phase applications. The family of patents that covers NexoBrid specifically includes 31 granted patents worldwide and five pending applications. We submit applications under the Patent Cooperation Treaty, or PCT, which is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the member states. Although a PCT application is not itself examined and cannot issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

The main patents for our proteolytic enzyme technology, which underlies NexoBrid and our current pipeline products have been issued in Europe, the United States and other international markets. Our patents which cover NexoBrid claim specific mixtures of proteolytic enzymes, methods of producing such mixtures and methods of treatment using such mixtures. Although the protection achieved is significant for NexoBrid and our pipeline products, when looking at our patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents which claim chemical structures which were previously unknown. Absent patent-term extensions, the patents are nominally set to expire in 2025 in Europe and 2029 in the United States. Patents issued in other foreign jurisdictions will nominally expire in 2025.

While our policy is to obtain patents by application, license or otherwise, to maintain trade secrets and to seek to operate without infringing on the intellectual property rights of third parties, technologies related to our business have been rapidly developing in recent years. Additionally, patent applications that we may file or license from third parties may not result in the issuance of patents, and our issued patents and any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot predict the extent of claims that may be allowed or enforced in our patents nor be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications that also claim technology or therapeutics to which we have rights, we may have to partake in proceedings to determine priority of

invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us. Moreover, because of the extensive time required for clinical development and regulatory review of a product we may develop, it is possible that, before NexoBrid can be commercialized in additional jurisdictions and/or before any of our future products can be commercialized, related patents will have expired or will expire a short period following commercialization, thereby reducing the advantage of such patent. Loss or invalidation of certain of our patents, or a finding of unenforceability or limited scope of certain of our intellectual property, could have a material adverse effect on us. See "Risk Factors—Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our technology and products."

In addition to patent protection, we also rely on trade secrets, including unpatented know-how, technology innovation, drawings, technical specifications and other proprietary information in attempting to develop and maintain our competitive position. We also rely on protection available under trademark laws, and we currently various hold registered trademarks, including for the marks, "MediWound", "NexoBrid" and "EscharEx" in various jurisdictions, including the United States, the European Union, and Israel.

#### Klein License Agreement

In September 2000, we signed an exclusive license agreement, as amended in June 2007, with a third party for use of its patents and intellectual property, we refer to this as the Klein License Agreement. Under the agreement, we received an exclusive license to use the third party's patents and intellectual property for the purpose of developing, manufacturing, marketing and commercializing NexoBrid and its pipeline products for the treatment of burns and other wounds. The claims of such patents are directed to a process of preparing a mixture of escharase and proteolytic enzymes and covers the underlying proteolytic mixture of escharase and proteolytic enzymes prepared by that specific process. Pursuant to the agreement, we are obligated to keep accounting records related to the sales of NexoBrid and its pipeline products and pay royalties as discussed below. The Klein License Agreement may be terminated by Klein, subject to notice and dispute resolution, if we breach the agreement, our filing of a bankruptcy petition, our insolvency, or our failure to achieve a development milestone within six months of a target date. As of the date of this prospectus, we had already achieved all development milestones under the Klein License Agreement.

In consideration for the agreement, we paid an aggregate amount of \$1.0 million following the achievement of certain development milestones. In addition, we undertook to pay royalties of 3% to 5% from revenues, 20% of royalties received from sublicensing and 2% of lump-sum payments received from sublicensing, of products based on the licensed patents and intellectual property, for a period ranging between 10 to 15 years from the first commercial delivery in a major country. Thereafter, we will have a fully-paid, royalty-free license. Moreover, in jurisdictions where the underlying patent has expired, the royalty payments are reduced by 50%. As of the date of this prospectus, such patents are expired in every jurisdiction other than the United States, where the patent will expire on November 3, 2015. In addition, under the Klein License Agreement, we agreed to pay a one-time lump-sum amount of \$1.5 million upon reaching aggregate revenues of \$100 million from the sale of such products.

### Licensed Products

In the past, we entered into a license agreement with PolyHeal, pursuant to which we owned the exclusive, worldwide license for the development, production and commercialization of the PolyHeal Product. Our license agreement for PolyHeal, has expired, but we may enter into a new licensing agreement with third-parties in the future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Participation by others" for more information.

### Competition

NexoBrid received orphan drug status in the European Union on July 31, 2002 and in the United States on August 20, 2003 for debridement of deep partial- and full-thickness burns in hospitalized patients. In the United States and in the European Union, a sponsor that develops an orphan drug has marketing exclusivity for seven years post-approval by the FDA and for ten years post-approval by the EMA, respectively. The exclusive marketing rights in both regions are subject to certain exceptions, including the development of a clinically significant benefit over the prevalent SOC. Once the market exclusivity for our orphan indication expires, subject to other protections such as patents, we could face competition from other companies that may attempt to develop other products for the same indication.

The medical, biotechnology and pharmaceutical industries are intensely competitive and subject to significant technological change and changes in practice. While we believe that our innovative technology, knowledge, experience and scientific resources provide us with competitive advantages, we may face competition from many different sources with respect to NexoBrid and our pipeline products or any product candidates that we may seek to develop or commercialize in the future. Possible competitors may be medical practitioners, pharmaceutical and wound care companies, academic and medical institutions, governmental agencies and public and private research institutions, among others. Any product that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

In addition, we face competition from current SOC. The current SOC for eschar removal in severe burns is surgery, where debridement can be performed by tangential excision, dermabrasion or hydro jet, or non-surgical alternatives, such as applying topical medications to the eschar to facilitate the natural healing process. Consequently, we face competition from surgical procedures and topical agents such as Smith & Nephew Plc's Santyl, a collagenase-based product indicated for the debriding chronic dermal ulcers and severely burned area. However, based on our clinical trials, we believe that NexoBrid has a sustainable competitive advantage over the current non-surgical alternatives and is less invasive than surgery in removing eschar in patients with burn wounds. See "—NexoBrid and Our Clinical History" for the results of our clinical trials.

Although we are in the clinical and preclinical phases for our pipeline products for debridement of chronic and other hard-to-heal wounds and treating connective tissue disorders, respectively, if one of our pipeline products obtains approval in the future, we would compete with traditional surgery and existing non-surgical treatments. In chronic and other hard-to-heal wounds, we expect to face competition from other debriding agents and wound bed preparation techniques, such as topical medication, mechanical debridement and surgery. With respect to the treatment of connective tissue disorders, our primary competitor, if and when we enter this market, will likely be Auxulium Pharmaceuticals, Inc., which produces Xiaflex, a collagenase-based drug for the treatment of Dupuytren's and Peyronie's diseases. Xiaflex has received marketing approval in the United States for such indications and in the European Union, under the name Xiapex, for Dupuyten's disease. Additionally, in the United States, Xiaflex has orphan designation for treatment of bupuytren's diseases. Accordingly, if considered as a similar product, we may not be permitted to market a product that competes with Xiaflex in the United States for such indications until the expiration of its orphan market exclusivity period, which we believe occurs in 2017 and 2023 for Dupuytren's and Peyronie's diseases, respectively. We also cannot confirm at this stage of development that our pipeline products, if approved, will be superior or comparable to Xiaflex. See "—Government Regulation—United States—Orphan Designation and Exclusivity."

In addition to the currently available products, other products may be introduced to debride chronic and other hard-to-heal wounds or treat connective tissue disorders during the time that we engage in necessary development. Accordingly, if one of our pipeline products is approved, our main challenge in the market would be to convince physicians seeking alternatives to surgery to use our product instead of already existing treatments. While we are still in the preliminary stages, based on

our studies, we believe that our pipeline products will be more effective than the current non-surgical alternatives and less invasive than surgery in removing eschar in chronic and other hard-to-heal wounds and may be comparable or perhaps better than currently available treatments for connective tissue disorders.

## **Government Regulation**

Our business is subject to extensive government regulation. Regulation by governmental authorities in the United States, the European Union and other jurisdictions is a significant factor in the development, manufacture and marketing of NexoBrid and in ongoing research and development activities. NexoBrid has completed the EMA's preclinical and clinical trials and other pre-marketing approval requirements and received marketing authorization for the European Union on December 18, 2012. Our pipeline products would also have to complete such steps in the European Union. Additionally, we must also complete the approval processes in the United States and other jurisdictions in order to market NexoBrid or our pipeline products.

### European Union

The approval process of medicinal products in the European Union generally involves satisfactorily completing each of the following:

- laboratory tests, animal studies and formulation studies all performed in accordance with the applicable E.U. GLP or GMP regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting
  preclinical and clinical safety and efficacy as well as detailed information on the manufacture and composition and control of the product
  development and proposed labeling as well as other information;
- inspection by the relevant national authorities of the manufacturing facility or facilities and quality systems (including those of third parties) at which the product is produced, to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

### Quality/Preclinical studies

In order to assess the potential safety and efficacy of a product, tests include laboratory evaluations of product characterization, analytical tests and controls, as well as studies to evaluate toxicity and pharmacological effects in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant E.U. regulations and requirements. The results of such tests, together with relevant manufacturing control information and analytical data, are submitted as part of the CTA.

## Clinical trial approval

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of a European Union member state in which a study is planned to be conducted. To this end, a CTA is

submitted, which must be supported by an investigational medicinal product dossier and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

Clinical drug development is often described as consisting of four temporal phases (Phase 1-4), see for example EMA's note for guidance on general considerations for clinical trials (CPMP/ICH/291/95).

- Phase 1 (Most typical kind of study: Human Pharmacology);
- Phase 2 (Most typical kind of study: Therapeutic Exploratory);
- Phase 3 (Most typical kind of study: Therapeutic Confirmatory); and
- Phase 4 (Variety of Studies: Therapeutic Use).

Studies in Phase 4 are all studies (other than routine surveillance) performed after drug approval and are related to the approved indication.

The phase of development provides an inadequate basis for classification of clinical trials because one type of trial may occur in several phases. The phase concept is a description, not a set of requirements. The temporal phases do not imply a fixed order of studies since for some drugs in a development plan the typical sequence will not be appropriate or necessary.

#### Pediatric Investigation Plans

We have agreed and are consulting with the EMA on a PIP design for NexoBrid and expect to commence a PIP study in the second half of 2014.

On January 26, 2007, Regulation (EC) 1901/2006 came into force with its primary purpose being the improvement of the health of children without subjecting children to unnecessary trials, or delaying the authorization of medicinal products for use in adults. The regulation established the Pediatric Committee, or PDCO, which is responsible for coordinating the EMA's activities regarding pharmaceutical drugs for children. The PDCO's main role is to determine which studies the applicant needs to perform in the pediatric population as part of the PIP.

All applications for marketing authorization for new pharmaceutical products that were not authorized in the E.U. prior to January 26, 2007 have to include the results of studies carried out in children of different ages. The PDCO determines the requirements and procedures of such studies, describing them in a PIP. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PDCO can grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO can also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA confirms that the applicant complied with the studies' requirements and measures listed in the PIP. Since the regulation became effective, several incentives for the development of medicines for children become available in the E.U., including:

- medicines that have been authorized for marketing in the E.U. with the results of PIP studies included in the product information are eligible for an extension of their patent protection by six months. This is the case even when the studies' results are negative;
- for orphan medicines, such as NexoBrid, the incentive is an additional two years of market exclusivity instead of one;
- scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of medicines for children; and

medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate, can apply for a pediatric use marketing authorization, or PUMA. If a PUMA is granted, the product will benefit from 10 years of market protection as an incentive.

### Marketing authorization

Authorization to market a product in the European Union member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. A marketing authorization may be granted only to an applicant established in the European Union. We received, through our wholly-owned German subsidiary, approval for NexoBrid pursuant to the centralized authorization procedure.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases, and is optional for those products that are highly innovative or for which a centralized process is in the interest of patients. Products that have received orphan designation in the European Union, such as NexoBrid, will qualify for this centralized procedure, under which each product's marketing authorization application is submitted to the EMA. Under the centralized procedure in the European Union, the maximum time frame for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Scientific Advice Working Party of the Committee of Medicinal Products for Human Use).

In general, if the centralized procedure is not followed, there are three alternative procedures:

- Mutual recognition procedure. If an authorization has been granted by one member state, or the Reference Member State, an application may be made for mutual recognition in one or more other member states, or the Concerned Member State(s).
- Decentralized procedure. The decentralized procedure may be used to obtain a marketing authorization in several European member states when the applicant does not yet have a marketing authorization in any country.
- National procedure. Applicants following the national procedure will be granted a marketing authorization that is valid only in a single member state. Furthermore, this marketing authorization is not based on recognition of another marketing authorization for the same product awarded by an assessment authority of another member state. If marketing authorization in only one member state is preferred, an application can be filed with the national competent authority of a member state. The national procedure can also serve as the first phase of a mutual recognition procedure.

It is not always possible for applicants to follow the national procedure. In the case of medicinal products in the category for which the centralized authorization procedure is compulsory, that procedure must be followed. In addition, the national procedure is not available in the case of medicinal product dossiers where the same applicant has already obtained marketing authorization in one of the other European Union member states or has already submitted an application for marketing authorization in one of the other member states and the application is under consideration. In the latter case, applicants must follow a mutual recognition procedure.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

#### Period of authorization and renewals

Marketing authorization shall be valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder shall provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the U.S. Securities and Exchange Commission, or the Commission, or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid.

### Orphan Designation

On July 31, 2002, NexoBrid received orphan drug status in the European Union, and on December 20, 2012, the EMA confirmed NexoBrid's designation as an orphan drug for marketing authorization.

In the European Union, the Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition affecting not more than five in 10,000 persons in the European Union community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product.

In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or a safer, more effective or otherwise clinically superior product is available.

Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

#### Regulatory data protection

Without prejudice to the law on the protection of industrial and commercial property, all applications for marketing authorization receive an 8+2+1 protection regime. This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of ten years plus an additional market exclusivity of one further year if, during the first eight years of those ten years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the original sponsor beginning eight years after first approval, but the third party may market a generic version only after ten (or eleven) years have lapsed.

Additional data protection can be applied for when an applicant has complied with all requirements as set forth in an approved PIP.

### Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its cGMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

#### Marketing and promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Community, notably under Directive 2001/83 in the European Community code relating to medicinal products for human use, as amended by Directive 2004/27. The applicable regulation aims to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

#### **United States**

#### Review and Approval of Biologics

In addition to regulations in the European Union, NexoBrid is an investigational drug in the United States and subject to various regulations. In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act and implementing regulations and other laws, including the Public Health Service Act. On March 24, 2011, the FDA classified NexoBrid as a biological product. Biologics require the submission of a BLA and approval by the FDA prior to being marketed in the United States. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. 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 BLAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning 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.

The process required by the FDA prior to marketing and distributing a biologic in the United States generally involves the following:

- completion of laboratory tests, animal studies and formulation studies in compliance with the FDA's GLP or GMP regulations, as applicable;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;



- performance of adequate and well-controlled clinical trials in accordance with GCP to establish the safety and efficacy of the product for each indication;
- preparation and submission to the FDA of a BLA or supplemental BLA;
- 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 cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and
- payment of user fees and FDA review and approval of the BLA.

We commenced the process of seeking FDA approval for NexoBrid for the removal of eschar in adults with severe burns by submitting an IND briefing package to the FDA on July 30, 2002.

### Preclinical Studies

Preclinical studies include laboratory evaluation, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests must be conducted in compliance with FDA regulations regarding good laboratory practices. The results of the preclinical tests, 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 be commenced.

## Clinical Trials in Support of a BLA

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 study protocols detailing, among other things, the objectives of the study, 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 thirty 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, 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 and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

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

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

We intend to initiate a Phase 3 pivotal study for NexoBrid in the United States in the first half of 2014.

# Submission of a BLA to the FDA

In the United States, we intend to initiate a Phase 3 pivotal study for NexoBrid to support a BLA submission to the FDA. The results of the preclinical 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 a BLA 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 a BLA. These user fees, as well as the annual fees required for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed \$500,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within forty-five to sixty days following submission of the application. If found complete, the FDA will "file" the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of BLA applications and original efficacy supplements given Priority status within six months and 90% of applications and original efficacy supplements given is to be made. The FDA, however, may not approve a biologic 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 an "action letter" that describes additional work that must be completed before the application can be approved.

Before approving a BLA, the FDA generally 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. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or may never be granted. 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, and may require that additional studies 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.

Once a product is approved, marketing the product for other indicated uses or making certain manufacturing or other changes requires FDA review and approval of a supplement BLA or a new



BLA, which may require additional clinical data. In addition, further post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

#### Post-Approval Requirements

Any drug or biologic products for which we receive FDA approvals are 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, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in 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, 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.

The manufacturing of NexoBrid and our pipeline products is and will be required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. NexoBrid is manufactured at our production plant in Yavne, Israel, which is cGMP certified. 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 and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics 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 BLA, 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 4 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 NexoBrid.

## Orphan Designation and Exclusivity

On August 20, 2003, NexoBrid received orphan drug status in the United States. Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a BLA. If the request is granted, FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation entitles a party to seven years of market exclusivity following drug or biological product approval, but does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product will be entitled to orphan product exclusivity. Orphan product exclusivity means that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than that designated in its orphan product application, it may not be entitled to exclusivity.

### Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are 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 enactment of the Food and Drug Administration Safety and Innovation Act, or the FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study 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. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation. Accordingly, if NexoBrid is approved by the FDA for adults, it will be exempt from such requirements upon expanding its indication to children. However, our pipeline products may be subject to such requirements.

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 regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written

request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application.

### Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act,", which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date of a BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of fourteen 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 United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

### Biosimilar products

As part of the Patient Protection and Affordable Care Act of 2010, Public Law No. 111-148, under the subtitle of Biologics Price Competition and Innovation Act of 2009, or BPCI, a statutory pathway has been created for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products licensed under the Public Health Service Act. Also under the BPCI, innovator manufacturers of original reference biological products are granted twelve years of exclusive use before biosimilars can be approved for marketing in the United States. There are current legislative proposals to shorten this period from 12 years to seven years. The objectives of the BPCI are conceptually similar to those of the Hatch-Waxman Act, which established abbreviated pathways for the approval of drug products. The implementation of an abbreviated approval pathway for biological product is under the direction of the FDA and is currently being developed. In February 2012, the FDA published draft guidance documents on biosimilar product development. A biosimilar is defined in these documents as a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of safety, purity and potency. Under this proposed approval pathway, biological products are approved based on demonstrating they are biosimilar to, or interchangeable with, a biological product that is already approved by the FDA, which is called a reference product. The approval of a biologic product biosimilar to NexoBrid could have a materially adverse impact on our business, may be significantly less costly to bring to the market and may be priced significantly lower than NexoBrid, but such approval may only occur after our twelve-year exclusivity period.

#### Review and Approval of Drug Products Outside the European Union and the United States

In addition to the above regulations, we must obtain approval of a product by the comparable regulatory authorities of foreign countries outside of the European Union and the United States before we can commence clinical trials or marketing of NexoBrid in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA or

EMA approval. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In all cases, clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

## 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 products for which we receive regulatory approval for commercial sale will depend in part on the availability of 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 NexoBrid, in addition to the costs required to obtain the FDA approvals. Additionally, NexoBrid 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 one of the most significant healthcare reform measures in decades. The healthcare reform law substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The comprehensive \$940 billion dollar overhaul is expected to extend coverage to approximately 32 million previously uninsured Americans. The healthcare reform law contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact 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 healthcare reform law, as limited by the United States Supreme Court's decision in June 2012:

- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

There have been proposed in Congress a number of legislative initiatives regarding healthcare, including possible repeal of the healthcare reform law. At this time, it remains unclear whether there will be any changes made to the healthcare reform law, whether to certain provisions or its entirety.

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 that compare the cost-effectiveness of a particular drug 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, increasingly high barriers are being erected to the entry of 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 Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, third-party payors and other customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for 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 or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme
  to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act 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 false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices and medical supplies to
  report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and
  teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal



government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern 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.

## **Property and Infrastructure**

Our principal executive offices are located at 42 Hayarkon Street, Yavne 8122745, Israel. We lease these facilities from our largest shareholder, Clal Life Sciences L.P., pursuant to a sublease agreement, as amended, with a term of two years that expires on December 31, 2015, with an option to extend the term for two one-year periods. The facilities consist of approximately 10,764 square feet of space, and lease payments are approximately \$38,600 per month. These facilities house our administrative headquarters, our research and development laboratories and our manufacturing plant.

We also lease offices at Eisenstrasse 5, 65428 Rüsselsheim, Germany. We lease these facilities pursuant to a lease agreement with a term of three years that expires on April 30, 2016. The facilities consist of approximately 2,670 square feet of space, and lease payments are approximately  $\epsilon$ 2,692 (or \$3,698) per month. These facilities house our offices for our German sales and marketing team.

#### **Environmental, Health and Safety Matters**

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily Israel, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, 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 Yavne manufacturing 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.

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 2012 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.

### Legal and Corporate Structure

Our legal and commercial name is MediWound Ltd. We were formed as a company in the State of Israel on January 27, 2000.

Our corporate structure consists of MediWound Ltd., our Israeli parent company, (i) MediWound Germany GmbH, our active wholly-owned subsidiary, which was incorporated on April 16, 2013 under the laws of the Federal Republic of Germany, and (ii) MediWound UK Limited, our inactive wholly-owned subsidiary, which was incorporated on July 26, 2004 under the laws of England. We also hold a 7.5% ownership interest of Polyheal Ltd., although Polyheal Ltd. has a repurchase right exercisable until March 2014.

## Employees

As of December 31, 2013, we had 43 employees, 40 based in Israel and three based in Germany. The total number of our full-time employees and the distribution of our employees according to main areas of activity, as of the end of each of the last three years, are set forth in the following table:

		Number of full-time employees by area of activity as of December 31,		
	2011	2012	2013	
Area of Activity				
Administrative	4	5	6	
Research and development	10	9	10	
Manufacturing	16	19	19	
Sales and marketing	0	1	8	
Total	30	34	43	

During the periods covered by the above tables, we did not employ a significant number of temporary employees.

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While none of our employees is party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees in Israel by order of the Israeli Ministry of the Economy. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. We generally provide our employees with benefits and working conditions beyond the required minimums.

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

## Legal Proceedings

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any legal proceedings that could reasonably be expected to have a material adverse effect on our business, prospects, financial condition or results of operations. We may become involved in material legal proceedings in the future.

## MANAGEMENT

### **Executive Officers and Directors**

The following table sets forth information relating to our executive officers and directors as of the date of this prospectus. Unless otherwise stated, the address for our directors and executive officers is c/o MediWound Ltd., 42 Hayarkon Street, Yavne 8122745, Israel.

Name	Age	Position
Executive Officers		
Gal Cohen	41	President and Chief Executive Officer
Sharon Malka	41	Chief Financial and Operation Officer
Lior Rosenberg M.D.	68	Chief Medical Officer and Director
Sigal Aviel Ph.D	50	Chief Research and Development Officer
Carsten Henke	48	Managing Director of MediWound Germany GmbH
Yaron Meyer	35	General Counsel
Directors		
Ruben Krupik		Chairman of the Board of Directors
Ofer Gonen	40	Director
Marian Gorecki Ph.D		Director
Meron Mann		Director

# **Our Executive Officers**

*Gal Cohen* has served as our President and Chief Executive Officer since November 2006. From 2004 to 2006, Mr. Cohen served as Director of Strategic Business Planning and New Ventures at Teva Pharmaceutical Industries Ltd., or Teva, a public Israeli pharmaceutical company. He also launched Copaxone in Europe and the United States while he served as Projects Manager for Teva's Global Products Division from 2000 to 2004 and for its Corporate Industrial Engineering Department from 1998 to 2000. Mr. Cohen holds a B.Sc. in Industrial Engineering and Management (cum laude) from the Technion—Israel Institute of Technology and an M.B.A. (cum laude) from Tel Aviv University.

Sharon Malka has served as our Chief Financial and Operation Officer since April 2007. From 2002 to 2007, Mr. Malka was a partner at Variance Economic Consulting Ltd., a multi-disciplinary consulting boutique that specializes in financial and business services. Mr. Malka also served as a Senior Manager at Kesselman Corporate Finance, a division of PricewaterhouseCoopers Global Network, from 1998 to 2002. Mr. Malka holds a B.Sc. in Business Administration from the Business Management College in Israel and an M.B.A. from Bar Ilan University, Israel.

*Lior Rosenberg* is one of our co-founders and has served as our Chief Medical Officer and a member of our board of directors since 2001. Since 2001, Dr. Rosenberg has headed the unit for Cleft Lip Palate and Craniofacial Deformities at Soroka University Medical Center and Meir Medical Centers in Beer Sheva and Kfar Saba, Israel, respectively. Since 1987, he has served as a Professor of plastic surgery at the Ben-Gurion University Medical School in Beer Sheva, Israel. He also serves as the Chairman of the Burn Disaster Committees for the International Society of Burn Injuries and the Israeli Ministry of Health. From 1987 to 2012, Dr. Rosenberg served as the chairman of the Department of Plastic Surgery and Burn Unit at Soroka University Medical Center in Beer Sheva, Israel. He is a founding member of the Israeli Burn Association and the Mediterranean Burn Council, a member of the American Burn Association and a national representative at the European Burn Association. Dr. Rosenberg holds a M.D. degree from Tel-Aviv University, Israel and a Professor of Plastic Surgery degree from the Ben Gurion University, Israel.

Sigal Aviel has served as our Chief Research and Development Officer since March 2013. From 2010 to March 2013, Dr. Aviel served as Vice President of Regulation and Clinical Affairs at Biokine



Therapeutics Ltd., a private Israeli company focused on research and development of drugs for cancer patients. From 2005 to 2010, Dr. Aviel served as Senior Director of Research at Protalix Biotherapeutics, Inc., a public Israeli company focused on the development and manufacturing of recombinant therapeutic proteins. Dr. Aviel holds a B.Sc. in Biology from Tel Aviv University, Israel, a Kellogg-Recanati Executive M.B.A. from Tel Aviv University, Israel and Northwestern University, Chicago, Illinois, and a Ph.D. in Immunology and Microbiology from Duke University Medical Center.

*Carsten Henke* has served as the Managing Director of our wholly-owned subsidiary, MediWound Germany GmbH, since July 2013. From February 2009 to December 2012, Mr. Henke served as Teva's General Manager in Spain, and from January 2004 to January 2009, he served as Teva's Director of Marketing and Sales in Germany. Mr. Henke holds a B.Sc. in European Management from the ESB Business School at Reutlingen University and a Graduado Superior in International Business Administration—E-4 from Comillas Pontifical University ICAI—ICADE in Madrid, Spain.

*Yaron Meyer* has served as our General Counsel since December 2013. From April 2008 to November 2013, he served as the corporate secretary of Clal Biotechnology Industries Ltd. or CBI. From November 2010 to November 2013, he served as the general counsel and corporate secretary of D-Pharm Ltd. From April 2008 to May 2010, he served as a legal counsel of Clal Industries Ltd. From May 2005 to April 2008, he worked as an associate at Shibolet & Co. Advocates. Mr. Meyer holds an LL.B. degree from Haifa University, Israel.

#### Directors

*Ruben Krupik* has served as Chairman of our board of directors since 2003. Mr. Krupik is the Chief Executive Officer of CBI, an Israeli public holding company, traded on the TASE, specializing in investments in biotechnology and medical device companies. Mr. Krupik has served as the Chief Executive Officer of ARTE Venture Group Ltd., a management investment firm, since 2003. Mr. Krupik also currently serves on the board of directors of several Israeli companies, including CureTech Ltd., a biotechnology company. He previously served as Chairman of BioCancell Therapeutics Inc. from 2011 to 2012 and D-Pharm Ltd. from 2003 to 2012. Mr. Krupik holds a B.A. in Economics and Political Science from the Hebrew University of Jerusalem and an L.L.B. from Tel Aviv University, Israel.

*Ofer Gonen* has served as a member of our board of directors since September 2003. Mr. Gonen is also the Vice President of CBI. Since 2003, he has been a Partner at ARTE Venture Group Ltd. and has served as the Managing Director of Biomedical Investments and as Chairman of PolyHeal. He also currently serves on the board of directors of Andromeda Biotech Ltd., CureTech Ltd., D-Pharm Ltd., Avraham Pharmaceuticals Ltd. and Clal Life Sciences L.P. Mr. Gonen is a veteran of Talpiot, a prestigious unit of the Israel Defense Forces, and was awarded the Israeli National Security Medal. Mr. Gonen holds a B.Sc. in Physics, Mathematics and Chemistry from the Hebrew University of Jerusalem and an M.A. in Economics and Finance from Tel Aviv University, Israel.

*Marian Gorecki* is one of our co-founders and has served as a member of our board of directors since 2007. From 2000 to 2007, Dr. Gorecki served as our Chief Executive Officer and Chief Scientific Officer. Dr. Gorecki has also served as a Clinical Advisor of PolyHeal since 2005. From 2000 to 2008, he served as a consultant to Clal. Dr. Gorecki has served as Chairman of Thrombotech Technologies Ltd., an Israeli biotechnology company, since 2008 and currently serves on the board of directors of PROLOR Biotech, Inc., a biopharmaceutical company. From November 2005 to March 2011, Dr. Gorecki served on the board of directors of SciGen Ltd., a biotechnology company developing, manufacturing, and marketing biopharmaceuticals, where he was also Chairman of the Scientific Advisory Board. Dr. Gorecki was a Senior Research Scientist and an Associate Professor at the Weizmann Institute of Science from 1982 to 1986. Dr. Gorecki holds a B.Sc. and an M.Sc. in Chemistry from the Technion—Israel Institute of Technology, Israel and a Ph.D. in Biochemistry from

the Weizmann Institute of Science and was a post graduate fellow in the Biology Department at the Massachusetts Institute of Technology.

*Meron Mann* has served as a member of our board of directors since August 2007. From 2008 to 2010, he served as Chairman of Elcon Recycling Center Ltd., an Israeli industrial wastewater treatment service provider, and since 2010, he has served as one of its directors. Additionally, he currently serves as Chairman of Plastmed Ltd., an Israeli medical device company since 2008, Equashield Ltd., an Israeli medical device company since 2010 and KB Recycling Industries Ltd., a private Israeli company providing environment services, since 2013. Mr. Mann also serves on the board of directors of Kast Silicone Ltd., a silicone manufacturing and development company, and CaridoDex Ltd., a medical device company, since 2010 and Medical Compression System (DBN) Ltd., an Israeli biotechnology company since 2011. From 2002 to 2006, Mr. Mann served as Group Vice President of Europe of Teva Pharmaceutical Finance LLC and Teva. Mr. Mann holds a B.Sc. in Industrial and Management Engineering from Tel Aviv University, Israel, and an M.Sc. in Industrial Engineering from the Techniom—Israel Institute of Technology, Israel.

### Arrangements Concerning Election of Directors; Family Relationships

Our current board of directors consists of five directors. Currently-serving directors (other than external directors) that were appointed prior to this offering will continue to serve pursuant to their appointment until the first annual meeting of shareholders held after this offering. We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

## **Corporate Governance Practices**

After the completion of this offering, we will be a "controlled company" under the Nasdaq Stock Market 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. We will be a controlled company on the basis of Clal Biotechnology Industries Ltd.'s ownership in our company immediately following the offering. Pursuant to the "controlled company" exemption, we are not required and currently do not intend to comply with the requirements that we have a nominating committee composed entirely of independent directors. In the event that we cease to be a controlled company, we will be required to comply with this provision within the transition periods specified in the Nasdaq Stock Market rules, unless we elect to avail ourselves of the exemption from Nasdaq Stock Market rules afforded to foreign private issuers, as discussed below.

The "controlled company" exemption does not modify the independence requirements for our audit committee. Accordingly, immediately following this offering, we will have an audit committee comprised of at least three members all of whom meet the Nasdaq Stock Market independence requirements and which must include all of the external directors and consist of a majority of "unaffiliated directors" as defined under the Israeli Companies Law. See "—Audit Committee—Israeli Companies Law Requirements." Furthermore, while we are exempt under the "controlled company" exemption from the requirement under the NASDAQ Stock Market rules that we have a compensation committee which consists solely of independent directors, under the Israeli Companies Law, we are required to have a compensation committee consisting of three members, including all of the external directors, who must constitute a majority of the members of the compensation committee.

In addition to the controlled company exemption, as a foreign private issuer, companies incorporated under the laws of the State of Israel, whose shares are publicly traded, including companies with shares listed on the NASDAQ Global Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee and an internal auditor. This is the case even if our shares are not listed on the Tel Aviv Stock Exchange. These requirements are in

addition to the corporate governance requirements imposed by the NASDAQ Stock Market rules and other applicable provisions of U.S. securities laws to which we will become subject (as a foreign private issuer) upon the closing of this offering and the listing of our ordinary shares on the NASDAQ Global Market. Under the NASDAQ Stock Market rules, a foreign private issuer, such as us, may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the NASDAQ Stock Market rules, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the Commission.

We intend to rely on this "home country practice exemption" with respect to the quorum requirements. As permitted under the Israeli Companies Law pursuant to our amended and restated articles of association to be effective upon the closing of this offering, the quorum required for an ordinary meeting of shareholders will consist of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Israeli Companies Law, who hold at least 25% of the voting power of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of  $33^{1}/3\%$  of the issued share capital required under the NASDAQ Stock Market rules.

We otherwise 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 controlled company exemption or foreign private issuer opt-out with respect to some or all of the other NASDAQ Stock Market rules.

# **Board Practices**

#### **Board of Directors**

Under the Israeli Companies Law, the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors, subject to the employment agreement that we have entered into with him. All other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our amended and restated articles of association to be effective upon the closing of this offering, our board of directors must consist of at least five and not more than nine directors, including at least two external directors required to be appointed under the Israeli Companies Law. At any time the minimum number of directors (other than the external directors) shall not fall below three. Our board of directors will consist of directors upon the closing of this offering, including new directors and external directors whose service will commence upon the completion of this offering. The appointment of the external directors, for whom special election requirements apply under the Israeli Companies Law, as detailed below, the Israeli Companies Law and our amended and restated articles of association provide that directors are elected annually at the general meeting of our shareholders by a vote of the holders of a majority of the voting power represented present and voting, in person or by proxy, at that meeting. We have only one class of directors.

Upon the closing of this offering, we will comply with the rule of the NASDAQ Stock Market that a majority of our directors are independent. Our board of directors has determined that of our directors are independent under such rules. The definition of "independent director" under the NASDAQ Stock Market rules and "external director" under the Israeli Companies Law overlap to a significant degree such that we would generally expect the two directors serving as external directors to

satisfy the requirements to be independent under the NASDAQ Stock Market rules. However, it is possible for a director to qualify as an "external director" under the Israeli Companies Law without qualifying as an "independent director" under the NASDAQ Stock Market rules, or vice-versa. The definition of external director under the Israeli Companies Law includes a set of statutory criteria that must be satisfied, including criteria whose aim is to ensure that there is no factor that would impair the ability of the external director to exercise independent judgment. The definition of independent director under the NASDAQ Stock Market rules specifies similar, if slightly less stringent, requirements in addition to the requirement that the board of directors consider any factor which would impair the ability of the independent director to exercise independent judgment. In addition, external directors serve for a period of three years pursuant to the requirements of the Israeli Companies Law. However, external directors must be elected by a special majority of shareholders while independent directors may be elected by an ordinary majority. See "—External Directors" for a description of the requirements under the Israeli Companies Law for a director.

In accordance with the exemption available to foreign private issuers under NASDAQ rules, we do not intend to follow the requirements of the NASDAQ rules with regard to the process of nominating directors, and instead, will follow Israeli law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election.

Under the Israeli Companies Law and our amended and restated articles of association, nominees for directors may also be proposed by any shareholder holding at least one percent (1%) of our outstanding voting power. However, any such shareholder may propose a nominee only if a written notice of such shareholder's intent to propose a nominee has been given to our Secretary (or, if we have no such Secretary, our Chief Executive Officer). Any such notice must include certain information, including, among other things, a description of all arrangements between the nominating shareholder and the proposed director nominee(s) and any other person pursuant to which the nomination(s) are to be made by the nominating shareholder, the consent of the proposed director nominee(s) to serve as our director(s) if elected and a declaration signed by the nomine(s) declaring that there is no limitation under the Israeli Companies Law preventing their election, and that all of the information that is required under the Israeli Companies Law to be provided to us in connection with such election has been provided.

In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) have been vacated. External directors are elected for an initial term of three years and may be elected for additional three-year terms under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Israeli Companies Law. See "—External Directors."

Under the Israeli Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. See "-External Directors" below. In determining the number of directors required to have such expertise, our 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 the minimum number of directors of our company who are required to have accounting and financial expertise is one.

## **External Directors**

Under the Israeli Companies Law, we are required to include at least two members who qualify as external directors. and have agreed to serve as our external directors following the closing of this offering, subject to ratification at a meeting of our shareholders to be held no later than three months following the closing of this offering.

The provisions of the Israeli Companies Law set forth special approval requirements for the election of external directors. External directors must be elected by a majority vote of the shares present and voting at a meeting of shareholders, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions, to which we refer as a disinterested majority; or
- the total number of shares voted by non-controlling shareholders and by shareholders who do not have a personal interest in the election of the external director against the election of the external director does not exceed two percent (2%) of the aggregate voting rights in the company.

The term "controlling shareholder" is defined in the Israeli Companies Law as 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 be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its general manager. With respect to certain matters, a controlling shareholder is deemed to include a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company, but excludes a shareholder whose power derives solely from his or her position as a director of the company or from any other position with the company.

The initial term of an external director is three years. Thereafter, an external director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, provided that either:

- (i) 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, provided that the external director and certain of his or her related parties meet additional independence requirements; 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).

The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Global Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the reelection of the external director at a general meeting of shareholders, the company's shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

External directors may be removed from office by a special general meeting of shareholders called by the board of directors, which approves such dismissal by the same shareholder vote percentage required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualifications for appointment, or violating their duty of loyalty to the company.

If an external directorship becomes vacant and there are fewer than two external directors on the board of directors at the time, then the board of directors is required under the Israeli Companies Law to call a shareholders' meeting as soon as practicable to appoint a replacement external director.

Each committee of the board of directors that exercises the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must include all external directors then serving on the board of directors. Under the Israeli Companies Law, external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than for their services as external directors pursuant to the Israeli Companies Law and the regulations promulgated thereunder. Compensation of an external director is determined prior to his or her appointment and may not be changed during his or her term subject to certain exceptions.

The Israeli Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of a controlling shareholder of the company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subordinate, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation or other disqualifying relationship with the company, with any person or entity controlling the company or a relative of such person, or with any entity controlled by or under common control with the company; or (b) in the case of a company with no shareholder holding 25% or more of its voting rights, had at the date of appointment as an external director, any affiliation or other disqualifying relationship with a person then serving as chairman of the board or chief executive officer, a holder of 5% or more of the issued share capital or voting power in the company or the most senior financial officer.

The term "relative" is defined under the Israeli Companies Law as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons.

Under the Israeli Companies Law, the term "affiliation" and the similar types of disqualifying relationships include (subject to certain exceptions):

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder, excluding service as a director in a private company prior to the initial public offering of its shares 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 "office holder" is defined under the Israeli Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person's title, a director and any other manager directly subordinate to the general manager.

In addition, no person may serve as an external director if that person's position or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the Israel Securities Authority or an Israeli stock exchange. A person may furthermore not continue to serve as an external director if he or she received direct or indirect compensation from the company including amounts paid pursuant to indemnification or exculpation contracts or commitments and insurance coverage for his or her service as an external director, other than as permitted by the Israeli Companies Law and the regulations promulgated thereunder.

Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not be provided a direct or indirect benefit by the company, its controlling shareholder or any entity under its controlling shareholder's control. This includes engagement as an office holder or director of the company or a company controlled by its controlling shareholder or employment by, or provision of services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by the former external director. This restriction extends for a period of two years with regard to the former external director and his or her spouse or child and for one year with respect to other relatives of the former external director.

If at the time at which an external director is appointed all members of the board of directors who are not controlling shareholders or relatives of controlling shareholders of the company are of the same gender, the external director to be appointed must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

According to regulations promulgated under the Israeli Companies Law, a person may be appointed as an external director only if he or she has professional qualifications or if he or she has accounting and financial expertise (each, as defined below). In addition, at least one of the external directors must be determined by our board of directors to have accounting and financial expertise. However, if at least one of our other directors (i) meets the independence requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act, (ii) meets the standards of the NASDAQ Stock Market rules for membership on the audit committee, and (iii) has accounting and financial expertise as defined under the Israeli Companies Law, then neither of our external directors is required to possess accounting and financial expertise as long as each possesses the requisite professional qualifications.

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, possesses an expertise in, and an understanding of, financial and accounting matters and financial statements, such that he or she is able to understand the financial statements of the company and initiate a discussion about the presentation of financial data. A director is deemed to have professional qualifications if he or she has any of (i) an academic degree in economics, business management, accounting, law or public administration, (ii) an academic degree or has completed another form of higher education in the primary field of business of the company or in a field which is relevant to his/her position in the company, or (iii) at least five years of experience serving in one of the following capacities; 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 significant volume of business; (b) a senior position in the company's primary field of busines; or (c) a senior position in public administration or service. The board of directors is charged with determining whether a director possesses financial and accounting expertise or professional qualifications.

Our board of directors has determined that has accounting and financial expertise and possesses professional qualifications as required under the Israeli Companies Law.

# Leadership Structure of the Board

In accordance with the Israeli Companies Law and our amended and restated articles of association, our board of directors is required to appoint one of its members to serve as chairman of the board of directors. Our board of directors has appointed Mr. Ruben Krupik to serve as chairman of the board of directors.

# **Board Committees**

## Audit Committee

# Israeli Companies Law Requirements

Under the Israeli Companies Law, we will be required to appoint an audit committee following the closing of this offering. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include the chairman of the board, a controlling shareholder of the company, a relative of a controlling shareholder, a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder, or a director who derives most of his or her income from a controlling shareholder. In addition, under the Israeli Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors. In general, an "unaffiliated director" under the Israeli Companies Law is defined as either an external director or as a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for the requirement (i) that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed for trading outside of Israel) and (ii) for accounting and financial expertise or professional qualifications; and
- he or she has not served as a director of the company for a period exceeding nine consecutive years. For this purpose, a break of less than two
  years in the service shall not be deemed to interrupt the continuation of the service.

#### NASDAQ Listing Requirements

Under the NASDAQ Stock Market rules, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

Following the listing of our ordinary shares on the NASDAQ Global Market, our audit committee will consist of , along with our two external director nominees, and . will serve as the chairman of the audit committee. Upon the closing of this offering, all members of our audit committee will meet the requirements for financial literacy under the applicable rules and regulations of the Commission, and the NASDAQ Stock Market rules. Our board of directors has determined that is an audit committee financial expert as defined by the Commission rules and has the requisite financial experience as defined by the NASDAQ Stock Market rules.

Each of the members of our audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and satisfies the independent director requirements under the NASDAQ Stock Market rules.

# Audit Committee Role

We expect that our board of directors will adopt an audit committee charter to be effective upon the listing of our shares on the NASDAQ Global Market that will set forth the responsibilities of the audit committee consistent with the rules and regulations of the Commission and the NASDAQ Stock Market rules, as well as the requirements for such committee under the Israeli Companies Law, including the following:

oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;

- recommending the engagement or termination of the person filling the office of our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Israeli Companies Law, our audit committee is responsible for:

- (i) determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under the Israeli Companies Law) (see "—Approval of Related Party Transactions under Israeli Law");
- establishing the approval process (including, potentially, the approval of the audit committee) for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest;
- (iv) where the board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board of directors and proposing amendments thereto;
- (v) examining our internal audit controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to fulfill his responsibilities;
- (vi) examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and
- (vii) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Our audit committee may not approve any actions requiring its approval (see "—Approval of Related Party Transactions under Israeli Law"), unless at the time of the approval a majority of the committee's members are present, which majority consists of unaffiliated directors including at least one external director.

### **Compensation Committee and Compensation Policy**

Following the listing of our ordinary shares on the NASDAQ Global Market our compensation committee will consist of and . will serve as the chairman of the compensation committee.

Under the Israeli Companies Law, the board of directors of a public company must appoint a compensation committee. The compensation committee must be comprised of at least three directors, including all of the external directors, who must constitute a majority of the members of the compensation committee. However, subject to certain exceptions, Israeli companies whose securities are

traded on stock exchanges such as the NASDAQ Global Market, and who do not have a controlling shareholder, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Israeli Companies Law composition requirements, as well as the requirements of the jurisdiction where the company's securities are traded. As we currently have a controlling shareholder, we are obligated to meet the majority requirement. Each compensation committee member who is not an external director must be a director whose compensation does not exceed an amount that may be paid to an external director. The compensation committee is subject to the same Israeli Companies Law restrictions as the audit committee as to who may not be a member of the compensation committee.

The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. That policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be brought for approval by the company's shareholders, which approval requires what we refer to as a Special Majority Approval for Compensation. A Special Majority Approval for Compensation requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (a) such majority includes 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 compensation arrangement; or (b) the total number of shares not exceed 2% of the company's aggregate voting rights. We will be required to adopt a compensation policy within nine months following our listing on the NASDAQ Global Market.

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, the company's business plan and its 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 knowledge, skills, expertise and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average compensation of the other employees of the company, including those employed through manpower companies;
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors;
- the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

the link between variable compensation and long-term performance and measurable criteria;

- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

The compensation committee is responsible for (a) recommending the compensation policy to a company's board of directors for its approval (and subsequent approval by its shareholders) and (b) duties related to the compensation policy and to the compensation of a company's office holders as well as functions previously fulfilled by a company's audit committee with respect to matters related to approval of the terms of engagement of office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than three (3) years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);
- recommending to the board of directors periodic updates to the compensation policy;
- assessing implementation of the compensation policy; and
- determining whether the compensation terms of the chief executive officer of the company need not be brought to approval of the shareholders.

### Compensation Committee Role

Our board of directors will adopt a compensation committee charter setting forth the responsibilities of the compensation committee, which include:

- the responsibilities set forth in the compensation policy;
- reviewing and approving the granting of options and other incentive awards to the extent such authority is delegated by our board of directors; and
- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

#### Internal Auditor

Under the Israeli Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an office holder (including a director) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on its behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. We intend to appoint an internal auditor following the closing of this offering.

# Approval of Related Party Transactions under Israeli Law

# Fiduciary Duties of Directors and Executive Officers

The Israeli Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "-Executive Officers and Directors" is an office holder under the Israeli Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the 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 any such action.

The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- · refrain from exploiting any business opportunity of the company to receive a personal gain 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.

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

The Israeli Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with 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. A personal interest includes an interest of any person in an action or transaction of a company, including a personal interest of such person's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the company.

A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction. Under the Israeli Companies Law, an extraordinary transaction is defined 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 a company's profitability, assets or liabilities.

If it is determined that an office holder has a personal interest in a transaction, approval by the board of directors is required for the transaction, unless the company's articles of association provide for a different method of approval. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the office holder that would otherwise be deemed a breach of his or her duty of loyalty. However, a company may not approve a transaction or action that is not in the company's interest or that is not performed by the office holder in good faith. An extraordinary transaction in which an office holder has a personal interest requires approval first by the company's audit committee and subsequently by the board of directors. The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors. If such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy, or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is further subject to a Special Majority Approval for Compensation. Arrangements by ordinary majority, in that order, and under certain circumstances, a Special Majority Approval for Compensation.

Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless the chairman of the relevant committee or board of directors (as applicable) determines that he or she should be present in order to present the transaction that is subject to approval. If a majority of the members of the audit committee or the board of directors (as applicable) has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

# Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. The approval of the audit committee, the board of directors and the shareholder so the company, in that order, is required for (a) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (b) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (c) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (d) the employment of a controlling shareholder or his or her relative who is not an office approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approves the transaction, excluding abstentions; or
- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the voting rights in the company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a Special Majority and the terms thereof may not be inconsistent with the company's stated compensation policy.

Pursuant to regulations promulgated under the Israeli Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors. Under these regulations, a shareholder holding at least 1% of the issued share capital of the company may require, within 14 days of the publication of such determinations, that despite such determinations by the audit committee and the board of directors, such transaction will require shareholder approval under the same majority requirements that would otherwise apply to such transactions.

We expect that following this offering, Clal Biotechnology Industries Ltd., which prior to this offering beneficially owned 65.3% of our ordinary shares, will be a controlling shareholder, although this status may change in the future.

### Shareholder Duties

Pursuant to the Israeli Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- 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.

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include a controlling shareholder, a shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and a shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Israeli Companies Law does not define the substance of the duty of fairness, 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.

## Exculpation, Insurance and Indemnification of Directors and Officers

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. 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 which will be effective upon the closing of

this offering include such a provision. A company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

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

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a 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 attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding, and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies 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; and
- a financial liability imposed on the office holder in favor of a third party.

Under the Israeli 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 harm 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 Israeli 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 certain office holders or under certain circumstances, also by the shareholders. See "—Approval of Related Party Transactions under Israeli Law."

Our amended and restated articles of association to be effective upon the closing of this offering will permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Israeli Companies Law.

We have obtained directors and officers liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, prior to the closing of this offering, we intend to enter into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association to be effective upon the closing of this offering and the Israeli Companies Law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. In the opinion of the Commission, however, indemnification of directors and office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

# **Code of Business Conduct and Ethics**

We intend to adopt a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the Commission. Upon the effectiveness of the registration statement of which this prospectus forms a part, the full text of the Code of Business Conduct and Ethics will be posted on our website at www.MediWound.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the Commission. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Business Conduct and Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

# **Compensation of Executive Officers and Directors**

The aggregate compensation paid and equity-based compensation and other payments expensed by us and our subsidiaries to our directors and executive officers with respect to the year ended December 31, 2013 was \$1.5 million. This amount includes approximately \$0.2 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 office holders, and other benefits commonly reimbursed or paid by companies in our industry. As of December 31, 2013, options to purchase 396,883 ordinary shares granted to our directors and executive officers were outstanding under our share option plan at a weighted average exercise price of \$22.91 per share. We do not have any written agreements with any director providing for benefits upon the termination of such director's relationship with our company or its subsidiaries.

#### Agreements with Executive Officers; Consulting and Directorship Services Provided by Directors

We have entered into written confidentiality, non-competition/solicitation and inventions assignment agreements with all of our executive officers. These agreements contain standard provisions for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. Our executive officers will not receive benefits upon the termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment, which varies for each individual. See "Certain Relationships and Related Party Transactions—Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" for additional information.

# **Share Incentive Plan**

In November 2003, we adopted our 2003 Israeli Share Option Plan, or the 2003 Plan. The 2003 Plan provides for the grant of options to our and our subsidiaries' directors, employees, officers, consultants and service providers, among others.

The initial reserved pool under the 2003 Plan was 450,000 ordinary shares and subsequently increased to a total of 850,000 ordinary shares. The 2003 plan expired on December 31, 2013. The 2003 Plan is administered by our board of directors or a committee designated by our board of directors, which determines, subject to Israeli law, the grantees of options, the terms of the options, including exercise prices, vesting schedules, acceleration of vesting, the type of option and the other matters necessary or desirable for, or incidental to the administration of the 2003 Plan. The 2003 Plan provides for the issuance of options under various tax regimes including, without limitation, pursuant to Sections 102 and 3(i) of the Israeli Income Tax Ordinance (New Version) 1961, or the Ordinance.

Section 102 of the Ordinance allows employees, directors and officers, who are not controlling shareholders and who are Israeli residents, to receive favorable tax treatment for compensation in the form of shares or options. Section 102 of the Ordinance 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. Section 102(b)(2) of the Ordinance, which provides the most favorable tax treatment for grantees, permits the issuance to a trustee under the "capital gains track." In order to comply with the terms of the capital gains track, all options granted under a specific plan and subject to the provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of such options and other shares received following any realization of rights with respect to such options, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant employee, director or officer. The trustee may not release these options or shares to the relevant grantee before the second anniversary of the registration of the options in the name of the trustee. However, under this track, we are not allowed to deduct an expense with respect to the issuance of the options or shares.

The 2003 Plan provides that options granted to our employees, directors and officers who are not controlling shareholders and who are considered Israeli residents are intended to qualify for special tax treatment under the "capital gains track" provisions of Section 102(b)(2) of the Ordinance. Our Israeli non-employee service providers and controlling shareholders may only be granted options under Section 3(i) of the Ordinance, which does not provide for similar tax benefits.

Options granted under the 2003 Plan are subject to vesting schedules and generally expire ten years from approval of the option and vest over a four-year period commencing on the date of grant, such that 25% of the granted options vest annually on each of the first, second, third and fourth anniversaries of the date of grant. In the event of termination of employment or services for reasons of disability or death, the grantee, or in the case of death, his or her legal successor, may exercise options that have vested prior to termination within a period of six months after the date of termination. If a

grantee's employment or service is terminated for cause, all of the grantee's vested and unvested options expire on the date of termination. If a grantee's employment or service is terminated for any other reason, the grantee may exercise his or her vested options within 90 days after the date of termination. Any expired or unvested options are returned to the pool for reissuance.

The 2003 Plan provides that in the event of a merger or consolidation of our company, or a sale of all, or substantially all, of our assets, the unexercised options outstanding may be assumed, or substituted for an appropriate number of shares of each class of shares or other securities as were distributed to our shareholders in connection with such transaction and the exercise price will be appropriately adjusted. If not so assumed or substituted, all non-vested and non-exercised options will expire upon the closing of the transaction. Our board of directors or its designated committee, as applicable, may provide in the option agreement that if the acquirer does not agree to assume or substitute the options, vesting of the options shall be accelerated so that any unvested option or any portion thereof will vest 10 days prior to the closing of directors or the designated committee, as applicable, may, with the approval of the acquirer, provide that in lieu of the assumption or substitution of the options, the options will be substituted by another type of asset or property, including cash.

The following table presents certain data for our 2003 Plan as of December 31, 2013.

Plan	Total of ordinary shares reserved for option grants	Shares available for future option grants	Aggregate number of options exercised	Aggregate number of options outstanding	Weighted average exercise price of options outstanding	
2003 Israeli Share Option Plan	915,308	224,720	65,308	625,280	\$ 25.49	
		119				

# PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of the date of this prospectus and after this offering by:

- each person or entity known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors and executive officers individually; 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 Commission and generally includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table below, we deem ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of February 14, 2014 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 3,951,051 ordinary shares outstanding as of February 14, 2014. 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.

As of February 14, 2014, we were not aware of any U.S. persons that are holders of record of our shares. Additionally, all of our shareholders have identical voting rights.

Unless otherwise noted below, each shareholder's address is c/o MediWound Ltd., 42 Hayarkon Street, Yavne 8122745, Israel.

Name	Number and Percentage of Ordinary Shares Beneficially Owned Prior to Offering		Percenta Ordinary Beneficially O the Offe Assuming No Exercise of the Option to Purchase Additional Ordinary Shares	Shares wned After
5% or Greater Shareholders	Tumber	<u> </u>	Shares	Shares
Clal Biotechnology Industries Ltd.(1)	2,694,770	65.3%	%	%
Harel Insurance Investments & Financial Services Ltd.(2)	375,872	9.4%	%	%
Migdal Insurance and Finance Company Ltd.(3)	350,001	8.8%	%	%
Directors and Executive Officers				
Ruben Krupik	—	—	—	—
Ofer Gonen	—			—
Marian Gorecki(4)	152,224	3.7%	%	%
Meron Mann	*	*	*	*
Gal Cohen(5)	71,719	1.8%	%	%
Sharon Malka	*	*	*	*
Lior Rosenberg(6)	487,177	12.3%	%	%
Carsten Henke	—	—	—	—
Sigal Aviel		—		
Yaron Meyer	—	—	—	—
All Directors and Executive Officers as a Group (10 persons)	734,903	17.5%	%	%

- Less than 1%.
- (1) Consists of: (i) 2,160,256 ordinary shares held by Clal Life Sciences, LP, an Israeli limited partnership, whose managing partner is Clal Application Center Ltd., a wholly-owned subsidiary of Clal Biotechnology Industries Ltd., or CBI; and (ii) 356,342 ordinary shares and 178,172 ordinary shares issuable upon exercise of outstanding warrants held by CBI. Access Industries Group indirectly owns 100% of the outstanding shares of Clal Industries Ltd., which owns the majority of the outstanding shares of, and controls, CBI. The address of Clal Industries Ltd. is the Triangular Tower, 3 Azrieli Center, Tel Aviv 67023, Israel and Access Industries Group's address is 730 Fifth Avenue, New York, New York 10019, United States.
- (2) Consists of (i) 286,473 ordinary shares and 55,060 ordinary shares issuable upon exercise of outstanding warrants, which are held by certain subsidiaries of Harel Insurance Investments & Financial Services Ltd.; and (ii) 33,581 ordinary shares and 758 ordinary shares issuable upon exercise of outstanding warrants, which are beneficially held by Harel Insurance Investments & Financial Services Ltd. is a widely held public company listed on the Tel Aviv Stock Exchange. The address of Harel Insurance Investments & Financial Services Ltd. is 3 Abba Hillel Rd. Ramat Gan, Israel.
- (3) Consists of (i) 256,890 ordinary shares and 33,852 ordinary shares issuable upon exercise of outstanding warrants, which are held by certain subsidiaries of Migdal Insurance and Financing Holdings Ltd.; and (ii) 51,263 ordinary shares and 7,996 ordinary shares issuable upon exercise of

outstanding warrants, which are beneficially held by Migdal Insurance & Financing Holdings Ltd. for its own account. Migdal Insurance & Finance Holdings Ltd. is a widely held public company listed on the Tel Aviv Stock Exchange. The address of Migdal Insurance & Finance Holdings Ltd. is 4 Efal Street, Petah Tikva, Israel.

- (4) Consists of 152,224 ordinary shares issuable upon exercise of outstanding options.
- (5) Consists of 71,719 ordinary shares issuable upon exercise of outstanding options.
- (6) Consists of (i) 37,123 ordinary shares held directly by Lior Rosenberg; and (ii) 450,054 ordinary shares held by L.R. Research & Development Ltd., as a trustee for the benefit of Mr. Rosenberg. Mr. Rosenberg is the sole shareholder of L.R. Research & Development Ltd.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

# **Agreements with Related Parties**

### Shareholders' Right Agreement

We are party to a shareholders' right agreement, dated August 2, 2007, as amended on December 30, 2010, or the Shareholders' Right Agreement, with certain of our shareholders. The Shareholders' Right Agreement provides that certain holders of our ordinary shares have the right to demand that we file a registration statement or request that their ordinary shares be covered by a registration statement that we are otherwise filing. The registration rights will terminate five years following the closing of this offering. The Shareholders' Right Agreement also includes rights to demand an initial public offering of our company, tag-along rights and certain information rights, which will terminate upon the completion of this offering. The Shareholders' Right Agreement also sets forth the terms of our repurchase of our ordinary shares from Teva. The registration rights are described in more detail under "Description of Share Capital — Registration Rights." The terms of our repurchase of our ordinary shares from Teva are described in more detail under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Participation by others."

#### Founders and Shareholders Agreement

In January 2001, we entered into a founders' and shareholders agreement, or the Founders Agreement, with CBI, Prof. Lior Rosenberg, our Chief Medical Officer and a member of our board of directors, and L.R. R&D Ltd., an entity which is wholly-owned by Prof. Rosenberg. The Founders Agreement was amended in 2006. Pursuant to the Founders Agreement, in exchange for the issuance of ordinary shares and certain rights thereunder and the payment of certain fixed amounts, Prof. Rosenberg granted to us a perpetual, exclusive, non-revocable, royalty-free, sub-licensable, worldwide license for intellectual property relating to debridement using products based on our proteolytic enzyme technology. As of the date hereof, all of the payments under the Founders Agreement have been paid by us to Prof. Rosenberg in accordance with the Founders Agreement. The Founders Agreement also provided for anti-dilution, pre-emptive rights, a right of first refusal on the sale of our ordinary shares and bring-along rights, all of which were subsequently terminated.

#### Patent Purchase Agreement

In November 2010, we entered into a patent purchase agreement, or the Patent Purchase Agreement, with L.R. R&D, a private company owned by Prof. Rosenberg. In accordance with the Patent Purchase Agreement, we acquired from L.R. R&D a patent family covering an occlusive dressing system for use in treatment of burns, which is not a part of NexoBrid or our other pipeline products, in consideration of our reimbursement of his costs of filing and obtaining the patents, a onetime payment of \$50,000, and fixed annual payments of \$30,000 for every 12 months in which the patent remains valid. The patent expires in May 2018, and our accumulated outstanding obligation to Prof. Rosenberg is \$133,000 as of December 31, 2013.

#### Sublease Agreement

In July 2004, we entered into a sublease agreement, or the Sublease Agreement, with Clal Life Sciences, L.P., or CLS, a subsidiary of CBI, our indirect parent company. The Sublease Agreement has been amended multiple times, most recently in December 2013. Pursuant to the Sublease Agreement, as so amended, we currently sublease a total of 10,764 square feet of laboratory, office and clean room space from CLS and our monthly rent is currently \$38,600. The Sublease Agreement is scheduled to expire on December 31, 2015, with an option to extend the term for two one-year periods.

### Financings

In 2013, CLS made loans to us of approximately \$3.4 million (of which \$2.6 million were convertible loans) and CBI made convertible loans to us of approximately \$1.5 million. On June 30, 2013, we entered into a Share Purchase Agreement, or the 2013 SPA, with CBI and other investors, pursuant to which CBI, as assignee of the convertible loans from CLS, converted the convertible loans into an aggregate of 140,073 ordinary shares and purchased an additional 216,269 ordinary shares from us for an aggregate purchase price of \$8.5 million. In connection with the foregoing financing, we granted warrants to the parties convertible loans and purchasing ordinary shares. With respect to the conversion of its convertible loans and its share purchase, we issued CBI warrants to purchase 50,484 ordinary shares at an exercise price of \$25.55 per share and 127,688 ordinary shares at an exercise price of \$39.30 per share, respectively. The transactions under the 2013 SPA closed in August 2013. On June 14, 2013, we entered into a bridge loan agreement with CLS pursuant to which CLS provided us with a bridge loan of \$900,000 bearing interest at a rate of 10% per annum. This amount plus accrued interest was repaid to CLS concurrently with the closing of the 2013 SPA described above in accordance with the terms of the bridge loan agreement.

# Agreements and Arrangements with, and Compensation of, Directors and Executive Officers

We have entered into written confidentiality, non-competition/solicitation and inventions assignment agreements with each of our executive officers. However, the enforceability of the non-competition provisions may be limited under applicable law. Our executive officers will not receive benefits upon the termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment, which varies for each individual.

#### Indemnification agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and office holders to the fullest extent permitted by the Israeli Companies Law. We have entered into indemnification agreements with each of our directors and executive officers, undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from a public offering of our shares, to the extent that these liabilities are not covered by insurance. We have also 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."

# DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our amended and restated articles of association which will be effective upon the closing of this offering 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 0.01 per share, of which shares will be issued and outstanding (assuming that the underwriters do not exercise their option to purchase additional ordinary shares).

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

### **Purposes of the Company**

Our registration number with the Israeli Registrar of Companies is 51-289494-0. 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.

# **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 meeting of shareholders have the power to elect all of our directors, subject to the special approval requirements for external directors described under "Management—Board Practices—External Directors."

Under our amended and restated articles of association to be effective upon the closing of this offering, our board of directors must consist of at least five and not more than nine directors, including at least two external directors required to be appointed under the Israeli Companies Law. At any time the minimum number of directors (other than the external directors) shall not fall below three.

Pursuant to our amended and restated articles of association, each of our directors, other than the external directors, for whom special election requirements apply under the Israeli Companies Law, will be appointed by a simple majority vote of holders of our voting shares, participating and voting at an annual general meeting of our shareholders. Each director will serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal by a vote of the majority voting power of our shareholders at a general meeting of our shareholders or until his or her office expires by operation of law, in accordance with the Israeli Companies Law. In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on the board of directors to serve until the next annual general meeting of shareholders. 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 Israeli Companies Law. See "Management-Board Practices-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 Israeli 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 Israeli 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 end of the period to which the financial statements relate is not more than six months prior to the date of the distribution. If we do not meet such criteria, then we may distribute dividends 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 countries that are, or have been, in a state of war with Israel.

### **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 meetings other than the annual general meeting of shareholders are referred to in our amended and restated articles of association as extraordinary general meetings. Our board of directors may call extraordinary general meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law provides that our board of directors is required to convene an extraordinary general meeting upon the written request of (i) any two or more of our directors or one-quarter or more 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% of our outstanding voting power or (b) 5% or more of our outstanding voting power.

Subject to the provisions of the Israeli 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 Israeli Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

amendments to our 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;
- a merger; 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.

The Israeli Companies Law require that a notice of any annual general meeting or extraordinary 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, notice must be provided at least 35 days prior to the meeting.

Under the Israeli Companies Law and under our amended and restated articles of association, shareholders are not permitted to take action by way of written consent in lieu of a meeting.

### **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. As a foreign private issuer, the quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least 25% of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the notice of the meeting. At the reconvened meeting, any two or more shareholders present in person or by proxy shall constitute a lawful quorum.

# 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 Israeli Companies Law or by our amended and restated articles of association. Under the Israeli 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 such terms are not extraordinary) requires the approval described above under "Management—Approval of Related Party Transactions under Israeli Law—Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions." Under our amended and restated articles of association, the alteration of the rights, privileges, preferences or obligations 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.

Further exceptions to the simple majority vote requirement are 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 Israeli Companies Law, which requires the approval of holders of 75% of the voting rights represented at the meeting and voting on the resolution.

### Access to Corporate Records

Under the Israeli Companies Law, shareholders are provided access to: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and annual audited 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 Israeli 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 Israeli 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**

We have entered into the Shareholders' Right Agreement with certain of our shareholders. Upon the closing of this offering, holders of a total of 3,945,757 shares of our ordinary shares as of December 31, 2013, as well as an additional ordinary shares issuable upon the closing of this offering pursuant to a cashless exercise of 280,720 warrants, will have the right to require us to register these shares under the Securities Act under specified circumstances and will have incidental registration rights as described below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act.

#### Demand Registration Rights

At any time after 180 days after the closing of this offering, the holders of 20% of the registrable securities then outstanding may request that we file a registration statement with respect to at least 20% of the registrable securities then outstanding (or a lesser percentage if the anticipated aggregate offering price, net of selling expenses, exceeds \$3.0 million). Upon receipt of such registration request, we are obligated to file the registration statement, unless in the good faith judgment of our board of directors, such registration would be materially detrimental to the company and its shareholders, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving us; (ii) require premature disclosure of material information that we have a bona fide business purpose for preserving as confidential; or (iii) render us unable to comply with requirements under the Securities Act or Exchange Act. In addition, we have the right not to effect or take any action to effect a registration statement during the period that is 60 days before the date of filing our registration statement (as estimated by us in good faith), and ending on a date that is 180 days after the date of such filing. We are not obligated to file a registration statement pursuant to these demand provisions on more than two occasions.

### Piggyback Registration Rights

In addition, if we register any of our ordinary shares in connection with the public offering of such securities solely for cash, the holders of all registrable securities are entitled to at least 20 days' notice of the registration and to include all or a portion of their ordinary shares in the registration. If the public offering that we are effecting is underwritten, the right of any shareholder to include shares in the registration related thereto is conditioned upon the shareholder accepting the terms of the



underwriting as agreed between us and the underwriters and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of our offering.

#### Other Provisions

We will pay all registration expenses (other than underwriting discounts and selling commissions) and the reasonable fees and expenses of a single counsel for the selling shareholders, related to any demand or piggyback registration. The demand and piggyback registration rights described above will expire five years after our initial public offering.

### 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 Israeli 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 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 share 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 from shareholders who accepted the tender offer that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class.

### Special Tender Offer

The Israeli 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 Israeli 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 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) the offeror acquired shares representing at least 5% of the voting power in the company and (ii) the number of shares tendered by shareholders who accept the offer exceeds the number of shares held by shareholders who object to the offer (excluding the purchaser, controlling shareholders, 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). If a special tender offer is accepted, the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

# Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by a majority vote of each party's shareholders. In the case of the target company, approval of the merger further requires a majority vote of each class of its shares.

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 shares represented at the meeting of shareholders 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—Approval of Related Party Transactions under Israeli Law—Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain 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 petition of holders of at least 25% of the voting rights of a company. For such petition to be granted, the court must find that the merger is fair and reasonable, taking into account the respective values assigned to each of the parties to the merger and the consideration offered to the shareholders of the target 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 is filed 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 Israeli Companies Law allow 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 Israeli Companies Law as described above in "—Voting Rights."

# **Borrowing Powers**

Pursuant to the Israeli 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 Israeli Companies Law and must be approved by a resolution duly passed by our shareholders at a general meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

# **Transfer Agent and Registrar**

The transfer agent and registrar for our ordinary shares is . Its address is , and its telephone number is .

# Listing

We have applied to have our ordinary shares listed on the NASDAQ Global Market under the symbol "MDWD".

# 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 in full their option to purchase additional ordinary shares with respect to this offering and assuming no exercise of options or warrants 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, or Rule 144), 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 under Rule 144, Rule 701 or Rule 904 under the Securities Act. These rules are summarized below.

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

The following indicates approximately when the ordinary shares that are not being sold in this offering, but which will be outstanding at the time at which this offering is complete, will be eligible for sale into the public market under the provisions of Rule 144 and Rule 701 (but subject to the further contractual restrictions arising under the lock-up agreements described below):

- upon the closing of this offering, ordinary shares held by non-affiliates of our company that have been held for at least one year will be available for resale under Rule 144(b)(1)(ii);
- beginning 90 days after the closing of this offering, up to approximately ordinary shares, constituting shares issuable upon exercise of outstanding options under our 2003 Plan that have vested as of, or within 60 days of, , 2014, may be eligible for resale under Rule 701 and Rule 144, of which approximately are held by our affiliates and would therefore be subject to volume, current public information, manner of sale and other limitations under Rule 144; and
- approximately ordinary shares will be eligible for resale pursuant to Rule 144 upon the expiration of various six-month holding periods, so long as at least 90 days have elapsed after the closing of this offering, and subject to the current public information requirement under Rule 144 and, in the case of affiliates of our company, such eligibility will also be subject to the volume, manner of sale and other limitations under Rule 144.

### Lock-Up Agreements

We, all of our directors and executive officers and holders of substantially all of our outstanding shares and our shares issuable upon the exercise of warrants and vested options have signed lock-up agreements. Pursuant to such lock-up agreements, such persons have agreed, subject to certain exceptions, not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of days after the date of this prospectus without the prior written consent of Credit Suisse Securities (USA) LLC and Jefferies LLC. The underwriters may, in their sole discretion, 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 after the closing of this offering, a person (or persons whose shares are aggregated), 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 our company or from an affiliate of our company as restricted securities), is entitled to sell our shares, subject to the availability of current public information about us. 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 and notice requirements, and to a volume limitation that limits the number of shares to 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.

The six month holding period of Rule 144 does not apply to sales of unrestricted securities. Accordingly, persons who hold unrestricted securities may sell them under the requirements of Rule 144 described above without regard to the six month holding period, even if they were considered our affiliates at the time of the sale or at any time during the 90 days preceding such date.

# Shares Held by Non-Affiliates for One Year

Under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who is not considered to have been one of our affiliates at any time during the 90 days 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, any of our employees, directors, officers, consultants or advisors who received or purchased ordinary shares from us under our 2003 Plan or other written agreement before the closing of this offering is entitled to resell these shares.

The Commission has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of these options, including exercises after the closing of this offering. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described above (under "—Lock-Up Agreements"), may be sold beginning 90 days after 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.

### Options

As of December 31, 2013, options to purchase a total of 625,280 ordinary shares were issued and outstanding under our 2003 Plan, of which will be vested upon the closing of this offering. See "Management—Share Incentive Plan." All of our ordinary shares issuable under these options are subject to contractual lock-up agreements with us or the underwriters.

# Warrants

In December 2013, our Board of Directors, our shareholders and holders of warrants to purchase our ordinary shares agreed to amend such warrants so that the warrants expire upon our initial public offering and the warrant holders may exercise, either in a cash or cashless manner, such warrants immediately prior to our initial public offering. As of December 31, 2013, there were a total of 280,720 warrants outstanding.

# Form S-8 Registration Statements

Following the completion of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register up to ordinary shares, in the aggregate, issued or reserved for issuance under the 2003 Plan. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued upon exercise of a share option 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 \_\_\_\_\_\_\_-day lock-up or, if subject to the lock-up, immediately after the \_\_\_\_\_\_\_\_\_-day lock-up period expires. See "Management—Share Incentive Plan."

### **Registration Rights**

Upon the closing of this offering, holders of a total of 3,945,757 shares of our ordinary shares as of December 31, 2013, as well as an additional ordinary shares issuable upon the closing of this offering pursuant to a cashless exercise of 280,720 warrants, will have the right to require us to register these shares under the Securities Act under specified circumstances and will have incidental registration rights. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. For more information on these registration rights, see "Description of Share Capital—Registration Rights."

# TAXATION

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 brief summary of the material Israeli tax laws applicable to us, and certain Israeli Government programs that benefit us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our ordinary shares purchased by investors in this offering. 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 such investors include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli affect the tax consequences described below.

### General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax at the rate of 25% of a company's taxable income for 2013 and 26.5% for 2014 and thereafter. However, the effective tax rate payable by a company that derives income from an Approved Enterprise, a Benefited Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. In addition, commencing from 2010, Israeli companies are subject to regular corporate tax rate on their capital gains.

### 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". We currently qualify as an Industrial Company within the meaning of the Industry Encouragement Law.

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 patents or the rights to use a patent or know-how which are used for the development or advancement of the company;
- 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.

There can be no assurance that we will continue to qualify as an Industrial Company or that the benefits described above will be available in the future.

### 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).

The Investment Law was significantly amended effective April 1, 2005, or the 2005 Amendment, and further amended as of January 1, 2011, or the 2011 Amendment. Pursuant to the 2005 Amendment, tax benefits granted in accordance with the provisions of the Investment Law prior to its revision by the 2005 Amendment remain in force but any benefits granted subsequently are subject to the provisions of the 2005 Amendment. Similarly, 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. However, companies entitled to benefits under the Investment Law as in effect prior to January 1, 2011 were entitled to choose to continue to enjoy such benefits, provided that certain conditions are met, or elect instead, irrevocably, to forego such benefits and have the benefits of the 2011 Amendment apply.

# 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 the Economy (formerly the Ministry of Industry, Trade and Labor), 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 income 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 an 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.

If a company elects the alternative benefits track and distributes a dividend out of income derived by its Approved Enterprise during the tax exemption period, it will be subject to corporate tax in respect of the amount of the dividend distributed (grossed-up to reflect the pre-tax income that it would have earn in order to distribute the dividend) at the corporate tax rate which would have been applicable without the benefits under the alternative benefits track. In addition, dividends paid out of income attributed to an Approved 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 Investment Law also provides that an Approved Enterprise is entitled to accelerated depreciation on its property and equipment that are included in an Approved Enterprise program during the first five years in which the property and the equipment are used.

The benefits available to an Approved Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations and the criteria in the specific certificate of



approval. If a company does not meet these conditions, it would be required to refund the amount of tax benefits, as adjusted by the Israeli consumer price index, plus interest.

We do not have Approved Enterprise programs under the Investment Law.

## Tax Benefits Subsequent to the 2005 Amendment

The 2005 Amendment applies to new investment programs and investment programs approved after 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 may 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 a certificate from the Investment Center 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. 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.

The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Benefited Enterprise depends 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 10% to 25% for the remainder of the benefit period, depending on the level of foreign investment in the company in each year. The benefit period is limited to 12 or 14 years from the year the company requested to have the tax benefits apply, depending on the location of the company. 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 rate which would have otherwise been applicable. 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, plus interest, or other monetary penalties.

We currently have Benefited Enterprise programs under the Investments Law, which we believe will entitle us to certain tax benefits. The majority of any taxable income from our Benefited Enterprise programs (once generated) would be tax exempt for a period of ten years commencing with the year we will first earn taxable income relating to such enterprises, subject to the 12 or 14 year limitation described above.

### Tax Benefits Under the 2011 Amendment

The 2011 Amendment canceled the availability of the benefits granted to companies under the Investment Law prior to 2011 and, instead, introduced new benefits for income generated by a "Preferred Company" through its "Preferred Enterprise" (as such terms are defined in the Investment Law) as of January 1, 2011. The definition of a Preferred Company includes a company incorporated in Israel that is not wholly-owned by a governmental entity, and that has, among other things, Preferred Enterprise status and is controlled and managed from Israel. Pursuant to the 2011 Amendment, a Preferred Company is entitled to a reduced corporate tax rate of 15% with respect to its income derived by its Preferred Enterprise in 2011 and 2012, unless the Preferred Enterprise is located in a specified development zone, in which case the rate will be 10%. Under the 2011 Amendment, such corporate tax rate will be reduced from 15% and 10% for non-specified and specified development zones, respectively, to 12.5% and 7%, respectively, in 2013, and increased to 16% and 9% in 2014 and thereafter, respectively. Dividends paid out of income attributed to a Preferred Enterprise are generally subject to withholding tax at source at the rate of 15% (20% with respect to dividends to be distributed on after January 1, 2014, subject to certain conditions) or such lower rate as may be provided in an applicable tax treaty. However, if such dividends are paid to an Israeli company, no tax is required to be withheld, although, if subsequently distributed to individuals or a non-Israeli company, withholding tax at source at a rate of 15% will apply (20% with respect to dividends to be distributed on after January 1, 2014 and subject to certain conditions) or such lower rate as may be provided in an applicable tax treaty.

The 2011 Amendment also provided transitional provisions to address companies already enjoying existing tax benefits under the Investment Law. These transitional provisions provide, among other things, that unless an irrevocable request is made to apply the provisions of the Investment Law as amended in 2011 with respect to income to be derived as of January 1, 2011: (i) the terms and benefits included in any certificate of approval that was granted to an Approved Enterprise which chose to receive grants before the 2011 Amendment became effective will remain subject to the provisions of the Investment Law as in effect on the date of such approval; (ii) terms and benefits included in any certificate of approval that was granted to an Approved Enterprise which chose to receive grants before the 2011 Amendment became effective will remain subject to the provisions of the Investment Law as in effect on the date of such approval; (ii) terms and benefits included in any certificate of approval that was granted to an Approved Enterprise which had participated in an alternative benefits track before the 2011 Amendment became effective will remain subject to the provisions of the Investment Law as in effect on the date of such approval; and (iii) a Benefited Enterprise can elect to continue to benefit from the benefits provided to it before the 2011 Amendment came into effect, in each case provided that certain conditions are met.

We have examined the possible effect, if any, of these provisions of the 2011 Amendment on our financial statements and have decided, at this time, not to opt to apply the new benefits under the 2011 Amendment.

From time to time, the Israeli Government has discussed reducing the benefits available to companies under the Investment Law. The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

### Taxation of our Shareholders

*Capital Gains Taxes Applicable to Non-Israeli Resident Shareholders.* Israeli capital gains tax is imposed on the disposal of capital assets by a non-Israeli resident if such assets are either (i) located in Israel; (ii) shares or rights to shares in an Israeli resident company, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless a specific exemption is available or unless a tax treaty between Israel and the seller's country of residence provides otherwise. Capital gain is generally subject to tax at the corporate tax rate (25% as of 2013, 26.5% in 2014 and thereafter), if generated by a company, or if generated by an individual at the rate of 25% or at a rate of 30% in the case of sale of shares by a Substantial Shareholder (*i.e.*, a person who holds, directly or indirectly, alone or together with another, 10% or more of any of the company's "means of control" (including, among other things,

the right to receive profits of the company, voting rights, the right to receive proceeds upon liquidation and the right to appoint a director)) at the time of sale or at any time during the preceding 12-month period. Individual and corporate shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income (a corporate tax rate for a corporation and a marginal tax rate of up to 48% for an individual in 2013, and 50% for an individual in 2014).

Furthermore, beginning on January 1, 2013, an additional tax liability at the rate of 2% was added to the applicable tax rate on the annual taxable income of the individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 811,560 (in 2013).

Notwithstanding the foregoing, a non-Israeli resident who derives capital gains from the sale of shares in an Israeli resident company that were purchased after the company was listed for trading on a recognized stock exchange in Israel or outside of Israel will be exempt from Israeli tax so long as the shares were not held through a permanent establishment that the non-resident maintains in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a controlling interest of 25% or more in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption is not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be business income.

Additionally, a sale of securities by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, under the United States-Israel Tax Treaty, the disposition of shares by a shareholder who (i) is a U.S. resident (for purposes of the treaty), (ii) holds the shares as a capital asset, and (iii) is entitled to claim the benefits afforded to such person by the treaty, is generally exempt from Israeli capital gains tax. Such exemption will not apply if (i) the capital gain arising from the disposition can be attributed to a permanent establishment in Israel; (ii) the shareholder holds, directly or indirectly, shares representing 10% or more of the voting rights during any part of the 12-month period preceding the disposition, subject to certain conditions; or (iii) such U.S. resident is an individual and was present in Israel for 183 days or more during the relevant taxable year. In such case, the sale, exchange or disposition of our ordinary shares would be subject to Israeli tax, to the extent applicable; however, under the United States-Israel Tax Treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The United States-Israel Tax Treaty does not relate to U.S. state or local taxes.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale.

*Taxation of Non-Israeli Shareholders on Receipt of Dividends.* Non-Israeli residents are generally subject to Israeli withholding tax on the receipt of dividends paid on our ordinary shares at the rate of 25%, unless relief is provided in a treaty between Israel and the shareholder's country of residence. With respect to a person who is a Substantial Shareholder at the time of receiving the dividend or at any time during the preceding 12 months, subject to the terms of an applicable tax treaty, the applicable withholding tax rate is 30%, unless such Substantial Shareholder holds such shares through a nominee company, in which case the rate is 25%. If the dividend is distributed from income attributed to an Approved Enterprise or Benefited Enterprise, the applicable withholding tax rate is 15% or 20% with respect to dividends to be distributed on or after January 1, 2014 from income attributed to a Preferred Enterprise, subject to certain conditions, unless a reduced rate is provided under an applicable tax treaty. If the dividend is attributed from an Approved Enterprise, Benefited Enterprise or Preferred Enterprise, and partly from other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income.

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For example, under the United States-Israel Tax Treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our ordinary shares who is a U.S. resident (for purposes of the United States-Israel Tax Treaty) is 25%. However, for dividends not generated by an Approved Enterprise, a Benefited Enterprise or a Preferred Enterprise and paid to a U.S. corporation holding 10% or more of the outstanding voting rights throughout the tax year in which the dividend is distributed as well as during the previous tax year, the maximum rate of withholding tax is generally 12.5%, provided that not more than 25% of the gross income for such preceding year consists of certain types of dividends and interest. Notwithstanding the foregoing, dividends generated by an Approved Enterprise, a Benefited Enterprise or a Preferred Enterprise are subject to withholding tax at a rate of 15% for such U.S. corporation shareholder, provided that the condition related to our gross income for the previous year is met. U.S residents who are subject to Israeli withholding tax on a dividend may be entitled to a credit or deduction for United States federal income tax purposes in the amount of the taxes withheld, subject to detailed limitations under U.S. laws applicable to foreign tax credits.

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 for more than 180 days during the tax year and (ii) the taxpayer has no other taxable sources of income in Israel with respect to the period for which a tax return is required to be filed.

We cannot assure you that in the event we declare a dividend we will designate the income that we may distribute in a way that will reduce shareholders' tax liability.

#### **U.S. Federal Income Tax Consequences**

The following is a description of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our ordinary shares. This description addresses only the U.S. federal income tax consequences to holders that are initial purchasers of our ordinary shares pursuant to the offering and that will hold such ordinary shares as capital assets. This description does not address tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- dealers or traders in securities, commodities or currencies;
- tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the U.S. Internal Revenue Code, or the Code, respectively;
- certain former citizens or long-term residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;
- S corporations;
- holders that acquire ordinary shares as a result of holding or owning our preferred shares;
- U.S. Holders (as defined below) whose "functional currency" is not the U.S. Dollar; or
- holders that own or have owned directly or indirectly 10.0% or more of the voting power or value of our shares.

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Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences, or any state, local or foreign tax consequences, of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the Code existing, proposed and temporary U.S. Treasury Regulations and judicial and administrative interpretations thereof, in each case as in effect and available on the date hereof. All of the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of purchasing, owning and disposing of our ordinary shares in their particular circumstances.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is:

- a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof, including 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 if such trust has validly elected to be treated as a United States person for U.S. federal income tax purposes or if (1) a court within the United States is able to exercise primary supervision over its administration and (2) one or more U.S. persons have the authority to control all of the substantial decisions of such trust.

A "Non-U.S. Holder" is a beneficial owner of our ordinary shares that is neither a U.S. Holder nor a partnership (or other entity treated as a partnership for United States federal income tax purposes).

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the tax treatment of a partner in such partnership will generally depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor as to the particular U.S. federal income tax consequences of acquiring, owning and disposing of our ordinary shares in its particular circumstance.

Unless otherwise indicated, this discussion assumes that the Company is not, and will not become, a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes. See "—Passive Foreign Investment Company Considerations" below.

# You should consult your tax advisor with respect to the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ordinary shares.

#### Distributions

If you are a U.S. Holder, the gross amount of any distribution made to you with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom will generally be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. However, this will not apply to certain distributions, if any, of our ordinary shares that are distributed pro rata to all our shareholders. To the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be

treated first as a tax-free return of your adjusted tax basis in our ordinary shares and thereafter as either long-term or short-term capital gain depending upon whether the U.S. Holder has held our ordinary shares for more than one year as of the time such distribution is received. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles. Therefore, if you are a U.S. Holder you should expect that the entire amount of any distribution generally will be reported as ordinary dividend income to you. Non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year), provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. Moreover, such lower rate of taxation shall not apply if the Company is a PFIC for the taxable year in which it pays a dividend, or was a PFIC for the preceding taxable year. However, such dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders.

If you are a U.S. Holder, dividends paid to you with respect to our ordinary shares will be treated as foreign source income, which may be relevant in calculating your foreign tax credit limitation. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from your taxable income or credited against your U.S. federal income tax liability. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute generally should constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor to determine whether and to what extent you will be entitled to this credit.

If you are a U.S. Holder, dividends paid in NIS will be included in income in a U.S. dollar amount calculated by reference to the prevailing spot market exchange rate in effect on the day the dividends are received by you, regardless of whether the NIS are converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. Holder realizes on a subsequent conversion of NIS into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in NIS are converted into U.S. dollars on the day they are received, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

Subject to the discussion below under "Backup Withholding Tax and Information Reporting Requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income (or withholding) tax on dividends received by you on your ordinary shares, unless you conduct a trade or business in the United States and such income is effectively connected with that trade or business (or, if required by an applicable income tax treaty, the dividends are attributable to a permanent establishment or fixed base that such holder maintains in the United States).

### Sale, Exchange or Other Disposition of Ordinary Shares

If you are a U.S. Holder, you generally will recognize gain or loss on the sale, exchange or other disposition of our ordinary shares equal to the difference between the amount realized on such sale, exchange or other disposition and your adjusted tax basis in our ordinary shares, and such gain or loss will be capital gain or loss. If Israeli tax is imposed on the sale, exchange or other disposition of our ordinary shares, a U.S. Holder's amount realized will include the gross amount of the proceeds of the deposits before deduction of the Israeli tax. The adjusted tax basis in an ordinary share generally will be equal to the cost of such ordinary share. Except as discussed below with respect to foreign currency gain or loss, if you are a non-corporate U.S. Holder, capital gain from the sale, exchange or other disposition of ordinary shares is generally eligible for a preferential rate of taxation applicable to capital gains, if your holding period for such ordinary shares exceeds one year. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code.

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Any such gain or loss that a U.S. Holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. Because gain for the sale or other disposition of our ordinary shares will be so treated as U.S. source income; and you may use foreign tax credits to offset only the portion of U.S. federal income tax liability that is attributed to foreign source income; you may be unable to claim a foreign tax credit with respect to the Israeli tax, if any, on gains. You should consult your tax advisor as to whether the Israeli tax on gains may be creditable against your U.S. federal income tax on foreign-source income from other sources.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of our ordinary shares that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. An accrual basis taxpayer who does not make such election may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder realizes will be U.S. source ordinary income or loss.

The determination of whether our ordinary shares are traded on an established securities market is not entirely clear under current U.S. federal income tax law. Please consult your tax advisor regarding the proper treatment of foreign currency gains or losses with respect to a sale or other disposition of our ordinary shares.

Subject to the discussion below under "Backup Withholding Tax and Information Reporting Requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income or withholding tax on any gain realized on the sale or exchange of such ordinary shares unless:

- such gain is effectively connected with your conduct of a trade or business in the United States (or, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base that such holder maintains in the United States); or
- you are an individual and have been present in the United States for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

#### Passive Foreign Investment Company Considerations

If we were to be classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either:

- at least 75% of its gross income is "passive income"; or
- at least 50% of the average quarterly value of its total gross assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests

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as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we will generally continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

Based on certain estimates of our gross income and gross assets, our intended use of the proceeds of this offering, and the nature of our business, we do not expect that we will be classified as a PFIC for the taxable year ending December 31, 2014. However, because PFIC status is based on our income, assets and activities for the entire taxable year, it is not possible to determine whether we will be characterized as a PFIC for the 2014 taxable year until after the close of the year. Moreover, we must determine our PFIC status annually based on tests which are factual in nature, and our status in future years will depend on our income, assets and activities in those years. In addition, our status as a PFIC may depend on how quickly we utilize the cash proceeds from this offering in our business. There can be no assurance that we will not be considered a PFIC for any taxable year.

If we were a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ordinary shares) and (b) any gain realized on the sale or other disposition of the ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over your holding period, (ii) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax, at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest change discussed below), and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Distributions." Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares.

If a U.S. Holder makes the mark-to-market election, then, in lieu of being subject to the tax and interest charge rules discussed above, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of included as a result of the mark-to-market election).

The mark-to-market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange." Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ordinary shares, are traded on a qualified exchange on at least 15 days during each calendar quarter. The NASDAQ Global Market is a qualified exchange for this purpose. Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the tax and interest charge rules discussed above with respect to such holder's 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, including stock

in any of the Company's subsidiaries that are treated as PFICs. If a U.S. Holder makes a mark-to market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless our ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC, the U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. Holder's federal income tax return for that year.

U.S. Holders should consult their tax advisors regarding whether we are a PFIC and the potential application of the PFIC rules.

#### Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

#### Backup Withholding Tax and Information Reporting Requirements

United States backup withholding tax and information reporting requirements may apply to certain payments to certain holders of stock. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale or redemption of, our ordinary shares made within the United States, or by a United States payor or United States middleman, to a holder of our ordinary shares, other than an exempt recipient (including a payee that is not a United States person that provides an appropriate certification and certain other persons). A payor will be required to withhold backup withholding tax from any payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a United States payor or United States payor or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a United States payor or United States payor or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a United States payor or United States middleman, to a holder, other than an exempt recipient, if such holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Any amounts withheld under the backup withholding rules will be allowed as a credit against the beneficial owner's United States federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

#### Foreign Asset Reporting

Certain U.S. Holders who are individuals are required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

The above description is not intended to constitute a complete analysis of all tax consequences relating to acquisition, ownership and disposition of our ordinary shares. You should consult your tax advisor concerning the tax consequences of your particular situation.



### UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement dated , 2014, we have agreed to sell to the underwriters named below, for whom Credit Suisse Securities (USA) LLC and Jefferies LLC are acting as representatives, the following respective numbers of ordinary shares:

	Number of
	Ordinary
Underwriters	Shares
Credit Suisse Securities (USA) LLC	
Jefferies LLC	
BMO Capital Markets Corp.	
Oppenheimer & Co. Inc.	
Total	

The underwriting agreement provides that the underwriters are obligated to purchase all the ordinary shares in the offering, if not terminated, other than those ordinary shares covered by the underwriters' option to purchase additional ordinary shares described below. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated.

We have granted to the underwriters a 30-day option to purchase on a pro rata basis up to additional ordinary shares at the initial public offering price less the underwriting discounts and commissions.

The underwriters propose to offer the ordinary shares initially at the public offering price on the cover page of this prospectus. The underwriters may allow a discount of \$ per ordinary share on sales to other broker and dealers. After the initial public offering, the representatives may change the public offering price and discount to broker and dealers.

Prior to this offering, there has been no public market in the United States for our ordinary shares. The initial public offering price is being negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

The following table summarizes the compensation and estimated expenses we will pay, which includes an amount not to exceed \$ that we have agreed to reimburse the underwriters for certain expenses incurred by them in connection with this offering:

	Per Ordinary Share		Total	
	Without Option to Purchase Additional Ordinary Shares	With Option to Purchase Additional Ordinary Shares	Without Option to Purchase Additional Ordinary Shares	With Option to Purchase Additional Ordinary Shares
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Expenses payable by us	\$	\$	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ million, which includes no more than \$ that we have

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agreed to reimburse the underwriters for certain expenses incurred by them in connection with this offering. The underwriters have agreed to reimburse us for certain documented expenses incurred in connection with this offering.

Rothschild Inc., or Rothschild, has acted as our financial advisor in connection with this offering. Rothschild is not acting as an underwriter in connection with this offering, and accordingly, Rothschild is neither purchasing ordinary shares nor offering ordinary shares to the public in connection with this offering. With gross offering proceeds of \$ million, the maximum aggregate compensation that Rothschild is eligible to receive in connection with this offering, including reimbursement of out-of-pocket expenses, is \$ (or \$ if the underwriters exercise in full their option to purchase additional ordinary shares).

The underwriters have informed us that they do not expect sales to accounts over which the underwriters have discretionary authority to exceed % of the ordinary shares being offered.

We have agreed that we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the Commission a registration statement under the Securities Act relating to, any of our ordinary shares or securities convertible into or exchangeable or exercisable for any of our ordinary shares, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, without the prior written consent of Credit Suisse Securities (USA) LLC and Jefferies LLC for a period of 180 days after the date of this prospectus, except issuances pursuant to the exercise of employee stock options outstanding on the date hereof and subject to certain additional exceptions. The underwriters have agreed to reimburse us for certain documented expenses incurred in connection with this offering.

Our officers and directors and certain of our shareholders have agreed that they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any of our ordinary shares or securities convertible into or exchangeable or exercisable for any of our ordinary shares, for a period of 180 days after the date of this prospectus, subject to certain exceptions. Such lock-up also prohibits (i) any transaction that would have the same effect, including any swap, hedge and other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our ordinary shares, for cash or otherwise, whether any such transactions are to be settled by delivery of our ordinary shares or other securities, and (ii) any public disclosure of the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement—in each case without the prior written consent of Credit Suisse Securities (USA) LLC and Jefferies LLC.

We agreed to indemnify the underwriters against liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in that respect.

We have applied to have our ordinary shares listed on the NASDAQ Global Market.

In connection with the listing of the ordinary shares on the NASDAQ Global Market, the underwriters will undertake to sell round lots of 100 shares or more to a minimum of beneficial owners.

In connection with the offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act.

- Stabilizing transactions permit bidders to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number

of shares that they may purchase in the option to purchase additional ordinary shares. In a naked short position, the number of shares involved is greater than the number of shares in the option to purchase additional ordinary shares. The underwriters may close out any covered short position by exercising their option to purchase additional ordinary shares, purchasing shares in the open market, or both.

- 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. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the underwriters' option to purchase additional ordinary shares. If the underwriters sell more shares than could be covered by the underwriters' option to purchase additional ordinary shares, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are 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.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the ordinary shares originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

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 our 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 or otherwise and, if commenced, may be discontinued at any time.

A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters, or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of ordinary shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations.

#### **United Kingdom**

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). The securities are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

#### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or each, a Relevant Member State, from and including the date on which the European Union Prospectus Directive, or the EU Prospectus Directive, was implemented in that Relevant Member State, or Relevant Implementation Date, an offer of securities described in this prospectus may not be made to the public in that Relevant Member State prior to the publication of a

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prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State (or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State)—all in accordance with the EU Prospectus Directive. However, an offer of securities described in this prospectus may be made to the public in that Relevant Member State at any time from the Relevant Implementation Date:

- to any legal entity which is a qualified investor as defined under the EU Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive); or
- in any other circumstances falling within Article 3(2) of the EU Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the EU Prospectus Directive.

For the purposes of this provision, the expression an "offer of securities to the public" in relation to any securities 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 the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State. The expression "EU Prospectus Directive" means Directive 2003/71/EC (and any 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.

#### Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances that 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 that do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong). Furthermore, 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), that is directed at, or the contents of which are likely to be accessed or read by the public in Hong Kong (except if permitted under the laws of Hong Kong), other than with respect to shares that 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, or the SFA, (ii) to a relevant person (or any person pursuant to Section 275(1A)) 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.

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Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person that is: (a) a corporation (which is not an accredited investor) whose sole business 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 (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of which is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of which is an accredited investor; then shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that corporation or trust shall not be transferable for six months after that corporation or trust had acquired the shares under Section 275. However, such restriction shall not apply: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; and (3) by operation of law.

#### Switzerland

This document, as well as any other material relating to the shares of our common stock, which are the subject of the offering contemplated by this prospectus, does not constitute an issue prospectus pursuant to Article 652a 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 the 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 us from time to time.

#### Notice to Residents of Canada

The distribution of the shares in Canada is being made only in the provinces of Ontario and Quebec on a private placement basis such that the shares may be sold only to purchasers resident in those provinces 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 Registrat Obligations.* Any resale of the shares must be made in accordance with an exemption from the prospectus requirements and in compliance with the registration requirements of applicable securities laws.

### Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and 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, underwriters purchasing for their own account, 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. Qualified investors may be required to submit written confirmation that they fall within the scope of the Addendum.

#### Address of Representative

The addresses of the representatives are: Credit Suisse Securities (USA) LLC, Eleven Madison Avenue, New York, New York 10010; and Jefferies LLC, 520 Madison Avenue, New York, New York 10022.



### EXPERTS

The consolidated financial statements as of December 31, 2012 and 2013, and for each of the three years in the period ended December 31, 2013, included in this prospectus have been so included in reliance on the report of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The offices of Kost Forer Gabbay & Kasierer are located at 3 Aminadav Street, Tel Aviv 6706703, Israel.

### 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 Meitar Liquornik Geva Leshem Tal, Ramat Gan, Israel. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by White & Case LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Gornitzky & Co., Tel Aviv, Israel, with respect to Israeli law, and by Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York, with respect to U.S. law.

### 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 registration statement, substantially all of whom reside outside of 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 of 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 been informed by our legal counsel in Israel, Meitar Liquornik Geva Leshem Tal, that it may be difficult to assert U.S. securities law claims in original actions instituted 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 bring 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 which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

We have irrevocably appointed Puglisi & Associates, as our agent to receive service of process in any action against us in any United States federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. Subject to specified 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 a judgment 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 among other things:

- the judgment was obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment was given and the rules of private international law currently prevailing in Israel;
- the prevailing law of the foreign state in which the judgment was rendered allows for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgment is not contrary to public policy of Israel, and the enforcement of the civil liabilities set forth in the judgment is not likely to impair the security or sovereignty of Israel;
- the judgment was not obtained by fraud and do not conflict with any other valid judgments in the same matter between the same parties;
- an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- the judgment is enforceable according to the laws of Israel and according to the law of the foreign state in which the relief was granted.

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 Commission 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 Commission 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 Commission without charge at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the Commission at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. The Commission also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the Commission. Our filings with the Commission are also available to the public through the Commission's website at http://www.sec.gov.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file reports with the Commission. Those other reports or other information may be inspected without charge at the locations described above. 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. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the Commission, sintin 120 days after the end of each fiscal year, or such applicable time as required by the Commission, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the Commission, on Form 6-K, unaudited quarterly financial information for the first three quarters of each fiscal year.

We maintain a corporate website at www.MediWound.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus.

# CONSOLIDATED FINANCIAL STATEMENTS

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Kost Forer Gabbay & Kasierer 3 Aminadav St. Tel-Aviv 6706703, Israel Tel: +972-3-6232525 Fax: +972-3-5622555 ey.com

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

#### To the Shareholders and Board of Directors of

### MEDIWOUND LTD. AND ITS SUBSIDIARIES

We have audited the accompanying consolidated balance sheets of MediWound Ltd. and its subsidiaries (the "Company") as of December 31, 2012 and 2013 and the related consolidated statements of comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2011, 2012 and 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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 management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2012 and 2013 and the consolidated results of operations and cash flows for each of the three years in the period ended December 31, 2011, 2012 and 2013, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

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/s/ KOST FORER GABBAY & KASIERER

Tel-Aviv, Israel January 31, 2014 KOST FORER GABBAY & KASIERER A Member of Ernst & Young Global

# CONSOLIDATED BALANCE SHEETS

### U.S. dollars in thousands

		Decemb	er 31,
	Note	2012	2013
CURRENT ASSETS:			
Cash and cash equivalents	5	337	7,053
Short-term bank deposits		—	2,500
Inventories	7	862	_
Other receivables	6,21	2,053	2,512
		3,252	12,065
LONG-TERM ASSETS:			
Long term deposits and deferred costs		2	204
Derivative instruments	12	15,400	
Property, plant and equipment, net	8	1,274	1,136
Intangible assets, net	9,18	5,093	1,004
Other assets	18	417	417
		22,186	2,761
		25,438	14,826
CURRENT LIABILITIES:			
Trade payables		775	1,180
Loan from a related party	21	1,555	
Other payables	10,21	1,034	843
		3,364	2,023
LONG-TERM LIABILITIES:			
Liabilities in respect of Chief Scientist government grants	11	6,434	6,604
Contingent consideration for the purchase of treasury shares	12		16,800
Warrants to shareholders	12	_	9,200
Severance pay liability, net	13	6	3
		6,440	32,607
SHAREHOLDERS' EQUITY (DEFICIT):	15		
Ordinary shares of NIS 0.01 par value:			
Authorized: 10,000,000 shares as of December 31, 2012 and 2013; Issued: 4,127,414 and 4,706,543 shares respectively; Outstanding: 4,127,414 and 3,951,051 shares			
respectively		9	11
Share premium		47,686	62,229
Treasury shares			(34,600)
Foreign currency translation adjustments			(32)
Accumulated deficit		(32,061)	(47,412)
		15,634	(19,804)
		25,438	14,826
		, -	

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

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

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

		Year ended December 31,		er 31,
	Note	2011	2012	2013
Operating expenses:				
Research and development, net of participations	19a	3,021	1,557	3,635
Selling and marketing	19b	—	—	2,259
General and administrative	19c	1,266	1,173	1,687
Total operating expenses		(4,287)	(2,730)	(7,581)
Operating loss		(4,287)	(2,730)	(7,581)
Financial income	19d	96	15,406	2,401
Financial expense	19d	(628)	(691)	(3,321)
Income (loss) from continuing operations		(4,819)	11,985	(8,501)
Loss from discontinued operation	18	(1,350)	(1,045)	(6,850)
Net income (loss)		(6,169)	10,940	(15,351)
Other comprehensive loss:				
Items to be reclassified to profit or loss in subsequent periods:				
Foreign currency translation adjustments		_	_	(32)
Total other comprehensive loss			_	(32)
Total comprehensive income (loss)		(6,169)	10,940	(15,383)
Basic and diluted net income (loss) per share:				
Basic net income (loss) per share		(1.49)	2.65	(3.72)
Diluted net income (loss) per share		(1.49)	2.42	(3.72)

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

# CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

### U.S. dollars in thousands

	Share capital	Share premium	Treasury shares	Foreign currency translation reserve	Accumulated deficit	Total equity
Balance as of January 1, 2011	9	46,658			(36,832)	9,835
Total comprehensive loss	_				(6,169)	(6,169)
Share-based compensation	_	664		_	_	664
Balance as of December 31, 2011	9	47,322			(43,001)	4,330
Total comprehensive income		_	_	_	10,940	10,940
Share-based compensation		364	_			364
Balance as of December 31, 2012	9	47,686			(32,061)	15,634
Loss for the period					(15,351)	(15,351)
Other comprehensive loss	—			(32)	—	(32)
Total comprehensive loss				(32)	(15,351)	(15,383)
Exercise of options	(*)	279	—	—		279
Purchase of treasury shares	_		(34,600)		_	(34,600)
Share-based compensation	—	607		_	—	607
Issuance of shares, net	2	13,657	—	_	—	13,659
Balance as of December 31, 2013	11	62,229	(34,600)	(32)	(47,412)	(19,804)

(\*) Represents an amount lower than \$1.

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

# CONSOLIDATED STATEMENTS OF CASH FLOWS

### U.S. dollars in thousands

	Year ended December 31,		er 31,
	2011	2012	2013
Cash Flows from Operating Activities			
Net Income (loss)	(6,169)	10,940	(15,351)
Adjustments to reconcile net income (loss) to net cash used in continuing operating activities:			
Adjustments to profit and loss items:			
Loss from discontinued operation (Note 18)	1,350	1,045	6,850
Depreciation and amortization	196	267	336
Revaluation of derivatives instruments to fair value		(15,400)	—
Revaluation of warrants to shareholders		_	820
Share-based compensation	555	334	531
Revaluation of liabilities in respect of Chief Scientist government grants	139	611	(106)
Revaluation of contingent consideration for the purchase of treasury shares	—	—	(2,400)
Accrued interest in respect of financial loans	—	—	1,669
Net financing expenses (income)	1	(42)	(35)
Interest income on bank deposits	(19)	(6)	(*)
	2,222	(13,191)	7,665
Changes in asset and liability items:			
Decrease (increase) in other receivables	782	(1,604)	(532)
Increase (decrease) in trade payables	(252)	30	405
Increase (decrease) in other payables	(140)	(374)	(262)
	390	(1,948)	(389)
Net cash used in continuing operating activities	(3,557)	(4,199)	(8,075)
Net cash provided by (used in) discontinued operating activities	597	(529)	(1,665)
Net cash flows used in operating activities	(2,960)	(4,728)	(9,740)

(\*) Represents an amount lower than \$1.

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

# CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

### U.S. dollars in thousands

	Year ended December 31,		er 31,
	2011	2012	2013
Cash Flows from Investing Activities			
Purchase of property and equipment	(761)	(63)	(268)
Purchase of intangible assets	(88)	(350)	(90)
Interest received	25	6	3
Proceeds from (investment in) short term bank deposits, net of investments	4,201		(2,500)
Net cash provided by (used in) continuing investing activities	3,377	(407)	(2,855)
Net cash used in discontinued investing activities	(6,750)		
Net cash used in investing activities	(3,373)	(407)	(2,855)
Cash Flows from Financing Activities			
Proceeds from exercise of options	52		279
Proceeds from issuance of shares and warrants, net	6,675	—	15,800
Proceeds from shareholders' loans	_	1,555	3,930
Repayment of shareholders' loans	—	—	(915)
Deferred issuance costs	_	—	(129)
Proceeds from the Chief Scientist government grants	541	213	276
Net cash provided by continuing financing activities	7,268	1,768	19,241
Net cash provided by discontinued financing activities	_	_	_
Net cash provided by financing activities	7,268	1,768	19,241
Exchange rate differences on cash and cash equivalent balances	(1)	42	70
Increase (decrease) in cash and cash equivalents from continuing activities	7,087	(2,796)	8,381
Decrease in cash and cash equivalents from discontinued activities	(6,153)	(529)	(1,665)
Balance of cash and cash equivalents at the beginning of the year	2,728	3,662	337
Balance of cash and cash equivalents at the end of the year	3,662	337	7,053
Non-cash activities			
Contingent consideration for the purchase of treasury shares	—	_	19,200
Exercise of derivative instrument into treasury shares			15,400
Conversion of loans and realization of derivatives into shares and warrants	_		6,239

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

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

#### NOTE 1: GENERAL

a. General description of the company and its operations:

MediWound Ltd. (the "Company" or "MediWound"), is a fully integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel products to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds and connective tissue disorders. The Company's innovative biopharmaceutical product, NexoBrid, received marketing authorization from the European Medicines Agency, or the EMA, in December 2012 for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns.

- b. The Company has two wholly-owned subsidiaries: MediWound Germany GmbH, acting as EU marketing authorization holder and EU sales and marketing arm and MediWound UK Limited, an inactive company. In addition, the Company owns 7.5% of PolyHeal Ltd., a private life sciences company ("PolyHeal").
- c. Since its inception in 2000, the Company has achieved a number of significant milestones:
  - From 2002 to 2007, the Company conducted preclinical studies on NexoBrid (the Company's principal product) and completed three phase 2 studies on NexoBrid in the United States, Israel and internationally.
  - In August 2007, the Company entered into an agreement, which was terminated effective as of December 31, 2012, with Teva Pharmaceutical Industries Ltd., a global pharmaceutical company ("Teva"), to commercialize NexoBrid (see Note 15).
  - In 2009, the Company completed a European phase 3 study of NexoBrid confirming that NexoBrid effectively and safely removes the eschar.
  - In 2011, the Company received European Union cGMP certification for its manufacturing facility in Yavne, Israel.
  - In December 2012, the Company received EMA marketing authorization for NexoBrid in Europe.
  - In December 2013, the Company launched NexoBrid in the European Union, beginning in Germany.
- d. The Company has historically incurred significant operating losses. The Company's net operating losses were \$4,287, \$2,730 and \$7,581 for the years ended December 31, 2011, 2012 and 2013, respectively. As of December 31, 2013, the Company had an accumulated deficit of \$47,412 and has not generated any revenue to date from sales of NexoBrid.
- e. In January 2013 and June 2013, the Company and certain of its existing shareholders entered into convertible bridge financing agreements in the amounts of \$3,000 (of which \$2,579 were received from Clal Biotechnology Industries Ltd. (the "Parent Company")) and \$1,585 (of which \$1,500 were received from the Parent Company). In June 2013, the Company further entered into a share purchase agreement pursuant to which the Company issued 402,693 ordinary shares in consideration for \$15,800 net of issuance expenses. In addition, the Company issued to the investors warrants to purchase 201,349 ordinary shares at an exercise price of \$39.30 per share. Upon the closing of such share purchase agreement on August 19, 2013, the convertible bridge

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 1: GENERAL (Continued)

loans were converted into 158,734 ordinary shares and warrants to purchase 58,719 and 20,652 ordinary shares at exercise prices of \$25.55 and \$39.30, respectively.

### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

The following accounting policies have been applied consistently in the financial statements for all periods presented unless otherwise stated.

a. Basis of presentation of financial statements

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The Company's consolidated financial statements have been prepared on a cost basis, except for:

Financial instruments which are measured at fair value through profit or loss.

The Company has elected to present profit or loss items using the "function of expense" method.

- b. The Company's operating cycle is one year.
- c. Consolidated financial statements include the financial statements of companies that the Company controls (subsidiaries). Control is achieved when the company is exposed, or has rights, to variable returns from its investment with the investee and has the ability to affect those returns through its power over the investee.

The financial statements of the Company and its subsidiaries are prepared as of the same dates and periods. The consolidated financial statements are prepared using uniform accounting policies by all entities of in the Company. Significant intercompany balances and transactions and gains or losses resulting from intercompany transactions are eliminated in full in the consolidated financial statements. Commencing January 1, 2013, the Company has adopted IFRS 10, "*Consolidated Financial Statements*". The adoption of the new standard did not have an effect on the consolidated financial statements.

- d. Functional currency, reporting currency and foreign currency
  - 1. Functional currency and reporting currency

The reporting currency of the financial statements is the U.S. dollar.

The Company determines the functional currency based on the currency in which it primarily generates and expends cash. The Company determined that its functional currency is the U.S. dollar since most of the Company's expenses are in U.S. dollars and the economic environment in which the Company operates in and performs its transactions is mostly affected by the U.S dollar. A certain portion of the Company's costs are denominated in NIS mainly due to payroll and related benefit costs incurred in Israel. To further support the Company's determination, the Company has analyzed the currency in which funds from financing activities are generated or held and the currency in which receipts from operating activities are usually retained. In this respect, funds from financing activities were principally derived from significant funds raised in U.S. dollars during the years 2007 and 2010 pursuant to the investment agreements with Teva (see Note 15(b)).

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company operates and plans its activities in U.S. dollars and accordingly its periodic budgets and internal management reports are prepared and monitored using the U.S. dollar as the primary currency and provides the basis for the determination of share-based compensation.

The functional currency of the Company's subsidiary in Germany has been determined to be its local currency—the Euro. Assets and liabilities of this subsidiary are translated at year end exchange rates and its statement of operations items are translated using the actual exchange rates at the dates of which those items are recognized. Such translation adjustments are recorded as a separate component of accumulated other comprehensive income (loss) in shareholders' equity.

### 2. Transactions, assets and liabilities in foreign currency

Transactions denominated in foreign currency are recorded upon initial recognition at the exchange rate on the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange differences are recognized in profit or loss.

e. Cash equivalents

Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of deposit.

f. Short-term bank deposits

Short-term bank deposits have a maturity of more than three months, but less than one year, from the deposit date.

g. Inventories

Inventories are measured at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs. The Company periodically evaluates the condition and age of inventories and makes provisions for slow moving inventories accordingly.

Cost of inventories is determined as follows:

# Raw materials — At cost of purchase using the first-in, first-out method.

Finished goods — At the average costs for month of manufacturing including materials, labor and other direct and indirect manufacturing costs on the basis of each batch.

h. Chief Scientist government grants

Government grants are recognized when there is reasonable assurance that the grants will be received and the Company will comply with the attendant conditions.



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

Research and development grants received from the Office of the Chief Scientist in Israel ("OCS") are recognized upon receipt as a liability if future economic benefits are expected from the project that will result in royalty-bearing sales.

A liability for the grant is first measured at fair value using a discount rate that reflects a market interest rate. The difference between the amount of the grant received and the fair value of the liability is accounted for as a government grant and recognized as a reduction of research and development expenses. After initial recognition, the liability is measured at amortized cost using the effective interest method. Royalty payments are treated as a reduction of the liability. In that event, the royalty obligation is treated as a contingent liability in accordance with IAS 37, "*Provisions, Contingent Liabilities and Contingent Assets*" ("IAS 37").

At the end of each reporting period, the Company evaluates whether there is reasonable assurance that the liability recognized, in whole or in part, will not be repaid based on its best estimate of future sales and, if so, the appropriate amount of the liability is derecognized against a corresponding reduction in research and development expenses.

#### i. Property, plant and equipment, net

Property, plant and equipment are measured at cost, including directly attributable costs, less accumulated depreciation, accumulated impairment losses and excluding day-to-day servicing expenses. Cost includes spare parts and auxiliary equipment that are used in connection with the plant and equipment.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	70
Laboratory equipment	15 - 20
Office furniture	6 - 15
Computers	33
Leasehold improvements	See below

Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the renewal option held by the Company which is expected to be exercised) and the expected life of the improvement.

### j. Intangible assets, net

Separately acquired intangible assets with finite useful life are measured on initial recognition at cost.

Intangible assets are amortized over their useful life using the straight-line method beginning in the period in which the intangible assets generates net cash inflows to the Company. The intangible assets are reviewed for impairment at each reporting date until they begin generating net cash inflows and subsequently whenever there is an indication that the asset may be impaired.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

Licenses and knowledge

The estimated useful life and amortization of licenses to patents and knowledge is over the length of the patent or knowledge life, which begins when revenues are generated from the use of the patent or knowledge.

#### k. Research and development expenses, net of participations

Research and development expenses are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development. Since Company research and development projects are often subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not normally satisfied and, therefore, research and development expenses are recognized in profit or loss when incurred.

1. Impairment of non-financial assets

The Company evaluates the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs, and is calculated based on the projected cash flows that will be generated by the cash generating unit.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, may not increase the value above the lower of (i) the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years, and (ii) its recoverable amount.

m. Financial instruments

1. Financial assets:

Financial assets within the scope of IAS 39, "Financial Instruments: Recognition and Measurement" ("IAS 39") are initially recognized at fair value plus directly attributable transaction costs, except for financial assets measured at fair value through profit or loss in respect of which transaction costs are recorded in profit or loss.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

After initial recognition, the accounting treatment of financial assets is based on their classification as follows:

### Financial assets at fair value through profit or loss

This category includes financial assets designated upon initial recognition as at fair value through profit or loss.

#### Loans and receivables

The Company has receivables that are financial assets with fixed or determinable payments that are not quoted in an active market.

#### 2. Financial liabilities:

Financial liabilities within the scope of IAS 39 are initially measured at fair value.

After initial recognition, the accounting treatment of financial liabilities is based on their classification as follows:

#### Financial liabilities measured at amortized cost:

Loans and other liabilities are measured at amortized cost using the effective interest method taking into account directly attributable transaction costs.

#### Financial liabilities at fair value through profit or loss:

Financial liabilities at fair value through profit or loss include financial liabilities classified as held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

#### 3. Fair value

The fair value of financial instruments that are traded in an active market is determined by reference to market prices at the end of the reporting period. For financial instruments where there is no active market, fair value is determined using valuation techniques. Such techniques include using recent arm's length market transactions; reference to the current market value of another instrument which is substantially the same; discounted cash flow or other valuation models. A detailed analysis of the fair value measurement of financial instruments is provided in Note 12. Beginning January 1, 2013, the Company has adopted IFRS 13, *Fair Value Measurement*. The adoption of the new standard did not have a material effect on the measurement of the Company's financial instruments.

### 4. Offsetting financial instruments

Financial assets and financial liabilities are offset and the net amount is presented in the statement of financial position if there is a legally enforceable right to set off the recognized amounts and there is an intention either to settle on a net basis or to realize the asset and settle the liability simultaneously.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### 5. De-recognition of financial instruments

a) Financial assets:

A financial asset is derecognized when the contractual rights to the cash flows from the financial asset expire or the Company has transferred its contractual rights to receive cash flows from the financial asset or assumes an obligation to pay the cash flows in full without material delay to a third party and has transferred substantially all the risks and rewards of the asset, or has neither transferred nor retained substantially all the risks and rewards of the asset.

b) Financial liabilities:

A financial liability is derecognized when it is extinguished, that is when the obligation is discharged or cancelled or expires. A financial liability is extinguished when the debtor (the Company) discharges the liability by paying in cash, other financial assets, goods or services; or is legally released from the liability.

6. Treasury shares

Company shares held by the Company are recognized at fair value of the consideration and deducted from equity. Any gain or loss arising from a purchase, sale, issue or cancellation of treasury shares is recognized directly in equity.

The contingent consideration liability for acquisition of treasury shares is measured at fair value and initially recorded against equity. Subsequent changes in the fair value are recognized in profit or loss.

n. Provisions

A provision in accordance with IAS 37 is recognized when the Company has a present (legal or constructive) obligation as a result of a past event, it is expected to require the use of economic resources to clear the obligation and a reliable estimate can be made of it.

#### o. Severance pay liability, net

The Company has several employee benefit plans:

1. Short-term employee benefits

Short-term employee benefits include salaries, paid annual leave, paid sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered. A liability in respect of a cash bonus is recognized when the Company has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits

Post-employment benefit plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

The Company has defined contribution plans pursuant to Section 14 of the Severance Pay Law into which the Company pays fixed contributions and has no legal or constructive



#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Continued)

obligation to pay further contributions on account of severance pay if the fund does not hold sufficient amounts to pay all employee benefits relating to employee service in current and prior periods.

Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services.

The Company adopted IAS 19R effective January 1, 2013. The adoption of this new standard did not have an effect on the Company's consolidated financial statements.

#### p. Share-based compensation

Certain Company employees and directors are entitled to remuneration in the form of equity-settled share-based compensation.

#### Equity-settled transactions

The cost of equity-settled transactions with employees is measured at the fair value of their equity instruments granted at grant date. The fair value is determined using an acceptable option pricing model.

As for other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for equity instruments. In cases where the fair value of the goods or services received as consideration of equity instruments cannot be measured, they are measured by reference to the fair value of the equity instruments granted.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period which the performance or service conditions are to be satisfied, ending on the date on which the relevant employees become fully entitled to the award.

#### q. Discontinued operation

Non-current assets or a disposal group are classified as held for sale if their carrying amount will be recovered principally through a sale transaction rather than through continuing use.

A discontinued operation is a component of the Company that either has been disposed of or is classified as held for sale. Disposal group to be abandoned meets the criteria for being a discontinued operation at the date of which it ceases to be used. The operating results relating to the discontinued operation are separately presented in the consolidated statements of comprehensive income.

### r. Income (loss) per share

Income (loss) per share is calculated by dividing the income (loss) attributable to Company shareholders by the weighted average number of outstanding ordinary shares during the period. Potential ordinary shares are only included when their conversion decreases income per share or increases loss per share from continuing operation. Furthermore, potential ordinary shares converted during the period are included in diluted income (loss) per share only until the conversion date and from that date in basic income (loss) per share.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

# NOTE 3: SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

The preparation of the financial statements requires management to make estimates and assumptions that have an effect on the application of the accounting policies and on the reported amounts of assets, liabilities and expenses.

Discussed below are the key assumptions made in the financial statements concerning uncertainties at the end of the reporting period and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Determining the fair value of share-based compensation to employees and directors, and warrants to shareholders:

The fair value of share-based compensation to employees and directors as well as of warrants to shareholders is determined using acceptable option pricing models.

The assumptions used in the models include the expected volatility, expected life, expected dividend and risk-free interest rate.

Chief Scientist government grants:

Government grants received from the OCS are recognized as a liability if future economic benefits are expected from the research and development activity that will result in royalty-bearing sales. There is uncertainty regarding the estimated future cash flows and the estimated discount rate used to measure the amortized cost of the liability.

Contingent consideration for the purchase of treasury shares

Contingent consideration for acquisition of treasury shares was first measured at fair value. After initial recognition, the liability is measured at amortized cost using the effective interest method. As the contingent consideration is calculated based on future royalty-bearing sales, there is uncertainty regarding the estimated future cash flows and the estimated discount rate used to measure the fair value of this liability.

• Derivative instruments related to the Company's right to repurchase its shares from Teva

The Company's right to repurchase its shares from Teva is accounted for as a derivative instrument which is measured at fair value. The fair value of the repurchase options was determined by using an acceptable option pricing model. The assumptions used in the model include the expected volatility, expected life, expected dividend and risk-free interest rate.

### NOTE 4: DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

#### IAS 32—Financial Instruments: Presentation

The IASB issued certain amendments to IAS 32 ("the amendments to IAS 32") regarding the offsetting of financial assets and liabilities. The amendments to IAS 32 are to be applied retrospectively commencing from the financial statements for periods beginning on January 1, 2014, or thereafter.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 4: DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Continued)

The Company estimates that the amendments to IAS 32 will not have a material impact on its financial statements.

#### IFRS 9—Financial Instruments:

1. The IASB issued IFRS 9, "Financial Instruments", the first part of Phase 1 of a project to replace IAS 39, "Financial Instruments: Recognition and Measurement".

According to the IFRS 9, all financial assets should be measured at fair value upon initial recognition. In subsequent periods, debt instruments should be measured at amortized cost only if both of the following conditions are met:

- The asset is held within a business model whose objective is to hold assets in order to collect the contractual cash flows.
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Subsequent measurement of all other debt instruments and financial assets should be at fair value.

Financial assets that are equity instruments should be measured in subsequent periods at fair value and the changes recognized in profit or loss or in other comprehensive income, in accordance with the election by the Company on an instrument-by-instrument basis. If equity instruments are held for trading, they should be measured at fair value through profit or loss.

2. The IASB issued certain amendments to IFRS 9 regarding de-recognition and financial liabilities. According to those amendments, the provisions of IAS 39 will continue to apply to de-recognition and to financial liabilities for which the fair value option has not been elected.

Pursuant to the amendments, the amount of the adjustment to the liability's fair value that is attributable to changes in credit risk should be presented in other comprehensive income. All other fair value adjustments should be presented in profit or loss.

The Company believes that the application of IFRS 9 is not expected to have a material effect on the financial statements.

### NOTE 5: CASH AND CASH EQUIVALENTS

	Decen	iber 31,
	2012	2013
Cash for immediate withdrawal	337	2,052
Bank deposits(*)	—	5,001
	337	7,053

(\*) Bank deposits bore interest ranging from 0.16% to 0.24%.

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# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

## NOTE 6: OTHER RECEIVABLES

	Decemb	oer 31,
	2012	2013
Government authorities	101	173
Related parties	17	183
Former related parties	1,685	1,648
Prepaid expenses and other	250	508
	2,053	2,512

### NOTE 7: INVENTORIES

	Decemb	oer 31,
	2012	2013
Raw materials	254	_
Finished goods	608	
	862	_

The inventory balances as of December 31, 2012 are related to the PolyHeal discontinued operation. Upon the expiration of the PolyHeal license (see Note 18), the Company recorded during 2013, a write off of the aforesaid inventories in the amount of \$490 which was classified as a loss from discontinued operation in the statements of comprehensive income.

### NOTE 8: PROPERTY, PLANT AND EQUIPMENT, NET

Balance as of December 31, 2013:

Office furniture	Electronic machinery and lab equipment	Computers	Leasehold improvements	Total
98	2,503	224	1,944	4,769
—	(887)	(140)		(1,027)
71	107	35	55	268
169	1,723	119	1,999	4,010
		·		
27	1,551	179	1,738	3,495
	(887)	(140)		(1,027)
27	240	31	108	406
54	904	70	1,846	2,874
115	819	49	153	1,136
	fumiture 98 71 169 27 27 54	Office furniture         machinery and lab equipment           98         2,503           —         (887)           71         107           169         1,723           27         1,551           —         (887)           27         240           54         904	Office furniture         machinery and lab equipment         Computers           98         2,503         224           —         (887)         (140)           71         107         35           169         1,723         119           27         1,551         179           —         (887)         (140)           27         1,551         179           —         (887)         (140)           27         240         31           54         904         70	Office furniture         machinery and lab equipment         Computers         Leasehold improvements           98         2,503         224         1,944            (887)         (140)            71         107         35         55           169         1,723         119         1,999            (887)         (140)            27         1,551         179         1,738            (887)         (140)            27         240         31         108           54         904         70         1,846

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

# NOTE 8: PROPERTY, PLANT AND EQUIPMENT, NET (Continued)

Balance as of December 31, 2012:

	Office Furniture	Electronic Machinery and Lab Equipment	Computers	Leasehold Improvements	Total
Cost					
Balance as of January 1, 2012	97	2,459	206	1,944	4,706
Additions	1	44	18		63
Balance as of December 31, 2012	98	2,503	224	1,944	4,769
Accumulated Depreciation					
Balance as of January 1, 2012	20	1,298	153	1,602	3,073
Additions	7	253	26	136	422
Balance as of December 31, 2012	27	1,551	179	1,738	3,495
Depreciated cost as of December 31, 2012	71	952	45	206	1,274

# NOTE 9: INTANGIBLE ASSETS, NET

Balance as of December 31, 2013

	License and Know-how	PolyHeal License	Total
Cost			
Balance as of January 1, 2013	1,316	6,333	7,649
Additions	90		90
Balance as of December 31, 2013	1,406	6,333	7,739
Accumulated Amortization (including Impairment)			
Balance as of January 1, 2013	402	2,154	2,556
Additions	—	522	522
Impairment losses	—	3,657	3,657
Balance as of December 31, 2013	402	6,333	6,735
Amortized cost			
Balance as of December 31, 2013	1,004	_	1,004

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### NOTE 9: INTANGIBLE ASSETS, NET (Continued)

Balance as of December 31, 2012:

	License and Know-how	PolyHeal License	Total
Cost			
Balance as of January 1, 2012	966	6,333	7,299
Additions	350	—	350
Balance as of December 31, 2012	1,316	6,333	7,649
Accumulated Amortization (including Impairment)			
Balance as of January 1, 2012	402	1,462	1,858
Additions		698	698
Balance as of December 31, 2012	402	2,154	2,556
Amortized cost			
Balance as of December 31, 2012	914	4,179	5,093

Intangible assets include exclusive licenses to use patents, know-how and intellectual property for the development, manufacturing and marketing of products related to burn treatments and other products in the field of wound care. These licenses were purchased from third parties, PolyHeal and from one of the Company's shareholders (see Note 14 and 18).

### NOTE 10: OTHER PAYABLES

	Decemb	er 31,
	2012	2013
Employees and payroll accruals	467	526
Accrued expenses	236	154
Related parties	331	163
	1,034	843

# NOTE 11: CHIEF SCIENTIST GOVERNMENT GRANTS

	2012	2013
Balance as of January 1	5,610	6,434
Grants received	213	276
Amounts carried to profit or loss	611	(106)
Balance as of December 31	6,434	6,604

The Company is committed to pay royalties to the OCS up to the total grants received plus the applicable accrued interest. The total gross amount of grants actually received by the Company from the OCS including accrued LIBOR interest as of December 31, 2013 is approximately \$9,888, while the amortized cost of this liability as of that date is approximately \$6,604, using the interest method as described in Note 12c. As of December 31, 2013, the Company had not paid any royalties to the OCS (see Note 14b).

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### NOTE 12: FINANCIAL INSTRUMENTS

#### a. Classification of financial assets and liabilities

	December 31,		
	2012	2013	
Financial assets			
Derivatives instruments	15,400		
Financial liabilities			
Liabilities in respect of Chief Scientist government grants	6,434	6,604	
Contingent consideration for the purchase of treasury shares	—	16,800	
Warrants to shareholders	_	9,200	
	6,434	32,604	

### b. Financial risk factors

The Company's activities expose it to various market risks (mainly foreign currency risk and interest rate risk). The Company's Board of Directors has provided guidelines for risk management and specific policies for various risk exposures.

#### Foreign currency risk

The Company operates primarily in an international environment and is exposed to foreign exchange risk resulting from to the fact that a certain portion of the Company's costs are denominated in NIS mainly due to payroll and related benefit costs incurred in Israel.

#### c. Fair value

The carrying amount of cash and cash equivalents, short-term investments, trade and other receivables and others payables approximates their fair value due to the short-term maturities of such instruments.

The fair value of the derivative instrument related to the Company's right to repurchase its own shares was determined by using the binomial model with the following main assumptions: Dividend yield of 0%, Expected volatility of 55% and a risk free interest of 0.11%-0.16% (see Note 15).

The fair value of liabilities in respect to government grants with fixed interest is based on a calculation of the present value of the cash flows at the interest rate for a loan with similar terms (see Note 11). The Company used a discount rate of 12% based in part of the Company's cost of capital at the time of the Company's initial recognition of the OCS grants which was assumed to reflect the market interest rate on that date.

The fair value of the contingent consideration in respect of the purchase of treasury shares is based on a calculation of the present value of future royalty payments using a discount rate that reflects the applicable market rate of interest at the date of the initial recognition. The Company used a discount rate of 16% based in part on the Company's cost of capital, at the time of the Company's initial recognition of the contingent consideration. The amount and timing of the future royalty payments are based on the Company's projected revenues.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 12: FINANCIAL INSTRUMENTS (Continued)

The fair value of the warrants to shareholders was determined by using acceptable option pricing model with the main following assumptions: Dividend yield of 0%, expected volatility of 80%-84% and a risk free interest of 0.07%-0.33%.

d. Classification of financial instruments by fair value hierarchy

The financial instruments presented on the balance sheet at fair value are grouped into classes with similar characteristics using the following fair value hierarchy which is determined based on the source of input used in measuring fair value:

- Level 1 quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs other than quoted prices included within level 1 that are observable either directly or indirectly.
- Level 3 inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

The Company's financial instruments presented in the above table in (a) are classified as level 3 in the fair value hierarchy.

e. Sensitivity tests relating to changes in market factors:

	December 31,					
	20	11	201	2	20	)13
Sensitivity test to changes in exchange rate						
Gain (loss) from change:						
5% increase in exchange rate	\$	(1)	\$ (2	22)	\$	15
5% decrease in exchange rate	\$	1	\$ 2	22	\$	(15)

Sensitivity tests and principal work assumptions:

The selected changes in the relevant risk variables were determined based on management's estimate as to reasonable possible changes in these risk variables.

The Company has performed sensitivity tests of principal market risk factors that may affect its reported operating results or financial position.

The sensitivity tests present the profit or loss for the relevant risk variable chosen as of each reporting date.

### NOTE 13: SEVERANCE PAY LIABILTY, NET

The Israeli Severance Pay Law, 1963 ("Severance Pay Law"), specifies that employees are entitled to severance payment, following the termination of their employment. Under the Severance Pay Law, the severance payment is calculated as one month salary for each year of employment, or a portion thereof.

The majority of the Company's liability for severance pay is covered by Section 14 of the Severance Pay Law ("Section 14"). Under Section 14, employees are entitled to have monthly deposits,

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 13: SEVERANCE PAY LIABILTY, NET (Continued)

at a rate of 8.33% of their monthly salary, made on their behalf to their insurance funds. Payments in accordance with Section 14 release the Company from the liability for any future severance payments in respect of those employees. As a result, the Company does not recognize any liability for severance pay due to these employees and the deposits under Section 14 are not recorded as an asset in the Company's balance sheet. These contributions for compensation represent defined contribution plans.

The Company's liability for employee benefits is based on a valid labor agreement, the employee's salary, and the applicable terms of employment, which together generate a right to severance compensation. Post-employment employee benefits are financed by deposits with defined contribution plans, as detailed below.

		Year ended		
	I	December 31,		
	2011	2012	2013	
Expenses—defined contribution plan	45	65	42	

### NOTE 14: CONTINGENT LIABILITIES AND COMMITMENTS

a. In 2000, the Company signed an exclusive license agreement (as amended in 2007) with a third party with regard to its patents and intellectual property. Pursuant to the agreement, the Company received an exclusive license to use the third party's patents and intellectual property, for the purpose of developing, manufacturing, marketing, and commercializing products for treatment of burns and other wounds.

In consideration for this exclusive license, the Company paid an aggregate amount of \$950 following the achievement of certain development milestones as set forth in the agreement. In addition, the Company undertook to pay royalties of 1.5% to 2.5% from future revenues from sales of products which are based on this patent for a period ranging between 10 to 15 years from the first commercial delivery in a major country, and thereafter the Company will have a fully paid-up royalty-free license for these patents. In addition, royalties will be paid at the rate of 10% - 20% from sub-licensing of such patents. Moreover, the Company agreed to pay a one-time lump-sum amount of \$1,500 when the aggregate revenues based on these patents reach \$100,000.

b. Under the Research and Development Law, (the "R&D Law") the Company undertook to pay royalties of 3% - 3.5% on the revenues derived from sales of products or services developed in whole or in part using these OCS grants. The maximum aggregate royalties paid generally cannot exceed 100% of the grants received by the Company, plus annual interest generally equal to the 12-month LIBOR applicable to dollar deposits, as published on the first business day of each calendar year. The maximum royalty amount payable by the Company as of December 31, 2013 is approximately \$9,888, which represents the total gross amount of grants actually received by the Company from the OCS including accrued interest. As of December 31, 2013, we had not paid any royalties to the OCS.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 14: CONTINGENT LIABILITIES AND COMMITMENTS (Continued)

- c. On November 24, 2010, the Company signed an agreement with one of its shareholders, to purchase a patent for the production and sale of related products for the treatment of burns. In consideration for the transfer and assignment of all rights and title relating to the patent, the Company paid a one-time payment in the amount of \$88 and undertook to pay annual fixed payments in the amount of \$30 as long as the patent is valid in the US and/or in any EU member country. The patent expires in May 2018, and the Company's accumulated outstanding obligation with respect to this agreement as of December 31, 2013 is \$133.
- d. Operating Lease Agreements:
  - 1. The Company's offices and its production facility are located in a building that the Company leases from its Parent Company, in accordance with a sub-lease agreement from July 2004. According to the amendment of the sub-lease in December 2013 the Company subleased an additional 1,000 square meters of laboratory, office and clean room space. This sub-lease agreement expires in December 2017. Regarding the Company's subsidiary, MediWound Germany the monthly rent for its offices is currently €2.7 (approximately \$3.7) while the lease agreement expires on April 30, 2016.
  - 2. The Company and its subsidiary have operating lease agreements for 15 vehicles. According to these agreements, the Company leases cars for its employees for a period of three years. As of December 31, 2013, the Company deposited \$69 in respect of the vehicle operating leases.
  - 3. Minimum future lease fees for both agreements as of December 31, 2013 are as follows:

2014	655
2015 2016	651
2016	613
2017	491
	2.410

#### NOTE 15: EQUITY

a. Rights attached to shares:

An ordinary share confers upon its holder(s) a right to vote at the general meeting, a right to participate in distribution of dividends, and a right to participate in the distribution of surplus assets upon liquidation of the Company. The right to appoint the members of the Board is vested in certain shareholders of the Company, rather than in the general meeting.

b. Transactions between the Company and Teva

In August 2007, the Company entered into a set of agreements with Teva, certain institutional investors and other private investors, consisting of investments, license and collaboration, and buyout option agreements (collectively, the "2007 Teva Agreement").

As part of the 2007 Teva Agreement, Teva received an exclusive right to market and distribute NexoBrid, in specific countries. The agreement stipulated that both the Company and Teva would be responsible for the continued development of NexoBrid, the Company would be responsible for manufacturing and Teva would be responsible for commercialization, all subject to payments and to

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 15: EQUITY (Continued)

other terms and conditions that were set forth in the agreements. Additionally, as part of the 2007 Teva Agreement, Teva made certain investments in our ordinary shares.

On December 30, 2010, as part of the 2010 PolyHeal Agreement (see Note 18), the 2007 Teva Agreement was amended. The amended 2010 PolyHeal Agreement provided that in the event of a termination of the collaboration with Teva for the development of NexoBrid or PolyHeal, the Company would have the right to repurchase all of its shares that were purchased by Teva under both agreements as may be the case (the "Repurchase Rights"), in exchange for either:

- (i) a cash payment amounting to the total amount actually paid by Teva to the Company and its shareholders for the shares purchased under the agreement, or
- (ii) future royalty payments of 20% on sales of NexoBrid and the PolyHeal product, up to certain caps as set forth in the Amended Agreements.

The Repurchase Rights were exercisable for a period of 180 days from the termination of the collaboration agreements.

Under the agreements, the Company had the right to choose either of the options, at its sole discretion.

On December 10, 2012, the Company reached an agreement with Teva regarding the termination of the collaborations under both the 2007 Teva Agreement and the 2010 PolyHeal Agreement, effective as of December 31, 2012. Following to the termination of agreements, Teva's right to the commercialization of both NexoBrid and the PolyHeal product expired.

As a derivative instrument, the Repurchase Rights were measured at fair value through profit or loss at each reporting period. However, from the grant date through the termination of the collaboration with Teva, the Repurchase Rights value was zero and only upon the termination of the collaboration, they became exercisable, following which the Company revalued the rights and recorded a financial gain amounting to \$15,400 as a revaluation of a derivative instrument as of December 31, 2012.

On September 2, 2013, the Company exercised its rights to repurchase all of its shares held by Teva, in consideration for future royalty payments of 20% of the Company's revenues from the sale or license of NexoBrid up to a total amount of \$30,600 and from the sale or license of the PolyHeal Product up to a total amount of \$10,800.

The abovementioned obligation to pay Teva future royalty payments no longer includes amounts from the sale or license of the PolyHeal Product, since the license to the PolyHeal Product has expired.

The total amortized cost of the future royalty obligation to Teva at the exercise date on September 2, 2013 was estimated at approximately \$19,200. In accordance with IAS 32, the Company recorded the fair value of the liability to pay royalties against a reduction in equity (treasury shares). Subsequent changes in this liability will be recorded in profit or loss. Accordingly, the liability was remeasured to \$16,800 as of December 31, 2013, as a result of a revaluation in the amount of \$2,400 which was recorded within financial income.

In addition, upon the exercise of the right to repurchase all its shares held by Teva, the Company reclassified the derivative instrument related to its right to repurchase its ordinary shares from

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 15: EQUITY (Continued)

Teva, which had a fair value in the amount of \$15,400 as of December 31, 2012, into equity as treasury shares.

### c. The 2013 Share Purchase Agreement and Convertible Loans

In January 2013, the Company and certain of its existing shareholders entered into a convertible bridge financing agreement in the amount of \$3,000 (of which \$2,579 were received from the Parent Company). The financing amount bore no interest and, in the event that within 12 months from the closing, the Company consummated an equity financing, it was to be automatically converted into shares of the type issued to the investors in such equity financing, at a price per share equal to 65% of the price per share paid by the investors in such equity financing. The Company measured the beneficial conversion feature embedded in the above convertible bridge loan in accordance with IAS 39 and initially recognized it separately as a financial derivative instrument. The balance of the convertible bridge loan was attributed to the debt component of such loan. After initial recognition, the derivative is measured at fair value with changes to be recorded in profit or loss.

In June 2013, the Company and certain of its existing shareholders entered into a convertible loan agreement in the amount of \$1,585 (of which \$1,500 were received from the Parent Company). The principal amount bore interest at the rate of 10% per annum (compounded annually) and, in the event that, within 12 months from the closing, the Company consummated an equity financing, it was to be automatically converted into shares of the type issued to the investors in such equity financing, at a price per share equal to 100% of the equity financing price per share paid by the investors in such equity financing.

In June 2013, the Company and certain of its existing shareholders further entered into a share purchase agreement. Under such agreement, which closed on August 19, 2013, the Company issued 402,693 ordinary shares, in consideration for \$15,800, net of issuance expenses. In addition, the Company granted warrants to purchase 201,349 ordinary shares at an exercise price of \$39.30 per ordinary share.

Upon the closing of the share purchase agreement, the convertible bridge financing and loans along with the abovementioned embedded derivative instrument were converted into a total of 158,734 ordinary shares and warrants to purchase 58,719 and 20,652 ordinary shares at exercise prices of \$25.55 and \$39.30, respectively. In December 2013, the warrants were amended so that they expire upon the Company's initial public offering and the warrant holders may exercise, either in a cash or cashless manner, such warrants immediately prior to the Company's initial public offering. These warrants were accounted for as a derivative liability in accordance with IAS 32 because they contain a net settlement feature. Accordingly, the warrants are measured at fair value through profit or loss.

### NOTE 16: SHARE-BASED COMPENSATION

a. Expense recognized in the financial statements

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

# NOTE 16: SHARE-BASED COMPENSATION (Continued)

The expense that was recognized for services received from employees and directors is as follows:

		Year ended December 31,		
	2011	2012	2013	
Research and development	182	124	315	
Selling and marketing	_		24	
General and administrative	373	210	192	
Expenses attributable to continuing operations	555	334	531	
Expenses attributable to discontinued operation	109	30	76	
Total share-based compensation	664	364	607	

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 16: SHARE-BASED COMPENSATION (Continued)

b. Share-based payment plan for employees and directors:

The Company has reserved for issuance as stock options a total of 850,000 ordinary shares. As of December 31, 2013, 224,720 ordinary shares of the Company were still available for future grant. Any options, which are forfeited or not exercised before expiration, become available for future grants.

Options granted under the Company's 2003 Israeli Share Option Plan ("Plan") are exercisable in accordance with the terms of the Plan, within 10 years from the date of grant, against payment of an exercise price. The options generally vest over a period of three or four years.

- c. Option grants:
  - 1. On January 6, 2013, the Company granted 16,500 options to purchase ordinary shares under the Plan for an exercise price of \$52.28 per share to its employees.
  - 2. On December 24, 2013, the Company granted 238,000 options to purchase ordinary shares under the Plan for an exercise price of \$49.00 per share to its employees.
- d. Share options activity:

The following table lists the number of share options, the weighted average exercise prices of share options and changes that were made in the option plan to employees and directors:

	201	1	2012		2013	3
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	390,293	6.16	436,793	9.24	398,670	8.15
Granted	46,500	37.30			254,500	49.21
Exercised	—				(17,702)	15.77
Forfeited		_	(38,123)	0.33	(10,188)	32.54
Outstanding at end of year	436,793	9.24	398,670	10.09	625,280	25.49
Exercisable at end of year	397,043	6.47	372,170	8.15	358,030	8.20

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 16: SHARE-BASED COMPENSATION (Continued)

The following table summarizes information about share options outstanding as of December 31, 2013:

December 31, 2013	
Detember 51, 2010	
remaining av	eighted verage tercise
Range of exercise prices (\$) options life	price
0.33 179,534 3.95	0.33
4.00 - 10.00 116,478 1.63	7.23
30.29 - 37.30 74,768 5.83	33.57
49.00 - 52.28 254,500 9.92	49.21
Total 625,800 6.17	25.49

e. The fair value of the Company's share options granted to employees for the years ended December 31, 2011 and 2013 was estimated using an acceptable option pricing model using the following assumptions:

	As of December 31,				
	2011 2012(*)		2013		
Dividend yield (%)	_	_	_		
Expected volatility of the share prices (%)	85		84		
Risk-free interest rate (%)	2.09 - 2.66	—	1.03 - 2.09		
Expected life of share options (years)	6.25		5.5 - 7.0		
Weighted average share prices (Dollar)	\$37.30		\$54.75		

### (\*) There were no grants during 2012.

The expected life of the share options is based on the midpoints between the available exercise dates (the end of the vesting periods) and the last available exercise date (the contracted expiry date), as adequate historical experience is not available to provide a reasonable estimate.

The expected share price volatility is based on the historical equity volatility of the share prices of comparable companies that are publicly traded.

### NOTE 17: TAXES ON INCOME

a. Corporate tax rates in Israel:

The Israeli corporate tax rate was, 24% in 2011 and 25% in 2012 and 2013.

On July 30, 2013, the Israeli Parliament (the Knesset) approved the Economic Plan for 2013-2014 ("Amended Budget Law") which consists of fiscal changes whose main aim is to enhance the collection of taxes in those years. These changes include: (i) raising the Israeli corporate tax rate from 25% to 26.5%, (ii) cancelling the reduction of the tax rates applicable to preferred enterprises (9% in development area A and 16% in other areas), and (iii) in certain cases increasing the tax rates on dividends within the scope of the Law for the Encouragement of Capital Investments to 20% effective from January 1, 2014. Other changes introduced by the

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 17: TAXES ON INCOME (Continued)

Amended Budget Law include taxing revaluation gains effective from August 1, 2013. The changes regarding the taxation of revaluation gains, however, will only become effective once regulations that define "non-corporate taxable retained earnings" are issued as well as regulations that set forth provisions for avoiding double taxation of assets outside of Israel. As of the date of publication of these interim financial statements, no such regulations have been issued. The change in tax rates did not have an effect on the Company's consolidated financial statements.

b. Tax benefits under the Israel Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"):

Under the Investment Law, the Company has been granted "Beneficiary Enterprise" status which provides certain benefits, including tax exemptions and reduced tax rates. Income not eligible for Beneficiary Enterprise benefits is taxed at a regular rate.

During the benefit period, the Company will be tax exempt in the first two years of the benefit period and subject to tax at the reduced rate of 10%-25% for an additional period of five to eight years (depending on the percentage of foreign investments in the Company) of the benefit period. The benefit entitlement period starts from the first year that the Beneficiary Enterprise first earned taxable income, and is limited to 12 years from the year in which the Company requested to have tax benefits apply. In the event of distribution of dividends from the said tax-exempt income, the amount distributed will be subject to corporate tax at the reduced rate ordinarily applicable to the Beneficiary Enterprise's income. Tax-exempt income generated under the Company's "Beneficiary Enterprise" program will be subject to taxes upon dividend distribution or complete liquidation. The entitlement to the above benefits is conditional upon the Company's fulfilling the conditions stipulated by the Investment Law and regulations published thereunder. Should the Company fail to meet such requirements in the future, income attributable to its Beneficiary Enterprise programs could be subject to the statutory Israeli corporate tax rate and the Company could be required to refund a portion of the tax benefits already received, with respect to such programs.

c. Final tax assessments:

The Company received final tax assessments through 2009.

Net operating carry-forwards losses for tax purposes and other temporary differences:

As of December 31, 2013, the Company had carry-forwards losses and other temporary differences amounting to approximately \$52,000.

e. Deferred taxes:

d.

The Company did not recognize deferred tax assets for carry-forwards losses and other temporary differences because their utilization in the foreseeable future is not probable.

f. Current taxes on income

The Company did not record any current taxes for the years ended December 31, 2011, 2012 and 2013 as a result of its carry-forward losses.



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 17: TAXES ON INCOME (Continued)

g. Theoretical tax:

The reconciliation between the tax expense, assuming that all the income and expenses, gains and losses in the statement of income were taxed at the statutory tax rate and the taxes on income recorded in profit or loss, does not provide significant information and therefore was not presented.

#### NOTE 18: DISCONTINUED OPERATION

a. In December 2010, the Company, Teva and PolyHeal, entered into a series of agreements to collaborate in the development, manufacturing and commercialization of PolyHeal's wound care product, or the PolyHeal Product. The Company refers to these agreements as the 2010 PolyHeal Agreement.

Additionally, in connection with entering into the 2010 PolyHeal Agreement, the Company and its shareholders also amended the 2007 Teva Agreement (see Note 15).

### License agreements:

Under the 2010 PolyHeal Agreement, PolyHeal granted the Company an exclusive global license to manufacture, develop and commercialize all the Polyheal Products in consideration for royalty payments. Concurrently, the Company granted Teva an exclusive global sub-license to commercialize the Polyheal Products in consideration for certain royalties and milestone payments. In addition, Teva undertook to finance the Company's future development of the Polyheal Product and all of its manufacturing costs.

The 2010 PolyHeal Agreement also stipulated that in the event that the collaboration with Teva with respect to the Polyheal Product terminated, the Company's agreements with PolyHeal (other than the shareholders' rights agreement) would expire nine months thereafter, unless the Company engaged a qualified strategic successor to take over Teva's sub-license.

#### Share purchase agreements:

Under the 2010 PolyHeal Agreement, Teva initially invested \$6,750 in the Company, and undertook to invest an additional \$6,750 in the Company subject to the achievement of a development milestone. Concurrent with Teva's investment in the Company, the Company purchased shares of PolyHeal for total consideration of \$6,750. Additionally, the Company undertook to purchase additional shares of PolyHeal for the same amount, subject to the achievement of the same abovementioned development milestone.

The Company has accounted this transaction as an acquisition of a group of assets since the assets acquired did not constitute a business as defined in IFRS 3. The Company allocated the consideration paid for the group of assets acquired based on their fair value to two identifiable assets: the license for the Polyheal Products in the amount of \$6,333 and royalty rights arising from the Company's ownership of shares of PolyHeal in the amount of \$417 (see Note 9).

b. On November 15, 2012, the Company informed Teva of the commencement of a feasibility study for the next generation of the PolyHeal Product, which constituted a milestone under the 2010 PolyHeal Agreement. In accordance with the terms of the agreement, achievement of the milestone should have led to an investment of \$6,750 in the Company's ordinary shares by Teva, and a purchase by the Company of \$6,750 of PolyHeal's shares. Teva has indicated that it disputes

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### NOTE 18: DISCONTINUED OPERATION (Continued)

its obligation to make the milestone investment, and as of December 31, 2013, Teva had not made the investment despite the Company's requests. The Company has commenced discussions regarding this matter with Teva; however, there is no certainty that Teva will make the investment or that the Company will purchase the PolyHeal shares.

c. As of December 31, 2012, all of the Company's collaborations with Teva under both the 2007 Teva Agreement and the 2010 PolyHeal agreement were terminated and consequently the Company's exclusive license for the PolyHeal Product expired as a result of the Company's failure to find a substitute strategic successor to Teva within the nine month period following the termination of the Company's agreement with Teva. Following the expiration of the license agreement with PolyHeal, the Company classified the results of PolyHeal operations for all periods presented, and the related cash flows, as a discontinued operation in accordance with IFRS 5. Furthermore, during the year ended December 31, 2013, the Company has fully impaired the license for the PolyHeal Product in the amount of \$3,657.

Pursuant to the 2010 PolyHeal Agreement, Polyheal has the right to repurchase all of its shares held by the Company either for cash or royalty payments from revenues generated by sale or licensing of the PolyHeal Product. PolyHeal's right to repurchase its shares will expire 180 days after the date that the PolyHeal license expired.

d. As discussed above, the Company decided to classify the results of operations in PolyHeal as discontinued operation.

Below is the data of the operating results attributed to the discontinued operation:

2011         2012           Revenues         299         67           Cost of sales(*)         1,091         821           Gross loss         (792)         (754)           Research and development, net of participations         (179)         107           Selling and marketing         71         184           Impairment of intangible assets(**)         666         —	2013
Cost of sales(*)1,091821Gross loss(792)(754)Research and development, net of participations(179)107Selling and marketing71184Impairment of intangible assets(**)666—	
Gross loss(792)Research and development, net of participations(179)Selling and marketing71Impairment of intangible assets(**)666	392
Research and development, net of participations(179)Selling and marketing71Impairment of intangible assets(**)666	2,015
Selling and marketing     71     184       Impairment of intangible assets(**)     666	(1,623)
Impairment of intangible assets(**) 666	607
	963
	3,657
Total operating expenses(558)(291)	(5,227)
Operating loss (1,350) (1,045)	(6,850)
Loss from discontinued operation (1,350) (1,045)	(6,850)

(\*) During the year ended December 31, 2013, the cost of sales included a write- off of inventory in the amount of \$490.

(\*\*) The impairment of intangible assets in the year ended December 31, 2013 was a result of the expiration of the license to the PolyHeal Products.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

# NOTE 19: SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF COMPREHENSIVE INCOME.

### a. Research and development expenses, net of participations

	Year en	r 31,	
	2011	2012	2013
Salary and benefits (including share-based compensation)	1,628	1,438	2,137
Subcontractors	3,567	1,668	1,372
Depreciation and amortization	172	235	278
Materials	398	107	181
Others	384	356	545
	6,149	3,804	4,513
Participation by the Chief Scientist	(452)	(62)	(878)
Participation by others	(2,676)	(2,185)	
	3,021	1,557	3,635

### b. Selling and marketing expenses

	Year e	Year ended December 31	
	2011	2012	2013
Salary and benefits (including share-based compensation)		_	890
Marketing and advertising	—	_	1,165
Other	—	—	204
		_	2,259

# c. General and administrative expenses

	Year e	Year ended December 31,	
	2011	2012	2013
Salary and benefits (including share-based compensation)	960	830	951
Professional fees	80	113	349
Depreciation and amortization	24	33	57
Other	202	197	330
	1,266	1,173	1,687



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

# NOTE 19: SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF COMPREHENSIVE INCOME. (Continued)

# d. Financial income and expense:

	Year ended December 31		per 31
	2011	2012	2013
Financial income:			
Interest income	32	6	1
Revaluation of financial derivatives		15,400	—
Revaluation of contingent consideration for the purchase of treasury shares			2,400
Exchange differences, net	64		_
	96	15,406	2,401
Financial expense		·	
Revaluation of liabilities in respect of Chief Scientist government grants	591	673	772
Revaluation of warrants to shareholders	_		820
Exchange differences, net		6	44
Interest in respect to convertible loans	_		1,669
Other	37	12	16
	628	691	3,321

### NOTE 20: NET INCOME (LOSS) PER SHARE

a. Details of the number of shares and income (loss) used in the computation of income (loss) per share from continuing operations:

	Year ended December 31,					
	2011		201	2	201	3
	Weighted average number of shares	Loss	Weighted average number of shares	Income	Weighted average number of shares	Loss
	of sinares	LOSS	of shares	Income	of shares	Loss
Basic income (loss)	4,127	(4,819)	4,127	11,985	4,124	(8,501)
Effect of potential dilutive ordinary shares			399			
Diluted income (loss)	4,127	(4,819)	4,526	11,985	4,124	(8,501)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

### NOTE 20: NET INCOME (LOSS) PER SHARE (Continued)

b. Details of the number of shares and income (loss) used in the computation of income (loss) per share from discontinued operation:

	Year ended December 31,					
	2011	1	201	2	201	3
	Weighted average number of shares	Loss	Weighted average number of shares	Loss	Weighted average number of shares	Loss
Basic income (loss)	4,127	(1,350)	4,127	(1,045)	4,124	(6,850)
Effect of potential dilutive ordinary shares	_	—	399	—	_	—
Diluted income (loss)	4,127	(1,350)	4,526	(1,045)	4,124	(6,850)

c. Net income (loss) per share from continuing and discontinued operations:

	Year en	Year ended December 31,		
	2011	2012	2013	
Basic net income (loss) per share:				
Net income (loss) from continuing operations	(1.17)	2.90	(2.06)	
Loss from discontinued operation	(0.32)	(0.25)	(1.66)	
Net income (loss) per share	(1.49)	2.65	(3.72)	
Diluted net income (loss) per share:				
Income (loss) from continuing operations	(1.17)	2.65	(2.06)	
Loss from discontinued operation	(0.32)	(0.23)	(1.66)	
Net income (loss) per share	(1.49)	2.42	(3.72)	

# NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES AND KEY OFFICERS

- a. Related parties consist of:
  - Clal Biotechnologies Industries Ltd.—the Parent Company.
  - Teva—a former shareholder which the Company had a collaboration agreement with (see Note 15(b)).
  - PolyHeal—in which the Company holds 7.5% (see Note 18).

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

# NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES AND KEY OFFICERS (Continued)

### b. Balances with related parties:

As of December 31,	Receivables	Payables	Loans
Parent Company(1)(2):			
2012		331	1,555
2013		163	
Other related parties:			
2012	17		
2013	183		
Former related party(3):			
2012	1,685	_	—
2013	1,648		

(1) The Company leases office space and a production facility from the Parent Company in accordance with a sub-lease agreement for two years with an option for extension (see Note 14 (d)).

- (2) See Note 15 (c).
- (3) Participation by Teva.

### c. Transactions with related parties:

As of December 31,	Rent expenses	Revenues (1)	Participations (2)	Royalties
Parent company:				
2011	(424)	—	—	—
2012	(523)			_
2013	(612)			
Other related parties:				
2011	—	—	—	—
2012		_	78	(14)
2013			219	(16)
Former related party:				
2011		299	5,189	
2012		63	3,559	18
2013		368		

(1) Attributable to the discontinued operation.

(2) Including certain participation by Teva which is attributable to the discontinued operation.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

#### NOTE 21: BALANCES AND TRANSACTIONS WITH RELATED PARTIES AND KEY OFFICERS (Continued)

### d. Compensation of key officers of the Company:

The following amounts disclosed in the table are recognized as an expense during the reporting period related to key officers:

		Year ended December 31,		
	2011	2012	2013	
Short-term employee benefits	691	792	1,307	
Share-based compensation	388	206	170	
	1,079	998	1,477	
Number of key officers	3	3	6	

In December 2007, the Company's board of directors approved one-time bonus payments to the Chief Executive Officer and Chief Medical Officer in the amounts of \$120 each, to be paid upon achieving marketing approval in the United States.

In addition, the Company's board of directors approved a bonus of \$400 in the aggregate to pay certain of the Company's executive officers subject to certain conditions for their contribution to completing the initial public offering process.

#### NOTE 22: SUBSEQUENT EVENT

In connection with preparation of the consolidated financial statement and in accordance with authoritative guidance for subsequent events, the Company evaluated subsequent events after the balance sheet date of December 31, 2013 through January 31, 2014 the date on which the audited consolidated financial statements were issued.

Through and including , 2014 (the 25<sup>th</sup> day after the date of this prospectus), all dealers effecting transactions in the ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares



# Mediwound Ltd.

**Ordinary Shares** 

PROSPECTUS

**Credit Suisse** 

Jefferies

**BMO** Capital Markets

# **Oppenheimer & Co.**

,2014

#### PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 6. Indemnification of Directors, Officers and Employees.

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. 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 to be effective upon the closing of this offering include such a provision. A company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

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

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a 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 attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies 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; and
- a financial liability imposed on the office holder in favor of a third party.

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Under the Israeli 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 harm 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 Israeli 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 certain office holders or under certain circumstances, also by the shareholders. See "Management—Approval of Related Party Transactions under Israeli Law."

Our amended and restated articles of association to be effective upon the closing of this offering will permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Israeli Companies Law.

We have obtained directors and officers liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, prior to the closing of this offering, we intend to enter into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association to be effective upon the closing of this offering and the Israeli Companies Law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

Insofar as the indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling the registrant, we have been informed that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### Item 7. Recent Sales of Unregistered Securities.

Set forth below are the sales of all securities of the registrant sold by the registrant within the past three years (i.e., since January 1, 2011, up to the date of this registration statement) which were not registered under the Securities Act:

In August 2013, we issued (i) 402,693 ordinary shares for \$15,826,999 to certain investors; (ii) 117,432 ordinary shares to certain lenders as a conversion of a \$3,000,000 convertible loan; (iii) 41,302 ordinary shares to a lender as a conversion of a \$1,585,266 convertible loan; and (iv) warrants to purchase up to 280,720 ordinary shares at a weighted average exercise price of \$36.42.

The sales of the above securities were deemed to be exempt from registration under the Securities Act because they were made outside of the United States to certain non-U.S. individuals or entities pursuant to Regulation S or, in reliance upon the exemption from registration provided under Section 4(a)(2) of the Securities Act and the regulations promulgated thereunder.

• We granted share options to employees, directors and consultants under our 2003 Israeli Share Option Plan covering an aggregate of 684,225 ordinary shares, with exercise prices ranging from

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\$0.33 to \$52.28 per share. As of the date of this registration statement, 58,944 of these options have been forfeited and cancelled without being exercised.

We claimed exemption from registration under the Securities Act for these option grants described above under Section 4(a)(2), Regulation S, or under Rule 701 of the Securities Act as transactions pursuant to written compensatory plans or pursuant to a written contract relating to compensation.

No underwriters were employed in connection with the securities issuances set forth in this Item 7.

#### Item 8. Exhibits and Financial Statement Schedules.

- (a) The Exhibit Index is hereby incorporated herein by reference.
- (b) Financial Statement Schedules.

All financial statement schedules have been omitted because either they are not required, are not applicable or the information required therein is otherwise set forth in the Registrant's consolidated financial statements and related notes thereto.

#### Item 9. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described in Item 6 hereof, 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 Securities 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 Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

- 1. To provide the underwriters specified in the Underwriting Agreement, at the closing, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- 2. That for purposes of determining any liability under the Securities Act, 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.
- 3. That for the purpose of determining any liability under the Securities Act, 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 this offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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\*By:

### 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 Yavne, Israel on this 18th day of February, 2014.

### MEDIWOUND LTD.

By: /s/ GAL COHEN

Name:Gal CohenTitle:President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated:

President and Chief Executive Officer	February 18, 2014
- (principal executive officer)	
Chief Financial and Operation Officer	February 18, 2014
accounting officer)	
Chairman of the Board of Directors	February 18, 2014
-	
Director	February 18, 2014
Director	February 18, 2014
_	
Director	February 18, 2014
Director	February 18, 2014
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	<ul> <li>(principal executive officer)</li> <li>Chief Financial and Operation Officer (principal financial officer and principal accounting officer)</li> <li>Chairman of the Board of Directors</li> <li>Director</li> <li>Director</li> <li>Director</li> <li>Director</li> </ul>

# SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the requirements of the Securities Act of 1933, the Registrant's duly authorized representative has signed this registration statement on Form F-1 in Newark, Delaware, on February 18, 2014.

By: /s/ DONALD J. PUGLISI

Name: Donald J. Puglisi Title: *Managing Director* 

# EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement*
3.1	Articles of Association of the Registrant**
3.2	Form of Amended and Restated Articles of Association of the Registrant, to be effective upon closing of this offering*
3.3	Memorandum of Association of the Registrant*
4.1	Specimen Share Certificate*
4.2	First Amendment to Shareholders' Rights Agreement, dated December 30, 2010, by and among Teva Pharmaceutical Industries Ltd., the Registrant and certain shareholders of the Registrant*
5.1	Opinion of Meitar Liquornik Geva Leshem Tal, Israeli counsel to the Registrant, as to the validity of the ordinary shares (including consent)*
10.1	2003 Israeli Share Option Plan**
10.2	Founders Agreement, dated January 2001, by and among Clal Biotechnology Industries Ltd., L.R. R & D Ltd., Professor Lior Rosenberg and the Registrant**
10.3	Unprotected Sub-Lease Agreement, dated July 27, 2004, as amended, by and between the Registrant and Clal Life Sciences L.P.**
10.4	Patent Purchase Agreement, dated November 24, 2010, by and between the Registrant and L.R. R & D Ltd.**
10.5	Form of indemnification agreement by and between the Registrant and each of its directors and executive officers*
10.6	Supply Agreement, dated January 11, 2001, as amended, by and between the Registrant and Challenge Bioproducts Corporation Ltd. <sup>†**</sup>
10.7	License Agreement, dated September 22, 2000, as amended, by and between the Registrant and Mark Klein <sup>†**</sup>
21.1	List of subsidiaries of the Registrant**
23.1	Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm
23.2	Consent of Meitar Liquornik Geva Leshem Tal (included in Exhibit 5.1)*
24.1	Power of Attorney (included in signature pages of Registration Statement)**
* Т	o be filed by amendment.
** P	reviously filed.
	confidential treatment has been requested for portions of this document. The omitted portions of this document have been filed w ne Securities and Exchange Commission.
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### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated January 31, 2014, in the Registration Statement (Amendment No. 1 to Form F-1 No. 333-193856) and related Prospectus of MediWound Ltd. dated February 18, 2014.

Tel Aviv, Israel February 18, 2014 /s/ KOST FORER GABBAY & KASIERER

Kost Forer Gabbay & Kasierer A Member of Ernst & Young Global